An Bille um Shábháilteacht Othar (Teagmhais Sábháilteachta Othair Infhógartha), 2019

Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

Meabhrán Mínitheach

Explanatory Memorandum

AN BILLE UM SHÁBHÁILTEACHT OTHAR (TEAGMHAIS SÁBHÁILTEACHTA OTHAIR INFHÓGARTHA), 2019

PATIENT SAFETY (NOTIFIABLE PATIENT SAFETY INCIDENTS) BILL 2019

EXPLANATORY MEMORANDUM

Purpose of the Bill

The main purpose of the Bill is to set out the legislative framework for a number of important patient safety measures. These include: mandatory open disclosure of specified serious patient safety incidents, including a process to designate other patient safety incidents by regulation in line with advancements in clinical practice; the notification of these serious incidents externally to the Health Information and Quality Authority (HIQA), the Chief Inspector of Social Services (CISS) and the Mental Health Commission (MHC) as appropriate, to contribute to national learning and system-wide improvements; provisions regarding clinical audit; amendments to the *Health Act 2007* to extend HIQA's remit to private hospitals; and amendments to Part 4 of the *Civil Liability (Amendment) Act 2017* to align certain of its provisions with the provisions of this Bill.

Provisions of the Bill

The Bill is divided into eight Parts with 54 sections and two Schedules.

Part 1
Preliminary and general provisions (sections 1 to 4)

Section 1- Short title and commencement

Subsection (1) provides for the short title of the Bill, and *subsection* (2) concerns the commencement by order(s) to be made by the Minister for Health.

Section 2 - Interpretation

Section 2 provides for the definition of certain terms used in the Bill, including key definitions such as "apology", "designated person", "health practitioner", "health service", "notifiable incident", "open disclosure of a notifiable incident", "patient" and "relevant person".

Section 3 - Health services provider

Section 3 provides the definition of a "health services provider" which is closely aligned with the *Civil Liability (Amendment) Act 2017* and encompasses a wide range of providers of health services, both public and private.

Section 4 - Expenses

Section 4 allows for approved expenses incurred by the Minister for Health associated with the administration of the Bill to be paid out of the monies provided by the Oireachtas.

Part 2
Open disclosure of notifiable incident procedure (sections 5 to 12)

Section 5 – Obligation to make an open disclosure of notifiable incident

Section 5 places an obligation on the health services provider to make an open disclosure to the patient and / or their relevant person, when satisfied that a notifiable patient safety incident has occurred.

Section 6 – Health practitioner to inform health services provider of notifiable incident

Section 6 places an obligation on a health practitioner, when they have formed the opinion that a notifiable incident has occurred in relation to a patient, to inform the health services provider of the incident.

Section 7- Persons to whom open disclosure of notifiable incident is made

Section 7 identifies to whom the open disclosure of a notifiable patient safety incident is made. In the first instance, open disclosure of a notifiable patient safety incident is made to the patient concerned. However, if the patient has died or there are concerns with regard to the age, capacity or health of the patient, it may be more appropriate to make the disclosure to the relevant person.

Section 8- Regulations specifying notifiable incident

Section 8 provides for the Minister for Health to make regulations prescribing further patient safety incidents as notifiable incidents for the purposes of this legislation.

All notifiable patient safety incidents, whether listed in Schedule 1 to the Bill or prescribed in regulations made by the Minister under this section are subject to mandatory open disclosure to the patient and / or their relevant person in accordance with this Bill and must be notified by the health services provider to the relevant regulator (the Health Information and Quality Authority, Chief Inspector of Social Services or Mental Health Commission as appropriate). This section gives the Minister wide scope to prescribe further patient safety incidents as notifiable incidents bearing in mind learning from incidents which have occurred in the Irish health service or internationally as well as learning from advances in clinical practice, healthcare and patient safety.

In prescribing new patient safety incidents as notifiable incidents for the purposes of this legislation, the Minister must have regard to a number of patient safety matters including: the nature of the incident; the consequences of the incident for a patient including the harm caused; the need to obtain and disseminate information and knowledge regarding an incident so as to avoid, lessen or eradicate reoccurrence through system-wide learning. Regulations made under this section may make different provisions for different incidents or classes of incidents or provisions for different patients or categories of patients.

Section 9 – Open disclosure of notifiable incident

Section 9 provides that when a health services provider engages in an open disclosure in accordance with the Act, the disclosure (including an apology) shall be treated as an open disclosure of a notifiable patient safety incident.

Section 10 – Open disclosure of notifiable incident: information and apology not to invalidate; insurance; constitute admission of liability or fault; or not to be admissible in proceedings

Section 10 sets out that the information and apology given at an open disclosure notifiable patient safety incident meeting shall not:

- constitute an express or implied admission of fault or liability;
- be admissible as evidence of fault;
- invalidate insurance;
- constitute an express or implied admission, by a health practitioner of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission in relation to notifying a notifiable patient safety incident.

The following terms are also defined in this section: clinical negligence, clinical negligence action, medical defence organisation and professional indemnity insurance.

Section 11 – Statement in relation to procedure for open disclosure of notifiable incident and application of section 10 to information and apology

Section 11 provides that health service providers must prepare a statement in writing setting out its procedures for making an open disclosure of notifiable patient safety incidents to patients of information provided, and any apology made, at the notifiable incident disclosure meeting, the additional notifiable meeting, or the information provided in respect in a clarification under *section 23* and any statements in writing provided in respect to those meetings or that clarification.

Section 12 - Disclosure of information by health services provider and health practitioner

Section 12 deals with openness and transparency and sets out that both health service providers and health practitioners, when making an open disclosure under this Bill, must provide all relevant information in the provision of a health service to the patient (or the relevant person as the case may be) and where appropriate any other health service to address the consequences of that incident.

Part 3
Procedure for making open disclosure of notifiable incident (sections 13 to 25)

Section 13 – Making of open disclosure of notifiable incident by health services provider

Section 13 requires that an open disclosure must be made on behalf of the health services provider by the principal health practitioner. If the principal health practitioner is not available or not in a position to make the open disclosure the health services provider will identify an appropriate health practitioner to make the disclosure.

Section 14 – Time of making of open disclosure

Section 14 addresses the timing in relation to when an open disclosure should occur. This section requires the health services provider to take all reasonable steps to make the disclosure to the patient and / or their relevant person as soon as practicable, having regard to the circumstances of the notifiable patient safety incident.

Section 15 – Matters to be addressed by health services provider before making open disclosure of notifiable incident

Section 15 details the matters to be addressed by the health services provider before making the open disclosure of the notifiable patient safety incident. These matters include determining: the appropriate time (given an assessment of the circumstances); to whom the disclosure should be made; the making of an apology; the complexity of the information; the assignment of a designated person to liaise with the patient and or their relevant person; and making arrangements for the preparation of the statement in writing about the incident.

Section 16 – Designated person

Section 16 provides for the designation by health services providers of a person (such as an employee or health practitioner) to act as a designated contact person for the patient / family in relation to the open disclosure.

Section 17 - Notifiable incident disclosure meeting generally to be held in person

Section 17 requires that the notifiable patient safety incident disclosure meeting shall be held in person unless the patient and / or their relevant person requests that it is held by telephone or other method of communication.

Section 18 - Notifiable incident disclosure meeting

Section 18 requires the health services provider to make arrangements for the notifiable patient safety incident meeting with the patient and / or their relevant person including the information regarding the open disclosure that must be given orally at the meeting and in writing either at the meeting or within 5 days of the meeting. This information must include:

- names of the persons present at the open disclosure meeting;
- description of the notifiable patient safety incident concerned;
- manner in which the notifiable incident came to the notice of the health services provider;
- physical and psychological consequences of the notifiable incident for the patient;
- treatment and care plan for the patient in relation to any of the consequences arising out of the incident that occurred to them;
- actions, policies or procedures proposed or that have been taken by the health services provider to address the incident;
- any apology to be made by the health services provider to the patient and / or their relevant person.

Section 19 - Refusal, by patient or relevant person, to participate in open disclosure of notifiable incident

Section 19 makes it clear that a patient (or relevant person) may choose not to participate in the open disclosure of a notifiable incident or may opt to refuse to accept receipt of written information regarding the incident. However, importantly the patient and / or their relevant person may change their mind within 5 years from the day of refusal, and request the health service provider to make the open disclosure. In addition, the health services provider shall keep a record of the refusal.

Section 20 - Failure to contact patient or relevant person (or both) for purpose of open disclosure of notifiable incident

Section 20 requires a health services provider to take all necessary steps to contact a patient (or relevant person) to arrange a notifiable incident disclosure meeting. If a health services provider fails to make contact with a patient (or relevant person) to arrange an open disclosure meeting the health services provider is required to set out in a statement in writing the steps taken to establish contact. If at a later date the patient (or relevant person) can be contacted, the health services provider must proceed to hold a notifiable incident disclosure meeting.

Section 21 - Additional notifiable information

Section 21 provides for a health services provider to hold an additional notifiable incident disclosure meeting to give the patient (or relevant person) information that may not be available at the time of the first meeting.

Section 22 - Additional notifiable information to be provided at additional notifiable information meeting

Section 22 details the information that must be given orally and in a statement in writing by the health services provider that is additional to what was provided at the first open disclosure meeting (as outlined in section 18).

Section 23 - Clarification of information provided at notifiable incident disclosure meeting or additional notifiable information provided at additional notifiable information meeting

Section 23 provides that a patient (or relevant person) who attended a notifiable incident disclosure meeting may, at any time, make a request to the designated person for clarification in relation to the information provided. The designated person as soon as practicable will liaise with the health practitioner to arrange a meeting with the patient and / or their relevant person to provide the clarification orally and in writing. If the health practitioner that previously made the notifiable disclosure to the patient (or relevant person) is not available, the designated person shall inform the health services provider to identify an appropriate alternative person to make the clarification.

Section 24 - Statements specifying information given at certain meetings

Section 24 deals with the statements in writing which are given to the patient and / or their relevant person at a notifiable information disclosure meeting, an additional meeting or a request for a clarification meeting. This section clarifies that the health services provider must ensure that the patient and / or their relevant person is provided with these written statements either at the relevant meeting but not later than 5 days from the day on which that meeting was held.

Section 25 - Records relating to open disclosure of notifiable incident

Section 25 details the records that must be maintained by the health services provider in relation to a notifiable patient safety incident. In addition, the Minister may prescribe the form of records to be kept and maintained by the health services provider.

Part 4
Notification to certain bodies of notifiable incidents (sections 26 to 34)

Section 26 - Interpretation for Part

Section 26 is the Interpretation section for Part 4 and includes a new definition for the "National Treasury Management Agency incident management system" established in accordance with the *National Treasury Management Agency (Amendment) Act 2000* that is used for the purpose of

the reporting, under section 11 of that Act of an adverse incident (within the meaning of section 11(2) of that Act).

Section 27 - Notification to Authority by health services providers of notifiable incident

Section 27 sets out that a health services provider under the remit of the HIQA, shall make a notification of a notifiable patient safety incident as soon as practicable and not later than 7 days from when the provider is satisfied that an incident has occurred. The notifiable incidents are those specified in Schedule 1, Part 1 and 2 and those specified in regulations made under section 8.

The notification to the HIQA must include:

- name of the health services provider;
- identification of the type of notifiable incident that has occurred;
- date the notifiable incident came to the notice of the health services provider;
- having regard to the incident and causes insofar as they are known, the health services provider will notify of action that is being taken (or proposed to be taken):
  - in response, to prevent a reoccurrence, or mitigate the consequences of any similar incident;
  - for the purposes of sharing the knowledge and learning arising from the incident.

HIQA must acknowledge receipt in writing within 21 days of the notification.

Section 28 - Notification to chief inspector of notifiable incident by certain health services providers

Section 28 sets out that a health services provider carrying on the business of a designated centre, shall make a notification of a notifiable patient safety incident to the Chief Inspector of Social Services (CISS) as soon as practicable and not later than 7 days from when the provider is satisfied that an incident occurred. The definition of "designated centre" is defined in subsection (6) of this section. The notifiable incidents are those specified in Schedule 1, Part 1 and those specified in regulations made under section 8.

The notification to the CISS must include:

- name of the health services provider;
- identification of the type of notifiable incident that has occurred;
- date the notifiable incident came to the notice of the health services provider;
- having regard to the incident and its causes insofar as they are known, the health services provider will notify of action that is being taken (or proposed to be taken):
  - in response to prevent a reoccurrence, or mitigate the consequences of any similar incident;
  - for the purposes of sharing the knowledge and learning arising from the incident.

CISS must acknowledge receipt in writing within 21 days of the notification.

Section 29 - Notification to Commission of notifiable incident by certain health services providers

Section 29 sets out that where a health services provider is an approved centre construed in accordance with section 63 of the *Mental Health Act 2001*, it shall notify the Mental Health Commission (MHC) of a notifiable patient safety incident as soon as practicable and not later than 7 days from when the provider is satisfied that an incident occurred. The notifiable incidents are those specified in Schedule 1, Part 1 and those specified in regulations made under section 8.

The notification to the MHC must include:

- name of the health services provider;
- identification of the type of notifiable incident that has occurred;
- date the notifiable incident came to the notice of the health services provider;
- having regard to the incident and causes insofar as they are known, the health services provider will notify of action that is being taken (or proposed to be taken):
  - in response to prevent a reoccurrence, or mitigate the consequences of any similar incident;
  - or for the purposes of sharing the knowledge and learning arising from the incident.

MHC must acknowledge receipt in writing within 21 days of the notification.

Section 30 - Method of making notifications under sections 27, 28 and 29

Section 30 provides that the method for making notifications to HIQA or CISS or MHC shall be by means of the National Treasury Management Agency incident management system.

Section 31 - Provision of additional and further information by health services provider

Section 31 provides that where a notifiable patient safety incident is reported to HIQA or CISS or MHC and there is a requirement for additional information, the regulatory bodies may request further information from the health services provider. The request for additional information by the regulatory bodies must arise from these bodies' consideration of the incident and having regard to the safety of patients and the performance of their regulatory functions.

Section 32 - Sharing information

Section 32 provides that HIQA or CISS or MHC may share information in relation to notifiable patient safety incidents with other health regulatory bodies, as well as Coroners, for the purposes of the safety of patients and if the information relates to the function of the relevant body, including functions of a health service or the regulation of a health practitioner. The relevant body shall only use any information provided for the purposes of the performance of its functions. Bodies with which information may be shared include: the Coroner, the Health Products Regulatory Authority, the Health and Safety Authority, the Child and Family agency and a body established by or under any enactment (other than the *Companies Act 2014*) whose functions include regulation of any matter relating to a health service or the regulation of a health practitioner.

Section 33 - Notification under Part 4: information not to invalidate insurance; constitute admission of liability or fault; or not to be admissible in proceedings

Section 33 clarifies that information relating to a notification made to HIQA, CISS or MHC in accordance with this Part, including further information or sharing information, shall not:

- constitute an express or implied admission of fault or liability;
- be admissible as evidence of fault;
- invalidate insurance;
- constitute an express or implied admission, by a health practitioner of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission in relation to notifying a notifiable patient safety incident.

This section also defines "clinical negligence", "clinical negligence action" "medical defence organisation" and "professional indemnity insurance".

Section 34 - Restriction of Act of 2014 in respect of notification made under this Part

Section 34 states that, in respect of a notification made under Part 4 to HIQA or CISS or MHC the *Freedom of Information Act 2014* shall not apply to a record of or relating to that notification (including further information, additional information and sharing of information).

Part 5
Clinical audit (sections 35 to 39)

Section 35 - Interpretation for Part

Section 35 is the interpretation section for Part 5 and contains definitions of clinical audit, clinical standard, clinical guideline, aggregated data and clinically-led.

Section 36 - "Clinical audit" and "clinical guideline"

Section 36 provides a detailed definition of clinical audit and clinical guideline. The definition of clinical audit, clinical standard and clinical guideline is the key to this Part of the Bill, in that a health services provider or a health practitioner who undertakes and publishes an audit may only seek protection from the *Freedom of Information Act 2014* in respect of that clinical audit where the audit has been conducted in accordance with these definitions in the Bill.

Section 37 - Clinical audit to which Part applies

Section 37 details how a clinical audit to which this Part applies, should have been carried out, e.g., collected solely for the purpose of improving patient safety and quality improvement and published as aggregated data in order to avail of the protections.

Section 38 - Restriction of Act of 2014

Section 38 provides that a record of a clinical audit, a component of or information provided in respect of a clinical audit, to which this Part of the Bill applies, is exempt from the *Freedom of Information Act 2014.*

Section 39 - Clinical audit data: information not to invalidate insurance; constitute admission of liability or fault; or not to be admissible in proceedings

Section 39 provides that information or data provided in a clinical audit shall not:

- constitute an express or implied admission of fault or liability;
- be admissible as evidence of fault;
- invalidate insurance;

- constitute an express or implied admission, by a health practitioner of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission in relation to notifying a notifiable patient safety incident.

Part 6
Amendment of Act of 2007 (sections 40 to 48)

Section 40 - Amendment of section 2 of Act of 2007

Section 40 amends the definitions section of the *Health Act 2007*. Definitions in the 2007 Act are amended to reflect the requirements of this Bill and definitions amended include "Act of 2004", "health service", "medical speciality", "prescribed private health service" and the new definition of "private hospital".

Section 41 - Amendment of section 8 of Act of 2007

Section 41 amends Section 8 of the *Health Act 2007* to allow for HIQA standards to apply to both the public and private health care services. The standards will apply to services provided by private hospitals and to such other services as prescribed by the Minister.

Section 42 - Amendment of section 9 of Act of 2007

Section 42 relates to Section 9 of the *Health Act 2007*, which deals with investigations by HIQA where HIQA believes there is a serious risk to the health or welfare of people receiving a particular service. Investigations may be carried out by HIQA on its own initiative or where required by the Minister or the Minister for Children and Youth Affairs as the case may be. This section amends section 9 to take account of the investigations into services provided by private healthcare providers.

Section 43 - Standards set by Authority

Section 43 details the amendment to section 10 of the *Health Act 2007* which will enable HIQA to set standards for the private healthcare sector.

Section 44 - Provision of information to Authority

Section 44 refers to section 12 of the *Health Act 2007*, which provides that HIQA may require the HSE, the Child and Family Agency or a service provider to give HIQA any information or statistics HIQA needs in order to determine the level of compliance by these organisations with standards set by HIQA. Section 42 amends section 12 to include private healthcare providers.

Section 45 - Amendment of section 73 of Act of 2007

Section 45 amends subsection (1) of section 73 of the *Health Act 2007* to also apply to premises owned, used or proposed to be used by persons carrying on the business of a private hospital or a prescribed private health service.

Section 46 - Reports of Authority or chief inspector

Section 46 deals with section 78 of the *Health Act 2007*, which relates to reports. This section amends the *Health Act 2007* by providing that HIQA may prepare and publish a report relating to the monitoring of compliance with standards by private hospitals, and the manner in which those reports should be prepared.

Section 47 - Prescribed private health services

Section 47 provides that the Minister may prescribe, by means of regulations, a health service to be a prescribed private health service for the purposes of this legislation.

Section 48 - Repeal

Section 48 repeals Section 100 of the *Health Act 2007*, an aspect of the Act which deals with standard setting and which has not proven to be necessary during the period in which the Act has been in operation.

Part 7
Offences and penalties (section 49)

Section 49 - Offences

Section 49 sets out that a health services provider who fails to comply with the obligation to make an open disclosure of a notifiable patient safety incident (section 5(1), 19(9), 20(5)) to a patient and / or their relevant person, without reasonable excuse, shall be liable on summary conviction to a class A fine.

A health services provider who fails to comply with the obligation to report the notifiable patient safety incident externally to the appropriate body will be liable on summary conviction to a class A fine.

In proceedings for an offence this section also provides a defence if all reasonable efforts to ensure compliance have been made.

Part 8
Miscellaneous and general (section 50 to 54)

Section 50 - Guidelines

Section 50 provides that the Minister may prepare, issue and publish guidelines in relation to the operation of, and compliance with this Bill and regulations made under it.

Section 51 - Regulations

Section 51 provides that the Minister has the power to make regulations for any matters prescribed or to be prescribed in the Bill.

Section 52 - Amendment of Act of 2000

Section 52 amends section 11 of the *National Treasury Management Agency (Amendment) Act 2000* so the National Treasury Management Agency may provide the incident management system as the means of making the notification regarding a notifiable incident to the Health Information Quality Authority, Chief Inspector of Social Services and Mental Health Commission.

Section 53 - Amendment of Act of 2017

Section 53 - provides for the amendment of the *Civil Liability (Amendment) Act 2017* in the manner specified in Schedule 2.

Section 54 - Savings and transitional provisions in respect of open disclosure under Part 4 of the Act of 2017

Section 54 contains the savings and transitional provisions. Where a health services 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 Bill before the coming into operation of this legislation, Part 4 of the Act of 2017 shall continue to apply to that open disclosure.

Schedule 1
Part 1 notifiable incidents

This part of the Schedule includes twelve unintended or unanticipated notifiable patient safety incidents, that are of a very serious nature (all death-related) and that mostly fall into the category of preventable incidents.

Schedule 1
Part 2 notifiable incidents

This part of the Schedule provides for situations in which a baby is referred for therapeutic hypothermia (this is included as an indicator for neonatal hypoxic-ischemic encephalopathy, for example).

Schedule 2
Amendments of Act of 2017

This part of the Schedule details the amendments to the *Civil Liability (Amendment) Act 2017*, including: section 7(1), section 8(a), section 8(b), section 12(b), section 12(c), and substitution for section 17(1) of the *Civil Liability (Amendment) Act 2017*. In addition, there are two new sections, 9A and 12A for insertion in the Act of 2017 in order to align with the *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.*

An Roinn Sláinte,

Nollaig, 2019.

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