

Health Legislation Amendment Regulation 2023

Explanatory notes for SL 2023 No. 2

made under the

Hospital and Health Boards Act 2011
Transplantation and Anatomy Act 1979

General Outline

Short title

Health Legislation Amendment Regulation 2023

Authorising law

Sections 151(1)(a) and 282 of the *Hospital and Health Boards Act 2011*
Sections 42A(6) and 52 of the *Transplantation and Anatomy Act 1979*

Policy objectives and the reasons for them

The purpose of the *Health Legislation Amendment Regulation 2023* (Amendment Regulation) is to amend the:

- *Hospital and Health Boards Regulation 2012* to prescribe the updated Electronic Donor Record (EDR) Agreement to allow Queensland Health to continue to share confidential patient information with other States and Territories and the Commonwealth Organ and Tissue Authority for organ and tissue donation purposes; and
- *Transplantation and Anatomy Regulation 2017* to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank from the list of entities included in the definition of *tissue bank* as the functions of these entities are now performed by the Queensland Tissue Bank.

Hospital and Health Boards Regulation 2012 to update the EDR Agreement

Queensland Health shares confidential information between health authorities of the States and Territories and the Organ Tissue Authority, for organ and tissue donation purposes. This information is recorded in the EDR, which is a national clinical information system. The EDR provides real time access to essential information about organ and tissue donors to facilitate the organ and tissue donation and transplantation process. The Organ and Tissue Authority is a Commonwealth Government entity that works with States and Territories, clinicians and the community sector to deliver the national program to improve organ and tissue donation and transplantation outcomes in Australia.

Section 151 of the *Hospital and Health Boards Act 2011* provides an exception to the prohibition on the disclosure of confidential information by health services or public servants in Queensland Health. The exception in section 151(1)(a) allows for confidential information to be shared with the Commonwealth or another State, or an entity of the Commonwealth or another State if the disclosure is required or allowed under an agreement; and the agreement is prescribed under a regulation; and the chief executive (Director-General of Queensland Health) considers the disclosure is in the public interest and states this in writing.

Schedule 3, part 1 of the Hospital and Health Boards Regulation prescribes the agreements that are within the exception to the prohibition of confidential information for section 151(a)(i)(B) of the Hospital and Health Boards Act.

Schedule 3, part 1, item 9A of the Hospital and Health Boards Regulation prescribes an agreement called '2014-2017 Agreement between the Health Authorities of the States and Territories of Australia and the Organ and Tissue Authority'. This agreement is known as the EDR Agreement. It allows Queensland Health to share confidential information between health authorities of the States and Territories and the Organ Tissue Authority for organ and tissue donation purposes. This agreement has been extended five times and will expire on 12 February 2023.

On 17 August 2022, Queensland Health signed the new EDR Agreement. After all States and Territories had signed the agreement, it was executed by the Commonwealth Government on 24 November 2022. It is necessary to prescribe the new EDR Agreement in schedule 3, part 1, item 9A of the Hospital and Health Boards Regulation, to allow Queensland Health to continue to share confidential information with the other States and Territories and the Organ and Tissue Authority.

The objective of the Amendment Regulation is to allow Queensland to continue to participate in the EDR. Participation in this program provides benefits for Queenslanders by ensuring efficient processes for organ allocation. The EDR significantly reduces errors of content and communication, resulting in safer, timelier and more efficient organ and tissue allocation and transplantation.

Transplantation and Anatomy Regulation 2017 to remove three redundant entities

In March 2019, Queensland Health determined the Queensland Tissue Bank should become the single human tissue bank for the Queensland Government. The Queensland Tissue Bank combined the capabilities of the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank. The integration of these three tissue banks into one tissue bank has proved successful due to a streamlined governance approach.

The *Transplantation and Anatomy (Tissue Banks) Amendment Regulation 2020* prescribed the Queensland Tissue Bank into section 12(b) of the Transplantation and Anatomy Regulation, but did not remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank. This is because the Therapeutic Goods Administration was yet to make licencing changes that would allow the Queensland Tissue Bank to operate. In April 2022, these licence variations were finalised to allow the Queensland Tissue Bank to operate and to revoke the licences of the other three tissue banks.

The objective of the Amendment Regulation is to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank from the list of prescribed entities for the definition of *tissue bank* in section 12(b) of the Transplantation and Anatomy Regulation. This will clarify that the Queensland Tissue Bank is the sole tissue bank for Queensland Health.

Achievement of policy objectives

Amendments relating to the Hospital and Health Boards Regulation 2012

The Amendment Regulation amends schedule 3 of the Hospital and Health Boards Regulation by removing the reference to the EDR Agreement, which expires on 12 February 2023, and prescribes the new organ and tissue donation information sharing agreement called, ‘Agreement between Australian state and territory health departments and the Organ and Tissue Authority concerning the use and maintenance of the EDR to facilitate effective and efficient organ and tissue donation for transplantation across Australia.’

The new agreement will allow Queensland Health to continue to share confidential patient information for the EDR, which will provide a more efficient process of organ allocation and significantly reduce errors of content and communication and enable safer, timelier and more efficient organ allocation for transplantation.

Amendments relating to the Transplantation and Anatomy Regulation 2017

The Queensland Tissue Bank now performs the functions of the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank. It is unnecessary to prescribe entities that no longer perform the function of a tissue bank. The Amendment Regulation amends section 12(b) of the Transplantation and Anatomy Regulation to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank as entities prescribed for the definition of *tissue bank*. Removing these entities will clarify that the Queensland Tissue Bank is the only tissue bank operated by Queensland Health.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the Hospital and Health Boards Act and 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 Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The Amendment Regulation does not impose costs on persons or organisations. The cost of implementing the amendments will be met within existing budget allocations.

The amendments do not impose any new or increased fees.

The amendment to the Hospital and Health Boards Regulation to prescribe the new EDR Agreement will allow Queensland Health to continue to share confidential patient information with the health agencies of other states and territories and the Organ and Tissue Authority to improve the clinical outcomes of patients requiring transplant or organ and tissue donations.

The amendment to the Transplantation and Anatomy Regulation to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank as entities prescribed for the definition of tissue bank will clarify that the Queensland Tissue Bank is the only tissue bank operated by Queensland Health.

Consistency with fundamental legislative principles

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

Fundamental legislative principles not contained in the Legislative Standards Act

Right to privacy

The right to privacy, the disclosure of private or confidential information, doctor-patient confidentiality, and privacy and confidentiality issues have generally been identified by the former Scrutiny of Legislation Committee as relevant to consideration of whether legislation has sufficient regard to individuals' rights and liberties.

Clause 3 amends schedule 3 of the Hospital and Health Boards Regulation by inserting the agreement of 2022 called 'Agreement between Australian state and territory health departments and the Organ and Tissue Authority concerning the use and maintenance of the EDR to facilitate effective and efficient organ and tissue donation for transplantation across Australia'.

This clause may be seen to infringe upon the privacy of individuals as the amendment prescribes an agreement under the exception to the prohibition on the disclosure of confidential information by health services or public servants in Queensland Health.

Section 151(1)(a)(i) of the Hospital and Health Boards Act allows for confidential information to be shared to the Commonwealth or another State, or an entity of the Commonwealth or another State if the disclosure is required or allowed under an agreement and the agreement is prescribed under a regulation. The infringement on the right to privacy is considered justified as the prescribed agreement allows for participation in the EDR that supports safer, timelier and more efficient organ allocation for transplantation.

Consultation

The health authorities from the Commonwealth, States and Territories that are parties to the EDR Agreement were consulted and supported the continued operation of the EDR.

The amendment to the Hospital and Health Boards Regulation to prescribe the updated EDR Agreement and the amendment to the Transplantation and Anatomy Regulation to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank as entities prescribed for the definition of tissue bank was assessed by Queensland Health, in accordance with the *Queensland Government Guide to Better Regulation*, as being excluded from further regulatory impact assessment on the basis that both amendments are of a machinery nature (exclusion category 'g'). Therefore, consultation with the Office of Best Practice Regulation was not required.

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 states the short title is the *Health Legislation Amendment Regulation 2023*.

Part 2 Amendment of Hospital and Health Boards Regulation 2012

Regulation amended

Clause 2 states that part 2 amends the *Hospital and Health Boards Regulation 2012*.

Amendment of sch 3 (Agreements)

Clause 3 amends schedule 3, part 1, item 9A by omitting the current agreement listed in this item and inserting the agreement of 2022 called ‘Agreement between Australian state and territory health departments and the Organ and Tissue Authority concerning the use and maintenance of the EDR to facilitate effective and efficient organ and tissue donation for transplantation across Australia’.

Part 3 Amendment of Transplantation and Anatomy Regulation 2017

Regulation amended

Clause 4 states that part 3 amends the *Transplantation and Anatomy Regulation 2017*.

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

Clause 5 replaces section 12(b) and prescribes the facilities under the Queensland Tissue Bank controlled by Metro South Hospital and Health Service for the definition of *tissue bank* in section 42A of the Transplantation and Anatomy Act. The purpose of this amendment is to remove the Queensland Bone Bank, Queensland Eye Bank and Queensland Heart Valve Bank as entities prescribed for the definition of tissue bank.