Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEPARTMENT OF HEALTH
AFFORDABLE MEDICINES DIRECTORATE
LICENSING AND REGULATION SUB-DIRECTORATE

GUIDELINE AND APPLICATION FORM:

A permit issued in terms of **Regulation 31** of Regulations issued in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) for **Midwifery Services**

Enquiries: ndohpermits@health.gov.za Effective Date: 01/01/2024

GUIDELINE

General Information

1. Regulation 31 of the Regulations issued in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (*the Medicines Act*) provides for the authorisation of midwives to obtain pain medicines.
2. Regulation 31(1) states: *"Any person registered in the category, **midwife in terms of the Nursing Act, 2005 (Act No. 33 of 2005)**, providing intra- partum care in accordance with the relevant scope of practice who wishes to purchase, acquire or keep for administration to patients Schedule 5 or Schedule 6 medicines for intra -partum care in accordance with the latest version of the Standard Treatment Guidelines /Essential Medicines List as approved by the National Essential Medicines List Committee shall apply in writing to the Director -General for a permit."*.
3. Regulation 31(3) further states: *"The Director -General may, upon receipt of such application and after making such inquiries as he or she may deem necessary, issue a permit authorising the applicant to purchase, acquire, keep or administer the requested Schedule 5 or Schedule 6 medicines."*. The Director-General may add, to this permit, other medicines that the midwife may require for provision of midwifery
4. Permits issued in terms of Regulation 31 of *the Medicines Act* are issued with a list of conditions and medication that the permit holder may access in order to provide the midwifery services. This list is in line with the Department of Health's latest Standard Treatment Guidelines and Essential Medicines List (STG EML). It is the permit holder's responsibility to keep abreast with changes in the STG EML.
5. There is no application fee payable for a Regulation 31 Permit.
6. The permit issued in terms of Regulation 31 remains valid for 5 years from date of issue, or until it is suspended or revoked by the Director-General. The permit may be renewed.
7. A permit may be withdrawn if the holder thereof fails to comply with any condition of the permit.

Required Supporting Documents

Ensure that certification is not older than 6 months

- Certified copy of existing permit (if you are currently in possession of a valid permit)
- Certified copy of South African identity document/passport or other relevant document issued by the Department of Home Affairs
- Proof of current registration with the South African Nursing Council (SANC) as a midwife
- Proof of payment of current annual fees with applicable Statutory Council
- Certified copy of qualifications (primary and midwifery)

Submission of Application

Applications must be sent by email to ndohpermits@health.gov.za – with the subject line:

- **Midwifery Permit Application – Initials, Surname, SANC Number**
  (e.g. Midwifery Permit Application – A.B. Permit, SANC12345678)

Application Outcome

Applications are processed within **90 days** of receipt of all required documents.
Your application outcome will be communication by email.

The collection address is:
National Department of Health, Dr AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-Jr, Pretoria, 0187

health
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Section A: Applicant's General Information

Regulation 31 Permit for Midwifery Services (Mark with X)	**New**		**Renewal**		**Relocation**		**Additional**		**EXISTING PERMIT NUMBER:**	
1	*** Title**									
2a	*** Name(s)**									
2b	*** Surname**									
3	*** Gender**	Female			Male					
4	**Race** (for statistical purposes)	**African**	**White**	**Indian**	**Asian**	**Coloured**				
5	***Date of Birth** [DD-MM-YYYY]	-	-							
6a	***Are you a South African citizen?**	Yes		No		*If no, continue with Q6c*				
6b	***Identity No.**	*Continue with Section B*								
6c	**Passport No.**									
	Country of Issue									
	Passport Expiry Date [DD-MM-YYYY]	-	-							
	Visa Expiry Date [DD-MM-YYYY]	-	-							

Section B: Applicant's Contact Details

1a	***Email** preferred	
2a	*** Cellphone No**	
2b	***Alternative No.**	

3 **Domicilium Citandi et Executandi** - ***Address to be used for all correspondence***

Is Domicilium Citandi et Executandi the same as the home address?	Yes		No	*If yes, continue with Section C* *If no – please completed this section*
Complex/Building Name *(if applicable)*			Unit No.	
Street Name			Street No.	
Suburb				
City / Town				
Province		**Postal Code**		

Section C: Statutory Council Details

1	***Statutory Council Name** *(abbreviation)*	
2	***Council Registration No.**	
3	***Profession**	

Section D: Facility / Business Details

1	**Facility/Business Name**	
2	**Facility Phone No.**	

3		**Facility/Business Physical Address**

Complex/Building Name		**Unit No.**	
***Street Name**		***Street No.**	
***Suburb**			
***City**			
***Province**		***Postal Code**	

4		**Facility Postal Address**			
4a		**Is the Facility Postal Address the same as the above Facility Physical Address?**	**Yes**	**No**	*If yes, continue with Section E*
	Complete appropriate section				
4b	**PO Box No**				
	Private Bag				
	PostNet Suite				
	City				
	Province				
	Postal Code				

Section D: Nature of Midwifery Services to be provided

1			3	
2			4	

Section E: Conditions and Diagnostic Codes for which Schedule 5 & 6 Medicines will be required

1			
2			
3			
4			

Section E: Compliance

By initialing this section of the application form, the applicant agrees to ensure compliance with the conditions/standards listed in this section upon approval of the permit.

PREMISES – GENERAL The premises will have**:** • A suitable waiting area, in accordance with Good Pharmacy Practice guidelines • A suitable private area, for provision of information and advice while dispensing, in accordance with Good Pharmacy Practice standards • A suitable area for screening and performing tests • The floor, working surfaces and countertops will be finished with smooth, impermeable, and washable material • The walls, floors, ceilings, fixtures will be kept clean at all times • Sufficient and adequate lighting • A designated, lockable medicine room / lockable cupboard for storage of medicines • A separate, designated area for receiving stock • A separate facility for washing hands • A separate facility for washing equipment, with cold and hot water • A fire extinguisher on the premises, with records of annual maintenance	**Initials:** _____
SECURITY & CONTROL OF ACCESS The following will be done to ensure controlled access and security of premises: • There will be sufficient security to prevent unauthorised access to the medicine room/cupboard • Only the authorised permit holder will have keys to the medicine room/cupboard	**Initials:** _____
STORAGE CONDITIONS The following will be done to ensure correct storage conditions • Measures will be taken to prevent unauthorised entry into the medicines room / area where medicines are kept • Schedule **6 medicines will be kept in a loackable cupbaord** • There will be sufficient shelving for pharmaceuticals • The medicines room / consulting room with a medicine cupboard will be air-conditioned • No medicines will be exposed to direct sunlight • Inflammable products will be kept in a separate storage place • There will be a designated refrigerator for thermolabile medicines • The temperature in the fridge is monitored twice daily & recorded on a schedule • Only patient ready or original packs will be kept • No bulk stock will be kept on the premises	**Initial:** _____
EQUIPMENT The following minimum equipment will be available at all times: • Clean tablet / capsule counting trays for tablets and capsules • Adequate graduated measures for reconstituting medicines from powder form • Sufficient appropriate containers for dispensing • Labels suitable for dispensing, including warning labels • Suitable containers for the disposal of sharps	**Initial:** _____
SCHEDULED MEDICINES & RELEVANT RECORD KEEPING • Patient records will be readily retrievable and will include: patient demographic information, consultation date, diagnosis, prescriber (who should be the dispenser), medicine dispensed, allergies, adverse drug reactions, family history, comorbid diseases, concomitant medication, etc) • The holder of a permit issued shall keep a register of medicines kept in a form as determined by the Authority, in which shall be entered at least the following particulars: (i) Schedule number; (ii) name of medicine; and (iii) strength; • the midwife shall enter the following particulars in the register after administration of the Schedule 5 or Schedule 6 medicines:	**Initials:** _____

(i) Date and time of administration; (ii) name and address of patient; (iii) quantity administered; (iv) full signature; (v) qualifications; (vi) reason for administration; and (vii) the balance on hand. • The relevant prescription books / records of scheduled medicines dispensed will be kept for at least 5 years	
STANDARD OPERATING PROCEDURES (SOP) The following SOPs will be in place: • Handling, storage of medicines, which will include stock rotation • Issuing of medicines to patients • Disposal of expired or obsolete medicines • Prevention of pest infestation • Effective stock rotation • Reporting of adverse drug reactions • Recall of medicines • Room temperature control • Handling of Schedule 5 and 6 medicines, including the balancing of registers • Handling of thermolabile medicines (Cold chain management) (where applicable)	**Initials:** _____

Section F: Declarations and Undertakings

Please Initial each undertaking to confirm that you will comply with the undertakings

		Initials:
1.	* I undertake to comply with all applicable laws, regulations, rules and professional obligations and to familiarise myself with all legislation relating to the permit for which this application is made	
2.	* I undertake to remain abreast of revisions and updates to the Primary Health Care Level Standard Treatment Guidelines (PHC STG) and Essential Medicines List (EML) as applicable to any permit issued	
3.	*I undertake to partake in continued professional development pertaining to the permit applied for	
4.	*I have not been convicted of an offence that is of such a nature that renders me unsuitable to perform any function or provide a service authorised by any permit issued	
5.	*I declare that I am registered with, and in good standing with my statutory council(s)	
6.	*I undertake comply with all conditions upon which the permit may be issued	
7.	*I understand that any permit issued will only entitle me to provide services within my scope of practice	
8.	*I am aware that any permit issued is not transferable to any other person(s)	
9.	*I hereby give consent for an inspection of the premises in terms of the applicable legislation either before a permit is issued, while any permit issued is valid, or after it has been cancelled / withdrawn	
10.	*I undertake to only handle medicines in accordance with the applicable list provided as an annexure to the permit issued to me.	
11.	*I undertake to display any permit issued conspicuously at the premises for which I have applied	
12.	*I undertake to inform the Director General of any changes pertaining to any permit issued, including but not limited to loss or damages, and changes in name, physical address and contact details	

Section G: Supporting Documents

A copy of each of the supporting documents, as specified below, must be submitted with the application. (*Certified copies must not be older than 6 months*)	***Mark with X below***
• Certified copy of existing permit (if you are currently in possession of a valid permit)	☐
• Certified copy of South African identity document/passport or other relevant document issued by the Department of Home Affairs	☐
• Certified proof of current registration with the South African Nursing Council as a midwife	☐
• Proof of payment of current annual fees with applicable Statutory Council	☐
• Certified copy of applicable primary nursing qualification certificates	☐
• Certified copies of secondary qualifications (list below): _____ _____ _____ _____	☐

Section H: Declaration by Applicant (To be signed in front of commissioner of oaths)

1. I, _____ (name and surname) hereby give consent for an inspection of the premises in terms of the applicable legislation.
2. The information furnished herewith is true and correct and all supporting documents are valid.

.....	.....	.....
APPLICANT'S FULL NAME	**SIGNATURE**	**DATE:** *dd/mm/yyyy*

SECTION I: DECLARATION BY COMMISSIONER OF OATHS

SIGNED and SWORN to before me on this _____day of _____in the year _____

The deponent (applicant) having acknowledged that he/she understands the contents of this declaration.

.....

NAME, DESIGNATION & SIGNATURE OF COMMISSIONER OF OATHS **COMMISSIONER STAMP**