Health Insurance (Quality Assurance Activity—Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022

I, Professor Paul Kelly, as delegate for the Minister for Health and Aged Care, make the following declaration.

Dated 14 June 2022

Professor Paul Kelly
Chief Medical Officer
Department of Health

Contents

1 Name

This instrument is the *Health Insurance (Quality Assurance Activity—Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022*.

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.	18 June 2022

Note: This table relates only to the provisions of this instrument as originally made.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 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1 Before clause 1 of Schedule 1

Insert:

1A Definitions

In this Schedule:

SAER (short for serious adverse event or reaction) means:

(a) a serious adverse event; or

(b) a serious adverse reaction.

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.

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.

2 Clause 2 of Schedule 1

Omit “Serious Adverse Events and Reactions (SAER)”, substitute “SAERs”.