An Roinn Sláinte
Department of Health

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023: Guidance

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Introduction

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (PSA 2023) was signed into law on 2 May 2023. The Act provides for a number of important patient safety issues including:

- The mandatory open disclosure of a list of specified serious patient safety incidents that must be disclosed to the patient and/or their family;
- The mandatory external notification of those same events to the appropriate regulatory body;
- The Act also provides for similar mandatory open disclosure requirements for completed individual patient reviews of their cancer screening by the HSE's National Screening Service;
- The extension of the Health Information and Quality Authority's (HIQA) remit into prescribed private health services and private hospitals; and
- The Act provides the Chief Inspector within HIQA with a discretionary power to carry out a review of certain serious patient safety incidents which have occurred during the provision of health care in a nursing home **(this provision will be commenced at a later date following a required technical amendment)**.

The overarching purpose of the Act is to support and further embed a culture of openness and transparency in relation to patient safety within the wider healthcare system, including private healthcare.

This guidance document is to assist stakeholders in understanding the provisions of the PSA 2023. This guidance is not intended to be a definitive legal interpretation of the PSA 2023. The guidance is not exhaustive, nor should it be considered a replacement of the Act. In the case of any conflict between this guidance and the PSA 2023, the PSA 2023 will provide the definitive guidance. However, following a notifiable incident, alongside the Act, organisations should follow the guidance in implementing the processes outlined. This will help ensure consistency of approach and equity of response across organisations.

In this guidance the word **must** refers to actions that are a legal requirement as set out in legislation. The remainder of the guidance provides details of best practice in following arrangements for open disclosure and notification when there has been a notifiable incident or a Part 5 review.

Organisations should also develop local guidance and procedures to support notification, meetings, review, training and support requirements in a manner that is tailored to the particular services they provide.

We recognise that while the Act is important, it is only one part of the process. It is also necessary to overcome the known barriers to an open and honest culture in order for mandatory open disclosure to become truly embedded. The barriers include fear, a culture of secrecy and/or blame, lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture. The Act is just one part of moving towards a 'just culture', which is based on fairness and recognises the capacity for human error. It recognises the role of the system and environment in patient safety incidents and adverse events and the importance of everyone seeking to learn and improve.

Part 1: Preliminary and General

Part 1 of the PSA 2023 is primarily concerned with the short title of the Act and definitions and interpretations of terms used throughout the Act.

Definitions of “health practitioner”, “health services provider” and “health service”

Health Practitioners

The definition of “health practitioner” is based on the definition in the Civil Liability (Amendment) Act 2017. This ensures consistency between the two pieces of legislation. See Appendix 1 for definition of ‘health practitioner’.

The Act places a clear obligation on, firstly, health practitioners to make a report to their superiors when they have formed an opinion that a notifiable incident has occurred. This is a very important advance, as too often there can be a culture of silence around incidents when they take place. Going forward, there can be no doubt among health practitioners that they have a positive obligation to report issues where they have a concern, and this should remove any element of uncertainty that may hold people back from flagging incidents. This will be explored in more detail under Part 3.

Health Services Provider (HSP)

Section 3 provides the definition of a "health services provider", which encompasses a wide range of providers of health services, public and private. See Appendix 1 for definition of ‘health services provider’ and ‘health service’. There will be an onus on the particular health services provider to ensure that once it becomes aware of an incident, that it takes the appropriate steps to disclose that issue to the patient, and to report it to the regulator. The Act is very clear on the kinds of information that the patient should be given so that they understand what has happened, what the effects of that may be and what further treatment may be required as a result.

The health services provider also must inform the patient of what it is doing in response to the incident, what is being done in terms of a review process for example, or what is being proposed in order to prevent the same thing happening again. Sharing the learning out of an incident with the rest of the health service is often uppermost in the minds of patients who have been affected by an incident as they do not want to see the same thing happening again to someone else. The role of the health services provider will be explored in more detail in Part 3 & 4.

Part 2: Open Disclosure of Notifiable Incidents

What is Open Disclosure?

Open disclosure is an open and honest approach to communicating with patients and their families when things go wrong in healthcare.

The ethos of open disclosure is to ensure that the rights of all patients and staff involved in and/or affected by patient safety incidents are met and respected, that they are communicated with in an honest, open, timely, compassionate and empathetic manner and that they are treated with dignity and respect.

Open disclosure applies to patient safety incidents and reflects the right of patients to have full knowledge about their healthcare as and when they so wish and to be informed about any failings in that care process, however and whenever they may arise.

The National Open Disclosure Framework was launched by the Minister for Health in October 2023. This Framework sets out a consistent system-wide approach for our health and social care services to open communication following a patient safety incident. The Framework applies beyond the Health Service Executive (HSE) to all private health and social care providers, as well as health regulators and educational bodies.

It is the policy of the Health Service Executive that incidents are identified, managed, disclosed, and reported and that learning is derived from them. The service user/patient must be informed in a timely manner of the facts relating to the incident and an apology provided, where appropriate. The HSE has its own National Open Disclosure Policy.

National Open Disclosure Policy and Guidelines - Corporate (hse.ie)

Individual Health practitioners also have a requirement to disclose in line with their individual professional codes (see Appendix 2).

Although the National Open Disclosure Framework and Health Service Executive National Open Disclosure Policy and Guidelines provide policy supporting open disclosure**, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 moves one step further and introduces mandatory open disclosure for certain specified serious patient safety incidents and patient requested reviews of cancer screening.** It also sets out a specified process for their disclosure. This legislation applies to all health services, both public and private. It embeds in legislation, for the first time, a process by which health services providers will be required to ensure that patients and families be given all relevant information in the event of a notifiable patient safety incident. Sanctions will apply to any health services providers that fail to meet these obligations.

Why have Mandatory Open Disclosure?

Patients have a right to know what happened to them when a serious event has occurred. The provisions of this Act ensure that there is a clear framework for disclosure in place, for both patient and practitioners, when a notifiable incident, as set out in this Act, has taken

place. It embeds in legislation, for the first time, a process by which health services providers will be required to ensure that patients and families be given all relevant information in the event of a notifiable incident.

This is a very important advance, as too often there can be a culture of silence around incidents when they take place. Going forward, there can be no doubt among doctors and nurses and other healthcare professionals that they have a positive obligation to report issues where they have a concern, and this should remove any element of uncertainty that may hold people back from flagging incidents.

There will be an onus on the particular health services provider to ensure that once it becomes aware of an incident, that it takes the appropriate steps to disclose that issue to the patient, and also to report it to the regulator. The Act is very clear on the kinds of information that the patient should be given so that they understand what has happened, what the effects of that may be and what further treatment may be required as a result.

Under this Act, patients will receive open disclosure in an open and honest manner as soon as is practicable when things go wrong in healthcare. This legislation supports a safe space for staff to be open and honest with patients. Disclosure and reporting are opportunities to learn, to improve, to address incidents that have happened and to apply the lessons to make the service safer for the next patient and the patient after that.

The provisions support the policy of the Health Service Executive that incidents are identified, managed, disclosed, and reported and that learning is derived from them.

The provisions support an open and just culture for patient safety, balancing the need for an open and honest reporting environment that facilitates the learning process, and quality healthcare with accountability for both individuals and organisations.

What incidents does mandatory open disclosure apply to?

The legislation is not drafted to provide for a mandatory approach to every incident that occurs. The current definition of a patient safety incident is very broad and includes near misses and no harm events. Mandatory disclosure of every such incident would represent a massive administrative burden and such a system is not in place in any other country.

One subset of all serious incidents is described by the HSE as ‘Serious Reportable Events’ (SREs). These are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. It is a mandatory requirement of the HSE that all SREs are reported on the National Incident Management System (NIMS) and through the Safety Incident Management Communication/Escalation Form process. This will continue but not all SREs will fall under the list of notifiable incidents that require mandatory open disclosure under the Act.

The processes in this Act have been as streamlined as possible to reduce the bureaucratic and administrative burden on organisations. The number of serious incidents which are specified in this Act is quite limited and specific and should not give rise to undue burdens for small organisations.

The Act includes a schedule containing a list of very serious, primarily death related incidents, that will be subject to mandatory open disclosure and notification. These are

called ‘notifiable incidents’ (see Appendix 3). Examples of ’notifiable incidents’ include patient death due to wrong site surgery, patient death associated with a medication error, death associated with a diagnostic error, patient death due to the administration of incompatible blood or blood products etc.

The full text of the Act, including the schedule of notifiable incidents can be found at the link below:

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (irishstatutebook.ie)

Can the List of Notifiable Incidents be expanded?

Section 8 is intended to ensure that the list of notifiable patient safety incidents subject to mandatory open disclosure can be kept up to date on an ongoing basis. The section gives the Minister wide scope to prescribe further patient safety incidents as notifiable incidents, bearing in mind the learning from incidents that have occurred in the Irish health service or internationally, as well as learning from advances in clinical practice. All notifiable patient safety incidents, whether listed in the Act or prescribed in regulations, are subject to mandatory open disclosure and must be notified by the health services provider to the appropriate regulator.

The Minister may at any time amend the list of notifiable incidents by way of regulation. This is addressed in Section 7 of the Act.

To whom should open disclosure of a notifiable incident be made?

A health services provider shall make the open disclosure of the notifiable incident to the patient concerned or a relevant person, as outlined in Section 7 of the Act (or in Section 39 of the Act in relation to Part 5 reviews).

There are a number of situations where the open disclosure would be made to a relevant person:

- Where, the patient’s principal health practitioner, having regard to the clinical circumstances of the patient, believes that the patient does not have the capacity to participate in the open disclosure or consent to that open disclosure being made to a relevant person. For this to be the case, the patient’s principal health practitioner has to be of the opinion that the lack of capacity is unlikely to be temporary.
- The patient has died.
- The patient has requested that the health services provider make the open disclosure of the notifiable incident to a person whom the patient has nominated as a relevant person for the purposes of this Act and not the patient.
- The open disclosure can also be made to both the patient and a relevant person where, before the meeting is held, the patient has requested that a person whom they have nominated as a relevant person for the purposes of this Act attends that meeting to assist them. In addition to making the open disclosure to the patient, the

health services provider would also make the open disclosure of the notifiable incident to that relevant person at the same meeting.

In situations, other than the death of a patient, the relevant person shall consult with the patient in respect of the information provided at the notifiable incident disclosure meeting, and shall convey to the health services provider, with the consent of the patient, the instructions, preferences and wishes of the patient in respect of any matter arising from that information.

The Act outlines in Section 7 (2) who an open disclosure shall be made to when a patient does not have the capacity to participate in that open disclosure or consent to the open disclosure being made to a relevant person. This also applies if the patient is deceased. This includes:

- Where an appointment has been made under Part 3, 4, 5, 7 or 8 of the Assisted Decision-Making (Capacity) Act 2015 in relation to health matters.
- Where the patient has, under the Powers of Attorney Act 1996, made an enduring power of attorney (within the meaning of that Act) which includes a personal care decision (within the meaning of that Act), to the attorney appointed pursuant to that Act.
- Where the patient is a ward of court, to the Committee of the Person of that ward, duly authorised in that behalf.
- Where the patient has nominated, in writing, a person to whom his or her clinical information may be disclosed.
- Where the patient is a child, to the parent or guardian of that child or where—
    - An order in respect of the child has been made under section 18 of the Child Care Act 1991.
    - The child has been taken into the care of the Agency under section 4 of the Child Care Act 1991.
    - An order in respect of the child has been made under section 13, 17 or 20 of the Child Care Act 1991.

  to the parents or guardian of the child and the Child and Family Agency (or an authorised person) or, where an order under section 23H of the Child Care Act 1991 has been made in respect of the child, to the parents or guardian of the child and that Agency (or the social worker assigned responsibility for the child by the Agency)
- Where the patient does not fall into one of the above, the open disclosure shall be made to:
    - The spouse, civil partner or cohabitant of the patient
    - An adult son or daughter of the patient, or
    - The mother, father, brother or sister of the patient.

If the patient regains capacity after a notifiable incident disclosure meeting, the health services provider shall inform the patient that such meeting was held with the relevant person and shall provide the patient with the information given at that meeting.

What protections are in place for open disclosure and why are they in place?

International experience shows that open disclosure will be best facilitated by fostering the development of an open and honest culture. A persistent barrier to open disclosure is the perception of negative legal consequences arising from engaging in open disclosure. This is a real issue which was recognised by the Commission on Patient Safety and Quality Assurance, international experience, the HSE's 2016 evaluation of open disclosure and the Pre-legislative Scrutiny Report on this Act in September 2018. There is evidence that the most effective means of improving open disclosure is to identify and remove common barriers to open disclosure such as fear of litigation or a perceived lack of competence or know-how on the part of the health practitioner. If we want to promote open disclosure, we must focus on removing any barriers that we can.

Under the Act, protections are applicable when open disclosure takes place in line with the provisions of the Act.

Section 10 of the Act sets out the legal protection for the information and apology made to a patient when made in line with the legislation. Under the Act, open disclosure of a notifiable incident shall not:

- constitute an express or implied admission of fault or liability for the purposes of a clinical negligence action;
- be admissible as evidence of fault in court in a clinical negligence action;
- invalidate insurance;
- constitute an express or implied admission, by a health practitioner of fault, in professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission.

Section 11 of the Act provides that a health services provider shall prepare a statement in writing of the manner in which section 10 of the Act applies to the restrictions on the use of information provided, and any apology made, at the notifiable incident disclosure meeting, the additional information meeting, or the information provided in a clarification meeting. This also applies to any statements in writing provided in respect of those meetings or that clarification.

This legislation is designed to prevent the fear of admissibility of the open disclosure statement. This will free health practitioners to interact openly and honestly with patients without legitimate fear of litigation. These are interactions that need to occur within any reasonable health service if our care is to be person-centred and focused on safety and quality.

Open disclosure is about building patient and public trust in the health system. For that reason, it is important to make it very clear that the provisions do not provide protections for incompetent, negligent or other unprofessional patient care. Organisations and health professionals continue to have accountability mechanisms to address this.

What is the position on medical records?

Medical records are not affected by the protections available under this legislation. Patients have full access to their medical records which, in line with good professional practice, will contain all information relevant to their care and treatment. They are still available to the patient for use, including in litigation.

Part 3: Procedure for Making Open Disclosure of Notifiable Incident

When must open disclosure occur?

The obligation to make the open disclosure arises when the health services provider is satisfied that a notifiable incident has occurred. The Act is quite clear that complete satisfaction or perfect knowledge of all the details of the notifiable incident is not required to make an open disclosure.

In practice, the Act refers to the appropriate timing (Section 14) for making the open disclosure, taking into account all the circumstances of the patient and the nature and consequences of the notifiable incident concerned (Section 15). This gives the health services provider the time to determine that a notifiable incident listed in Schedule 1 has occurred and gives them the time to gather information in advance of the open disclosure meeting. The provision for incomplete information gives a certain amount of cover/discretion to the clinician/health practitioner if he/she is of the opinion that full details of that matter are not yet available.

While introducing some discretion to the health services provider, Section 14 emphasises the importance of the timeliness of making an open disclosure even in the absence of all the information as referred to in Section 14 (2). Open disclosure should take place at the earliest possible opportunity.

Who should make the open disclosure?

As per section 13, open disclosure shall be made on behalf of the health services provider by the principal health practitioner, in relation to the patient to whom the open disclosure of the notifiable incident is to be made. If they are not available or otherwise not in a position to make the open disclosure, or if the health services provider or principal health practitioner is satisfied that the open disclosure of the incident should be made by another health practitioner, then it can be made by another health practitioner who the health services provider deems appropriate. The Act is clear that the open disclosure must be done by a health practitioner, as defined in the Act.

Who makes the open disclosure when there is more than one body involved?

Section 5 (1) of the Act provides for 2 scenarios under which a health services provider will make an open disclosure:

(i) where a health services provider is satisfied that a notifiable incident occurred, either in that health services provider's provision of care to a patient, or

(ii) the provision of care by another health services provider to the patient.

Example: A patient may be transferred from one health services provider to another after receiving care from the former and die as a result of that care in the second health services provider , e.g., a patient has an operation in Hospital A, subsequently deteriorates medically, is transferred to Hospital B for emergency care and dies there. In this scenario, Hospital B, once satisfied that a notifiable incident has occurred, shall hold the notifiable incident disclosure meeting in order to make the open disclosure to the relevant person in this case as the patient has passed away.

Sections 14 and 15 of the Act provide discretion to the system for the appropriate timing of making the open disclosure, taking into account all the circumstances of the patient and the nature and consequences of the notifiable incident concerned. As mentioned previously, many of the 13 notifiable patient safety incidents listed in Schedule 1, Part 1 and 2, are also classed as SREs in the HSE's list of SREs published in 2015. As is the case with SREs, the application of clinical judgement and discretion are important factors in the determination of the "satisfied" threshold.

Organisations currently have processes in place for the transfer of information in the case of SREs and other matters. These processes should be refined and/or put in place in the case of notifiable incidents.

How is open disclosure conducted under the Act?

Under section 18 of the Act, open disclosure under the Act takes place during a notifiable incident disclosure meeting. As per section 17 of the Act, this meeting will generally be held in person. A patient or relevant person can ask that the proposed meeting be held other than in person.

What is a 'Designated Person' under the Act?

A 'Designated Person' is someone who has been assigned to act as a liaison between the health services provider and the patient or relevant person (or both of them) in relation to the open disclosure of the notifiable incident and in respect of a request for clarification under section 23. Section 15 (e) of the Act provides that the designation of such a person must happen before making an open disclosure of a notifiable incident. Section 16 outlines who this person may be. The designation shall be documented in writing and kept in the records. Sections 46 and 47 have the same provisions in respect of Part 5 Reviews (see below).

Things to consider before a notifiable incident disclosure meeting:

- Who from the organisation is already in contact with the patient and/or family?
- Has a designated person been appointed and what contact have they had?
- What discussions or information exchange has already taken place?
- What is the patient and/or family's current understanding of the incident and organisational response to this?
- Where the conversation takes place? A quiet room should be used, free from distraction and where the meeting will not be interrupted. It may not be appropriate to host the meeting close to where the incident happened as this could be emotionally difficult for the relevant person.
- Who should be part of, and who should lead that conversation?
- Staff should try to avoid the use of jargon or explain technical terms when speaking with relevant persons.
- What support should be available to the patient and/or relevant person during the conversation and afterwards?
- Who will be the single point of contact following the discussion with the patient and/or family?
- Are there linguistic needs or reasonable adjustments that might need to be made for someone who has a disability? In some circumstances it will be necessary to have an interpreter or any other appropriate support person present

What should be included in a notifiable incident disclosure meeting?

Section 18 (3) & (4) sets out what the notifiable incident disclosure meeting should include. This information may be provided orally and, in the order considered most appropriate. It includes:

- The names of the people present at the meeting.
- A description of the notifiable incident concerned.
- The date on which the notifiable incident occurred (if known) and the date it came to the notice of the health services provider.
- The manner in which the notifiable incident came to the notice of the health services provider.
- Where, in the opinion of the health services provider, physical or psychological consequences of the notifiable incident (i.e. harm to the patient) which, at the time of the notifiable incident disclosure meeting is held, are present or have developed, information in respect of those consequences.
- Where physical or psychological consequences have not yet presented or developed but the health services provider has such grounds for believing they are likely to present or develop at any time after the notifiable incident disclosure meeting, information in respect of those consequences. The same applies if the health services provider has such grounds for believing they are less likely or unlikely to present or develop at any time after the holding of the notifiable incident disclosure meeting.
- A statement that the health services provider has reasonable grounds for believing that no physical or psychological consequences are likely to present or develop from the notifiable incident if this is the case.
- If at the time of the meeting, physical or psychological consequences have arisen and the patient is under the clinical care of the health services provider concerned, the health services provider shall provide the patient with information in respect of the treatment, and relevant clinical care, that the provider is providing (or proposes to provide) to the patient to address those consequences.
- The actions the health services provider has taken or proposes to take and the procedures or processes to be implemented. This is to allow the health services provider, in so far as it is reasonably open to that provider to do so, to address the knowledge the provider has obtained from its consideration of that incident and the circumstances giving rise to it.
- An apology, if appropriate.

This meeting should provide an opportunity for the patient or relevant person to ask questions about the incident and an opportunity for them to express their views about the incident.

Apology

An apology should be provided, where appropriate.

The Act defines an apology in relation to an open disclosure of a notifiable incident as:

“an expression of sympathy or regret”

Not all patients want an apology but when they do, such an apology needs to be personalised, sincere and honest. This approach is further underpinned by the HSE’s Policy on Open Disclosure, the Medical Council’s new Guide to Professional Conduct and Ethics for Doctors and other professional codes.

The apology to be given must be a considered expression of regret, where this is the right and appropriate thing to do, and that will depend on the individual circumstances of the incident. The Ombudsman outlines that it is important that, when making an apology, the person providing this apology understands the person’s circumstances and what their wishes are in relation to what has occurred. This principle is very important, and it is not possible to put together a meaningful apology without understanding what the patient has experienced and how that has impacted on their individual concerns and requirements.

The Ombudsman's Guide To Making A Meaningful Apology | Ombudsman.ie | The Office Of The Ombudsman

There may still be misconceptions and misunderstanding that the provision of an apology equates to an admission of liability and that organisations should never offer apologies for this reason, but this is not the case.

Section 10 of the Act provides that open disclosure of a notifiable incident to a patient or a relevant person (or both of them) and an apology where it is made does not invalidate insurance, constitute admission of liability or fault and cannot be admissible in proceedings.

What should a person be provided with after the open disclosure meeting?

After the meeting, the person should be provided with a statement in writing of the meeting, as per Section 18 (2)(c) of the Act.

The information that should be contained in the statement is set out in Section 18 (5). This should include:

- The information that was provided to the patient or the relevant person at the meeting.
- An apology if one was made.
- The date on which the open disclosure of the notifiable incident was made,
- Statements that the open disclosure of the notifiable incident was made pursuant to section 5 (1) and that the notifiable incident disclosure meeting was held in compliance with section 5 (1)

This statement should be signed by the principal health practitioner or the health practitioner who made the open disclosure of the notifiable incident on behalf of the health services provider.

The health services provider should keep this statement in the records referred to in Section 25.

When should a written statement be provided in respect of open disclosure?

The written statement must be presented to the patient/relevant person not more than 5 days after the notifiable incident disclosure meeting.

What if a meeting is refused by the patient or relevant person?

Section 19 of the Act makes it clear that a patient or relevant person may choose not to participate in the open disclosure of a notifiable incident. However, this section of the Act ensures that the patient or a relevant person may change his or her mind within five years from the date of refusal and request the health services provider to make the open disclosure. The provider must also keep a record of the refusal and the information to be kept in this is outlined in Section 19. If the patient/relevant person has chosen not to participate in the open disclosure process, the Act does not provide for a written report/statement of the information which would have been provided under Section 18 to be given to them. As the open disclosure process has not taken place the indemnities/protections set out in Section 10 will not apply to the Health Services Provider in this case.

To summarise, if the procedure outlined in Section 18 is followed this will provide for the indemnities set out in Section 10. Procedures outside the provisions of the Act will not attract the protections of Section 10.

What information should be recorded?

Section 25 outlines what health services providers must keep and maintain in terms of written records. This includes:

- Written confirmation of who has been assigned as the 'Designated Person'.
- A copy of the statement that was provided in respect of the notifiable incident disclosure meeting.
- If a patient or relevant person refuses to participate in open disclosure of the notifiable incident, the relevant statements in this regard, as per Section 19. For example:
    - a statement that the patient or relevant person refused and that they have an entitlement to make a later request.
    - a record of their refusal to accept receipt of this statement, if relevant.

    - If a patient or relevant person subsequently requests open disclosure within 5 years from the date of refusal, as is their entitlement, a record of this request including the date of request and who made it.
- If when arranging a notifiable incident disclosure meeting, the health services provider concerned is unable to contact a patient based on the contact information provided to it by the patient, the health services provider must set out in a statement, the steps taken by it to establish contact. This statement should be kept, along with any document (or any copy or record of a document) used by the provider to contact the patient or relevant person (or both of them).
- If an additional notifiable information meeting takes place, a copy of the relevant statement in respect of this meeting, as per Section 22.
- If after a notifiable incident disclosure meeting or the additional notifiable information meeting, the patient or relevant person requests further clarification on any information
    - a statement relating to this request, as per Section 23 (2) (e), which includes the request for clarification and the date on which it was made.
    - A statement setting out the information provided in the clarification and the date on which it is was provided.
- A record of any request by the patient or relevant person that the notifiable incident disclosure meeting or additional notifiable information meeting be held other than in person.

Does the Act provide for retrospective open disclosure of notifiable incidents?

The Act only applies prospectively to notifiable incidents which occur after the date of commencement of the Act. It does not apply retrospectively.

Part 4: Notification to Certain Bodies of Notifiable Incidents

What do we mean by Notification?

As outlined above, the Act includes a schedule containing a list of very serious, primarily death related incidents, that will be subject to mandatory notification and open disclosure. Examples of notifiable incidents include patient death due to wrong site surgery, patient death associated with a medication error, death associated with a diagnostic error, patient death due to the administration of incompatible blood or blood products etc.

Where a health services provider is satisfied that a notifiable incident, as defined in the Act, has occurred in the course of the provision by the health services provider of a health service to a patient, it is mandatory that they notify the relevant body of that notifiable incident. The relevant body will be the Health Information and Quality Authority, the Chief Inspector within HIQA, or the Mental Health Commission. The circumstances of the notifiable incident and the regulatory oversight of the service where the notifiable incident has occurred will determine which regulator is notified. The regulators will provide further guidance on this, which can be accessed on their website. It is relevant to note that the requirement to report notifiable incidents via NIMS does not remove the need to also report such incidents via existing reporting routes.

What is the timeframe for making a Notification?

A notification must be made as soon as practicable and, in any event, no later than 7 days from the day on which the health services provider was satisfied that the incident had occurred.

The intention of this legislation is to allow for notification of incidents to the relevant regulatory body at the earliest opportunity. There is not an expectation that a health services provider needs to have complete information about every aspect of the incident before they make the notification.

In fact, Section 27 3(e) provides for notification “having regard to the notifiable incident and the causes of the notifiable incident insofar as they are known at the time.” Provision is made in the Act for additional information in relation to the incident to be supplied to the relevant regulatory body after the initial notification if the regulatory body requests same (Section 31).

The relevant regulatory body will acknowledge receipt of the notification not later than 21 days from receipt of the notification.

Why is notification necessary?

A core purpose of this new legislation is to enable national learning from serious patient safety incidents and to support health service-wide improvements so that harm to patients

can be minimised. The Act requires that when a notifiable patient safety incident occurs in a health service, this must be notified to the regulatory body most relevant to that service i.e. the Health Information and Quality Authority (HIQA), the Chief Inspector within HIQA or the Mental Health Commission (MHC). This is to contribute to national patient safety learning and improvement.

How to make a notification

The Act stipulates the means by which notification is to take place, namely, through the National Treasury Management Agency incident management system, also known as the National Incident Management System (NIMS).

To facilitate this notification process, an additional module within the existing NIMS has been developed. For those that are not existing NIMS users, a notification portal/website has been set up, which can be accessed through the HIQA or MHC websites.

As the Act has now been commenced, this portal is now 'live' and can be accessed through the relevant regulator's website at:
https://www.higa.ie/
or
Mental Health Commission | Mental Health Commission (mhcirl.ie)

The requirements of the Act apply to all healthcare bodies. Non-HSE bodies, such as the following, can submit a Notifiable Incident using the above portal:

- Section 39 organisations who don't have access to NIMS
- Private Hospitals
- Private health and social care providers such as GPs, Dentists, Pharmacists, etc.

Who makes the notification?

Under the Act, ultimately it is the responsibility of the health services provider to ensure that the notification is made, as opposed to the health practitioner. It is for the health services provider to determine the exact process for this within the service. As per Part 8 (see below), a health services provider which fails to comply with the obligation to report a notifiable patient safety incident externally to the appropriate body will be liable on summary conviction to a class A fine.

What protections are in place for notification?

As with open disclosure, protections are applicable when notification takes place in line with the provisions of the Act. Information provided in a notification shall not:

- constitute an express or implied admission of fault or liability for the purposes of a clinical negligence action;
- be admissible as evidence of fault in court in a clinical negligence action;

- invalidate insurance;
- constitute an express or implied admission, by a health practitioner of fault, in professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission; or
- be subject to Freedom of Information legislation.

Part 5: Open Disclosure of Part 5 Reviews

What is a Part 5 Review?

As per section 35 of the Act, a patient may request a review of the results of a screening which has been carried out by a cancer screening service in relation to the patient. Cancer screening service refers to:

- the service known as the national breast screening programme carried out by the National Cancer Screening Board and provided by the HSE
- CervicalCheck, and
- the service known as the national colon cancer screening programme provided by the HSE

Who can request a Part 5 Review and how?

A request for a Part 5 Review must be made by a patient. A request for a Part 5 review shall be made in writing to the health services provider who provided the cancer screening to the patient. All patients in respect of whom a cancer screening is to be or is being carried out should be informed in writing by the health services provider of their right to make a request for a Part 5 review.

Will the same requirements for open disclosure of Notifiable Incidents apply to Part 5 Reviews?

A Part 5 patient requested review will be subject to mandatory open disclosure of all the relevant information related to that Part 5 patient requested review, in exactly the same manner as a notifiable patient safety incident elsewhere in the Act. The purpose of Part 5 Reviews is to create the same obligation for mandatory open disclosure and to put the same processes in place.

What protections are in place for Part 5 Reviews

Under Section 41, protections are applicable when open disclosure of Part 5 reviews takes place in line with the provisions of the Act. Information provided in a Part 5 review disclosure meeting shall not:

- constitute an express or implied admission of fault or liability for the purposes of a clinical negligence action;
- be admissible as evidence of fault in court in a clinical negligence action;
- invalidate insurance;

- constitute an express or implied admission, by a health practitioner of fault, in professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission; or
- be subject to Freedom of Information legislation.

Part 6: Clinical Audit

What is Clinical Audit?

Clinical Audit is a tool which can be used to discover how well health care is being provided and to learn if there are opportunities for improvement. Clinical audit can be used to improve aspects of care in a wide variety of areas, and to confirm that current health care practice meets an expected level of performance.

"Clinical Audit" is defined in the Act as a clinically-led quality improvement process in healthcare –

a) for the purpose of improving patient care and outcomes through the systematic review of care against explicit clinical standards or clinical guidelines and taking action to improve care where those standards or guidelines are not met, and
b) which selects aspects of the structures, processes and outcomes of care for systematic evaluation against explicit clinical standards or guidelines.

This definition of clinical audit in the Act has been developed through extensive engagements with stakeholders and experts in clinical audit. The definition, as set out in the Act, when taken in conjunction with definitions for clinical standards and clinical guidance, is quite broad but deliberately does not cover all quality improvement processes.

The Patient Safety Act does not seek to alter the current way in which clinical audits are conducted but instead adds new protections for clinical audits which meet the definition contained in the Act (see below).

What are the protections being given to clinicians in respect of clinical audit?

For those healthcare processes that fall within the definition of clinical audit, information or data submitted as part of clinical audit activities shall not-

- constitute an express or implied admission of fault or liability for the purposes of a clinical negligence action;
- be admissible as evidence of fault in court in a clinical negligence action;
- invalidate insurance; or
- constitute an express or implied admission, by a health practitioner of fault, in professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission;
- be subject to Freedom of Information legislation.

This represents significant legal protection to enable an environment which is supportive of a wide range of quality assurance activities. It should be noted that clinicians are already required to participate in clinical audit processes. This provision provides a new level of protection to clinicians which was not previously available to them.

Patients will continue to have full access to their medical records which, in line with good professional practice, will contain all information relevant to their care and treatment.

When do the protections apply?

In order for the above protections to apply, the data obtained from that clinical audit must have been:

- collected solely for the purpose of improving patient safety and quality improvement in healthcare of patients,
- collected and analysed by the health services provider or the health practitioner (or both of them) or more than one health services provider or practitioner.
- published as aggregated information, and
- used by that health services provider or health practitioner for the purpose of improving patient safety and quality improvement in healthcare of patients or for sharing with another health services provider or health practitioner solely for the purpose of improving patient safety and quality improvement in healthcare of patients.

What is meant by aggregated information and why is it necessary?

As per Section 57 of the Act, "aggregated information", in relation to data, means data obtained from a clinical audit which excludes information that identifies or could reasonably lead to the identification of a person in that clinical audit.

National and international practice guidance documents on clinical audit state that clinical audit data should be anonymised. This is for a number of reasons, including the need to maintain and protect patient confidentiality.

Clinical audit should only use the minimum, relevant data needed, and this does not typically extend to patient specific or personal data as clinical audit is aimed at assessing a programme against specific standards to identify areas for improvement in the provision of the service.

What is meant by 'published' in the context of Section 59(c) of the Act?

The form of publication is not specified in the section. Whether that is reported in a journal or published on a hospital website is within the discretion of those wishing to benefit from the Section. However, it is clear from the section that the data obtained from a clinical audit must be published as aggregated information.

'Published' means that the aggregated data is disseminated in some form to the public, in a form or manner to be determined by the health services provider/those wishing to benefit from the Section.

Part 7: Amendment of Act of 2007

How does the Act extend HIQA's remit to private health care?

The definition of 'prescribed private health service' and 'private hospital' can be found in Section 62 (a) of the Act.

The Act brings prescribed private health services and private hospitals within the remit of the Health Act 2007. In this way, HIQA will have the same powers for standard setting, monitoring, and undertaking investigations in both public and these private settings.

The amendment in this Act will allow HIQA to monitor compliance of prescribed private health services and private hospitals with standards set under the provisions of the Health Act 2007.

In this way these providers will be subject to the same standards that apply currently to public providers. HIQA will be able to monitor compliance with the National Standards for Safer Better Healthcare in prescribed private health services and private hospitals. The National Standards will enable HIQA to identify and report on where quality and safety improvements might be made in the delivery of services.

How will this approach work?

The extension of HIQA's remit to prescribed private health services and private hospitals does not at this time include powers of sanction. The Department plans a phased approach to the regulation of prescribed private health services and private hospitals. It is intended that this Act will be followed by additional legislation on licensing which will introduce sanctions for non-compliance.

Under the provisions of the PSA 2023 the publication by HIQA of reports on prescribed private health services and private hospitals will, at a minimum, provide patients with information that would allow them to make an informed choice before seeking services in that institution. A HIQA investigation or a report will help to ensure that the relevant institution addresses HIQA's concerns.

How is a private health service prescribed?

Section 75 of the PSA 2023 amends the Health Act 2007 and provides that the Minister may prescribe, by regulation, a health service to be a prescribed private health service for the purposes of this legislation.

What does Section 9 of the Health Act 2007 do and why are we amending it?

Section 9 of the Health Act 2007 gives the Minister for Health and Minister for Children, Equality, Disability, Integration and Youth the power to direct HIQA to undertake a statutory investigation, to address serious ongoing risks to patient safety in Ireland's health and social services. Investigations may be carried out by HIQA on its own initiative or where required by the Minister for Health or Minister for Children and Youth Affairs, as the case may be.

An amendment to Section 9 of the Health Act 2007 is being made to clarify and strengthen relevant Ministers' powers to request an investigation by HIQA into Ireland's Health and Social services. This amendment is contained in Section 64 of the PSA 2023.

In addition to this, Section 73 of the PSA 2023 amends the Health Act 2007, introducing a provision enabling HIQA or the Chief Inspector within HIQA to publish reports containing information on the monitoring and compliance with standards and any investigation undertaken under Section 9 of the Health Act 2007. These reports are in addition to the annual report to be laid before the Minister and the Oireachtas by HIQA on the performance of its functions, which is required by statute.

How will the amending provisions change the current Section 9 investigations?

Amendments to Section 9 of the Health Act to 2007 will ensure that when directing an investigation into Ireland's health or social services:

- The Minister(s) and/or HIQA must believe on reasonable grounds that there "may be a serious risk" to health or welfare of people receiving services that will be the subject of the investigation. This replaces the previous requirement for a belief that there "is a serious risk".
- The purpose of the investigation will include a public interest element where a need for learning and improvement of services will form part of the rationale for requiring an investigation under Section 9.

Nursing Home Incident Reviews

(A minor technical amendment is required to Section 68 so this will not be commenced with the rest of the Act and will be commenced at a later date)

Section 68 provides that a new Section (41A) be inserted into the Health Act 2007 to provide the Chief Inspector with a discretionary power to undertake a review of a defined type of serious patient safety incident where some or all of the care of a patient was carried out in a nursing home to include both public and private nursing homes.

Care which takes place in these nursing homes will often be carried out in conjunction with interactions with services owned and operated by the HSE or private hospitals. Therefore, the Chief Inspector will have the power to include these services in its review, where necessary to complete the process.

The Chief Inspector will have the power to carry out a review of an incident which may have caused an unintended or unanticipated death or serious injury to the patient, and which occurred in the course of the provision of care to that patient.

The Chief Inspector's review will seek to establish the facts concerning the serious patient safety incident, identify any learning for the service to allow action to be taken to reduce risk and improve quality and safety in the service going forward.

The review will not be for the purpose of assessing or determining blame, civil or criminal liability or deciding whether action needs to be taken in respect of an individual by any panel, committee or tribunal or a regulatory body.

The Chief Inspector within HIQA's powers described in Part 9 of the Health Act 2007, currently in place for the carrying out of inspections as part of its monitoring programme and for investigations under Part 9, will be extended to include reviews carried out under this provision.

There will be a requirement for reports to be shared with residents who are the subject of the review and/or any appropriate complainant and other appropriate designated persons and the relevant service providers. This provision will include fair procedure processes.

A review may be instigated by the Chief Inspector through the performance of his or her function or upon receipt of a complaint by certain defined persons to include the resident and relevant family members. The timeframe for commencing a review will be reasonable, limited by statute (as set out in Section 68 of the Act) and will not operate retrospectively.

The PSA 2023 amends the Health Act 2007 to allow HIQA to publish a report relating to the monitoring of compliance with standards set by it, including reports on the new section 41 A reviews. This is done in Section 73 of the PSA 2023.

Part 8 – Offences and Penalties

What are the Offences for not complying with the obligation to disclose?

Section 77 of the PSA 2023 addresses the offences and penalties. A health services provider which fails to comply with the obligation to make an open disclosure of a notifiable patient safety incident or a patient requested review of cancer screening, without reasonable excuse, shall be liable on summary conviction to a class A fine.

A health services provider which fails to comply with the obligation to report a notifiable patient safety incident externally to the appropriate body will also be liable on summary conviction to a class A fine. A summary offence is one which can only be dealt with by a judge sitting without a jury, that is, in the District Court. Under the Fines Act 2010, since January 2011 there are five categories or classes of maximum fine applying to summary convictions. If someone is liable on summary conviction to a class A fine, the maximum fine is €5,000.

The health services provider must make all reasonable efforts to ensure compliance with the relevant provisions of the Act that are alleged to have been contravened.

It is important to note that the obligation to carry out open disclosure will be on the health services provider, not the individual health practitioner. This supports the principle of making the employer accountable for ensuring the appropriate governance, process, procedures, education, and resources are in place for a health practitioner to be supported to make an appropriate open disclosure to the patient and / or their family.

Practitioners will have an obligation to inform the relevant health services provider when they are of the opinion that a notifiable incident has occurred. It is then the responsibility of the health services provider to ensure notification and disclosure take place.

If individual practitioners are refusing to engage in mandatory open disclosure, while they are not liable for an offence under this Act, it would be a matter for their relevant regulatory body to examine and act on as appropriate.

- https://www.medicalcouncil.ie/
- https://www.nmbi.ie/Home
- https://www.dentalcouncil.ie/
- https://www.phecit.ie/
- https://www.thepsi.ie/gns/home.aspx
- https://www.coru.ie/

Part 9 Miscellaneous and General

Part 9 includes a number of different provisions including:

Section 80 provides that the Minister may carry out a review of the operation of the Act, not later than 2 years after the coming into operation of this Act.

Section 82 provides for the amendment of the Civil Liability (Amendment) Act 2017 to bring it in line with the provisions of the PSA 2023.

Section 83 contains the savings and transitional provisions. Where a health service provider makes an open disclosure in accordance with Part 4 of the Civil Liability (Amendment) Act 2017 of an incident which would be a notifiable incident under this Act before the coming into operation of this legislation, Part 4 of the Act of 2017 shall continue to apply to that open disclosure.

Appendix 1

Definitions of 'Health Practitioner', 'Health Services Provider' & 'Health Service'

Under the Act a "health practitioner" means:

(a) 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,
(b) a registered dentist within the meaning of the Act of 1985,
(c) a registered pharmacist, or registered pharmaceutical assistant, within the meaning of the Pharmacy Act 2007,
(d) a registered nurse, or registered midwife, within the meaning of the Act of 2011,
(e) a registrant within the meaning of section 3 of the Act of 2005, or
(f) a person whose name is entered in the register referred to in Article 4(s) of the Order of 2000;

A Health Services provider is defined as:

Health services provider
3. (1) In this Act, "health services provider" means—
(a) a person, other than a health practitioner, who provides one or more health services and for that purpose—
(i) employs a health practitioner for the provision (whether for, or on behalf of, that person) by that practitioner, of a health service,
(ii) enters into a contract for services with a health practitioner for the provision (whether for, or on behalf of, that person) by that health practitioner of a health service,
(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, that person,
(iv) enters into an arrangement with a health practitioner—
(I) for the provision by that health practitioner of a health service (whether for, or on behalf of, that person, or through or in connection with that person),
(II) for the provision by that health practitioner of a health service on his or her own behalf (whether through or in connection with, or by or on behalf of, that person or otherwise), or
(III) without prejudice to the generality of clause (II), to provide that health practitioner with privileges commonly known as practising privileges (whether such privileges are to operate through or in connection with, or by or on behalf of, the person or otherwise),
or

(v) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,

(II) enters into a contract for services with one or more persons,

(III) enters into an agency contract for the assignment of an agency worker, or

(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business,

(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 by reason of employment or otherwise), a person referred to in paragraph (a) and includes a health practitioner who—

(i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner of a health service,

(ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner) by that other health practitioner, of a health service,

(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner, or

(iv) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,

(II) enters into a contract for services with one or more persons,

(III) enters into an agency contract for the assignment of an agency worker, or

(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business,

(c) a partnership of 2 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 person referred to in paragraph (a) and includes a partnership which—

(i) employs another health practitioner for the provision (whether by or on behalf of, the partnership) by that other health practitioner of a health service,

(ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the partnership) by that other health practitioner of a health service,

(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the partnership, or

(iv) insofar as it relates to the carrying on of the business of providing a health service—

(I) employs one or more persons,
(II) enters into a contract for services with one or more persons,
(III) enters into an agency contract for the assignment of an agency worker, or
(IV) enters into an arrangement with one or more persons,

in respect of the carrying on of that business, or

(d) in the case of a cancer screening service, the Executive or, in respect of the cancer screening service referred to in paragraph (b) of the definition of "cancer screening service", a provider referred to in paragraph (b) or (c).

(2) For the purposes of paragraphs (b) and (c) of the definition of "health services provider", references in each such paragraph to "through or in connection with" do not include the use by a health services provider referred to in each such 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 that 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.

A "health service" is defined in section 2 of the Act.

"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;

Appendix 2

Professional Codes

Medical Council

- https://www.medicalcouncil.ie/news-and-publications/reports/guide-to-professional-conduct-and-ethics-for-registered-medical-practitioners-amended-.pdf

Nursing and Midwifery Board of Ireland

- https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf

Dental Council

- https://www.dentalcouncil.ie/wp-content/uploads/2023/06/Code-of-Practice-Professional-Behaviour-and-Ethical-Conduct-20220301.pdf

Pre-Hospital Emergency Care Council

- https://www.phecit.ie/Custom/BSIDocumentSelector/Pages/DocumentViewer.aspx?id=oGsVrspmiT3dSZilHPLNbk6bnx%252fcClbdo4OVmEjc7W595rrVWD79OqT4qvQLkUaAFLylFyLcMArMXqnQH71VDQJbYdA7ktLGZByp8hq3NevHjtWHGe9%252b5OjCGQVJamjNBd4G4gQitq4RqptaYrOuW0gkqGkuJmmOxmKp%252b6nx5HQ%253d

Pharmaceutical Society of Ireland

- https://www.thepsi.ie/Libraries/Publications/Code_of_Conduct_for_pharmacists.sflb.ashx

CORU

- https://coru.ie/health-and-social-care-professionals/codes-of-professional-conduct-and-ethics/

Appendix 3

Schedule 1: List of Notifiable Incidents

Section 2

Part 1

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.

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.

Disclaimer: This document is a summary guide and does not purport to be an interpretation of the Patient Safety (Notifiable Incident and Open Disclosure) Act 2023. The information within this summary guide is made available on the understanding that it does not constitute professional, expert or legal advice. Whilst every effort

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