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

I, PAUL KELLY, delegate for the Minister for Health and Aged Care, make the following declaration under section 124X of the *Health Insurance Act 1973*.

Dated 14 December 2021

Professor Paul Kelly
Chief Medical Officer
Department of Health

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Part 1— Preliminary

1 Name

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

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 124X(1) of the *Health Insurance Act 1973*.

4 Repeal

This instrument is repealed when it ceases to be in force in accordance with subsection 124X(4) of the *Health Insurance Act 1973*.

5 Schedule

The quality assurance activity described in the Schedule to this declaration is, to the extent that the quality assurance activity relates to health services provided in Australia, declared to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* applies.

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Schedule 1— Description of quality assurance activity

1 Name of activity:

Australian Vigilance and Surveillance System for Organ Donation for Transplantation.

2 Description of activity:

The Australian Vigilance and Surveillance System for Organ Donation for Transplantation (the Activity) is the central location for reporting Serious Adverse Events and Reactions (SAER) relating to organs from deceased donors and is managed by the Australian Organ and Tissue Donation and Transplantation Authority, also known as the Organ and Tissue Authority (OTA). The Activity is 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 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 Australian Vigilance and Surveillance System for Organ Donation and Transplantation collects data through notification of SAERs.

a) The Activity operates in the following ways: 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 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; and

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.

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

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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) VSEAC's annual report, of which a high-level version is publicly available 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.