

DEPARTMENT OF HEALTH

NO. 7538

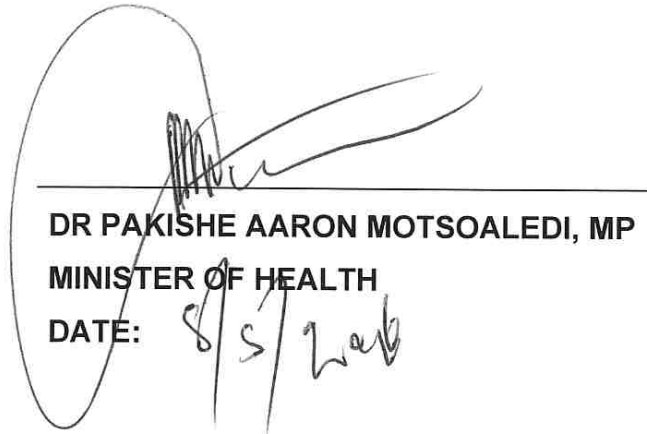
29 May 2026

NATIONAL HEALTH ACT, 2003 (ACT No. 61 OF 2003)

REGULATIONS RELATING TO RENAL DIALYSIS

The Minister of Health intends, in terms of section 90(1)(q) of the National Health Act, 2003 (Act No. 61 of 2003), and in consultation with the National Health Council and Office of the Health Standards Compliance, to make regulations contained in the Schedule.

Interested persons are invited to submit any substantiated comments on the proposed Regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 for the attention of the Deputy Director: Organ Transplant and Renal dialysis, Lindsey Jacobs, or email: lindsey.jacobs@health.gov.za within three months of this Notice.



DR PAKISHE AARON MOTSOLEDI, MP
MINISTER OF HEALTH
DATE: 8/5/2026

SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act, has the meaning so assigned, and unless the context otherwise indicates—

“clinical technologist” means a person registered with Health Professions Council of South Africa as a clinical technologist;

“dialysis” means a process of removing waste and excess water from the blood; and includes both haemodialysis and peritoneal dialysis modalities;

“dialysis facility” means any facility that provides any form of dialysis for adults or Children and includes home-based therapies;

“hospital” means a health establishment which is classified as a hospital by the Minister in terms of section 35 of the National Health Act, 2003 (Act No 61. of 2003);

“MEC” means the Member of the Executive Council of a province responsible for health;

“nephrologist” means a physician who has been formally trained in the diagnosis and management of kidney diseases, who is registered as a nephrologist with the Health Professions Council of South Africa;

“nephrology nurse specialist” means a nurse who is registered as such with the South African Nursing Council;

“OHSC” means the Office of the Health Standards Compliance established in terms of section 77 of the Act;

“palliative care” means an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other problems, physical, psycho-social and spiritual;

“registered nurse” means a person registered as such by the South African Nursing Council;

“specialist physician” means a medical practitioner registered as such with the Health Professions Council of South Africa, with experience in renal care and dialysis;

“**staff nurse**” means a person registered as such by the South African Nursing Council; and

“**the Act**” means the National Health Act, 2003 (Act No. 61 of 2003).

Application of regulations

2. These Regulations apply to all public and private health establishments in the Republic of South Africa.

Licensing of renal dialysis facilities

3. (1) No person may establish a renal dialysis facility or conduct dialysis without a license issued by the Provincial Department of Health.

(2) A renal dialysis facility license is required for all dialysis facilities, except the facilities housed in state health establishments, state health establishments must register dialysis facilities with the Provincial Department of Health.

(3) Separate licenses are required for facilities not operating on the same premises even though they belong to the same entity or person.

(4) Dialysis facilities not situated within a licensed health care facility must comply with all the requirements of a dialysis facility contemplated in regulation 8 and all other regulations applicable to medical facilities.

(5) A license is not transferable and is subject to revocation by the Provincial Department that granted it, for failure to comply with all the requirements of a dialysis facility contemplated in regulation 8 and all applicable regulations to such medical facilities.

(6) A facility may be licensed only if a nephrologist or group of nephrologists or where no nephrologist is available a specialist physician with experience in dialysis formally agrees to take responsibility for the care of the patients serviced by the facility.

(7) Each patient must be assigned under the care of a nephrologist or group of nephrologists, physicians or paediatricians with experience in dialysis where a nephrologist is not available.

Application for licence

4. (1) Any person who wishes to establish a renal dialysis facility or conduct dialysis services must apply for a licence to the Head of Department of the Provincial Department of Health on a form obtainable from the Provincial Department of Health.

(2) The application for each renal dialysis facility must contain the following information:

- (a) The name, address and telephone number of the renal dialysis facility;
- (b) the name and address of the licensee;
- (c) the name of the parties with at least five per cent ownership;
- (d) the name of the person in charge of the renal dialysis facility;
- (e) the name of the person in charge of the nursing services;
- (f) the name, practice address and contact details of the nephrologist or specialist physician in charge of the facility;
- (g) the name and contact details of the transplant coordinator;
- (h) the name and contact details of the responsible clinical technologist (in Nephrology) or nephrology nurse specialist;
- (i) the number of home haemodialysis patients to be served from the facility;
- (j) the number of patients served by the facility on any form of peritoneal dialysis;
- (k) evidence of an arrangement with medical practitioner(s) practising within five kilometres of the renal dialysis facility, who will provide emergency care and resuscitation of patients, if the responsible nephrologist or specialist physician is located off-site;
- (l) evidence of an arrangement with the Emergency Medical Services or hospital to transfer and receive the patient for inpatient care;
- (m) any other information the Head of Department may consider necessary for the consideration of the application; or
- (n) Nephrologist or responsible overseeing medical practitioner

(3) The licensing body needs to be informed of any changes in the information in sub-regulation (1).

(4) The pre-existing dialysis facilities must apply for licences within twelve months of the date of publication of these Regulations.

(5) The Head of Department must grant or refuse the licence within 30 days after the receipt of the application, and if the application for a license is refused, the Head of Department must provide reasons in writing for such refusal.

(6) The applicant whose license has not been granted may lodge an appeal with the MEC within ten calendar days of receiving a notice of the decision from the Head of Department.

(7) The MEC may uphold or set aside the decision of the Head of Department within 30 calendar days of receipt of the appeal from the appellant.

(8) If a renal dialysis facility expands its services an addendum to the existing license must be filed with the relevant Head of Department of the Provincial Department for approval of the expansion.

(9) A license is valid for a period not exceeding four years.

(10) The application must be accompanied by a fee determined by the Provincial Department's office responsible for licensing of facilities.

Requirements for renewal of license

5. (1) Application forms for renewal of a license must be submitted at least 90 calendar days before the expiry date of the license.

(2) The application for renewal of the license must be accompanied by a fee as determined by the Provincial Department's office responsible for licensing of private facilities.

Inspection

6. (1) All renal dialysis facilities must be subjected to inspection by OHSC on a regular basis to a minimum of once every four years and or additional inspections on an *ad hoc* basis based on investigations following complaints or Early Warning System Surveillance to ensure compliance with these Regulations and Norms and Standards Regulations as published on Government Notice No. R67 in *Regulation Gazette No. 41419* of 2 February 2018.

(2) A certificate of compliance or non-compliance must be issued by the OHSC on successful completion of its inspection.

(3) The inspections may be conducted as frequently as is necessitated by circumstances or clinical needs or as directed by the provincial authorities or deemed necessary by OHSC.

Suspension or revocation of license

7. (1) Where a non-compliance with these Regulations is found, the applicant or person responsible for the renal dialysis facility must be notified of the violation and must be given a period of 90 calendar days to take corrective measures.

(2) If non-compliance threatens the safety of patients or staff, the license must be withdrawn with immediate effect by the Provincial Department of Health.

(3) If the applicant or person responsible for the renal dialysis facility fails to take corrective measures as contemplated in sub-regulation (1), the certificate of compliance issued by OHSC and license may be suspended or revoked.

Application for change of license

8. (1) The license may not be transferred to any party when the renal dialysis facility ceases to operate.

(2) When a license is revoked it must be returned to the Provincial Department of Health within one month of the revocation.

(3) Whenever the ownership of the renal dialysis facility changes, the new owner must submit an application for a new license within 90 calendar days of such change.

(4) Failure by the new owner to acquire a license will result in the closure of the renal dialysis facility by the Provincial Department of Health.

(5) Should any licencing conditions change, the Provincial Department of Health must be notified to ensure that the facility remains compliant with the licensing conditions.

Requirements for dialysis facilities

9. (1) Every dialysis facility must comply with the guidelines for dialysis facilities in the following areas:

- (a) Infection prevention, control and surveillance;
- (b) sterilisation service;
- (c) the provision of water for dialysis according to the Association for the Advancement of Medical Instrumentation dialysis water standards and should maintain a documented water quality monitoring and maintenance programme.
- (d) the management of waste products (disposables and fluids);
- (e) the supply and storage of pharmaceuticals and dialysis consumables;
- (f) all requirements relating to food and beverage supply;
- (g) fully equipped resuscitation trolley and dialysis chairs or beds designed to lie the patient flat for resuscitation; Cardiopulmonary Resuscitation staff training and certification
- (h) the acquisition of assets, equipment and consumables;
- (i) laundry and linen supply;
- (j) cleaning services;
- (k) engineering service including preventive and maintenance services;
- (l) security of patients, staff and equipment;

- (m) fire extinguishers, fire hydrants and appropriate signage, exits, evacuation plan, emergency vehicles access;
- (n) medical record management;
- (o) communication systems;
- (p) dialysis quality assurance programme which includes monitoring of dialysis adequacy, infection rates, vascular access outcomes and other relevant clinical indicators determined by the Director-General;
- (q) occupational safety;
- (r) each facility must a contingency plan in the event of any interruption of dialysis services that could severely influence a patient's clinical outcomes; and
- (s) patient confidentiality must be maintained, and safe storage of personal information and medical records as per relevant legislation.

(2) The dialysis facility must provide—

- (a) restricted access to the dialysis treatment area;
- (b) isolation cubicles for treatment of patients with contagious diseases or for arrangements for the transfer and management of patients requiring isolation;
- (c) If peritoneal dialysis is offered, a dedicated area to consult with patients on this treatment must be provided for; and
- (d) access for an ambulance as well as have access for stretchers and wheelchairs.

(3) A valid licence and the OHSC certificate of compliance must be displayed conspicuously.

Staff complement

10. (1) A nephrologist must be assigned to a renal dialysis facility.

(2) Where a nephrologist is not available, a specialist physician with credentialing in dialysis must be in charge of the renal dialysis facility.

(3) A nephrology nurse specialist must be in charge of the nursing component of a dialysis facility.

(4) There must be one registered nurse who is adequately trained in nephrology available, together with trained assistants or enrolled nurses; the nephrology nurse specialist to patient ratio should be one for every five patients receiving haemodialysis.

(5) There must be at least one clinical technologist (in Nephrology) available for each renal dialysis facility.

(6) Peritoneal dialysis nurses need to be specially trained in this speciality area.

(7) The patient-to-nurse ratio in the peritoneal dialysis facility must not be less than 1: 20 patients.

(8) All the facilities must designate a recipient transplant facilitator.

Clinical support services

11. Each renal dialysis facility must have access to a psychosocial service, palliative care services, a dietician as well as transplant services to address the patients' relevant needs of the patients and their families.

Shared management or transfer agreement

12. (1) Each dialysis facility must have access to a vascular surgeon or an experienced surgeon to create permanent dialysis access, including arterio-venous fistula, arterio-venous graft, tunnelled venous catheter, and tunnelled peritoneal dialysis catheter.

(2) When a patient is transferred from one renal dialysis facility to another, irrespective of whether the renal dialysis facility is private or state owned, appropriate arrangements must be made before the patient is transferred.

(3) The transfer of patients contemplated in sub-regulation (2) must be accompanied by a written comprehensive clinical report, including:-

- (a) relevant clinical information, including transplant waitlisting;
- (b) the prescribed medication;
- (c) the dialysis prescription and the details of dialysis access;
- (d) the recent laboratory and other relevant test results, including recent (less than three months) hepatitis B, C virus and HIV status tests; and
- (e) the current attending doctor's name and contact details.

Patient's rights and responsibilities

13. (1) All renal dialysis facilities must have written policies, protocols and documentation on procedures, which must be available on request to patients, their guardians and next of kin.

(2) A patient must be—

- (a) fully informed of their rights and their responsibilities prior to receiving dialysis;
- (b) fully informed of the treatment options that are available including peritoneal dialysis, haemodialysis and transplantation.
- (c) afforded the opportunity to participate in the planning of their treatment;
- (d) treated with consideration, respect and full recognition of their rights and individual needs;
- (e) afforded an opportunity to be assessed for eligibility for kidney transplantation and must be informed about the potential benefits of kidney transplantation; and
- (f) given the right to request withdrawal from dialysis treatment.

(3) A patient entering into renal dialysis treatment must sign a form in which their consent to therapy is given.

Chronic dialysis priority setting in state health establishments

14. Where public health establishments with renal dialysis facilities are limited and prioritisation is practised, preference should be given to patients with a better

prognosis in accordance with national clinical guidelines or approved clinical protocols by the Director-General.

Establishment and composition of the Assessment Committee for chronic dialysis where prioritisation is practised

15. (1) A public health sector renal dialysis facility must establish an Assessment Committee for chronic dialysis where prioritisation is practised.

(2) The Assessment Committee must be comprised of at least a Nephrology Nurse, a Social Worker, a Medical Manager and a Nephrologist.

(3) A quorum for the committee meeting must be at least three members, including the Nephrologist or a medical practitioner with experience in renal care.

- (4) The functions of the Assessment Committee are to ensure—
- (a) that the clinical assessment and the decision for admission or prioritisation to the renal replacement programme (chronic dialysis and transplantation) are fair and in accordance with the criteria set out by the Director-General;
 - (b) that the decision of the Assessment Committee and the reasons for exclusion are conveyed to the patient or the family as soon as possible by the doctor caring for the patient in terms and language that he or she understand, and that the appeals process is explained as well;
 - (c) that the meeting is minuted and all decisions with reasons are clearly stated in the minutes;
 - (d) that the attendance register is signed by all attendees; and
 - (e) that there is referral pathway for palliative care if the patient is rejected for the chronic dialysis program.

Appeal procedure

16. (1) If the patient or his or her spouse or partner or parent or guardian or the siblings or children of the patient is dissatisfied with the decision of the Assessment Committee, he or she may lodge an appeal to the Chief Executive Officer of the institution within 10 working days of being informed of the committee's decision.

(2) On lodging or making a representation, the appellant or person making representation must set out clearly the basis for the appeal or representation.

(3) The CEO must—

- (a) request the Assessment Committee to provide reasons for its decision;
- (b) convene a meeting of the Assessment Committee to review the decision of the Committee and make an executive decision based on the recommendations of the Assessment Committee.
- (c) finalise the appeal within 10 calendar days; and
- (d) inform in writing the Assessment Committee and the patient or family of the decision.

Documentation and medical records

17. (1) All facilities providing dialysis must keep the medical records on a system designed to provide readily available information on each patient.

(2) All procedures, blood results, test results, treatment, clinical notes, must be adequately documented.

(3) The dialysis facility records system must provide information on:-

- (a) the number of patients currently on chronic dialysis;
- (b) the number of patients refused acceptance to the chronic dialysis programme and the reasons therefor;
- (c) the number of patients referred and transplanted; and
- (d) mortality and morbidity data.

- (4) Service records of all equipment and dialysis water system

Reporting

18. (1) The facility manager must inform the patients on dialysis that all dialysis facilities are required to provide identifiable patient data to the National Department of Health, or a juristic person assigned by the department.

(2) All facilities performing chronic dialysis or kidney transplantations must submit requisite patient data and a complete questionnaire to the National Department of Health on an annual basis or within a timeframe determined by the National Department of Health or whenever there are changes to the treatment regime.

Short title

19. These Regulations are called the Regulations Relating to Renal Dialysis, 2026.