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Towards stronger oversight of organ transplantation: Proposed regulations out for comment

In September 2026, the National Department of Health (NDoH) published the long-awaited Regulations on Organ Transplantation[1] for public comment. The proposed regulations constitute a comprehensive revision of the regulatory framework governing organ donation and transplantation in South Africa (SA), and seek to strengthen governance, oversight, accountability and equity within the transplantation system. Interested parties are encouraged to submit comments and representations by 4 December 2026. To assist readers in navigating the proposed changes, the regulations are summarised below, with particular emphasis on their principal provisions and potential implications for organ donation and transplantation practice in SA.

A central feature of the regulations is the establishment of a formal governance structure for transplantation. The framework provides for a National Transplant Co-ordinator within the NDoH, supported by Provincial Transplant Co-ordinators and transplant co-ordinators at authorised facilities. This tiered structure is intended to improve co-ordination of transplant services, standardise practices across institutions, facilitate implementation of national policies, and monitor compliance, outcomes and quality-improvement initiatives. The co-ordinators will also be responsible for public awareness programmes and for supporting research and innovation in the field of transplantation.

One of the most significant innovations is the creation of a national organ donation and transplantation database. The database will serve as a central repository for information relating to donor referrals, organ donation, waiting lists, transplant procedures and post-transplant outcomes. All authorised transplant centres will be required to contribute data. The intention is to improve transparency, facilitate regulatory oversight, support service planning and provide reliable national data for research and quality improvement.

The regulations also introduce detailed standards governing organ procurement and preservation. Before transplantation, donors must undergo blood-group testing, tissue typing and screening for infectious diseases and malignancies. Organs must be preserved using South African Health Products Regulatory Authority (SAHPRA)-approved preservation solutions. In addition, a documented chain of custody must be maintained throughout the donation and transplantation process, with each donor assigned a unique identifier to ensure traceability. These provisions are intended to strengthen patient safety and quality assurance.

Considerable emphasis is placed on record-keeping and reporting. All referrals, donations, procurements and transplant procedures must be documented, including information relating to donors and recipients, donor-recipient relationships, retrieval teams, transplant clinicians and the disposition of organs that are retrieved but not transplanted. Transplant facilities will be required to submit regular reports to the NDoH, thereby enabling ongoing monitoring of transplantation activities and outcomes at a national level.

The regulations place strong emphasis on protecting living donors. Prospective donors must provide fully informed consent after receiving information regarding the risks, benefits and implications of donation. Psychological assessment is required, and donors must be free from coercion or undue influence. Importantly, consent may be withdrawn at any stage prior to donation. Consistent with existing ethical and legal principles, financial rewards and other inducements for donation are expressly prohibited, reinforcing the principle that organ donation should remain voluntary and altruistic.

Notably, the regulations retain the requirement for ministerial approval for living donations involving donors who are not biologically related to the recipient. Parents, children, siblings, grandparents, grandchildren and certain extended blood relatives are regarded as biologically related donors. Applications involving unrelated donors must be supported by comprehensive medical, psychosocial and ethical assessments demonstrating donor suitability and the absence of coercion or financial motivation. While this provision is intended to prevent organ trafficking and exploitation, some transplant professionals may question whether ministerial approval could continue to create administrative delays.

The regulations also introduce stricter controls relating to transplantation involving non-SA citizens. Such procedures require ministerial approval, verification of identity, evidence that appropriate post-transplant care will be available in the recipient's country of residence, and tissue typing undertaken in SA. These measures appear directed at discouraging transplant tourism, strengthening oversight of cross-border transplantation and reducing opportunities for organ trafficking and commercialisation.

A significant section of the regulations deals with allocation of deceased donor organs. Allocation decisions may not be based on race, religion, political affiliation, culture, gender, sexual orientation, disability or social origin. Instead, allocation must be guided by objective clinical criteria, including ABO compatibility, human leukocyte antigen (HLA) matching, medical urgency, waiting time and organ suitability. The inclusion of explicit equity provisions is intended to promote fairness, transparency and public confidence in the allocation process.

The regulations further introduce oversight of organ allocation systems. Allocation programmes must be authorised by the Director-General of the NDoH and operate according to approved standard operating procedures with appropriate reporting and monitoring mechanisms. The Director-General may establish an oversight body to evaluate allocation systems and ensure compliance with ethical and regulatory requirements. These provisions seek to strengthen accountability and ensure consistent application of allocation criteria.

Minimum requirements for authorised institutions (transplant centres) are also outlined. Facilities must demonstrate appropriate clinical leadership, multidisciplinary expertise and the capacity to provide long-term follow-up care to recipients. Transplant institutions will be required to report transplant activity regularly, and the Director-General must publish licensing criteria for transplant units within 12 months of promulgation of the regulations. The aim is to ensure that transplantation is undertaken only in facilities that meet prescribed standards of quality and safety.

To support compliance, authorised institutions will be subject to annual inspections and audits, with additional investigations permitted where complaints, adverse events or safety concerns arise. The regulations empower authorities to suspend or withdraw authorisation where facilities fail to meet regulatory requirements, thereby strengthening accountability and quality assurance within the transplantation sector.

An innovative provision concerns transplants performed outside SA. Healthcare professionals will be required to report instances where SA residents either donate organs abroad or receive transplants in foreign countries. Their data must be captured within the national transplantation database. The requirement is intended to improve monitoring of cross-border transplantation activities, assist with long-term follow-up and provide greater visibility of potential transplant tourism. Failure to report may constitute professional misconduct.

The regulations also reinforce the importance of confidentiality. Information identifying donors or recipients is protected, and may generally only be disclosed with written consent or where authorised by law. At the same time, the regulations strengthen prohibitions against the commercialisation of human organs by forbidding financial rewards, inducements and unauthorised payments to donors, recipients or intermediaries.

Significant penalties are prescribed for non-compliance. Individuals who contravene the regulations may face fines, imprisonment of up to 10 years, or both. These sanctions underscore the seriousness with which unethical transplantation practices, organ trafficking and regulatory breaches are regarded.

The regulations could be seen as representing the most comprehensive reform of SA's transplantation framework in many years. Positive developments include the establishment of formal governance structures, creation of a national transplant database, strengthened oversight mechanisms, enhanced protection of living donors, explicit equity principles in organ allocation and tighter regulation of transplant tourism. However, concerns may be raised regarding the continued requirement for ministerial approval of unrelated living-donor transplants and the increased administrative burden associated with extensive reporting obligations. In addition, the regulations stop short of establishing a single national organ allocation organisation comparable with those operating in several high-income countries.

Nevertheless, the proposed framework represents an important step towards a more co-ordinated, transparent and accountable transplantation system. If effectively implemented, the regulations have the potential to strengthen public trust, improve oversight and support the continued development of organ donation and transplantation services in SA.



Declaration. AD is a member of the Ministerial Advisory Committee for Unrelated Organ Transplantation.

AI contribution. Copilot was used to assist with language refinement.

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1. South Africa. National Health Act No. 61 of 2003. Government Gazette No. 55299, Notice No. 7879. Regulations on Organ Transplantation (4 September 2026). https://www.gov.za/sites/default/files/gcis_document/202609/55299gon7879.pdf (accessed 28 October 2026).