

3. Transplantation of Human Organs and Tissues Rules, 2025 - Polity

The Union Ministry of Health and Family Welfare has amended the Transplantation of Human Organs and Tissues (Amendment) Rules, 2025 under the Transplantation of Human Organs and Tissues Act, 1994

Context and Purpose of the Amendment

The Government of India has amended rules governing corneal transplantation centres to improve efficiency, accessibility, and quality of eye-care services. The amendment strengthens the National Organ Transplant Programme (NOTP) by simplifying requirements and removing barriers for setting up corneal transplant facilities. It aims to expand the nationwide network of eye banks and corneal transplant centres, ensuring timely availability of donor corneas, especially in underserved regions. The reform supports India's long-term vision of universal, equitable, and affordable eye-care services as part of national blindness control strategies.

Key Changes Introduced (Highlights of the Amendment)

The amendment removes the mandatory requirement of having a Clinical Specular Microscope in corneal transplantation centres. Earlier, the microscope was used to analyze endothelial cell density to assess corneal suitability; however, advancements in screening protocols and decentralised eye-banking have made this requirement less essential. This step significantly reduces infrastructure costs, enabling more hospitals and eye-care centres to participate in corneal transplantation. The amendment also focuses on streamlining administrative processes for transplant centres to improve coordination between -

1. Hospitals
2. Eye banks / tissue banks
3. Regulatory bodies
4. National Organ & Tissue Transplant Organisation (NOTTO)

Understanding the Cornea (Structure and Function)

The cornea is the transparent, dome-shaped outer layer of the eye that allows light to pass into the lens and retina. It accounts for two-thirds of the eye's total focusing power. Acts as the first line of defence against external threats like dust, microorganisms, and mechanical injury. Maintains the curvature and structural integrity of the eyeball through fluid balance. Has an extremely high density of nerve endings—300–600 times more than skin—which ensures immediate protective reflexes. Composed of six distinct layers, each crucial for clarity and refractive ability -

1. **Epithelium** - Protective outer layer; regenerates quickly.
2. **Bowman's Layer** - Tough layer providing structural support.
3. **Stroma** - Thickest layer; contributes to transparency via orderly collagen arrangement.
4. **Pre-Descemet's (Dua's) Layer** - A recently discovered layer aiding structural stability.
5. **Descemet's Membrane** - Supports endothelial cells.
6. **Endothelium** - Maintains fluid balance; damage leads to swelling and opacity.

Why Corneal Transplantation Is Needed

The cornea's clarity can be compromised due to -

1. Infections (keratitis)
2. Injuries and chemical burns
3. Nutritional deficiencies
4. Congenital disorders
5. Age-related degeneration
6. Post-surgical complications

Minor injuries often self-heal, but deeper scarring or endothelial damage leads to irreversible opacity, causing severe visual impairment. Treatment options include -

7. Keratoplasty (corneal transplantation)
8. Keratoprosthesis (artificial cornea) for complex cases

Burden of Corneal Blindness in India

Corneal blindness is the second-leading cause of blindness in India, particularly in people aged 50 years and above. India has approximately 1.2 million people suffering from corneal blindness. An additional 25,000–30,000 new cases are reported every year. Majority of cases are preventable with improved eye care, prompt treatment of injuries, and increased availability of transplantable corneas.

Significance and Expected Impact of the Amendment

A. Strengthening Healthcare Infrastructure – Reduction in mandatory equipment cost allows more hospitals—including district hospitals and medical colleges—to be certified as corneal transplantation centres. Increases availability of trained personnel and decentralizes corneal transplantation services.

B. Boosting Eye Donation and Transplantation Ecosystem – Streamlined processes improve coordination among –

1. Eye donation counselors
2. Retrieval centres
3. Eye banks
4. Corneal surgeons

Enhances timely retrieval, preservation, transport, and allocation of donor corneas.

C. Supporting NOTP and National Blindness Control Initiatives – Strengthens integration with the National Organ Transplant Programme (NOTP) and National Programme for Control of Blindness and Visual Impairment (NPCBVI). Helps align India's eye-care framework with global best practices.

D. Advancing Equity and Accessibility – By reducing regulatory and financial hurdles, more rural and semi-urban centres can offer corneal transplantation. Benefits economically weaker sections who lack access to tertiary eye-care facilities.

E. Long-Term Vision – Contributes to reducing the national burden of visual impairment. Supports India's goal to become self-sufficient in cornea availability, reducing dependence on imported donor tissues. Improves quality of life and economic productivity for millions affected by corneal diseases.

Overall Conclusion

The amendment is a critical health sector reform that simplifies regulations, removes barriers to eye transplantation services, and strengthens the overall ecosystem of cornea donation and transplantation. In the long run, it is expected to significantly reduce the burden of corneal blindness in India and promote equitable access to vision-restoring surgeries.

Source – <https://www.thehindu.com/sci-tech/health/simplification-in-corneal-transplantation-rules-to-boost-cornea-donation-and-transplantation-services/article70263185.ece#~text=A%20notification%20in%20this%20regard,been%20removed%20under%20this%20amendment>