

# **Transplantation and Anatomy (Tissue Banks) Amendment Regulation 2020**

Explanatory notes for SL 2020 No. 255

made under the

*Transplantation and Anatomy Act 1979*

## **General Outline**

### **Short title**

*Transplantation and Anatomy (Tissue Banks) Amendment Regulation 2020*

### **Authorising law**

Section 52 of the *Transplantation and Anatomy Act 1979*.

### **Policy objectives and the reasons for them**

The *Transplantation and Anatomy Act 1979* provides for a general prohibition on trading in human tissue and allows tissue banks to recover costs associated with removing, evaluating, processing, storing or distributing donated tissue, and to sell donated tissue for a cost-recovery amount.

Metro South Hospital and Health Service (HHS) operates an Organ and Tissue Donation Service, which trades in various types of tissue products under three separate trading entities – the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank. Metro South HHS has committed to the Queensland Tissue Bank becoming the single tissue bank for Queensland, combining the capabilities of the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank.

The purpose of the *Transplantation and Anatomy (Tissue Banks) Amendment Regulation 2020* (the Amendment Regulation) is to amend the *Transplantation and Anatomy Regulation 2017* (the Regulation) to prescribe the Queensland Tissue Bank as an entity that can recover costs under section 42A of the *Transplantation and Anatomy Act*.

A *tissue bank* is defined under section 42A of the *Transplantation and Anatomy Act* as a facility prescribed by regulation at which donated tissue is stored. Section 12 of the Regulation prescribes the following tissue banks: Queensland Bone Bank; Queensland Eye Bank; Queensland Heart Valve Bank; and Australian Red Cross Lifeblood – for blood and products derived from blood, for medical or scientific purposes.

In 2018, the Australian Commission on Safety and Quality in Health Care released a report of a health service investigation into the Queensland Heart Valve Bank. The Director-General of Queensland Health accepted all recommendations in the report, including the recommendation to combine all existing tissue banks in Queensland into a single structure.

To enable the Queensland Tissue Bank to deal with tissue, a licence to manufacture therapeutic goods is required under the *Therapeutic Goods Act 1989* (Cth). The Therapeutic Goods Administration (TGA) administers the *Therapeutic Goods Act 1989* (Cth) and issues the licences. The process for obtaining the licence variation from the Queensland Bone Bank to the Queensland Tissue Bank has commenced. The licence will allow for the current tissue banks to amalgamate under the Queensland Tissue Bank. The TGA licence is expected to be issued in December 2020 for the Queensland Tissue Bank. It is expected that the tissue products held by the Queensland Eye Bank will fully transition under the licence in 2021.

Once arrangements to amalgamate the existing tissue banks to the Queensland Tissue Bank are completed, a further amendment regulation will be progressed to remove the existing tissue banks from the Regulation.

## **Achievement of policy objectives**

The Amendment Regulation achieves the policy objectives by:

- prescribing the Queensland Tissue Bank as a tissue bank for section 42A of the Transplantation and Anatomy Act, to enable the recovery of costs associated with removing, evaluating, processing, storing or distributing donated tissue and to sell donated tissue for a cost-recovery amount; and
- allowing the current tissue banks to finalise operations as part of the future amalgamation under the Queensland Tissue Bank.

## **Consistency with policy objectives of authorising law**

The Amendment Regulation is consistent with the policy objectives of the Transplantation and Anatomy Act.

## **Inconsistency with policy objectives of other legislation**

No inconsistencies with the policy objectives of other legislation have been identified.

## **Alternative ways of achieving policy objectives**

The Transplantation and Anatomy Act requires that only tissue banks prescribed by regulation can recover costs under the Transplantation and Anatomy Act. Therefore, the Amendment Regulation is the only effective means of achieving the policy objective to recover reasonable costs associated with tissue removal and handling activities, including processing and storing donated tissue.

## **Benefits and costs of implementation**

All operational costs associated with the amalgamation of the tissue banks with the Queensland Tissue Bank will be met within existing budget allocations.

The amendments will allow the Queensland Tissue Bank to recover costs associated with trading tissue products and allow remaining tissue banks to continue to recover costs as they move towards amalgamation into a single tissue bank. There are no cost impacts as a result of the inclusion of the Queensland Tissue Bank in the Regulation.

The amendments also support the implementation of the Australian Commission on Safety and Quality in Health Care recommendation to merge all tissue banking operation to provide for the same oversight and governance procedures to be considered by the single structure of the Queensland Tissue Bank, to help ensure best practice is achieved.

## **Consistency with fundamental legislative principles**

The Amendment Regulation is consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

## **Consultation**

As the Amendment Regulation relates to the cost recovery arrangements for tissue banks operated by Queensland Health and makes no underlying policy changes, it was not necessary to undertake public consultation. Queensland Health consulted with Metro South HHS to advise of the change to the Regulation to support the future amalgamation of the existing tissue banks under the Queensland Tissue Bank.

The Amendment Regulation was assessed by Queensland Health, in accordance with *The Queensland Government Guide to Better Regulation*, as being for the internal management of the public sector or statutory authority under exclusion category (c). Therefore, consultation with the Office of Best Practice Regulation was not required for these amendments.

## **Notes on provisions**

### **Short Title**

*Clause 1* provides the short title of the Amendment Regulation.

### **Regulation amended**

*Clause 2* amends the *Transplantation and Anatomy Regulation 2017*.

### **Amendment of s 12 (Tissue banks—Act, s 42A)**

*Clause 3* amends section 12 of the Regulation to prescribe the Queensland Tissue Bank as a tissue bank that can recover costs for trading donated tissue in accordance with section 42A of the *Transplantation and Anatomy Act 1979*.