

Health Legislation Amendment Act (No 3) 2018 No 73

[2018-73]



Status Information

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Provisions in force

Some, but not all, of the provisions displayed in this version of the legislation have commenced.

Notes-

• Note

Amending Acts and amending provisions are subject to automatic repeal pursuant to sec 30C of the *Interpretation Act 1987* No 15 once the amendments have taken effect.

Authorisation

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Health Legislation Amendment Act (No 3) 2018 No 73



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Health Legislation Amendment Act (No 3) 2018 No 73



An Act to make miscellaneous amendments to various Acts that relate to health and associated matters.

1 Name of Act

This Act is the Health Legislation Amendment Act (No 3) 2018.

2 Commencement

- (1) This Act commences on the date of assent to this Act except as otherwise provided by this section.
- (2) Schedule 1 commences 1 month after the date of assent to this Act.
- (3) Schedules 2 [1], 3 [1] and [2], 4 [3] and 6 commence on a day or days to be appointed by proclamation.

Schedule 1 Amendment of Assisted Reproductive Technology Act 2007 No 69

[1] Section 4 Definitions

Insert in alphabetical order in section 4 (1):

donated embryo—see section 4B.

health services provider means any of the following:

- (a) an ART provider or a person that has at any time been an ART provider,
- (b) a registered medical practitioner, a person who has at any time been a registered medical practitioner or a person who, at any time before the repeal of the *Medical Practice Act 1992*, was registered as a medical practitioner under that Act,
- (c) a public health organisation within the meaning of the Health Services Act 1997,

- (d) a private health facility within the meaning of the Private Health Facilities Act 2007,
- (e) any person or body of a class prescribed by the regulations.

[2] Section 4 (1), definition of "donated gamete"

Omit the definition. Insert instead:

donated gamete-see section 4B.

[3] Section 4 (2)

Omit the subsection.

[4] Sections 4A and 4B

Insert after section 4:

4A References to ART treatment involving gametes

A reference in this Act to ART treatment involving the use of a gamete includes a reference to ART treatment involving the use of an embryo created from a gamete.

4B References to "donated gametes" and "donated embryos"

- (1) A reference in this Act to a *donated gamete*:
 - (a) is a reference to a gamete donated by a gamete provider for use by a person other than the gamete provider or the gamete provider's spouse, and
 - (b) includes a reference to a gamete used to create a donated embryo (whether or not the gamete was originally obtained from the gamete provider as a donated gamete and whether or not the embryo was originally created for use as a donated embryo).
- (2) A reference in this Act to a **donated embryo** is a reference to an embryo donated after its creation for use by a person who is not:
 - (a) one of the gamete providers from whom the gametes used to create the embryo were obtained, or
 - (b) the spouse of one of those gamete providers.

[5] Section 12 Counselling to be available

Omit section 12 (2) (b).

[6] Section 12 (2A)-(2C)

Insert after section 12 (2):

- (2A) An ART provider that has possession of a gamete, or an embryo created using a gamete, that was not originally obtained from the gamete provider as a donated gamete must ensure that counselling services are made available to the gamete provider if the gamete provider proposes to donate the gamete or embryo for use by a person other than the gamete provider or the gamete provider's spouse.
- (2B) The counselling services under subsection (2A) must:
 - (a) be available at the premises of the ART provider, and
 - (b) be offered before the gamete or embryo is used.
- (2C) Counselling services under this section must be provided by a person with the qualifications (if any) prescribed by the regulations.

[7] Section 13

Omit sections 13 and 14. Insert instead:

13 Provision of information to participants in ART services

- (1) An ART provider must, in accordance with this section:
 - (a) inform a person specified in Column 1 of the Table to this subsection of the matters specified opposite in Column 2, and
 - (b) obtain confirmation from the person that the person understands those matters,

before providing an ART service specified opposite in Column 3.

Maximum penalty: 800 penalty units in the case of a corporation or 400 penalty units in any other case.

Table

	Column 1	Column 2	Column 3	
	Person	Matters	ART service	
1	A woman seeking ART treatment that does not use donated gametes	Basic list of matters	ART treatment to the woman	

2	A woman seeking ART treatment that uses donated gametes	Extended list of matters	ART treatment to the woman
3	A person proposing to provide a gamete (other than as a donated gamete)	Basic list of matters	Obtaining the gamete from the person
4	A person proposing to provide a donated gamete	Extended list of matters	Obtaining the gamete from the person
5	A gamete provider from whom the gamete was not originally obtained as a donated gamete	Extended list of matters	Using the gamete, or an embryo created using the gamete, in providing ART treatment to a person who is not the gamete provider or the gamete provider's spouse

- (2) The **basic list of matters** that a person must be informed of under this section is as follows:
 - (a) the availability of counselling services,
 - (b) the effect of a gamete provider's consent under Division 3, and how and until when such a consent may be modified or revoked,
 - (c) any other matter that is prescribed by the regulations.
- (3) The *extended list of matters* that a person must be informed of under this section is as follows:
 - (a) the availability of counselling services,
 - (b) the effect of a gamete provider's consent under Division 3, and how and until when such a consent may be modified or revoked,
 - (c) the obligations of the ART provider in relation to obtaining information about the person and the person's offspring,
 - (d) the application of section 62 to the person, including in relation to information provided to the ART provider by the person,
 - (e) the existence of the central register and the information about the person and the person's offspring that will be held on the register,
 - (f) the right of the person to obtain information held on the register about the

person,

- (g) the right of the person and the person's offspring to obtain information held on the register about other persons,
- (h) the right of other persons to obtain information held on the register about the person and the person's offspring,
- (i) any other matter that is prescribed by the regulations.
- (4) Any information required to be provided under this section is to be provided in the approved form (if any).
- (5) Any confirmation required to be obtained under this section is to be obtained in the approved form (if any).

[8] Section 16 Interpretation

Omit "by a gamete" from the definition of *consent* in section 16 (a).

Insert instead "of a gamete".

[9] Section 17 Giving, modifying and revoking consent

Insert ", in the approved form (if any)," after "notice" in section 17 (1).

[10] Section 17 (3)

Omit the subsection. Insert instead:

- (3) A gamete provider may modify or revoke his or her consent by giving written notice, in the approved form (if any), of the modification or revocation of consent to:
 - (a) the ART provider that obtained the gamete from the gamete provider, or
 - (b) any ART provider that is, or has ever been, in possession of the gamete or embryo to which the modification or revocation of consent relates.

[11] Section 17 (4) (b) and (c)

Omit section 17 (4) (b). Insert instead:

- (b) in the case of a gamete that is used to create a donated embryo—the embryo is implanted in the body of a woman, or
- (c) in any other case—the gamete is placed in the body of a woman or an embryo created using the gamete is implanted in the body of a woman.

[12] Section 17 (5)-(8)

Omit section 17 (5) and (6). Insert instead:

- (5) As soon as practicable after an ART provider is given written notice by a gamete provider of the modification or revocation of his or her consent, the ART provider must give written notice of the modification or revocation to any other ART provider to which the ART provider has supplied the gamete or any embryo created using the gamete.
- (6) As soon as practicable after an ART provider is given written notice by another ART provider of the modification or revocation of a gamete provider's consent, the ART provider must give written notice of the modification or revocation to any other ART provider to which the ART provider has supplied the gamete or any embryo created using the gamete.
- (7) Except as provided by section 17A, a modification or revocation of consent takes effect in relation to an ART provider as soon as the ART provider is given written notice of the modification or revocation in accordance with this section.
- (8) A reference in this section to a **donated gamete** does not include a reference to a gamete that becomes a donated gamete only after being used to create an embryo.

[13] Sections 17A and 17B

Insert after section 17:

17A Verification of identify of person giving, modifying or revoking consent

- (1) An ART provider that is given a written notice under section 17 must take the following steps to verify the identity of the person purportedly giving the consent to which the notice relates:
 - (a) the steps (if any) prescribed by the regulations,
 - (b) if there are no steps prescribed by the regulations, reasonable steps.

Maximum penalty: 800 penalty units in the case of a corporation or 400 penalty units in any other case.

- (2) A gamete provider's consent has no effect in relation to an ART provider that is required to comply with subsection (1) in connection with that consent until the ART provider so complies.
- (3) An ART provider that is given a written notice under section 17 (5) or (6) is not required to comply with subsection (1) in connection with the modification or

revocation to which the notice relates if the ART provider has reasonable grounds to believe that another ART provider has already complied with subsection (1) in connection with the modification or revocation.

(4) In this section, *consent* includes the modification or revocation of consent.

17B ART provider to take steps to obtain confirmation of consent in certain cases

- (1) An ART provider must not carry out any of the following activities in respect of a gamete or embryo (other than a donated gamete or donated embryo) unless the ART provider has taken the required steps, in accordance with this section, to obtain confirmation of the gamete provider's consent to the activity concerned:
 - (a) use the gamete to create an embryo outside the body of a woman,
 - (b) provide ART treatment to a woman using the gamete or embryo,
 - (c) supply the gamete or embryo to another person (including an ART provider),
 - (d) export, or cause to be exported, the gamete or embryo from this State.

Maximum penalty: 800 penalty units in the case of a corporation or 400 penalty units in any other case.

- (2) The *required steps* are the steps (if any) prescribed by the regulations or, if there are no steps prescribed by the regulations, reasonable steps.
- (3) The ART provider must take the required steps no earlier than the period of time, determined in accordance with the regulations, before the activity concerned.
- (4) An ART provider is not required to comply with this section:
 - (a) if the ART provider knows or believes on reasonable grounds that the gamete provider is deceased, or
 - (b) in any other circumstances prescribed by the regulations.

[14] Section 24 Use of gametes or embryos provided more than 5 years ago

Insert after section 24 (4):

(5) A reference in this section to the *supply* of a gamete includes a reference to the supply of an embryo created using the gamete.

[15] Section 25 Storage of gametes or embryos

Insert "or a donated embryo," after "donated gamete," in section 25 (3) (d).

[16] Section 26 Donated gametes or embryos-time limit on use

Omit section 26 (1). Insert instead:

- (1) An ART provider must not provide the following ART treatment without the written authorisation of the Secretary:
 - (a) ART treatment using a donated gamete (but not ART treatment referred to in paragraph (b)) if the gamete was obtained from the donor more than 15 years before the provision of the ART treatment,
 - (b) ART treatment using an embryo created from a donated gamete, or using a donated embryo, if the embryo was created more than 15 years before the provision of the ART treatment.

Maximum penalty: 400 penalty units in the case of a corporation or 200 penalty units in any other case.

[17] Section 30 Collection of information

Renumber section 30 (1A) as section 30 (2A) and insert it immediately after section 30 (2).

[18] Section 30 (2)

Omit "required under". Insert instead "specified in".

[19] Section 30 (3)

Omit the subsection. Insert instead:

- (3) An ART provider must not use a gamete in the provision of ART treatment to a woman unless the ART provider has obtained the following information:
 - (a) the full name, residential address and date of birth of the woman,
 - (b) any other information about the woman, the woman's spouse (if any) and any offspring of the woman that the regulations may require the ART provider to obtain.

[20] Section 30 (5)-(8)

Insert after section 30 (4) (before the penalty provision):

(5) An ART provider that provides ART treatment to a woman using a donated gamete must take reasonable steps to find out from the woman, no earlier than 1 month and no later than 4 months after the treatment, whether or not she is pregnant as a

result of the treatment.

- (6) The ART provider is not required to take those steps if the ART provider knows that the woman is not pregnant as a result of the treatment.
- (7) The ART provider must take further reasonable steps to find out from the woman, no earlier than 10 months and no later than 15 months after the ART treatment:
 - (a) whether or not an offspring was born as a result of the treatment, and
 - (b) the full name, sex and date of birth of the offspring.
- (8) The ART provider is not required to take those steps if the ART provider:
 - (a) is informed by the woman earlier than 10 months after the treatment that an offspring was born as a result of the treatment and the woman informs the ART provider of the full name, sex and date of birth of the offspring, or
 - (b) knows that no offspring was born as a result of the treatment.

[21] Section 31 Records to be kept by ART provider

Insert "or (2)" after "30 (1)" in section 31 (1) (a) (i).

[22] Section 31 (1) (b)

Omit the paragraph. Insert instead:

- (b) for each woman who is provided ART treatment by the ART provider:
 - (i) the full name, residential address and date of birth of the woman, and
 - (ii) any other information required to be obtained under section 30 (3) about the woman, the woman's spouse (if any) and any offspring of the woman,
- (b1) for each woman who has been provided ART treatment by the ART provider using a donated gamete:
 - (i) whether or not the woman is or has been pregnant, up until at least 1 month after the treatment, as a result of the treatment, or
 - (ii) if the ART provider does not know whether or not the woman is or has been pregnant, up until at least 1 month after the treatment, as a result of the treatment—information to that effect,

[23] Section 31 (1) (c)

Insert "known by the ART provider to have been" after "each offspring".

[24] Section 31 (1) (c) (ii)

Omit "name". Insert instead "full name".

[25] Sections 31 (1) (c) (iii), 40A (1) (b), 41R (a) and 41T (1)

Omit "of the gamete" wherever occurring.

[26] Section 31 (1) (c1)

Insert after section 31 (1) (c):

(c1) if at least 15 months have passed since the ART provider provided ART treatment to a woman and the ART provider does not know whether or not an offspring has been born as a result of the treatment—information to that effect,

[27] Part 3, Division 1, heading

Omit the heading. Insert instead:

Division 1 Preliminary

[28] Section 32B Disclosure of information on the central register generally

Insert "or Part 3A" after "this Part".

[29] Section 32B (2) and (3)

Insert at the end of section 32B:

- (2) For the purposes of the provisions of this Part and Part 3A relating to disclosure, the Secretary is entitled to assume that information provided to the Secretary and held on the central register is accurate.
- (3) Nothing in this section limits section 33D (1).

[30] Section 33 Mandatory giving of information by ART providers

Omit section 33 (1). Insert instead:

- An ART provider that provides ART treatment using a donated gamete must, within 2 months after becoming aware that a live offspring has been born as a result of the treatment, give the Secretary:
 - (a) the records that the ART provider is required to keep under section 31 (1) (a) (i) and (iii) in relation to the gamete and embryo created from that gamete, and

(b) the records that the ART provider is required to keep under section 31 (1) (c) in relation to the offspring.

Maximum penalty: 400 penalty units in the case of a corporation or 200 penalty units in any other case.

- (1A) An ART provider that provides ART treatment to a woman using a donated gamete must, no earlier than 15 months and no later than 16 months after the treatment, do the following if the ART provider does not know whether or not a live offspring has been born as a result of the treatment:
 - (a) inform the Secretary that the ART provider does not know whether or not a live offspring has been born as a result of the treatment,
 - (b) give the Secretary:
 - (i) the records that the ART provider is required to keep under section 31 (1) (a)(i) and (iii) in relation to the gamete and embryo created from that gamete, and
 - (ii) the full name of the woman.

Maximum penalty: 400 penalty units in the case of a corporation or 200 penalty units in any other case.

[31] Section 33B Voluntary giving of information about personal characteristics of donor

Omit "The donor of a gamete" from section 33B (1). Insert instead "A donor".

[32] Sections 33C (1) and 36 (1) (a)

Omit "of a gamete" wherever occurring.

[33] Section 33D Secretary to ensure accuracy of central register in relation to ART treatment

Insert "or" after "enter information," in section 33D (1) (a).

[34] Section 33D (1A)-(1C)

Insert after section 33D (1):

- (1A) The Secretary may, on the Secretary's own initiative, enter in the central register information relating to any of the following persons:
 - (a) a live offspring whom the Secretary has reasonable grounds to be satisfied was born as a result of the provision by an ART provider of ART treatment, on or after 1 January 2010, using a donated gamete,

- (b) a person whom the Secretary has reasonable grounds to be satisfied is the donor from whom the donated gamete was obtained (the *gamete provider*),
- (c) the woman who gave birth to the offspring.
- (1B) The information that may be entered on the central register under subsection (1A) includes any of the following:
 - (a) the full name, sex and date of birth of the offspring,
 - (b) the full name, residential address, date of birth, ethnicity, physical characteristics and relevant medical history of the gamete provider,
 - (c) the sex and year of birth of each offspring of the gamete provider,
 - (d) the gamete provider's consent (within the meaning of Division 3 of Part 2) relating to the gamete or embryo that the Secretary has reasonable grounds to be satisfied was used in the ART treatment,
 - (e) the full name of the woman who gave birth to the offspring,
 - (f) the full name of the spouse (if any) of that woman,
 - (g) any other matters that are prescribed by the regulations.
- (1C) Without limiting subsection (1) (c), the Secretary must note in the central register the source of any information entered in the central register under subsection (1A) (including whether the information was obtained in response to a direction under section 34).

[35] Section 33E

Insert after section 33D:

33E Disclosure of information on Secretary's own initiative

- (1) The Secretary may, on the Secretary's own initiative, disclose information held on the central register that has been revised or entered under section 33D.
- (2) The Secretary may disclose the information only to a person who would be entitled, if the person made an application under this Part, to be given the information.

[36] Section 34 Objectives of central register—ART treatment

Renumber the section as section 32C and insert it immediately before section 33 in Division 2 of Part 3.

[37] Sections 34 and 35

Insert after section 33E (as inserted by item [35]):

34 Direction to answer questions and provide information about donorconceived births

- (1) The Secretary may give a health services provider a written direction requiring the provider to answer specified questions, or to furnish any other information specified in the direction, for the purposes of:
 - (a) determining whether or not a live offspring was born as a result of the provision by an ART provider of ART treatment, on or after 1 January 2010, using a donated gamete, or
 - (b) determining whether or not any registrable information in connection with such an offspring has been correctly entered in the central register, or
 - (c) obtaining any registrable information in connection with such an offspring.
- (2) A direction under this section may require the questions to be answered, or the other information to be furnished, in a specified manner, by a specified time and in a specified form.
- (3) A person who is given a direction under this section must not, without reasonable excuse, refuse or fail to comply with the direction.

Maximum penalty: 200 penalty units in the case of a corporation or 100 penalty units in any other case.

- (4) In this section, *registrable information* means any of the following:
 - (a) the full name, sex and date of birth of an offspring who was born as a result of the provision by an ART provider of ART treatment using a donated gamete,
 - (b) the full name, residential address, date of birth, ethnicity, physical characteristics and relevant medical history of the gamete provider,
 - (c) the sex and year of birth of each offspring of the gamete provider,
 - (d) the gamete provider's consent (within the meaning of Division 3 of Part 2) relating to the gamete or embryo used in the ART treatment,
 - (e) the full name of the woman who gave birth to the offspring,
 - (f) the full name of the spouse (if any) of that woman,

(g) any other matters that are prescribed by the regulations.

35 Information sharing between Secretary and Registrar of Births, Deaths and Marriages about donor-conceived births

- (1) The Secretary and the Registrar of Births, Deaths and Marriages may share information for the purpose of enabling or assisting the Secretary to ensure the completeness and accuracy of the central register in relation to:
 - (a) live offspring born as a result of ART treatment provided by ART providers using donated gametes, and
 - (b) the donors from whom the gametes were obtained, and
 - (c) the women who gave birth to the offspring, and
 - (d) the spouses (if any) of those women.
- (2) This section has effect despite any law to the contrary.

[38] Sections 39 and 41S

Omit "the donor of a gamete" wherever occurring. Insert instead "a donor".

[39] Section 41W Entry of information provided under Part in central register

Insert "(1)" after "33D".

[40] Section 62

Omit the section. Insert instead:

62 Person must not make false or misleading representation

- (1) A person must not, without reasonable excuse, make a representation that is false or misleading in a material particular:
 - (a) in an application or notice under this Act, or
 - (b) in response to a request for information that an ART provider is required to obtain, or to take steps to obtain, under Part 2.

Maximum penalty: 200 penalty units in the case of a corporation or 100 penalty units in any other case.

- (2) Without limiting subsection (1), a person who forges a signature in any application or notice under this Act is taken to have made a representation that is false or misleading in a material particular.
- (3) A reference in this section to *information* includes a reference to the

confirmation of a gamete provider's consent within the meaning of Division 3 of Part 2.

[41] Section 69 Disclosure of information by ART providers and others

Omit "an ART". Insert instead "a health services".

[42] Schedule 1 Savings, transitional and other provisions

Insert at the end of the Schedule, with appropriate Part and clause numbering:

Part Provisions consequent on enactment of Health Legislation Amendment Act (No 3) 2018

Interpretation

(1) In this Part:

amending Act means the Health Legislation Amendment Act (No 3) 2018.

(2) A reference in this Part to a new provision is a reference to the provision as inserted by the amending Act.

Collection of information and keeping of records

- New section 30 (5) and (6) extend to ART treatment provided to a woman using a donated gamete within the period of 1 month before the commencement of those provisions.
- (2) New section 30 (7) and (8) extend to ART treatment provided to a woman using a donated gamete within the period of 10 months before the commencement of those provisions.
- (3) New section 31 (1) (b1) applies only in relation to a woman who has been provided ART treatment using a donated gamete on or after the period of 1 month before the commencement of that provision.
- (4) Section 31 (1) (c), as amended by the amending Act, applies only in relation to offspring who are born on or after the commencement of the amendment.
- (5) New section 31 (1) (c1) applies only in relation to ART treatment provided to a woman on or after the period of 15 months before the commencement of that provision.

Information required to be given to Secretary by ART providers

(1) New section 33 (1) applies only in relation to a live offspring born on or after the commencement of that provision.

- (2) Section 33 (1), as in force immediately before its substitution by the amending Act, continues to apply in relation to a live offspring born before that substitution.
- (3) New section 33 (1A) extends to ART treatment provided by an ART provider within the period of 15 months before the commencement of that provision.

Schedule 2 Amendment of Health Administration Act 1982 No 135

[1] Section 21S Regulations for purposes of Part

Insert after section 21S (f):

- (g) the notification by relevant health services organisations of incidents to persons or bodies who may be required to exercise functions under this Part or Part 4 of the *Private Health Facilities Act 2007*,
- (h) the exchange of information between a relevant health services organisation and persons or bodies who may be required to exercise functions under this Part or Part 4 of the *Private Health Facilities Act 2007* for the purposes of the exercise of those functions.

[2]-[5] (Repealed)

Schedule 3 Amendment of Health Practitioner Regulation (Adoption of National Law) Act 2009 No 86

[1] Schedule 1 Modification of Health Practitioner Regulation National Law

Insert before item [14A]:

[14AC] Section 142A

Insert after section 142:

142A Employers having dual notification requirements [NSW]

If an employer is required to report the same conduct under section 142 and under section 117A of the *Health Services Act 1997*, compliance with either section, or with alternative reporting requirements approved by the Secretary, satisfies the requirements of both those sections. **Note**—

This section is an additional New South Wales provision.

[2] Schedule 1 [15]

Insert after section 151A:

151B Alternative reporting [NSW]

- (1) The Secretary may approve alternative reporting requirements for the purposes of the giving of a notice or transcript under this Subdivision.
- (2) An alternative reporting requirement may authorise the giving of a notice or transcript in an alternative manner to that otherwise required by this Subdivision for giving the notice or transcript.
- (3) A person or court that gives a notice or transcript in accordance with an alternative reporting requirement approved by the Secretary for the giving of the notice or transcript is taken to have given the notice or transcript in accordance with the requirements of this Subdivision.

Schedule 4 Amendment of Health Services Act 1997 No 154

[1], [2] (Repealed)

[3] Section 117A Duty of chief executive to report certain conduct

Insert after section 117A (2):

- (3) If a chief executive is required to report the same conduct under this section and under section 142 of the *Health Practitioner Regulation National Law (NSW)*, compliance with either section, or with alternative reporting requirements approved by the Health Secretary, satisfies the requirements of both sections.
- (4) A report made because of a requirement under this section is taken to be a complaint both for the purposes of Part 8 of the *Health Practitioner Regulation National Law (NSW)* and for the purposes of the *Health Care Complaints Act 1993* (including sections 96 and 98 of that Act).

[4] (Repealed)

Schedule 5 (Repealed)

Schedule 6 Amendment of Private Health Facilities Act 2007 No 9

[1] Part 4

Omit the Part. Insert instead:

Part 4 Response to incidents

Division 1 Preliminary

41 Definitions

In this Part:

assessor means an assessor appointed under Division 2.

health practitioner has the same meaning it has in the *Health Practitioner Regulation National Law (NSW)*.

health service includes any administrative or other service related to a health service.

impairment has the same meaning it has in the *Health Practitioner Regulation National Law (NSW)*.

incident reviewer—see section 49B.

performance or impairment issue, in relation to a health practitioner, means:

- (a) professional misconduct, unsatisfactory professional conduct or unsatisfactory professional performance by the health practitioner, or
- (b) the health practitioner suffering from an impairment.

professional misconduct and **unsatisfactory professional conduct** have the same meanings as they have in Part 8 of the *Health Practitioner Regulation National Law (NSW)*.

reportable incident means an incident of a type prescribed by the regulations or set out in a document adopted by the regulations.

serious adverse event review means a root cause analysis or any other type of review prescribed by the regulations.

serious adverse event review team means a serious adverse event review team appointed under Division 3.

unsatisfactory professional performance means professional performance that is unsatisfactory within the meaning of Division 5 of Part 8 of the *Health Practitioner Regulation National Law (NSW)*.

Division 2 Preliminary risk assessment

42 Appointment of assessors to assess incidents

- (1) When an incident involving the provision of a health service by a private health facility is reported to the licensee of the facility, the licensee must appoint one or more assessors to carry out a preliminary risk assessment of the incident if:
 - (a) the licensee is of the opinion that the incident is (or may be) a reportable incident, or
 - (b) the incident is not a reportable incident but may be the result of a serious systemic problem and the licensee is of the opinion that a preliminary risk assessment of the incident should be carried out.
- (2) Assessors may be appointed in response to a particular incident or otherwise.
- (3) The persons appointed as assessors in respect of an incident must (subject to the regulations) be persons that the licensee reasonably considers can properly carry out a preliminary risk assessment of the incident.

43 Functions of assessors in relation to incidents

An assessor is to carry out a preliminary risk assessment of the incident and is to provide advice (in writing or otherwise) to the licensee to assist the licensee in understanding the events comprising the incident and the measures required to appropriately manage the incident and remove or mitigate any risk.

44 Immediate notification if person at risk

An assessor must immediately advise the licensee and the chair of the medical advisory committee for the private health facility in writing if the assessor is of the opinion that the incident in respect of which the assessor was appointed raises matters that indicate a problem giving rise to a risk of serious or imminent harm to a person.

45 Outcome of assessment of incidents

- (1) A licensee may only disclose an advice of an assessor or any information obtained from the advice as follows:
 - (a) to provide the advice to the Secretary,
 - (b) to advise a serious adverse event review team appointed to carry out a serious adverse event review of the incident to which the advice relates,
 - (c) to provide relevant information to a patient involved in the incident, a family member or carer of the patient or a person nominated by any such patient,

family member or carer,

- (d) to a law enforcement agency or regulatory body,
- (e) in any other manner as may be prescribed by the regulations.
- (2) A licensee must take reasonable steps to not disclose information that identifies a person (other than the patient involved in the incident) when it provides information under subsection (1) (c).

Division 3 Serious adverse event review

46 Appointment of team to review incidents

- (1) Following the preliminary risk assessment of an incident involving the provision of a health service by a private health facility, the licensee must appoint one or more persons as a serious adverse event review team to carry out a serious adverse event review of the incident if:
 - (a) the incident is a reportable incident, or
 - (b) the incident is not a reportable incident but may be the result of a serious systemic problem and the licensee is of the opinion that a serious adverse event review of the incident should be carried out.
- (2) The serious adverse event review team must be appointed within 30 days of the incident.
- (3) Despite subsection (1), a licensee may, but is not required to, appoint a serious adverse event review team to carry out a serious adverse event review of an incident in circumstances prescribed by the regulations.
- (4) The persons appointed as a serious adverse event review team in respect of an incident must (subject to the regulations) be persons that the licensee reasonably considers can properly carry out a serious adverse event review of the incident.
- (5) The licensee is to cause a written record to be kept of the persons appointed as a serious adverse event review team.
- (6) The Secretary may issue directions setting out the type of serious adverse event review, and the manner in which the serious adverse event review is to be carried out, in respect of an incident or a class of incidents.

47 Serious adverse event review of incident

(1) A serious adverse event review team is to carry out a serious adverse event review of the incident in respect of which it was appointed.

- (2) A serious adverse event review team must, on completion of the serious adverse event review of an incident, prepare a written report that sets out a description of the incident and details of the following findings identified by the team:
 - (a) how the incident occurred,
 - (b) any factors that caused or contributed to the incident.
- (3) The report must also include the serious adverse event review team's recommendations (if any) about changes or improvements in relation to a procedure, practice or system (including clinical redesign) arising out of the incident unless the licensee determines that those recommendations are instead to be developed and included in a second report.
- (4) If the licensee determines that the recommendations are to be developed and included in a second report, the licensee may appoint additional persons to the serious adverse event review team for the purpose of developing the recommendations and preparing the second report.
- (5) The serious adverse event review team must provide any report prepared under this section to the licensee and provide a copy of the report to the chair of the medical advisory committee for the private health facility.
- (6) The licensee must, within 30 days after being provided with a report under this section, forward a copy of the report to the Secretary.

Maximum penalty: 50 penalty units.

(7) Subject to section 49E, the contents of a report under this section may be disclosed to any person and used for any purpose.

48 Immediate notification if person at risk

A serious adverse event review team must immediately advise the licensee and the chair of the medical advisory committee for the private health facility in writing if it is of the opinion that the incident in respect of which it was appointed raises matters that indicate a problem giving rise to a risk of serious or imminent harm to a person.

49 Notification about performance or impairment of health practitioner

(1) A serious adverse event review team must advise the licensee and the chair of the medical advisory committee for the private health facility in writing as soon as practicable once it is of the opinion that the incident in respect of which it was appointed raises matters that may involve a performance or impairment issue (other than unsatisfactory professional performance) in relation to a health practitioner.

- (2) A serious adverse event review team may advise the licensee and the chair of the medical advisory committee for the private health facility in writing if it is of the opinion that the incident raises matters that may involve unsatisfactory professional performance by a health practitioner.
- (3) A written advice under this section must disclose the identity of the health practitioner to whom the notification relates (regardless of whether the health practitioner consents to the disclosure) and the nature of the concern, and specify whether the notification relates to:
 - (a) professional misconduct, unsatisfactory professional conduct or unsatisfactory professional performance by the health practitioner, or
 - (b) the health practitioner suffering from an impairment.

49A Discontinuing serious adverse event review

- The licensee may authorise a serious adverse event review team to discontinue taking any further steps in relation to a serious adverse event review of an incident:
 - (a) if advice has been provided to the licensee and the chair of the medical advisory committee for the private health facility under section 49 and the licensee and chair are both of the opinion that the incident was substantially caused by a performance or impairment issue in relation to a health practitioner and the team is not likely to identify any other root causes, contributory factors or system improvements, or
 - (b) in circumstances prescribed by the regulations.
- (2) A serious adverse event review team that is authorised under this section may, if it considers it to be appropriate, determine to take no further steps in relation to the serious adverse event review and in such a case may discontinue the review.

Division 4 Incident reviewers

49B Meaning of "incident reviewer"

In this Part:

incident reviewer means a member of a serious adverse event review team or an assessor.

49C Restrictions on incident reviewers

(1) An incident reviewer does not have authority to carry out an investigation relating to the competence of an individual in providing services.

- (2) Except as otherwise provided by or under this Part, an advice or report furnished by a serious adverse event review team must not disclose:
 - (a) the name or address of an individual who is a provider or recipient of services unless the individual has consented in writing to that disclosure, or
 - (b) as far as is practicable, any other material that identifies, or may lead to the identification of, such an individual.
- (3) An incident reviewer is to act in a fair and reasonable manner in the exercise of his or her functions as an incident reviewer.

49D Disclosure of information

A person who is or was an incident reviewer must not make a record of, or divulge or communicate to any person, any information acquired by the person as such a reviewer, except:

- (a) for the purpose of exercising the functions of an incident reviewer, or
- (b) for the purpose of any advice provided as an incident reviewer, or
- (c) for the purpose of any advice or report under this Part, or
- (d) in accordance with the regulations.

Maximum penalty: 50 penalty units.

49E Information not to be given in evidence

- (1) A person is neither competent nor compellable to produce any document or disclose any communication (or to disclose any information that the person obtained from any such document or communication) to a court, tribunal, board, person or body if the document was prepared, or the communication was made, for the dominant purpose of the exercise of a function under this Part by an incident reviewer.
- (2) This section does not apply to a requirement made:
 - (a) in proceedings in respect of any act or omission by an incident reviewer, or
 - (b) by a person or body who has been approved by the Secretary to carry out a review or audit of an assessment or review by an incident reviewer.

49F Advice and reports not to be admitted in evidence

- (1) Evidence as to the contents of an advice or report of an incident reviewer cannot be adduced or admitted in any proceedings.
- (2) Subsection (1) does not apply to proceedings in respect of any act or omission

by an incident reviewer.

49G Personal liability of incident reviewers

- (1) Anything done by an incident reviewer or any person acting under the direction of an incident reviewer, in good faith for the purposes of the exercise of the incident reviewer's functions, does not subject the incident reviewer or person personally to any action, liability, claim or demand.
- (2) Without limiting subsection (1), an incident reviewer has qualified privilege in proceedings for defamation in respect of:
 - (a) any statement made orally or in writing in the exercise of the functions of an incident reviewer, or
 - (b) the contents of any advice or report or other information published by an incident reviewer.
- (3) An incident reviewer is, and is entitled to be, indemnified in respect of any costs incurred in defending proceedings in respect of a liability against which the reviewer is protected by this section by the licensee in respect of the incident for which the incident reviewer was appointed.

Division 5 Miscellaneous

49H Regulations for purposes of Part

The regulations may make provision for or with respect to the following:

- (a) the appointment of persons as members of a serious adverse event review team or as assessors,
- (b) the functions of incident reviewers and the manner in which they are to exercise those functions,
- (c) the procedures of a preliminary risk assessment or a serious adverse event review,
- (d) permitting or requiring incident reviewers or a licensee to make specified information (including personal information and health information) available to the public,
- (e) permitting or requiring incident reviewers to furnish reports concerning their activities to the Minister, the Secretary or licensees,
- (f) the carrying out of reviews or audits of any preliminary risk assessment or serious adverse event review,
- (g) the notification by a licensee of incidents to persons or bodies who may be

required to exercise functions under this Part or Part 2A of the *Health Administration Act 1982*,

(h) the exchange of information between a licensee and persons or bodies who may be required to exercise functions under this Part or Part 2A of the *Health Administration Act 1982* for the purposes of the exercise of those functions.

[2] Schedule 4 Savings, transitional and other provisions

Insert after Part 3:

Part 4 Provisions consequent on enactment of Health Legislation Amendment Act (No 3) 2018

26 Definitions

In this Part:

amending Act means the Health Legislation Amendment Act (No 3) 2018.

RCA team means a root cause analysis team.

27 Existing incidents

Part 4 of this Act, as substituted by the amending Act, extends to an incident that occurred before the commencement of that Part.

28 Existing root cause analysis teams

Despite clause 27, Part 4 of this Act, as substituted by the amending Act, does not extend to an incident if an RCA team has been appointed in relation to the incident before the commencement of that Part and, in such a case, Part 4, as in force immediately before its substitution by the amending Act, continues to apply to and in respect of the RCA team.

29 Disclosure of information

Section 49D extends to a person who was a member of an RCA team before the commencement of that section in the same way as it applies to an incident reviewer but only in respect of information that the person was not able to make a record of, or divulge or communicate to any person under section 45 immediately before the substitution of that section.

30 Information not to be given in evidence

Section 49E extends to:

(a) a document that was prepared, or a communication that was made, before the

commencement of that section for the dominant purpose of the conduct of an investigation by an RCA team, and

(b) proceedings that are pending on that commencement.

31 Notifications and reports of former RCA teams not to be admitted in evidence

Section 49F extends to:

- (a) a notification that was given, or a report that was prepared, before the commencement of that section by an RCA team, and
- (b) proceedings that are pending on that commencement.

32 Personal liability of members of former RCA teams

Section 49G extends to a person who was a member of an RCA team before the commencement of that section, or to a person acting under the direction of any such person, in the same way as that section applies to an incident reviewer or any person acting under the direction of an incident reviewer.