REPLACEMENT EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021

Authority

The *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021* (instrument) is a declaration made under subsection 124X(1) of the *Health Insurance Act 1973* (Act).

Subsection 124X(1) of the Act provides that the Minister for Health may, by legislative instrument, declare a quality assurance activity described in the declaration to be a quality assurance activity to which Part VC applies. The instrument declares the Australian Vigilance and Surveillance System for Organ Donation for Transplantation (Activity) to be a quality assurance activity to which Part VC of the Act applies.

Purpose

Part VC of the Act creates a scheme to encourage efficient quality assurance activities in connection with the provision of health services. Those activities help to ensure the quality of health services that are funded by the Government, including through public hospital services and Health Program Grants as they relate to organ donation and transplantation. The scheme encourages participation in such activities by protecting certain information from disclosure and by providing some protection from civil liability to certain persons in respect of their engagement in those activities in good faith.

The purpose of the instrument is to declare the Activity to be a quality assurance activity to which Part VC of the Act applies.

The Activity is undertaken by the Australian Organ and Tissue Donation and Transplantation Authority, also known as the Organ and Tissue Authority (OTA). The OTA is a non-corporate Commonwealth entity established by s 8(1) of the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* for the purpose of working with states and territories, clinicians and the community sector to deliver the Australian Government's national reform program to improve organ and tissue donation and transplantation outcomes in Australia. The Activity applies to all stages of the donation and transplantation process for solid organs donated by deceased donors.

The purpose of the Activity is to ensure better quality and safety in organs donated and used for transplantation. The Activity achieves this purpose through the serious adverse event and reaction (SAER) notification process and the subsequent disclosure of information arising from that process to relevant stakeholders.

Consultation

The Organ and Tissue Authority, as the applicant for declaring the Activity, was consulted in relation to the content of the instrument. The instrument will not result in any direct or substantial indirect effect on business.

Commencement

The instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the instrument are set out in **Attachment A**.

The instrument is compatible with the rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A statement of compatibility with human rights is set out in **Attachment B**.

ATTACHMENT A

Section 1 – Name

This section provides that the name of the instrument is the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021* (instrument).

Section 2 – Commencement

This section provides that the instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the instrument is subsection 124X(1) of the *Health Insurance Act 1973*.

Section 4 – Repeal

This section provides that the instrument will be repealed when it ceases to be in force in accordance with subsection 124X(4) of the *Health Insurance Act 1973*.

Subsection 124X(4) of the *Health Insurance Act 1973* provides that a declaration of a quality assurance activity ceases to be in force at the end of 5 years after it is signed, unless sooner revoked.

Section 5 – Schedule

This section provides that the Activity described in the Schedule is declared to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* applies.

Schedule 1 – Description of quality assurance activity

Clause 1 – Name of activity

Clause 1 to Schedule 1 provides that the name of the Activity is the 'Australian Vigilance and Surveillance System for Organ Donation for Transplantation'.

Clause 2 – Description of activity

Clause 2 to Schedule 1 provides that the Activity as being designed to:

a) work in parallel with state and territory clinical incident management systems in deceased organ donation and transplantation;

b) receive and coordinate responses to serious adverse events and reactions (SAER) notifications;

c) monitor, record and retrospectively analyse SAER notifications;

d) inform future processes in organ donation for transplantation; and

e) improve the safety and quality of organ donation and transplantation, thereby improving patient outcomes.

The Schedule, following amendments made by the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022*, defines SAER as:

a) a serious adverse event; or

b) a serious adverse reaction.

A serious adverse event means any undesired or unexpected occurrence associated with any stage of an organ donation and transplantation process (from the donation of the organ to the transplantation of the organ) that might:

a) lead to:
   i. the transmission of a communicable disease to the transplantation recipient; or
   ii. the death of, or a life-threatening, disabling or incapacitating condition for, the transplantation recipient; or
b) result in, or prolong, hospitalisation or morbidity for the transplantation recipient.

A serious adverse reaction means any unintended response of an organ transplantation recipient, including a communicable disease in the transplantation recipient, that:

a) might be associated with any stage of the organ donation and transplantation process (from the donation of the organ to the transplantation of the organ); and
b) either:
   i. is fatal, life-threatening, disabling or incapacitating for the transplantation recipient; or
   ii. results in, or prolongs, hospitalisation or morbidity for the transplantation recipient.

The Schedule also describes how the SAER notification process operates and what information is disclosed. The Activity operates in the following ways:

a) A reporter, who is typically (but not always) a member of the medical, nursing or laboratory staff associated with the donation, retrieval or transplantation of an organ, becomes aware of a SAER and initiates the notification to the State Medical Director;
b) The State Medical Director (or a delegate) oversees the deceased donation process for consistency of practice within jurisdictions, completes preliminary assessments, reviews information provided by the reporter against the Severity Grading and Imputability Grading and generates a SAER notification form to inform the National Medical Director;
c) The National Medical Director (or a delegate) coordinates national communication and dissemination of information relating to a SAER notification as deemed necessary in conjunction with the State Medical Director and the Vigilance and Surveillance Expert Advisory Committee (VSEAC), which is established by the OTA;
d) The VSEAC monitors the performance of the Activity, recommends action to address non-compliance and risks, prepares submissions for international reporting, publishes de-identified data and case studies, recommends best practice and strategic intervention and formulates policy advice; and
e) SAER notifications include serious adverse events, serious adverse reactions or broader system issues which are analysed and categorised according to the part of the donation and transplantation process they relate to and their impact on patient outcomes. For example, previous SAER notifications have identified key issues relating to donor

screening and broader system issues such as information/transcription processes. Analysis of SAER notifications by the VSEAC has resulted in the Transplantation Society of Australia and New Zealand Clinical Guidelines being strengthened and updated with respect to real-time involvement of other experts when assessing risk of disease transmission and in correlation with the screening test results.

Deidentified information and key findings relevant to health service delivery and practice improvement arising from the Activity are disclosed through:

a) communiques disseminated to clinical and government stakeholders after each VSEAC meeting;
b) red Notices, which notify stakeholders of immediate and severe risks;
c) discussions with relevant national advisory groups, including the OTA's Transplant Liaison Reference Group and the Renal Transplant Advisory Committee;
d) The VSEAC's annual report, of which a high-level version is available publicly and a more detailed confidential version is available to clinicians; and
e) contributions to the international Project Notify Library, which catalogues adverse outcomes associated with organ and tissue donation.

Access to identifying information about patients is limited to the clinicians involved in their treatment and the VSEAC.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation and Transplantation) Declaration 2021* (instrument) declares the Australian Vigilance and Surveillance System for Organ Donation for Transplantation (Activity) to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* (Act) applies. The Activity will be conducted by the Australian Organ and Tissue Donation and Transplantation Authority, also known as Australian Organ and Tissue Authority (OTA). The OTA is a non-corporate Commonwealth entity established by s 8(1) of the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* for the purpose of working with states and territories, clinicians and the community sector to deliver the Australian Government's national program to improve organ and tissue donation and transplantation outcomes in Australia. Information obtained solely as the result of conducting the Activity, or documents created solely for the purposes of the Activity, will be covered by qualified privilege.

Human rights implications

This instrument engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standards of physical and mental health.

The qualified privilege scheme established by Part VC of the Act is aimed at encouraging participation in quality assurance activities that help to ensure that the highest possible health care standards are maintained. The Activity will provide participants with a greater degree of confidence and security that their participation is for the benefit of improving healthcare outcomes for patients involved in deceased donor organ donation and transplantation.

This instrument also engages, but does not limit, the right to privacy as contained in Article 17 of the International Covenant on Civil and Political Rights by involving the collection, storage, security, use, disclosure or publication of personal information. Data collected as part of the Activity will be de-identified to ensure that no individuals are identified prior to analysis or disclosure of the information. The OTA will publish a range of information relating to the Activity, including annual reports on the Activity, Vigilance and Surveillance Expert Advisory Committee quarterly communiques, recommendations for clinical practice improvements and contributions to the NOTIFY Library database.

Conclusion

This instrument is compatible with human rights as it promotes the right to health and does not limit the right to privacy.

Professor Paul Kelly

Chief Medical Officer

Department of Health