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CONTENTS · INHOUD

No.

Page Gazette

	BOARD NOTICES		
193	Pharmacy Act (53/1974): South African Pharmacy Council: Rules: Services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees	3	33898
194	do : do : Good pharmacy practice	13	33898

BOARD NOTICES

BOARD NOTICE 193 OF 2010

THE 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 18 on 23 February 2007. 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.
- 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**.

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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
vi.	A patient requests information regarding the use of medicine	A professional fee for provision of information	Procedure code 0008

	Scenario	Fees that may be levied for services provided	Procedure Codes
	dispensed by another entity authorised to dispense medicines.	concerning the medicines may be levied.	
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 exclusive) (Rands)	Fee (VAT inclusive) (Rands)
0001(a)	DISPENSING PROCEDURES 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),	Community and Public or Private Institutional	1	Refer to relating to a pricing s	
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	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	3	medicines scheduled Amendment (Dispensing pharmacists 1090, publi November 2	and substances: fee for GNR shed on 19
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	2.7.6(6)	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	108.20	123.30
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	208.40	237.50

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Procedure Code	Procedure	Performed by	Reference	of pharmacies in which services may be provided	Time in Minutes	Fee (VAT exclusive) (Rands)	Fee (VAT inclusive) (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	97.90	111.60
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	206.70	235.60
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	267.00	304.40
0007	CLINICAL PHARMACY 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	300.10	342.10
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	43.30	49.30
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	36.80	41.90

				Categories			
e e				of pharmacies		Fee (VAT	Fee (VAT
Procedure Code	Procedure	Performed by	Reference	in which services may be provided	Time in Minutes	exclusive) (Rands)	inclusive) (Rands)
0016	HIV and AIDS pre-test counselling	Pharmacist	GPP Manual 2.13.5	Community and Public or Private Institutional	24	349.00	397.80
0017	HIV and AIDS testing and post-test counselling	Pharmacist	GPP Manual 2.13.5	Community and Public or Private Institutional	17	248.70	283.50
0018	Pregnancy screening	Pharmacist	GPP Manual 2.13.8	Community and Public or Private Institutional	7	78.20	89.10
0019	Peak Flow measurement	Pharmacist	GPP Manual 2.13.4	Community and Public or Private Institutional	4	39.20	44.70
0020	Reproductive health service	Pharmacist	GPP Manual 2.15	Community and Public or Private Institutional	5	69.10	78.70
0021	Administration of an intra- muscular or sub-cutaneous injection.	Pharmacist	GPP Manual 2.15	Community and Public or Private Institutional	4	47.70	54.40
0022	Administration of immunisation.	Pharmacist	GPP Manual 2.14	Community and Public or Private Institutional	5	53.70	61.20
	REIMBURSABLE EXPENSE C		_	_	_		
	Chronic medicine authorisation assistance: A fee 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.	Pharmacist		Community and Public or Private 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 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		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 exclusive) (Rands)	Fee (VAT inclusive) (Rands)
	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 PR						
0027	Emergency post-coital contraception (EPC)	Pharmacist	GPP manual 2.26	Community and Public or Private Institutional	3.	36.30	41.40
0028	Pharmacist Initiated Therapy (PIT)	Pharmacist	GPP manual	Community and Public or Private Institutional	3	34.40	39.20

BOARD NOTICE 194 OF 2010

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes 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 of Board Notice 129 of 2004 in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended.

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 -
- 2.1 Minimum standards regarding destruction and disposal of medicines.

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MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES

1. INTRODUCTION

The destruction of Scheduled medicines and substances may only take place in accordance with the Medicines and Related Substances Act (Act 101 of 1965) and other applicable legislation.

Regulation 27 of the General Regulations published under the Medicines and Related Substances Act (Act 101 of 1965) states that no medicines may be disposed of into municipal sewerage systems and that the destruction or disposal of medicine or scheduled substances must be conducted in such a manner as to ensure that they are not retrievable.

In addition, pharmacists should not dispose of medicine in refuse that may be destined for landfill or municipal refuse sites.

2. PURPOSE

The purpose of this standard is to ensure that the destruction of medicines within pharmacies is undertaken safely and in accordance with the requirements of Regulation 27 of the *General Regulations of the Medicines and Related Substances Act, 101 of 1965*, relevant Waste Regulations and with due regard to minimizing the risk of such an activity causing pollution or harm to health.

3. GENERAL CONSIDERATIONS

Some of the elements in this standard are not statutory requirements but are good practice which pharmacists would be expected to follow whenever practicable.

- 3.1 All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The applicant (person requesting destruction) may be requested to prove that the method of destruction is in accordance with such regulations.
- 3.2 All medicines or scheduled substances (including medicines returned by patients) must be destroyed in such a manner that does not allow recovery or retrieval.
- 3.3 The inspector must, on behalf of the Medicines Regulatory Authority (MRA), provide a certificate of destruction and in the case of an officer of the SAPS; a case number must be provided. These references must be kept with the register for a period of 5 years.¹
- 3.4 All quantities destroyed must be recorded in the relevant record on the date of destruction and signed by the applicant, indicating the reference to the destruction certificate or case number as the case may be.

¹ Applicable to the destruction of schedule 5, 6,7 and 8

- 3.5 The destruction must be properly documented:-
 - (a) All quantities destroyed must be recorded and in the case of specified schedule 5 and schedule 6 medicines the quantities of medicines to be destroyed must be indicated in the relevant registers and signed by the witnesses required in the procedure:
 - (b) Destruction certificates (where applicable) and the letter of authorisation by the Medicine Regulatory Authority(MRA) must be referenced in, or attached to the relevant specified schedule 5 and schedule 6 register and retained for the same period of time as the register itself. (5 years).
- 3.6 The following details should be recorded-
 - (a) Name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines or scheduled substance;
 - (b) Date of expiry;
 - (c) The name, position and signature of the person destroying the medicines or scheduled substance and the witness;
 - (d) The reason for the destruction; and
 - Date of destruction. (e)
 - (f) The weight of the medicines or scheduled substances for medicines or scheduled substances returned by patients.

LEGISLATIVE REQUIREMENTS 4.

- A medicine containing Schedule 1, 2, 3, and 4 substances may only be 4.1 destroyed in the presence of a pharmacist or an authorised person in charge of a place where medicines or scheduled substances are kept. Such pharmacist or authorised person shall certify such destruction;
- 4.2 For medicines containing a Schedule 5 and 6, 7 or 8, the Responsible Pharmacist of the institution/facility where the medicines are kept, should first obtain approval for destruction from the MRA. The request should be made on the institution/facility letterhead stating the following details:
 - Name, quantity, strength, batch numbers (if applicable) and dosage (a) form of the medicines or scheduled substance;
 - (b) Date of expiry;
- The medicines in Rule 4.2 may only be destroyed in the presence of an 4.3 inspector, an officer of the South African Police Service or any other person authorized by the Director General. Such inspector or person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register,

4.4 Notwithstanding the Rule 4.1 and 4.2 the Medicines Control Council may authorize in writing the destruction of specified schedule 5 and 6 substances by a manufacturer of such substances in the absence of an inspector.

5. MINIMUM REQUIREMENTS FOR THE DESTRUCTION OF MEDICINES

A medicine or scheduled substance may be destroyed as follows:

- 5.1 Destruction by a contractor who specialises in waste disposal regarding the disposal of chemical or medicinal waste.
- 5.2 If a contractor is not used, **two pharmacists** employed by the applicant must witness the **removal and destruction** of the correct quantities of the medicines or scheduled substances authorised for destruction, regardless of the where the destruction will take place.
- 5.3 In the case of a contractor, where destruction does not take place at the premises of the applicant, the contractor must issue a certificate of destruction. **Two** pharmacists employed by the applicant must witness the **removal from the stock** of the correct quantities of the medicines or scheduled substances authorised for destruction. The contractor must have a Pharmacist in his/her employment to ensure that the goods are destroyed or disposed in such a manner that precludes their recovery.

6. DISPOSAL OF MEDICINES

Medicines destined for destruction should be separated into six types and labelled accordingly:

- (a) Solid dosage form medicines;
- (b) Ampoules;
- (c) Liquids, creams and ointments;
- (d) Aerosols;
- (e) Radioactive drugs
- (f) Cytostatic and cytotoxic medicines.

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