



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

made under section 124X of the

Health Insurance Act 1973

Compilation No. 1

Compilation date:	18 June 2022
Includes amendments up to:	F2022L00792
Registered:	4 July 2022

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021* that shows the text of the law as amended and in force on 18 June 2022 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1— Preliminary	1
1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Repeal	1
5 Schedule.....	1
Schedule 1— Description of quality assurance activity	2
1A Definitions	2
1 Name of activity:	2
2 Description of activity:	2
Endnotes	4
Endnote 1—About the endnotes	4
Endnote 2—Abbreviation key	5
Endnote 3—Legislation history	6
Endnote 4—Amendment history	7

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.	15 December 2021

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.

Schedule 1— Description of quality assurance activity

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.

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 SAERs 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:

- (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.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021	14 Dec 2021 (F2021L01783)	15 Dec 2021 (s 2(1) item 1)	
Health Insurance (Quality Assurance Activity— Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022	17 June 2022 (F2022L00792)	18 June 2022 (s 2(1) item 1)	—

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep <u>LA s 48D</u>
Schedule 1	
Schedule 1	am F2022L00792
