



GNR.553 of 25 April 2003: Regulations relating to the Ownership and Licencing of Pharmacies

DEPARTMENT OF HEALTH

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)

The Minister of Health has, in consultation with the South African Pharmacy Council, in terms of sections 22 and 22A of the Pharmacy Act, 1974 (Act No. 53 of 1974), made the regulations in the Schedule.

SCHEDULE

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1. Definitions.—In these regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates—

“authorised prescriber” means a medical practitioner, dentist, veterinarian or any other person authorised to prescribe medicines in terms of the Medicines Act;

“community pharmacy” means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public or any defined group of the general public, but excludes an institutional pharmacy;

“institutional pharmacy” means a pharmacy situated in a—

- (a) public health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that public health facility; or
- (b) private health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that private health facility;

“manufacturing pharmacy” means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 16 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicine only to the wholesale or retail sector or to the State;

“Medicines Act” means the Medicines and Related Substances Act, 1965, (Act No. 101 of 1965);

“private health facility” means any hospital, institution or facility at which provision is made for medical treatment or health care services which is not owned or controlled by the State, and includes facilities such as a clinic, mobile clinic, community health centre, maternity home, or unattached delivery suite, convalescent home, unattached operating theatre and sanatorium but does not include a consulting room, surgery or dispensary of an authorised prescriber;

“public health facility” means any hospital, institution or facility at which provision is made for medical treatment or other health care services and includes facilities such as a clinic, mobile clinic, community health centre, maternity home or unattached delivery suite, convalescent home, unattached operating theatre and sanatorium that is owned by the State or organ of the State;

“the Act” means the Pharmacy Act, 1974, (Act 53 of 1974);

“wholesale pharmacy” means a pharmacy wherein or from which some or all the services as prescribed in terms of regulation 17 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicines only to the retail sector or to the State.

CHAPTER I

2. Ownership of manufacturing or wholesale pharmacies.—The State or any person may, subject to the provisions of regulation 7 (a), own or have a beneficial interest in a manufacturing or wholesale pharmacy.

3. Ownership of institutional pharmacies in public health facilities.—

- (1) The State or a person referred to in regulation 4 may own or have a beneficial interest in an institutional pharmacy in a public health facility in the Republic.
- (2) Notwithstanding sub-regulation (1), the State may enter into arrangements with the private sector for the management of an institutional pharmacy in a public health facility.

4. Ownership of institutional pharmacies in private facilities.—Any person may, subject to the provisions of regulation 7, own or have a beneficial interest in an institutional pharmacy in a private health facility in the Republic, on condition that such a person or in the case of a body corporate, the shareholder, director, trustee, beneficiary or member, as the case may be, of such body corporate—

- (a) is not prohibited by any legislation from owning a pharmacy or having any direct or indirect beneficial interest in such a pharmacy;
- (b) is not an authorised prescriber;
- (c) does not have any direct or indirect beneficial interest in or on behalf of a person contemplated in paragraphs (a) and (b); or
- (d) is not the owner or the holder of any direct or indirect beneficial interest in a manufacturing pharmacy.

5. Ownership of consultant pharmacies.—Any person may own or have a beneficial interest in a consultant pharmacy.

6. Ownership of community pharmacies.—Any person may, subject to the provisions of regulation 7, own or have a beneficial interest in a community pharmacy in the Republic, on condition that such a person or in the case of a body corporate, the shareholder, director, trustee, beneficiary or member, as the case may be, of such body corporate—

- (a) is not prohibited by any legislation from owning or having any direct or indirect beneficial interest in such a pharmacy;
- (b) is not an authorised prescriber;
- (c) does not have any direct or indirect beneficial interest in or on behalf of a person contemplated in paragraphs (a) and (b); or
- (d) is not the owner or the holder of any direct or indirect beneficial interest in a manufacturing pharmacy.

7. Conditions for the ownership of pharmacies.—

- (1) A person who may own a pharmacy in terms of section 22A of the Act and who applies for a licence in terms of section 22 of the Act shall provide the Director-General with—
 - (a) proof that such person is able to comply with standards of Good Pharmacy Practice as determined by the council, and where applicable, Good Manufacturing Practice or Good Distribution Practice as determined by the Medicines Control Council, a body established in terms of section 2 of the Medicines Act; and
 - (b) an undertaking that such person shall comply with standards referred to in paragraph (a).
- (2) The person referred to in subregulation (1) must satisfy the criteria for the determination of a need for the pharmaceutical service in respect of an area for which the application is made, which includes but is not limited to—
 - (a) the location of the premises applied for;

- (b) the benefit to members of the specific community which the pharmacy intends serving;
- (c) the nature and extent of the pharmaceutical service to be provided;
- (d) a statutory requirement for the location of a pharmacy within a private or public health facility;
- (e) the approximate number of the population to whom a pharmaceutical service will be provided;
- (f) the relationship between the proposed pharmaceutical service and existing services and facilities;
- (g) the extent of the provision of services to persons outside the service area and the extent and nature of the availability of pharmaceutical services in the nearby areas;
- (h) any special care needs of the community to be served;
- (i) an inspection report by the council of the premises.

CHAPTER II

8. Licensing of pharmacy premises.—

- (1) A person desiring to own a pharmacy in terms of section 22A of the Act shall—
 - (a) submit to the Director-General:
 - (i) a duly completed application on a form approved by the Director-General; and
 - (ii) acceptable documentary evidence that the applicant complies with the applicable conditions contemplated in regulations 2, 3, 4, 5, 6 and 7; and
 - (b) pay the application fee as determined by the Director-General.
- (2) Notwithstanding sub-regulation (1), the Director-General may request the assistance of the council in determining whether a person contemplated in subregulation (1) complies with the conditions for ownership in respect of a specific pharmacy.
- (3) If the Director-General is satisfied that the application in terms of subregulation (1) and other documents submitted in support of such application, including an inspection report of the premises from the council, complies with the provisions of these regulations, he or she may issue a licence, subject to conditions as he or she may determine, for each one of the premises wherein or from which such pharmacy business may be conducted.
- (4) A person who is a holder of a licence issued in terms of subregulation (3) shall, within 30 days from the date of issue of such license, but prior to the provision of any pharmaceutical services from the premises specified in the licence, notify the council thereof on the form approved by the Director-General.
- (5) The council shall on receipt of the notification referred to in subregulation (4), and on payment of a recording fee as determined by the council, record the name, address, date of licence and licence number.
- (6) A licence issued in terms of sub-regulation (3) shall not be transferable to a person not authorised in terms of the Act to own a pharmacy.

9. Withdrawal of a licence.—The Director-General may withdraw a licence issued in terms of regulation 8 (3) if the person issued with such a licence—

- (a) has failed to comply with any of the conditions of ownership or the licensing requirements in terms of the Act and these regulations;
- (b) disposes of the whole or any part of his, her or its interest in a pharmacy or the body corporate that owns such pharmacy to any person not authorised to own a pharmacy or have any direct or indirect beneficial interest in a pharmacy;
- (c) contravenes any provision of the Act, the Medicines Act or any other legislation applicable to such pharmacy;
- (d) is sequestered or liquidated;
- (e) fails to pay any fees payable in terms of the Act and these regulations;
- (f) fails to comply with the registration or recording requirements prescribed in terms of the Act;
- (g) being a pharmacist, has been suspended from practising as a pharmacist or if such person's name has been removed from the register in terms of section 45 (1) of the Act and such name has not been restored in the register;
- (h) is not carrying on the business of a pharmacy or the pharmacy is not in operation;
- (i) fails to comply with Good Pharmacy Practice or Good Manufacturing or Distribution Practice referred to in regulation 7 (1) (a).

CHAPTER III

10. Appeals and procedure for appeal.—With regard to an appeal contemplated in section 22 (11) of the Act,

- (a) the appellant shall lodge his, her or its appeal within 30 days from the date when notice of such decision in writing was sent by registered mail to the appellant;
- (b) the notice of appeal shall be in writing and under oath, stating in full the decision appealed against and the grounds for the appeal and must also state the physical address, being not more than ten (10) kilometres from the office of the Minister, where the appellant will accept delivery of all documents relevant to the appeal;
- (c) the notice of appeal shall be lodged with the Minister who shall, within 30 days of receipt of such notice, appoint the appeal committee to decide the appeal;
- (d) the Minister shall within five (5) days of receipt of the notice of appeal acknowledge receipt in writing, allocate a case number and notify the appellant and all other parties to such appeal, as the case may be, of such notice;
- (e) the appeal committee—
 - (i) shall determine the procedure for its hearings;
 - (ii) may, if it deems necessary, call for oral evidence or argument or summon any person who may give information concerning the subject of the appeal;
 - (iii) shall, if it calls for oral evidence or argument, determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Director-General or the council; and

- (iv) shall administer an oath to or accept an affirmation from any person called as a witness in a case where it has called for oral evidence or argument;
- (f) the appeal committee shall consider the appeal and make a decision in regard thereto within a period of thirty days from the date—
 - (i) on which it was appointed; or
 - (ii) when the appeal hearing was completed, whichever is the later.

11. Commencement.—These regulations come into operation on 2 May 2003.

ME Tshabalala-Msimang
MINISTER OF HEALTH