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GENERAL NOTICES • ALGEMENE KENNISGEWINGS

DEPARTMENT OF HEALTH

NOTICE 431 OF 2017

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes amendments for implementation to the minimum standards as contained in Annexure A of the *Rules relating to good pharmacy practice* which was published on 17 December 2004 Government Gazette No: 27112, in Board Notice 129 of 2004 (as amended) in terms of Section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following rules to Annexure A of the *Rules relating to good pharmacy practice* in are hereby amended –

   (a) Rule 2.7.5

TA MASANGO
REGISTRAR

AMENDMENT TO RULE 2.7.5

The title of Rule 2.7.5 is hereby amended to read:

MINIMUM STANDARDS SPECIFICALLY RELATING TO THE COLLECTION AND THE DELIVERY OF MEDICINES TO PATIENTS FROM A COMMUNITY OR INSTITUTIONAL PHARMACY

Rule 2.7.5 is hereby withdrawn and substituted as follow:

2.7.5.1 Purpose

The purpose of this standard is to regulate activities relating to the collection by and the delivery of medicines to patients from a community or institutional pharmacy.

2.7.5.2 General considerations

(a) All efforts must be made to enable access to counselling of the patient by a pharmacist relevant to their healthcare needs;

(b) When a person other than a pharmacist delivers medicines to a patient or a patient's caregiver, the pharmacist must furnish written instructions, that shall include the patient's details and information regarding the correct use of medicine, and a patient information leaflet (where applicable);

(c) All medicines should, whenever possible, be delivered to patients at an agreed time or date; and

(d) In the absence of an adult (i.e. a person above 14 years old as defined by the Medicines Act) or another person entitled by law to receive the medicine, it must be retained and stored under appropriate conditions until delivery can be affected or be returned to the pharmacy.

2.7.5.3 Collection of medicines from the pharmacy

Definition: **Agent** – a person nominated, either formally or informally, by the patient

Caregiver: a person who has accepted responsibility for looking after a patient

The caregiver or agent may not practice the scope of practice of a pharmacist

(a) A patient's agent or caregiver may collect medicines and accept information pertaining to a particular patient provided that the pharmacist is satisfied that patient safety, confidentiality and

medicine quality is maintained and the patient has~~,~~ provided written consent;

(b) The patient's caregiver may only collect medicines for a patient or patients who are under their direct care, a patient's agent may only collect medicines for a patient or patients who have given written consent for such collection, and in the case of multiple patients the pharmacist must satisfy themselves that the patient's agent or caregiver is the appropriate person to give the medicines to.

2.7.5.4 Transportation for the delivery of medicines

(a) Transportation of medicines must be in such a way that it is secure and limits access to medicines by persons allowed to have access to medicine in law only, prevents any contamination and ensures integrity to the manufacturers product specifications;

(b) The vehicle should allow orderly storage to ensure safety, quality and efficacy of pharmaceutical products during transportation;

(c) Where relevant and to the extent that it is applicable, cold chain management must be observed, and delivery must prove compliance with the minimum standards for thermolabile pharmaceutical products;

(d) Personnel transporting pharmaceutical products must be appropriately trained and shall provide the suitable documentation as proof, for this function and they must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification;

(e) At any stage of transportation, a delivery document must show evidence that the transport requirements, inter alia temperature control have been met;

(f) Damage to containers or any other event or problem which occurs during transit must be reported to and recorded by the responsible pharmacist of the pharmacy from which the pharmaceutical products were sent;

(g) Upon arrival the person responsible for the transportation of the pharmaceutical products must inform the patient or patient's caregiver, that the package contains pharmaceutical products and provide information about specific storage requirements (as applicable); and

(h) Proof of delivery (signed by the patient or the patient's caregiver) must be presented to the pharmacy to ensure that the medicines have been received.

DEPARTMENT OF HEALTH

NOTICE 432 OF 2017

SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO THE SERVICES FOR WHICH A PHARMACIST MAY LEVY A FEE AND GUIDELINES FOR LEVYING SUCH A FEE OR FEES

The South African Pharmacy Council herewith publishes *Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such fee or fees*, in terms of sections 35A (b)(iii) and 49(4) of the Pharmacy Act, 1974 (Act 53 of 1974) as amended, which rules shall replace the existing Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such fee or fees, as published under Board Notice 193 on 20 December 2010. These rules must be read in conjunction with the *Rules relating to Good Pharmacy Practice* (GPP) as published by the South African Pharmacy Council.

SCHEDULE

Services for which a pharmacist may levy a fee or fees

1. A pharmacist may levy a fee or fees for one or more of the services that may be provided in the various categories of pharmacies as prescribed in the *Regulations relating to the practice of pharmacy* (GNR.1158 of 20 November 2000), subject to the guidelines for levying such a fee as approved by the Council from time to time.

2. A pharmacist who wishes to levy a fee or fees for the services referred to in **Annexure B** must comply with the provisions of these rules.

3. Services for which a pharmacist wishes to levy a fee or fees must be provided in accordance with Regulation 20 of the *Regulations relating to the practice of pharmacy* (GNR.1158 of 20 November 2000).

4. Council may add services for which a fee or fees may be levied as listed in **Annexure B** to the Schedule from time to time. The fee that may be charged for such a service may be based on a fee for a comparable service or procedure appearing in Annexure B.

5. A pharmacist must ensure, when a service for which he or she wishes to levy a fee or fees involves the supply of medicine, whether supplied on a prescription or not, that the patient for whom such medicine is supplied is furnished with adequate advice or information for the safe and effective use of the medicine(s) supplied by him or her, whether such medicine(s) is supplied personally (face-to-face) or by any other means.

6. Services for which a pharmacist may levy a fee or fees may not be advertised in any manner that –

(a) is not factually correct;
(b) is misleading;
(c) harms the dignity or honour of the pharmacy profession;
(d) disparages another pharmacist;
(e) is calculated to suggest that his or her professional skill or ability or his or her facilities or that of the pharmacy owner, as the case may be, for practising his or her profession or rendering the service(s) concerned are superior to those of other pharmacists.

7. A pharmacist may not tout or attempt to tout for services for which he or she wishes to levy a fee or fees.

8. A pharmacist may not levy a fee or fees for a service for which he or she is not trained or for which prior authorisation from the Council is required before he or she may provide such service(s) until such authorisation is obtained. Acceptable documentary evidence of training, experience or competence, must be provided if and when required by the Council, which could include but shall not be limited to-

(a) the successful completion of further education and training at a provider accredited by a competent authority; or

(b) practical experience gained under controlled circumstances and the mentorship of a competent person or authority; or

(c) the successful completion of continuing professional development (CPD) courses offered by a provider accredited by a competent authority.

9. A pharmacist may provide any one or more of the services referred to in **Annexure B** without levying a fee or fees.

10. A pharmacist who wishes to levy a fee or fees for the services referred to in **Annexure B** must inform patients regarding the fee to be levied prior to providing any of the services listed in the schedule.

11. A pharmacist who wishes to levy a fee or fees for the services referred to in **Annexure B** must display a list of services and fees conspicuously in the pharmacy.

12. A pharmacist who wishes to levy a fee or fees for the services referred to in **Annexure B** must indicate clearly on the invoice and/or receipt provided, the service for which a fee is levied and the amount of the fee per service.

Guidelines for the levying of a fee or fees

13. The guidelines published herewith as **Annexure A** shall constitute the only guidelines for levying a fee or fees for any one or more of the services referred to in **Annexure B**.

TA MASANGO
REGISTRAR

ANNEXURE A

GUIDELINES FOR LEVYING A FEE OR FEES

General guidelines governing the determination of a fee or fees

1. Definitions

"**Compounding**" means to the preparing, mixing, combining, packaging and labelling of a medicine for dispensing as a result of a prescription for an individual patient by a pharmacist or a person authorised in terms of Medicines and Related Substances Act, 101 of 1965.

"**Dispensing**" means the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient and "dispense" has a corresponding meaning.

"Therapeutic medicine monitoring" means the use of serum medicine concentrations, the mathematical relationship between a medicine dosage regimen and resulting serum concentrations (pharmacokinetics), and the relationship of medicine concentrations at the site of action to pharmacological response (pharmacodynamics) to optimise medicine therapy in individual patients taking into consideration the clinical status of the patient.

2. Nature of services provided

A pharmacist may, in charging a fee for professional services rendered by him/her take into account one or more of the following factors –

(a) the nature of the professional service rendered;

(b) the time of day and circumstances under which the service is rendered.

3. **Call out service, delivery of medicines and after-hour fees**

(a) Where a pharmacist is called out from his/her pharmacy, or the pharmacy in which he/she practises, or from his or her residence or other place where he or she may be, a fee including the travelling time and costs according the South African Revenue Services (SARS) travelling reimbursement table as published from time to time, may be charged.

(b) Where a pharmacist is required to deliver a service after normal operating hours, an after-hours fee may be charged. The recommended fee is one and a half times the normal fee for a specific procedure code. The hours of opening of a pharmacy must be clearly displayed.

(c) Where a pharmacist is required by the patient or caregiver to transport a medicine to a patient, the transport costs according the South Africa Revenue Services (SARS) travelling reimbursement table as published from time to time may be charged.

(d) Where a pharmacist is reclaiming expenses, details of the expenses must be individually itemised.

4. **Collaboration with other health care professionals**

Services may be provided in collaboration with a registered nurse or other registered health care professional as agreed to by the Council and other statutory health councils as applicable.

5. A pharmacist's guide to fees

5.1 **Procedures**

5.1.1 Services for which a fee or fees may be levied shall be divided into procedures as indicated in **Annexure B**. A separate fee shall be charged for each procedure.

5.1.2. The fee per procedure shall be based on a procedure code as listed in **Annexure B**.

5.1.3 The fee for after-hours and/or call-out services must be levied separately as per clause 3 using the designated procedure codes as listed in **Annexure B**.

5.1.4 The fees will be reviewed on an annual basis.

5.1.5 All expenses claimed must be indicated separately.

6. **Pharmacy support personnel**

The fee or fees may be levied by a pharmacist whether the service concerned is provided by the pharmacist, any other person registered in terms of the Pharmacy Act or a healthcare professional employed in the pharmacy: Provided that any such person may only provide a service or perform an act which falls within his or her scope of practice.

7. **Chronic Medicines Authorisation**

A fee may be levied by a pharmacist where he/she needs to liaise with a medical scheme, an entity concerned with the management of pharmaceutical benefits and/or a medical practitioner to initiate or renew a chronic medicine authorisation or update a chronic medicine authorisation.

8. **Guidelines for charging fees where one or more service may be provided**

The following examples are provided as guidelines:

	Scenario	**Fees that may be levied for services provided**	**Procedure Codes**
i.	A patient presents a prescription for dispensing to the pharmacist which requires the compounding of a product.	A professional fee for compounding plus the fee for dispensing may be levied.	Procedure codes 0002 and 0001
ii.	A patient presents a prescription for dispensing to the pharmacist which includes the preparation of a sterile product.	A professional fee for preparation of a sterile product plus the fee for dispensing may be levied.	Procedure codes 0003 and 0001
iii.	A patient presents a prescription for dispensing to the pharmacist which includes the preparation of an intravenous admixture or parenteral solution.	A professional fee for the preparation of an intravenous admixture or parenteral solution plus the fee for dispensing may be levied.	Procedure codes 0004 and 0001
iv.	A patient presents a prescription for dispensing to the pharmacist which includes the preparation of a total parenteral nutrition product	A professional fee for preparation of a total parenteral nutrition product plus the fee for dispensing may be levied.	Procedure codes 0005 and 0001
v.	A patient presents a prescription for dispensing to the pharmacist which includes a cytotoxic preparation.	A professional fee for cytotoxic preparation plus the fee for dispensing may be levied.	Procedure codes 0006 and 0001

	Scenario	Fees that may be levied for services provided	Procedure Codes
vi.	A patient requests information regarding the use of medicine dispensed by another entity authorised to dispense medicines.	A professional fee for provision of information concerning the medicines may be levied.	Procedure code 0008
vii.	A patient presents him/herself to the pharmacist with a prescription for dispensing and requests blood glucose monitoring.	A professional fee for blood glucose monitoring plus the fee for dispensing may be levied.	Procedure codes 0012 and 0001
viii.	A patient presents him/herself to the pharmacist with a prescription for dispensing and requests blood cholesterol and/or triglyceride monitoring.	A professional fee for blood cholesterol and/or triglyceride monitoring plus the fee for dispensing may be levied.	Procedure codes 0013 and 0001
ix.	A patient presents him/herself to the pharmacist with a prescription for dispensing and requests blood pressure monitoring.	A professional fee for blood pressure monitoring plus the dispensing fee may be levied.	Procedure codes 0015 and 0001
x.	A patient presents him/herself to the pharmacist with a prescription for dispensing and requests a peak flow measurement.	A professional fee for peak flow measurement plus the fee for dispensing may be levied.	Procedure codes 0019 and 0001
xi.	A patient requests immunisation.	A professional fee for administration of immunisation plus the fee for dispensing may be levied.	Procedure codes 0022 and 0001
xii.	A patient requests that the medicine on a prescription dispensed in the pharmacy be delivered to a given address.	A delivery fee plus the fee for dispensing may be levied.	Procedure codes 0025 and 0001
xiii.	The pharmacist is called to the pharmacy after hours to dispense a prescription.	A fee for a call out service plus the fee for dispensing may be levied.	Procedure codes 0024 and 0001
xiv.	A patient presents herself to the pharmacist for emergency post coital contraception (EPC).	A professional fee for EPC plus the fee for pharmacist initiated therapy may be levied.	Procedure codes 0027 and 0001
xv.	A patient presents him/herself for pharmacist initiated therapy.	A professional fee for pharmacist initiated therapy plus the fee for dispensing may be levied.	Procedure codes 0028 and 0001

ANNEXURE B

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
	DISPENSING PROCEDURES						
0001(a)	Independent evaluation of a prescription with regard to appropriateness of items prescribed for the individual, legality, content and correctness. It includes evaluating the dosage, safety of the medicine, interactions with other medicines used by the patient, pharmaceutical and pharmacological incompatibilities, treatment duplications and possible allergies to the medicine prescribed.	Pharmacist	GPP manual Sections: Facilities: 1.2.1 through 1.2.13, 1.3 (institutional pharmacies), 1.4 (mobile pharmacies) Dispensing service: 2.7.1, 2.7.2, 2.7.3, 2.7.4, Standards for patient information and advice: 2.8 and 2.7.5(b)	Community and Public or Private Institutional	1	Refer to *Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment (Dispencing fee for pharmacists*), GNR 1090, published on 19 November 2010 published in terms of the Medicines and Related Substances Act (Act 101 of 1965)	
0001(b)	Preparation of the medicine(s) as per a prescription, which includes the picking, packaging, labelling of medicine, checking of expiry dates and keeping of appropriate dispensing records in compliance with the Medicines and Related Substances Act, Act 101 of 1965, as amended.	Pharmacist		Community and Public or Private Institutional	3		

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
0001(c)	Handing of medicines to the patient/caregiver, including the provision of advice/instructions and a patient information leaflet/ written material regarding the safe and efficacious use of the medicine dispensed.	Pharmacist		Community and Public or Private Institutional	1		
0002	Compounding of an extemporaneous preparation for a specific patient. It refers to the compounding of any non-sterile pharmaceutical product prepared as a single preparation for a patient (a new product is manufactured) including the necessary documentation.	Pharmacist	GPP manual 2.18	Community and Public or Private Institutional	10	168,83	192,54
0003	Preparation of a sterile product including the preparation of the documentation, equipment, and the area for the preparation of sterile products.	Pharmacist	GPP manual 1.2, 2.4, 2.10, 2.17	Community and Public or Private Institutional	14	324,73	370,24

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
0004	Preparation of an intravenous admixture or parenteral solution, including the preparation of the documentation, equipment, the area for the preparation of the sterile products and the quality control of the final product.	Pharmacist	GPP manual 2.4, 2.10, 2.17.1	Public or Private Institutional	6	152,69	173,92
0005	Preparation of a total parenteral nutrition preparation (TPN), including the preparation of the documentation, equipment, the area for the preparation of the sterile products and the quality control of the final product.	Pharmacist	GPP manual 2.10, 2.17.2, 2.18	Public or Private Institutional	13	322,25	367,33
0006	Preparation of cancer chemotherapy for intravenous, intramuscular or intrathecal administration, including the preparation of the documentation, equipment, the area for the preparation of the sterile products, the admixing and reconstitution thereof for dispensing in a large/small volume parenteral, or a syringe for a specific patient.	Pharmacist	GPP manual 2.4, 2.10, 2.17.3,	Public or Private Institutional	17	416,34	474,51

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
	CLINICAL PHARMACY						
0007	Performance of a consultation to establish the pharmacokinetic dosing of a medicine and perform therapeutic medicine monitoring. This includes the review of the data collected, the necessary calculations, review and the formulation of recommendations and the necessary consultation with the prescriber.	Pharmacist registered as a specialist in pharmaco-kinetics	GPP Manual 2.11.3	Consultant, Public or Private Institutional	18	467,53	532,97
0008	Provision of information concerning a particular patient's condition or medicine following evaluation by the pharmacist in a situation where no dispensing activity occurs.	Pharmacist	GPP manual 2.8	Community or Consultant or Private or Public Institutional	4	67,62	77,07

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
0009	The application of pharmaceutical expertise to help maximise medicine efficacy and minimise medicine toxicity in individual patients by contributing to the care of the individual patient through the provision of medicine information and assisting in problem solving in the ward environment for individual patients, where no dispensing activity occurs.	Pharmacist	GPP manual 2.11	Private or Public Institutional	3	57,44	65,44
0010	PCDT: A face-to-face consultation with a patient where a pharmacist personally takes down a patient's history, performs an appropriate health examination including observations, and plans appropriate interventions/ treatment, which may include referral to another health care professional.	Pharmacist who has completed supplement-ary training in PCDT and registered such course with Council and who is the holder of a permit issued in terms of Section 22A(15) (or its predecessor) of the Medicines Act	GPP Manual section 2.12	Community	8	203,30	231,66

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
0011	Medicine use review: Reviewing of the patient's overall medication requirements, as requested by the patient or the patient's health care professional, to ensure the effective use of medicine in response to a diagnosis made by another health care professional in order to maximise therapeutic outcomes. It involves analysing the patient's medication record to assess the appropriateness and/or cost effectiveness of treatment to ensure rational medicine use, and to identify possible interactions and adverse drug reactions. It also involves developing a plan of action in collaboration with other health care professionals and the patient. It may involve a consultation with the patient. Full records must be kept in accordance with the GPP standard	Pharmacist	GPP manual 2.25	Community or Consultant or Private or Public Institutional	4	102,23	116,63
	PROMOTION OF PUBLIC HEALTH						

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
	SCREENING AND TESTING OF BIOLOGICAL AND PHYSICAL PARAMETERS.						
0012	Blood glucose	Pharmacist	GPP Manual 2.13.7	Community and Public or Private Institutional	4	76,78	87,54
0013	Blood cholesterol and/or tri-glycerides	Pharmacist	GPP Manual 2.13.6	Community and Public or Private Institutional	7	125,35	142,95
0014	Urine analysis	Pharmacist	GPP Manual 2. 13.9	Community and Public or Private Institutional	7	114,59	130,73
0015	Blood pressure monitoring	Pharmacist	GPP Manual 2.13.3	Community and Public or Private Institutional	4	68,06	77,65
0016	HIV and AIDS pre-test counselling	Pharmacist	GPP Manual 2.13.5	Community and Public or Private Institutional	24	544,17	620,37
0017	HIV and AIDS testing and post-test counselling	Pharmacist	GPP Manual 2.13.5	Community and Public or Private Institutional	17	387,69	442,08
0018	Pregnancy screening	Pharmacist	GPP Manual 2.13.8	Community and Public or Private Institutional	7	122,01	139,17
0019	Peak Flow measurement	Pharmacist	GPP Manual 2.13.4	Community and Public or Private Institutional	4	61,22	69,80
0020	Reproductive health service	Pharmacist	GPP Manual 2.15	Community and Public or Private Institutional	5	107,76	122,74
0021	Administration of an intra-muscular or sub-cutaneous injection.	Pharmacist	GPP Manual 2.15	Community and Public or Private Institutional	4	74,46	84,93
0022	Administration of immunisation.	Pharmacist	GPP Manual 2.14	Community and Public or Private Institutional	5	83,76	95,54
	REIMBURSABLE EXPENSE CODES						
0023	Chronic medicine authorisation assistance: A fee	Pharmacist		Community and Public or Private			

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
	may be levied by a pharmacist where she/he needs to liaise with a medical scheme / PBM and or doctor to initiate or renew a chronic medicine authorisation or update a chronic medicine authorisation where there has been a dosage or other prescription change, which may include completion of application forms.			Institutional			
0024	Call Out: Where a pharmacist is called out from his/her pharmacy, or the pharmacy in which he/she practises, or from his or her residence or other place where he or she may be, a fee including the travelling time and costs according the South African Revenue Services (SARS) travelling reimbursement table as published from time to time, may be charged.	Pharmacist	GPP manual 4.2.3.2 and 4.3.6	Community and Public or Private Institutional			
0025	Delivery of medicine: Where it is necessary, at the request of a patient or the patient's agent and by agreement with the patient or his or her agent, for medicine to be		GPP manual 2.7.5	Community and Public or Private Institutional			

Procedure Code	Procedure	Performed by	Reference	Categories of pharmacies in which services may be provided	Time in Minutes	Fee (VAT excl) (Rands)	Fee (VAT incl) (Rands)
	transported to a place requested by the patient or his or her agent, the costs involved in that transportation can be charged back to the patient as a reimbursable expense. The travelling cost per kilometre must be based on the SARS rate.						
0026	After-hours service: where a pharmacist is required to deliver a service after normal operating hours, an after-hours fee may be charged. The recommended fee is one and a half times the normal fee.		GPP manual 4.2.3.2 and 4.3.6	Community and Public or Private Institutional			
	ADDITIONAL DISPENSING PROCEDURES						
0027	Emergency post-coital contraception (EPC)	Pharmacist	GPP manual 2.26	Community and Public or Private Institutional	3.	56,71	64,57
0028	Pharmacist Initiated Therapy (PIT)	Pharmacist	GPP manual	Community and Public or Private Institutional	3	53,66	61,22

DEPARTMENT OF HEALTH

NOTICE 433 OF 2017

SOUTH AFRICAN PHARMACY COUNCIL

FEES PAYABLE TO THE COUNCIL UNDER THE PHARMACY ACT 53 OF 1974

In terms of section 4(zG) of the Pharmacy Act 53 of 1974, as amended, Council may determine the fees payable to Council. This means that any new fees or amendments to existing fees are determined annually by Council. As in the past, all efforts will be made to curtail costs and keep any increases in fees to the minimum. The fees for the year 2017 are published below for general information:

Description	Exclude VAT R	VAT R	Include VAT R
REGISTRATION FEES (payable with a duly completed application form)			
A **Pharmacy** for-			
• application for registration of a remote automated dispensing unit (RADU) (Public Sector)	5 143.22	720.05	5 863.27
ANNUAL FEES In terms of Regulation 106 of the *Regulations relating to the registration of persons and the maintenance of registers* (R.1160 of 20 November 2000), every person registered in terms of the regulations must renew such registration annually by paying the annual fee(s) as determined by Council. The annual fee due dates each year are as follows- 1 July -Pharmacies (Institutional public) and responsible pharmacists (public sector).			
A **Pharmacy** for-			
• remote automated dispensing unit (RADU) (Public Sector)	1 324.54	185.44	1 509.98

TA Masango
REGISTRAR

591 Belvedere Street, Arcadia, Pretoria, 0083, Private Bag X40040, Arcadia, 0007.
Telephone: 0861 7272 00. Facsimile 012-321 1479/92

DEPARTMENT OF HEALTH

NOTICE 434 OF 2017

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments and additional minimum standards to be added to Annexure A of the *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 in Board Notice 129 of 2004, in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974.

Interested parties are invited to submit, within **30 days** of publication of this notice, substantiated comments on or representation regarding the amendments to the existing minimum standards and/or the additional minimum standards. Comments must be addressed to the Registrar, the South African Pharmacy Council, Private Bag 40040, Arcadia, or fax (012)326-1496 or email BN@sapc.za.org.

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following minimum standard as published herewith shall constitute an additional standard to be added to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act –

   (a) Minimum standards for the selling of HIV screening test kits.

TA MASANGO
REGISTRAR

MINIMUM STANDARD FOR THE SALE OF HIV SELF-SCREENING TEST KITS

1. Definition

(a) HIV self-screening testing - is a process in which a person collects their own specimen (biological fluid) and then performs a test and interprets the result, often in a private setting, either alone or with a person they trust.

(b) HIV self-screening test kit – is a kit approved by an authority as defined in paragraph 3 for the purposes of self- screening for HIV infection.

2. Purpose

In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to increase the number of people who test, know their HIV status and receive treatment.

This was followed in 2016 when the National Department of Health adopted the UNAIDS 90-90-90 targets. These initiatives are an attempt to get the HIV epidemic under control and are based on the principle of universal testing and treating. The intention is that by 2020, 90% of people who are HIV infected will be diagnosed, 90% of people who are diagnosed will be on antiretroviral treatment and 90% of those who receive antiretrovirals will be virally suppressed. These principles support the goals laid out in the country's National Strategic Plan (NSP) 2017-2022, for HIV, Sexually Transmitted Infections and Tuberculosis, which inter alia, aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

In order for this to succeed, HIV testing needs to be taken out of the clinics and into the community, and requires new and innovative ways to get people tested for HIV infection. HIV self-screening test kits could increase the numbers of people that get tested and know their status. The pharmacist is ideally placed to deal with the sale of HIV self-screening test kits, given the sensitivity and the professionalism required in dealing with the condition and as such Council supports the responsible sale of self-testing kits by pharmacists.

The minimum standard for the sale of HIV self-screening test kits aims to provide guidance on how pertinent issues and concerns relating to HIV self-screening should be addressed. The pertinent issues and concerns include:

(a) the reliability and ease of use of the testing instrument;

(b) patient consent;

(c) patient confidentiality and anonymity;

(d) ready access to confirmation of diagnosis and treatment should the test be reactive; and

(e) ready access to information, support, assistance and counselling as required.

3. Specific Considerations

Pharmacists must only sell HIV self-screening test kits approved by suitable authorities such as:

(a) Medicine Control Council; or
(b) World Health Organisation; or
(c) Other regulatory health authorities recognised by South Africa that MCC aligns itself with such as FDA, EMEA or
(d) Kits with CE marking.

4. Accessibility of HIV self-screening test kits

(a) the HIV self-screening test kits may be sold to persons from the age of 12 years and above.

5. The Sale of HIV Self-screening Test Kits

A pharmacist must ensure that the person buying this kit has access to the following information:

(a) instructions for use (IFU) leaflet is included in the kit and should be followed when self-testing;

(b) screening test should not be taken as a conclusive diagnosis;

(c) diagnosis of HIV infection is dependent on a confirmatory test;

(d) there are three possible outcomes of the HIV self-screening test:

(i) “Reactive” or “Positive” - HIV antibodies have been detected indicating that the client **may** be HIV positive, and there is a need to perform a confirmatory test to validate the outcome;

(ii) “Non-Reactive” or “Negative” - no HIV antibodies have been detected. No further testing is required. The client should take steps to remain negative and may retest in minimum 6 weeks in cases of possible recent exposure (to exclude the window period); and

(iii) “Invalid” or “No Result” - the test has failed and the client should purchase another test kit and repeat the process.

(e) assistance, information and support if required before, during and after the test is available.

6. Knowledge

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of relevant aspects of HIV and HIV self-screening test kits as well as the ability to demonstrate the use of the test kit to any person as the need arises.

7. Support Information to be provided

The following information must be accessible to person(s) purchasing or requesting assistance with HIV self-screening test kit:

(a) referral centres for confirmatory testing and counselling in the case of a reactive or positive result;

(b) a pamphlet on HIV including how HIV is transmitted;

(c) information and referral on:

(i) Post Exposure Prophylaxis (PEP) in the case of unintended exposure within 72 hours;

(ii) Pre-exposure prophylaxis (PrEP) in the case of ongoing risk to infection; and

(iii) Prevention of Mother to Child Transmission (PMTCT) in the case of exposure during pregnancy, child birth and/or breast-feeding.

This standard must be read together with other relevant standards

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