Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

Guidance for health services providers on notifying HIQA of notifiable incidents under the Patient Safety Act

26 September 2024

Safer Better Care

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

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1 Introduction

The Health Information and Quality Authority (HIQA) is the independent authority established to drive continuous improvement in Ireland's health and personal social care services. This is achieved by monitoring the safety and quality of these services and promoting person-centred care for the benefit of the public. To do so, HIQA has the function to monitor compliance with standards under section 8(1)(c) of the Health Act 2007 (as amended) (the Health Act 2007). The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (referred to in this document as the Patient Safety Act) requires that certain incidents are notified to HIQA by health services providers (HSPs).

This document provides guidance on the statutory notifications of certain notifiable incidents that HSPs must make to HIQA under the Patient Safety Act*. These notifiable incidents are set out in Appendix 1 and relate to very serious adverse events resulting in unanticipated and unintended deaths or outcomes of traumatic births. Unfortunately, these types of adverse events can and do occur in healthcare services and many treatments or interventions have the potential to cause harm. The occurrence of an accident or adverse event in a health service is not necessarily an indication of poor care. The requirement for HSPs to notify HIQA on the occurrence of a notifiable incident is a patient safety measure which will enable HIQA to obtain and use information about incidents for the purposes of improving patient safety.

When care does not go as planned, there is a requirement for health practitioners to maintain honest and open communication with the services in which they work, with service users, their support persons and carers. While the list of notifiable incidents is set out in the Patient Safety Act and is included in Appendix 1 of this guide, the Minister can prescribe additional notifiable incidents by way of regulation. In doing so, the Minister is required to take certain prescribed criteria under Section 8 of the Patient Safety Act into account.

This guide provides:

- information on who is responsible for notifying HIQA of notifiable incidents
- guidance on what notifiable incidents should be reported to HIQA
- detail of the procedure of notification to HIQA

* Health services providers (HSPs) who carry on the business of a designated centre are required under the Patient Safety Act to notify the Chief Inspector of Social Services (Chief Inspector) on the occurrence of a notifiable incident and this is covered in a separate communication.

- details on what happens after HIQA receives a notification.

2 Who is required to notify HIQA of notifiable incidents?

The Patient Safety Act requires all HSPs, as defined in the Patient Safety Act, other than those that carry on the business of a designated centre[†] or those that provide a health service in an approved centre regulated by the Mental Health Commission,[‡] to notify HIQA of notifiable incidents. The HSP should be satisfied that a notifiable incident has occurred in the course of the provision by it of a health service to a patient, before notifying HIQA. Being satisfied that a notifiable incident has occurred requires a threshold of knowledge or clinical judgment as to the causation of the patient death, or other serious incident that may give rise to a notifiable incident. For this to happen, the HSP is not required to have complete or perfect knowledge of all the details of the incident. HSPs are obliged to make a mandatory notification notwithstanding that the date the incident occurred may not be known, or not all of the information relating to the incident and the cause of the incident is available.

If following further investigation and clinical assessment, the HSP believes that the original notification did not constitute a notifiable incident, this can be addressed by the HSP directly with HIQA at patientsafetyactincidents@hiqa.ie. HSPs should ensure that appropriate arrangements are in place to notify HIQA of notifiable incidents. The arrangements should ensure that the HSP is always aware of notifications made to HIQA on its behalf.

3 How will a health services provider become aware of the occurrence of notifiable incidents?

The Patient Safety Act does not prescribe how a HSP may become aware that a notifiable incident has occurred and may receive information about a notifiable incident from different sources and in different ways.

Health practitioners have an obligation to inform the HSP where, in the opinion of a health practitioner, a notifiable incident has occurred in relation to a patient. The health practitioner shall, as soon as practicable, inform the HSP which is providing the health service to the patient at the time they form their opinion, even if they are not sure when the incident occurred, or whether it occurred during the provision of a health service by another HSP.

[†] Note that health services providers who carry out the business of a designated centre are required to notify the Chief Inspector of Social Services on the occurrence of a notifiable incident.
[‡] Note that health services providers who provide a health service in an approved centre regulated by the Mental Health Commission are required to notify the Mental Health Commission on the occurrence of a notifiable incident.

4 What is a health service and who are health services providers?

A 'health service' is defined in section 2(1) of the Patient Safety Act. A 'health service' encompasses all aspects of typical healthcare delivery by HSPs including the use of surgery or interventions for non-medical purposes.

> *A "health service" means the provision, by or under the direction of a health services provider, of clinical care or any ancillary service to a patient for—*
>
> *(a) the screening (other than screening carried out by a cancer screening service), preservation or improvement of the health of the patient,*
>
> *(b) the prevention, diagnosis, treatment or care of an illness, injury or health condition of the patient,*
>
> *(c) the performance or surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the patient, or*
>
> *(d) without prejudice to paragraph (a), a cancer screening service;*

A HSP is defined in Section 3(1) of the Patient Safety Act. It is a broad and detailed definition encompassing the types of legal persons and entities that provide health services. Persons providing health services to patients should familiarise themselves with the definition in the Patient Safety Act. The four categories of HSP defined in the Patient Safety Act are, in summary:

(a) A person (other than a health practitioner) who provides one or more health services and for that purpose engages:

- a health practitioner to provide a health service
- another person (for example, an individual or company) in respect of carrying on the business of providing a health service.

This may include, for example, a private hospital, a body corporate (statutory hospital), or a body corporate (voluntary hospital).

(b) a health practitioner who provides a health service and does not provide that health service for, or on behalf of, or through or in connection with[§] (whether

[§] *"through or in connection with"* does not include the use by the health services provider referred to in this paragraph of a health service (or processes related to a health service) provided—
(a) by a health services provider referred to in paragraph (a) of the definition, and
(b) for the purpose of the provision, by a health services provider—
(i) referred to in paragraph (b) of that definition, of a health service on its own behalf, or
(ii) referred to in paragraph (c) of that definition, of a health service on behalf of a partnership.

by reason of employment or otherwise) a HSP referred to in paragraph (a) and includes a health practitioner who engages:

- another health practitioner to provide a health service for or on their behalf
- another person (for example, an individual or company) in respect of carrying on the business of providing a health service.

For example, this may include a sole practitioner health practitioner such as a GP, dentist, physiotherapist, or midwife.

(c) A partnership of two or more health practitioners who provide a health service in common which does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise) a HSP referred to in paragraph (a) and includes a partnership which engages:

- another health practitioner to provide a health service on their behalf
- another person in respect of carrying on the business of providing a health service.

For example this might include two or more health practitioners such as GPs, physiotherapists, or dentists providing a health service in common as a partnership.

(d) The HSE in the case of a cancer screening service[**], or, in the case of the CervicalCheck cancer screening program, a HSP referred to in paragraphs (b) or (c).

A HSP may engage a health practitioner to provide a health service or other person in respect of carrying on the business of providing a health service through:

- Contractual relationships whereby the HSP engages a health practitioner as an employee, an agency worker or an independent contractor.
- Other arrangements which are not defined in the Patient Safety Act but may include voluntary arrangements, service level agreements, a hospital's policies and procedures, permissions or other arrangements.
- In the case of a HSP referred to in paragraph (a), privileges commonly referred to as practicing privileges

[**] As defined in section 2(1) of the Patient safety Act.

Examples of a health services provider

Sole Trader	Dr Jane Doe providing a GP service
Partnership	Two pharmacists that combine to form a partnership that owns and runs a chain of pharmacy services
Statutory HSE Hospital established by the Ireland Hospitals Act 1990	e.g. Ireland General Hospital
Voluntary Hospital provided with funding under Section 38 of the Health Act, 2004	e.g. Anytown Hospital
Private Company	e.g. Private Hospital Group Limited or Private Clinic Limited

5 Who are health practitioners, as defined in the Patient Safety Act?

A 'health practitioner' is a registered healthcare professional as defined in section 2(1) of the Patient Safety Act as:

- A registered medical practitioner within the meaning of the Medical Practitioners Act 2007 or a medical practitioner practising medicine pursuant to section 50 of that Act.
- A registered dentist within the meaning of the Dentists Act 1985.
- A registered pharmacist, or registered pharmaceutical assistant, within the meaning of the Pharmacy Act 2007.
- A registered nurse, or registered midwife, within the meaning of the Nurses and Midwives Act 2011.
- A registrant within the meaning of section 3 of the Health and Social Care Professionals Act 2005. For example, a person whose name is entered on a an established register established and maintained by the relevant registration board, for example, dietitians, optometrists and dispensing opticians, medical scientists, occupational therapists, physical therapists,

physiotherapists, podiatrists and chiropodists, radiographers and radiation therapists, social care workers, social workers, speech and language.[††]

- a person whose name is entered in the register referred to in Article 4(s) of the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000) amended by the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (Amendment) Order 2004 (S.I. No. 575 of 2004). For example, Emergency Medical Technicians (EMTs), Paramedics and Advanced Paramedics.

6 What incidents must be notified to HIQA?

The notifiable incidents required to be submitted to HIQA have been defined in the Patient Safety Act and are listed in Appendix 1. There are 13 prescribed incidents of a serious nature as set out in Schedule 1, Parts 1 and 2 of the Patient Safety Act. Schedule 1, Part 1 prescribes as notifiable incidents the unintended and unanticipated deaths of patients resulting from specific situations including wrong surgeries, ABO incompatible blood transfusions, medication error, medical treatment, the unexpected death of a mother or child relating to or aggravated by the management of the pregnancy or the suicide of a patient while being cared for at a premises where the HSP provides a health service along with other incidents.

Schedule 1, Part 2 prescribes as notifiable incidents where a baby requires, is referred for or, has been considered for but did not undergo therapeutic hypothermia.

The term 'unintended' in relation to a death is defined in the Patient Safety Act, as meaning *"a death arising from an unintended event occurring, or arising from, the provision of a health* service". The term 'unanticipated' is not defined in the Patient Safety Act but can reasonably be considered to refer to a death that is not predicted or expected.

Given the nature of notifiable incidents, most are likely to occur in the hospital setting (public or private) However, a notifiable incident could also occur in other health service settings, for example, notifiable incidents arising from medication error, medical treatment, management of a pregnancy, or suicide of a patient.

7 How are notifiable incidents submitted to HIQA?

The Patient Safety Act requires the HSP to make a notification by means of the National Incident Management System (NIMS). NIMS is an end-to-end incident, risk

[††] The following registration boards do not currently have registers established for the registration of the relevant professions: Clinical Biochemists Registration Board, Orthoptists Registration Board, Psychologists Registration Board, The Counsellors and Psychotherapists Registration Board. When established, a person whose name is entered on any of these registers may be a health practitioner for the purposes of the Patient Safety Act.

management platform hosted on behalf of the State by the National Treasury Management Agency.

All HSE and HSE-funded services should use their local NIMS platform to notify HIQA (and the Chief Inspector of Social Services where appropriate) of a notifiable incident. A link to HSE NIMS webpage is available here.

All private HSPs should use the NIMS portal to notify HIQA of a notifiable incident here.

8 When should notifications be submitted to HIQA and what information should be included?

Notifications must be reported as soon as possible and in any event, not later than **seven days** from the day on which the HSP was satisfied the incident had occurred. The following information is to be included in the notification:

Information required	Comment
Regulator to be informed	Notify: 1. Chief Inspector of Social Services - for designated centres providing a health service e.g. nursing homes 2. Mental Health Commission - for approved centres‡‡ (as set out in the Patient Safety Act) providing a health service. This does not currently include notifiable events occurring in community mental health premises and these should be notified to HIQA. All approved centres that provide a health service should refer to guidance issued by the Mental Health Commission here. 3. HIQA - for all other health services providers.
Health Services Provider name	The name of the health services provider should be the full legal name of the legal entity responsible for providing the health service. For example, 'Health Service Executive' in respect of a statutory hospital or the name of the voluntary

‡‡ An approved centre has the meaning assigned to it under the Mental Health Act 2001 as amended

	hospital providing the health service, for example Anytown Hospital or 'Private Hospital Limited' for a private hospital company.
Incident location – hospital/service name and address	This is the name and address of the hospital or service where the incident occurred, for example Ireland General Hospital. This field may be pre-populated for HSE users.
Please enter the Point of Contact Nominee – Name, Email Address, Phone Number	There may be a requirement for HIQA to liaise with an appropriate contact on the details of the notification. Depending on assigned responsibilities, this may be a senior accountable person or other suitable delegate best placed to speak to in relation to the notifiable incident.
Type of Notifiable Incident	These are the notifiable incidents described in Schedule One of the Patient Safety Act. Select the type of notifiable incident from the dropdown menu which lists all of the notifiable incidents.
Date the Notifiable Incident Occurred	The date the notifiable incident occurred at the hospital/service, if known.
Date the notifiable incident came to the notice of the Health Services Provider	The date the notifiable incident came to the notice of the health services provider whether notified to the health services provider by a health practitioner or otherwise. This date may differ from the date the incident occurred.
Description of Notifiable Incident	The health services provider should provide a sufficiently detailed description of the incident having regard to the causes of the notifiable incident insofar as they are known at the time of the notification. This is a free-text field.
Mitigating Actions	This field should provide a description of the actions, if any, the health services provider has taken in response to that incident, or proposes to take, to prevent recurrence, or mitigate the consequences of any similar such incident should there be a recurrence.

Actions taken/planned to Share Learning	A statement of any action taken, or proposed to be taken, for the purpose of sharing what has been learnt, and knowledge obtained, from the occurrence of the notifiable incident.
(At the time of notification) has the Open Disclosure meeting occurred	There is a mandatory requirement to conduct open disclosure for notifiable incidents. Notwithstanding that the notification is required to be submitted within seven days, confirmation as to whether an Open Disclosure meeting has already taken place or is due to be progressed should be reported.
If No, please indicate plan for Open Disclosure including intended timeframe	If the Open Disclosure meeting has not occurred, then an intended timeframe to progress the open disclosure should be indicated here.

Once the information has been inputted in the NIMS module, a tab will appear which enables the user making the notification to review all of the details on the screen before submitting. There is also an option to go back to a previous screen to amend if required before selecting the 'Submit' option. Before the user can submit the notification they must confirm that the details provided are accurate to the best of their knowledge and that no personal data of the parties involved has been shared.

On selection of the 'Submit' button, a notification confirmation message will appear on the screen of the user making the notification with a notification reference ID number quoted. Finally, confirmation of receipt of the notification will also be automatically forwarded to the email of the user making the notification.

The receipt of the notification will be acknowledged by HIQA, not later than **21 days** following receipt of the notification, to the health services provider by means of the designated manager listed for the service in the case of publically funded services or to the Point of Contact Nominee – Email Address given in the notification for privately run HSPs.

9 What immediate actions should a health services provider progress following the occurrence of a notifiable incident?

Following the occurrence of a notifiable incident, the HSP should have adequate arrangements to take immediate actions in response to the incident to prevent recurrence, or mitigate the consequences of any similar such incident and share any

immediate relevant learning. The HSP should make arrangements to fulfil their statutory obligation to notify HIQA.

10 What happens after information is submitted to HIQA?

Following submission of the initial notification form, the notification will be reviewed and assessed by HIQA. If the information provided is incomplete or contains errors, or if HIQA requires further information or clarification, HIQA may contact the HSP. The individual notification reference number should be included on all future correspondence relating to the notifiable incident.

When the completed notification is received, the information will be risk-assessed within five days of receipt and HIQA will decide on an appropriate response. Possible responses include:

- Requesting additional or further information under Section 31 of the Patient Safety Act. Such information may be requested if it is required and or necessary for the performance of HIQA's functions, having had regard for the nature of incident and the safety of patients. The information provided on foot of a request under this section shall be provided in such manner as HIQA specifies in the request.
- Seeking further assurance from HSPs for which HIQA has a monitoring role under Section 8 of the Health Act 2007.
- Referring the information to an appropriate agency or body if required. The Patient Safety Act includes an express provision for HIQA to share the information received in a notification, or additional or further information provided under section 31 of the Patient Safety Act, with a relevant body where HIQA has determined that it is necessary to share the information for the purpose of patient safety and it is relevant to that body's functions. The relevant bodies with whom HIQA may share this information include the Coroner, the Health and Safety Authority, the Health Products Regulatory Authority, the Child and Family Agency and any other body established by enactment whose functions include the regulation of any matter relating to a health service or regulation of a health practitioner.[§§]
- Carrying out other regulatory activity such as an inspection of the service for which HIQA has a monitoring role under Section 8 of the Health Act 2007.[***]

[§§] Section 32(3) Patient Safety Act.
[***] Note: the Chief Inspector of Social Services has separate regulatory functions and powers under Parts 7 to 9 of the Health Act 2007.

- Closure and retention of the notification in line with HIQA's data retention policies.

11 What further actions should a health services provider consider following the occurrence of a notifiable incident?

Notifiable incidents must be managed in a culture that learns from errors and takes corrective action to improve patient safety. When things go wrong, HSPs need to act in a transparent, standardised and systematic way to review the incident and learn from it. When a review or investigation is initiated by the HSP to determine what happened following the occurrence of a notifiable incident to determine what learning can be derived to improve patient safety, any such review or investigation should be conducted in accordance with local policy, national guidance and relevant legislation.

HIQA and the Mental Health Commission (MHC) have developed *National Standards for the Conduct of Reviews of Patient Safety Incidents* for acute hospitals under HIQA's remit and mental health services under the remit of the MHC. The scope of these standards **do not** extend to private hospitals or designated centres, and at the time of writing, HIQA does not monitor compliance of private hospitals and designated centres against these standards. HSPs may, however, decide to apply the principles of these standards in these settings to inform best practice.

12 What are the data protection and confidentiality considerations?

HIQA collects and processes personal data for the performance of its functions under the Health Act 2007 and other relevant legislation. HSPs have a duty to comply with current data protection legislation. Names or personal details that can identify service users, staff members or any individual **must not** be included in notifications or information submitted to HIQA. People's personal data[†††] will only be sought where it is necessary to assess compliance with national standards or to allow HIQA to perform its functions. In such cases, providers should only ever use a unique identifier code to identify people in their correspondence with us.

13 Will notifications be released by HIQA under Freedom of Information Act 2014?

HIQA will not release information about notifications of notifiable incidents under the Freedom of Information Act 2014 (the "2014 Act"). The Patient Safety Act expressly

[†††] "Personal data" under Article 4(1) of the General Data Protection Regulation (GDPR) is defined as: *"Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person".*

provides that the 2014 Act does not apply to records of or relating to notifications of notifiable incidents to HIQA including any additional or further information about the notifiable incident that a HSP supplies to HIQA. Additionally, the 2014 Act does not apply to records of or relating to information obtained from a notification which is shared by HIQA with another relevant body and held by that body.

For more detailed information on how HIQA uses personal data and information about the rights of data subjects, please see its online Privacy Notice: https://www.hiqa.ie/reports-and-publications/corporate-publication/hiqa-privacy-notice

If you have any queries about the processing of your personal data, please contact HIQA's Data Protection Officer at dpo@hiqa.ie.

14 Offences

It is a criminal offence under section 77(4) of the Patient Safety Act for a HSP to fail to comply with their statutory obligation to notify the relevant authority (HIQA, the Chief Inspector, and Mental Health Commission) of the occurrence of a notifiable incident in accordance with sections 27, 28, 29, of the Patient Safety Act. A person guilty of an offence shall be liable on summary conviction to a class A fine.

Appendix 1 - Schedule of notifiable incidents reportable to HIQA

Item	Notifiable Incident
1.1	Surgery performed on the wrong patient resulting in unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.2	Surgery performed on the wrong site resulting in unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.3	Wrong surgical procedure performed on a patient resulting in an unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.4	Unintended retention of a foreign object in a patient after surgery resulting in an unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness.
1.5	Any unintended and unanticipated death occurring in an otherwise healthy patient undergoing elective surgery in any place or premises in which a health services provider provides a health service where the death is directly related to a surgical operation or anaesthesia (including recovery from the effects of anaesthesia) and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.6	Any unintended and unanticipated death occurring in any place or premises in which a health services provider provides a health service that is directly related to any medical treatment and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.7	Patient death due to transfusion of ABO incompatible blood or blood components and the death was unintended and unanticipated and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.8	Patient death associated with a medication error and the death was unintended and unanticipated as it did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.

1.9	An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to, or aggravated by, the management of the pregnancy, and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.10[***]	An unanticipated and unintended stillborn child where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child.
1.11[‡‡‡]	An unanticipated and unintended perinatal death where a child born with, or having achieved a prescribed gestational age and a prescribed birthweight who was alive at the onset of care in labour, from any cause related to, or aggravated by, the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the child or an underlying condition of the child.
1.12	An unintended death where the cause is believed to be the suicide of a patient while being cared for in or at a place or premises in which a health services provider provides a health service whether or not the death was anticipated or arose from, or was wholly or partially attributable to, the illness or underlying condition of the patient.

Part 2

Item	Notifiable Incident
2.1	A baby who — (a) in the clinical judgment of the treating health practitioner requires, or is referred for, therapeutic hypothermia, or (b) has been considered for, but did not undergo therapeutic hypothermia as, in the clinical judgment of the health practitioner, such therapy was contraindicated due to the severity of the presenting condition.

‡‡‡ *** The term “prescribed” has the meaning given to it in section 2 of the Patient Safety Act as meaning “prescribed in regulations made by the Minister under this Act”.

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