An Roinn Sláinte
Department of Health

Summary Guide to the
Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

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The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 and further information is available at: https://www.gov.ie/en/organisation/department-of-health/

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What is the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 and how will it become law?

The *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019* is a draft piece of legislation which was approved by Government on 3 December 2019. Publication of the Bill, as approved by Government, is the initial step taken before a Bill is introduced into the Houses of the Oireachtas to go through the process of becoming law. Once the Bill has been introduced into the Houses, it will proceed through the five principal stages in the legislative process of Dáil Éireann and Seanad Éireann and undergo refinement, adjustments and amendments before it is finalised and enacted into Irish law as an Act.

What is the purpose of this Summary Guide?

The purpose of this document is to give a short easy-to-use overview of the key provisions of the *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019*. It is intended to be used by the public, patients, health professionals, public and private health services providers and other key participants in the health sector. It should be noted though that this summary guide is **not** intended to be a ***definitive interpretation*** of the *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019*.

What is the purpose of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019?

The purpose of the *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019* is to introduce new law in relation to a number of important patient safety matters. This Bill, for the first time–

- introduces a new requirement for mandatory open disclosure of specific serious patient safety incidents (referred to as notifiable patient safety incidents in this legislation);
- lists a number of notifiable incidents within the Bill for which mandatory open disclosure must occur and sets up a new process by which the Minister for Health will, through Regulations, regularly update the list of serious patient safety incidents subject to mandatory open disclosure, in line with advancements in clinical practice and international developments;
- requires health services providers to notify these serious notifiable patient safety incidents to either the Health Information and Quality Authority (HIQA), the Chief Inspector of Social Services (CISS) or the Mental Health

Commission (MHC), as appropriate, for the purposes of ensuring that there is national learning and health service-wide improvement;

- extends HIQA's remit to private hospitals; and
- contains provisions supporting the conduct of clinical audit in the health service.

Under this new Bill, health services providers and health practitioners have an obligation to be open and transparent with patients and their families when a notifiable patient safety incident has occurred in the course of the patient's care. The Bill sets out a clear process for how open disclosure should occur so that patients and their families can be assured that they will receive comprehensive and timely information when things go wrong. Importantly, mandatory open disclosure and external notification of notifiable incidents applies to both the public and private health services.

The purpose of this new legislation is to put in place new structures to enhance regulation of health services. It also seeks to support a culture of patient safety, quality and learning in the delivery of health services, as well as openness, transparency and compassion.

How is the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 structured?

The Bill has 54 sections and is divided into 8 parts as follows:

- Part 1 deals with preliminary and general matters;
- Part 2 focusses on mandatory open disclosure of a notifiable incident;
- Part 3 sets out the procedures for making an open disclosure of a notifiable incident;
- Part 4 concerns the requirement to inform the relevant regulatory bodies of a notifiable incident;
- Part 5 contains provisions relating to clinical audit;
- Part 6 contains amendments to the Health Act 2007 concerning HIQA's remit in relation to private hospitals;
- Part 7 sets out the offences and penalties under this Bill;
- Part 8 contains miscellaneous and general provisions;

- Schedule 1 contains a list of notifiable incidents (which will be expanded over time); and
- Schedule 2 contains a number of amendments to Part 4 of the Civil Liability (Amendment) Act 2017 which established a scheme for open disclosure.

What are the key definitions used in the Bill?

In section 2 (Interpretation section) the Bill contains a number of key definitions to define and explain key words and terms used in the Bill. There are a number of key definitions that are important for patients and their families as well as for health services providers, health professionals and others in explaining how mandatory open disclosure is required to operate and the responsibilities of different people in the process.

The main definitions in section 2 are as follows:

- "Notifiable incident" – a notifiable patient safety incident (referred to in the Bill as 'notifiable incident' for short, is a patient safety incident which is subject to mandatory open disclosure. There are two categories of notifiable incidents: 1) those listed in Schedule 1 in the Bill **AND** 2) additional patient safety incidents which will be designated by the Minister for Health in Regulations that will be made and updated from time to time.
- "Health services provider" – section 3 of the Bill explains in detail which organisations and individuals fall within the scope of the definition of 'health services provider'. In essence, a health services provider is intended to include public and private organisations and entities involved in providing health services, such as hospitals, clinics, nursing homes, primary care centres etc.
- "Health practitioner" – for the purposes of this legislation a health practitioner is defined as including registered healthcare professionals such as medical doctors, nurses, midwives, dentists, pharmacists, health and social care professionals, ambulance personnel.
- "Relevant person" – this is a named person identified by the patient that accompanies a patient at an open disclosure meeting or attends the meeting on behalf of the patient. For example, a relevant person might be a family member, relative or friend who has been identified by the patient.
- "Designated person"– this is a named person who must be identified by the health services provider that will act as a liaison person between the patient

and / or their family member and the health service when mandatory open disclosure needs to occur.

What is mandatory open disclosure under this Bill and how does it work?

The purpose of this legislation is to make sure that, when a serious patient safety incident occurs, patients and their families can be assured that there is a structured and consistent process by which a health services provider must engage with them in open disclosure and that there are consequences for health services providers where this does not occur. In all circumstances where something goes wrong, health professionals and health services providers must be open and honest with their patients and respond compassionately and considerately to the needs of those patients and their families.

Importantly, mandatory open disclosure and the notification system for these serious patient safety incidents will apply to both public and private health services.

Serious patient safety incidents subject to mandatory open disclosure

The core intention of this new legislation is to establish a robust and future-proofed framework for mandatory open disclosure so that patients can be assured that mandatory open disclosure will continue to occur in line with advances in healthcare services and international developments in patient safety in the future.

The Bill does this in two ways:

1. Firstly, the Bill contains in Schedule 1 a list of a number of serious notifiable patient safety incidents which are subject to mandatory open disclosure and will always be so. Examples of these kinds of incidents would include: death due to surgery on the wrong part of the body, or the wrong procedure; maternal death; perinatal death (i.e. a stillbirth or a death of a baby shortly after birth); death due to a surgical operation, medical procedure or anaesthesia; death due to a medication error, blood transfusion or retention of a foreign object etc.

2. Secondly, and importantly, the Bill includes in section 8 a new process by which the Minister for Health will designate other patient safety incidents for which mandatory open disclosure must also occur through regulations.

It would not be appropriate to include in the Bill a very extensive list of incidents, as this list will need to expand and evolve over time in line with changes and advancements in clinical practice, international developments and greater knowledge regarding the risks associated with treatments. Instead, empowering the Minister to expand and update the list of notifiable incidents on a regular basis provides a flexible means of ensuring that the requirement for mandatory open disclosure to patients is kept up-to-date.

Duty of the health services provider to ensure that open disclosure occurs

In many situations where patients are harmed, the error or mistake occurred because systems were not in place to support the healthcare professional or team in identifying and avoiding that error. For this reason, this new *Patient Safety (Notifiable Patient Safety Incidents) Bill 2019* places clear responsibilities and obligations on the health services provider (i.e. hospitals, services, clinics etc.) to ensure that mandatory open disclosure occurs and that external notification to the regulator takes place. This is to ensure health service organisations and employers take responsibility for putting in place the appropriate governance, systems, processes and resources to support health practitioners in making open disclosure with patients and their families.

Health services providers may become aware of a notifiable patient safety incident from a number of sources, for example, the patient and / or relevant person, health practitioners, other staff etc. and on becoming aware must ensure that a notifiable open disclosure meeting takes place with the patient and that the appropriate regulator is informed within seven days.

Health services providers will also be responsible under this new legislation for ensuring that open disclosure of a notifiable incident occurs for any patient currently in their care, irrespective of whether the notifiable incident occurred during treatment provided by that health service or by another health service provider. This is to ensure that patients receive information as quickly as possible in relation to a notifiable incident that has occurred and that this process is not delayed by health services providers in trying to decide who is responsible.

Additionally, the Bill includes a duty of openness and transparency on health services providers. In section 12 of the Bill, a specific obligation is placed on health services providers (with an identical one also placed on health practitioners) to ensure that all relevant information is provided to the patient and their family in the course of making an open disclosure of a notifiable incident.

Procedure for making an open disclosure

Part 3 (sections 13 to 25) of the Bill sets out the procedures explaining how health services providers should organise open disclosure with patients, and deals with:

- appointing a designated person to liaise with the patient and their family;
- the information that should be provided to the patient and their family at the open disclosure meeting and in writing at or after the meeting;
- providing the patient and their family with any clarifications that they may require;
- what to do if a patient or their family does not want to engage in open disclosure at that time; and
- the records that should be kept by health services providers.

This Part of the Bill explains that open disclosure to the patient and their family should occur as soon as it is practical to arrange it, while taking into account all of the circumstances of the incident.

The Bill says that normally the open disclosure meeting should take place in person, unless the patient asks that it be made over the phone or by some other way, such as Skype.

Also, the Bill is clear that an open disclosure should be made by the main health practitioner who was providing care to the patient.

The Bill explains to the health services provider the kinds of things it needs to consider in preparing for the open disclosure meeting. These include: the appropriate time; who the disclosure should be made to; whether there needs to be an apology made and how difficult the information might be to communicate.

The health services provider also needs to ensure that the patient and their family are provided with information in writing about the open disclosure. This may involve writing a letter to the patient or their family to provide a written explanation of what happened. This letter or written explanation can be given to the patient and their family at the meeting or up to five days after the meeting. That letter or written explanation should be signed by the health practitioner on behalf of the health services provider. There is no requirement for the patient or their family to have to sign it.

The kinds of information that must be given to the patient and their family at the meeting, and in writing afterwards, includes:

- the names of the people at the meeting;
- a description of the incident;
- how the health service became aware of the incident;
- the effect that the incident might have on the patient;
- the treatment and care plan that the patient might need to deal with the effects of the notifiable incident;
- any steps that have been taken to investigate the incident or to prevent it happening again; and
- an apology, if that is appropriate in the circumstances.

The Bill makes clear that patients do not have to participate in an open disclosure meeting if they do not want to, and importantly, they have up to five years to change their minds.

Duties of health practitioners under this new legislation

As explained above, health practitioners in this legislation includes a large range of registered health professions such as medical doctors, nurses, midwives, dentists, pharmacists, physiotherapists, social workers, paramedics, psychologists and others.

Under section 6, all of these health practitioners have a duty to inform the relevant health services provider (usually their employer) when they are of the opinion that a notifiable incident has occurred. It is then the responsibility of the health services provider to ensure open disclosure with the patient and their family takes place.

The Bill also clearly places the duty to make the open disclosure to the patient and their family on the principal health practitioner involved in the care of the patient. If that health practitioner is not available, or not in a position to carry out the open disclosure, then the health services provider must ensure that another appropriate person can make the open disclosure to the patient and their family, instead.

As also referred to above, the Bill provides a clear instruction that, where open disclosure takes place, it should be done with full openness and transparency. In

section 12 of the Bill a specific obligation is placed on health practitioners (with an identical one also placed on health services providers) to ensure that all relevant information is provided to the patient and their family in the course of open disclosure.

Legislative protections

The Bill contains certain legal protections which provide that the information or an apology given in the context of an open disclosure meeting or in follow-up written information does not constitute an expressed or implied admission of fault or liability in certain legal actions or in professional conduct proceedings. Neither can it be used to invalidate insurance.

The purpose of these protections is to encourage an environment of open disclosure by ensuring that information relating to notifiable patient safety incidents can be shared with patients and their families by health practitioners and health services providers without fear of liability. This is in line with international experience which indicates that such protections support a culture of open disclosure and improve the rates of reporting of incidents within health services.

Why must notifiable patient safety incidents be nationally reported?

A second 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 new Bill 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 of Social Services (CISS) and the Mental Health Commission (MHC) to contribute to national patient safety learning and improvement.

Process for notification of serious patient safety incidents

Sections 27, 28 and 29 of the Bill require the health services provider to ensure that the notifiable patient safety incident is reported to the appropriate regulatory body within seven days.

Where a notifiable patient safety incident occurs in–

- a designated centre for the provision of residential services (e.g. a residential services for persons with disabilities, other dependent persons or a nursing

home), the health services provider must notify the Chief Inspector for Social Services;

- a mental health service approved by the Mental Health Commission, the health services provider must notify the Mental Health Commission; and
- any other health service, the health services provider must notify HIQA.

Health services providers must make the notification of a notifiable patient safety incident as soon as practicable and not later than seven days from when the provider is satisfied that an incident occurred.

The notification to the regulatory body must include the following information:

- the name of the health services provider;
- the type of notifiable incident that occurred;
- the date the notifiable incident came to the notice of the health services provider;
- any action the health services provider is taking in response to the incident to prevent it happening again, or to reduce the consequences of a similar incident; or
- any action the health services provider is taking to share its knowledge and learning from the incident with other providers.

The National Treasury Management Agency incident management system (currently the national incident management system) will be used by the health services providers to make notifications to the relevant regulatory body.

The regulatory bodies must acknowledge receipt in writing within 21 days of the notification.

Sharing information on notifiable patient safety incidents with relevant bodies

These regulatory bodies will also be empowered to share appropriate information regarding a notifiable patient safety incident with other regulatory bodies for the purposes of the safety of patients and if the information relates to the function of that other regulatory body (e.g. the Health Products Regulatory Authority, the Health and Safety Authority, the Child and Family Agency, the Coroner and other health regulatory bodies).

What are the consequences if the requirements of this legislation are not followed?

A health services provider found guilty of failing to comply with the obligation to ensure that open disclosure took place with the patient regarding a notifiable patient safety incident or the obligation to notify the relevant regulatory body will be liable on summary conviction to a Class A fine.

If a health practitioner does not engage in open disclosure as they are required to do under this legislation, then this would be a matter for the relevant health professional regulatory body (such as the Medical Council, the Nursing and Midwifery Board, the Dental Council and other regulatory bodies).

Other provisions

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.

The Bill contains an exemption from the provisions of the Freedom of Information legislation for a record that is a clinical audit. The purpose of these legislative protections is to encourage the conduct of clinical audit in the health service to drive improvements in patient care and outcomes by reviewing health care against explicit clinical standards.

Amendment of the Health Act 2007 to provide for the extension of HIQA's remit to private hospitals

At present HIQA has the power to set and monitor standards for public hospitals. This Bill will now allow HIQA to set and monitor standards in the private hospital sector.

The Bill provides for a number of amendments to definitions and sections in the *Health Act 2007*, including "prescribed private health service" and the new definition of "private hospital". The Bill will also enable HIQA to carry out an investigation in both public and private hospitals where they believe there is a

serious risk to the health or welfare of a person receiving services in that health service, including at the direction of the Minister for Health or the Minister for Children and Youth Affairs.

Disclaimer: This document is a summary guide and does not purport to be an interpretation of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019. 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 has been made to ensure the accuracy of the information contained in this guide, the Department of Health does not accept any liability whatsoever arising from any errors or omissions.

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