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

Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

Mar a tionscnaíodh

As initiated

[No. 100 of 2019]

AN BILLE UM SHÁBHÁILTEACHT OTHAR (TEAGMHAIS SÁBHÁILTEACHTA OTHAIR INFHÓGARTHA), 2019
PATIENT SAFETY (NOTIFIABLE PATIENT SAFETY INCIDENTS) BILL 2019

Mar a tionscnaíodh

As initiated

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Part 1

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SCHEDULE 2

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AN BILLE UM SHÁBHÁILTEACHT OTHAR (TEAGMHAIS SÁBHÁILTEACHTA OTHAIR INFHÓGARTHA), 2019
PATIENT SAFETY (NOTIFIABLE PATIENT SAFETY INCIDENTS) BILL 2019

Bill

entitled

An Act to provide for the mandatory open disclosure, by health services providers of certain incidents occurring in the course of the provision, to a person, of a health service; to provide, in the interest of the common good, for certain restrictions on the use of the information provided in such disclosures that are made in accordance with this Act and of any apologies made in the course of such disclosures and the use of any other information relating to the open disclosure provided, and apology made, after the notifiable incident disclosure meeting; to make provision for procedures in respect of clinical audit, and the data obtained in clinical audits; to provide for the notification of certain incidents to certain persons; to amend the National Treasury Management Agency (Amendment) Act 2000; to amend Part 4 of the Civil Liability (Amendment) Act 2017; to amend the Health Act 2007 to provide for the application of standards set by the Health Information and Quality Authority to private hospitals and for the Minister to prescribe certain health services as a prescribed private health service; and to provide for related matters.

Be it enacted by the Oireachtas as follows:

PART 1

Preliminary and General

Short title and commencement

1. (1) This Act may be cited as the Patient Safety (Notifiable Patient Safety Incidents) Act 2019.

(2) This Act shall come into operation on such day or days as the Minister may by order or orders appoint either generally or with reference to any particular purpose or provision and different days may be so appointed for different purposes or different provisions.

Interpretation

2. (1) In this Act—

"Act of 1985" means the Dentists Act 1985;

"Act of 2000" means the National Treasury Management Agency (Amendment) Act 2000;

"Act of 2005" means the Health and Social Care Professionals Act 2005;

"Act of 2007" means the Health Act 2007;

"Act of 2011" means the Nurses and Midwives Act 2011;

"Act of 2014" means the Freedom of Information Act 2014;

"Act of 2017" means the Civil Liability (Amendment) Act 2017;

"additional notifiable information" shall be construed in accordance with *section 21*;

"additional notifiable information meeting" shall be construed in accordance with *section 21*;

"agency contract" has the meaning assigned to it by section 7 of the Act of 2017;

"agency health practitioner" has the meaning assigned to it by section 7 of the Act of 2017;

"agency worker" has the meaning assigned to it by section 7 of the Act of 2017;

"apology", in relation to an open disclosure of a notifiable incident, means an expression of sympathy or regret;

"Authority" means the Health Information and Quality Authority;

"cancer screening service" means—

(a) the service known as the national breast screening programme carried out by the National Cancer Screening Board and, since the dissolution of the Board on 1 April 2010, provided by the Executive,

(b) CervicalCheck, and

(c) the service known as the national colon cancer screening programme provided by the Executive,

and a reference in this Act to a cancer screening service includes any or all of the services specified in *paragraph (a)*, *(b)* or *(c)*;

"CervicalCheck" has the meaning assigned to it by the CervicalCheck Tribunal Act 2019;

"Commission" has the meaning assigned to it by the Mental Health Act 2001;

"designated person" means the person designated under *section 16*;

"employee", in relation to a health services provider has the meaning assigned to it by section 7 of the Act of 2017;

"employment agency" has the meaning assigned to it by section 7 of the Act of 2017;

"enactment" has the same meaning it has in the Interpretation Act 2005;

"Executive" means the Health Service Executive;

"fixed-term employee" has the same meaning it has in section 7 of the Act of 2017;

"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;

"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 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;

"health services provider" shall be construed in accordance with *section 3*;

"Minister" means the Minister for Health;

"notifiable incident" means an incident specified in—

(a) *Schedule 1*, or

(b) regulations made under *section 8*;

"making an open disclosure of a notifiable incident" shall be construed in accordance with *section 9*;

"notifiable incident disclosure meeting" shall be construed in accordance with *section 18(1)*;

"open disclosure of a notifiable incident" shall be construed in accordance with *section 9* and references to the open disclosure of a notifiable incident, or open disclosure in relation to a notifiable incident shall be construed accordingly;

"other than in person", in relation to a notifiable incident disclosure meeting, an additional information disclosure meeting or a clarification given under *section 23*, shall be construed in accordance with *section 17*;

"Order of 2000" means the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000) amended by the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (Amendment) Order 2004 (S.I. No. 575 of 2004);

"patient", in relation to a health services provider, means a person to whom a health service is, or has been, provided;

"partnership", in relation to the provision of a health service, means 2 or more health practitioners who provide a health service in common;

"prescribed" means prescribed in regulations made by the Minister under this Act;

"principal health practitioner", in relation to a patient, means a health practitioner who has the principal clinical responsibility for the clinical care and treatment of the patient and, in the case of a cancer screening service, means the health practitioner who has the principal clinical responsibility for the cancer screening service;

"relevant person", in relation to the making of an open disclosure of a notifiable incident, means—

(a) a person specified in *paragraphs (a)* to *(f)* of *section 7(2)*, or

(b) a person nominated pursuant to *section 7(3)*;

"unintended", in relation to a death, means a death arising from an unintended event occurring, or arising from, the provision of a health service.

(2) References in this Act to—

(a) "information provided" or "an apology made" at an notifiable incident disclosure meeting,

(b) "additional notifiable information provided", or "apology made", at an additional notifiable information meeting, or

(c) information provided in a clarification under *section 23*,

includes information that is provided, or an apology that is made, orally or in writing.

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 professional 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, 5

(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, 10

(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, 15

(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— 20

(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, 25

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— 30

(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— 35

(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.

Expenses

4. The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure and Reform, be paid out of monies provided by the Oireachtas.

PART 2

Open Disclosure of Notifiable Incident

Chapter 1

General

Obligation to make an open disclosure of notifiable incident

5. (1) Where a health services provider is satisfied that a notifiable incident has occurred in the course of the provision by it of a health service to a patient, (whether the notifiable incident occurred when that provider was providing that service or another health services provider was providing a health service to that patient) the health services provider shall, subject to *sections 19* and *20*, hold a notifiable incident disclosure meeting in order to make the open disclosure of that notifiable incident to the patient or relevant person (or both of them) as specified in *section 7*.

(2) For the purposes of *subsection (1)*, where a health services provider is satisfied that a notifiable incident has occurred but—

(a) none, or not all, of the likely consequences of the notifiable incident have presented or developed, or

(b) not all of the information relating to the incident, including information relating to the cause of the incident, is available,

the health services provider shall make the open disclosure of the notifiable incident under *subsection (1)* notwithstanding the absence of some or all of those consequences or that information.

(3) For the purposes of *subsection (1)*, a health services provider may be satisfied that a notifiable incident has occurred as referred to in that subsection whether the provider has received information in respect of that notifiable incident pursuant to *section 6* or otherwise.

Health practitioner to inform health services provider of notifiable incident

6. (1) Without prejudice to *section 5*, where, in the opinion of a health practitioner a notifiable incident has occurred in relation to a patient, the health practitioner shall, as soon as practicable, inform the health services provider which is, at the time he or she has formed the opinion, providing the health service to the patient.

(2) A health practitioner shall inform the health services provider referred to in *subsection (1)* whether—

(a) the notifiable incident may have occurred during the provision of a health service to the patient by—

(i) that provider, or

(ii) another health services provider,

or

(b) he or she is unsure when the notifiable incident occurred.

Persons to whom open disclosure of notifiable incident is made

7. (1) A health services provider shall make the open disclosure of the notifiable incident to—

(a) the patient concerned,

(b) a relevant person where—

(i) in the opinion of the principal health practitioner providing clinical care to the patient, having regard to the clinical circumstances of the patient, who is the subject of the notifiable incident, the capacity of the patient is such that he or she is unable to—

(I) participate in that open disclosure, and

(II) consent to that open disclosure being made to a relevant person,

and that capacity is unlikely to be of a temporary duration, and the health services provider is satisfied that a notifiable incident has occurred, it is appropriate, having regard to *section 5*, that the open disclosure of that incident is made to a relevant person,

(ii) the patient has died, or

(iii) the patient has requested the health services provider to 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,

or

(c) both the patient and a relevant person where, before the notifiable incident disclosure meeting is held, the patient has requested that a person whom the patient has nominated as a relevant person for the purposes of this Act attends that meeting to assist the patient and that in addition to making the open disclosure to the patient that the health services provider makes the open disclosure of the notifiable incident to that relevant person.

(2) For the purposes of *subsection (1)(b)(i)*, and making an open disclosure of a notifiable incident to a relevant person, the health services provider shall make the open disclosure—

(a) 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, to the person appointed,

(b) 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,

(c) where the patient is a ward of court, to the Committee of the Person of that ward, duly authorised in that behalf,

(d) where the patient has nominated, in writing, a person to whom his or her clinical information may be disclosed, to that person,

(e) where the patient is a child, to the parent or guardian of that child or where—

(i) an order in respect of the child has been made under section 18 of the Act of 1991,

(ii) the child has been taken into the care of the Agency under section 4 of the Act of 1991, or

(iii) an order in respect of the child has been made under section 13, 17 or 20 of the Act of 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 Act of 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), or

(f) where the patient does not fall within the categories specified in *paragraphs (a)* to *(e)*, to—

(i) the spouse, civil partner or cohabitant of the patient,

(ii) an adult son or daughter of the patient, or

(iii) the mother, father, brother or sister of the patient.

(3) For the purposes of a request referred to in—

(a) *subsection (1)(b)(iii)*, and

(b) *subsection (1)(c)*,

without prejudice to *subsection (2)(d)*, where a patient makes a request referred to in *paragraph (a)* or *(b)*, the patient shall nominate the person in writing (including a person referred to in *subsection (2)*) as a person to whom clinical information may be disclosed in respect of information to be provided in an open disclosure of a notifiable incident.

(4) For the purposes of *subsection (1)(b)(ii)*, and making an open disclosure a notifiable incident, the open disclosure shall be made to a person specified in *subsection (2)*.

(5) Where an open disclosure of a notifiable incident is made pursuant to—

(a) *subsection (1)(b)(i)* or *(iii)*, to a relevant person, or

(b) *subsection (1)(c)*, to both the patient and the relevant person,

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.

(6) Where, after a health services provider has, in accordance with *subsection (1)(b)(i)*, held the notifiable incident disclosure meeting with the relevant person and after that meeting was held the patient regains capacity, 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.

(7) In this section—

"Act of 1991" means the Child Care Act 1991;

"authorised person" in relation to a child referred to in *subsection (2)(e)* who is—

(a) placed in residential care pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children in Residential Care) Regulations 1995 (S.I. No. 259 of 1995),

(b) placed in foster care pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children in Foster Care) Regulations 1995 (S.I. No. 260 of 1995), or

(c) placed with a relative pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children with Relatives) Regulations 1995 (S.I. No. 261 of 1995);

"civil partner" has the meaning assigned to it by the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

"cohabitant" means one of 2 adults (whether of the same or opposite sex) who live together as a couple in an intimate and committed relationship and who are not married to each other or civil partners of each other.

Regulations specifying notifiable incident

8. (1) Subject to *subsection (2)*, the Minister may prescribe as a notifiable incident:

(a) an incident which has occurred in the course of the provision of a health service;

(b) an incident which, having regard to developments in clinical practice, healthcare and patient safety, may occur;

(c) an incident which, having regard to such developments internationally, has occurred or may occur.

(2) Regulations under this section shall only be made where the Minister is satisfied that—

(a) the incident was or would be an unanticipated and unintended outcome of the health service provided, and would arise from the health service provided and not be attributable (in whole or in part) to the illness or underlying condition of the patient receiving the health service,

(b) the consequence, for a patient, of an incident referred to in *subsection (1)* is one which has caused—

(i) the death of the patient where the death was not wholly attributable to the illness of the patient or an underlying condition of that patient,

(ii) a permanent lessening of bodily, sensory, motor, physical or intellectual functions,

(iii) harm to that patient—

(I) resulting in one or more permanent changes to the structure of the body of that patient, the effect of which is to shorten the life expectancy of that patient, or

(II) the effect of which has impaired the sensory, motor or intellectual functions of that patient and the duration of the impairment has been, or is likely to be, for a continuous period of not less than 28 days,

(c) the obtaining, provision and dissemination of information in respect of an incident referred to in *subsection (1)*, or a consequence referred to in *paragraph (b)*, is required to provide knowledge and an understanding of the causes of such incident or such consequence,

(d) the application of such knowledge and understanding to the manner in which a health service is provided is required for the purposes of patient safety and avoiding, lessening or eradicating the repetition of such an incident, and

(e) it is appropriate, in respect of any such incident and such information, knowledge, application and understanding that—

(i) an open disclosure of an incident referred to in *subsection (1)* is made under this Act, and

(ii) notification of that incident is made under *section 27*, *28*, or *29*.

(3) Regulations under this section may make different provision for different incidents or classes of incidents referred to in *subsection (1)* and may make different provision for different patients and different classes of patients having regard to the different incidents and different classes of incidents and may, in respect of a consequence referred to in *subsection (2)* of an incident that is specified in those regulations, provide for different classes of consequences (including different classes of harm) referred to in *subsection (2)*.

Open disclosure of notifiable incident

9. Where a health services provider discloses, in accordance with this Act, at a notifiable incident disclosure meeting, to—

(a) a patient that a notifiable incident has occurred in the course of the provision of a health service to him or her,

(b) a relevant person that a notifiable incident has occurred in the course of the provision of a health service to the patient, or

(c) a patient and a relevant person that a notifiable incident has occurred in the course of the provision of a health service to the patient,

the disclosure shall be treated as an open disclosure by the health services provider of the notifiable incident and *section 10* shall apply to—

(i) the information in respect of the notifiable incident, provided to the patient or relevant person (or both of them) at the notifiable incident disclosure meeting, additional notifiable information provided at the additional notifiable information meeting and information provided in a clarification under *section 23*, and

(ii) an apology, in respect of the notifiable incident, where an apology is made at that meeting, or the additional notifiable information meeting as the case may be.

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

10. (1) Information provided, and an apology where it is made, to a patient or a relevant person (or both of them) by a health services provider at a notifiable incident disclosure meeting in respect of a notifiable incident, or pursuant to the provisions specified in *subsection (3)*, the statement referred to in *section 18(5)* and the statements referred to in the provisions specified in *subsection (3)*—

(a) shall not constitute an express or implied admission of fault or liability by—

(i) that health services provider,

(ii) an employee of that provider (whether the employee is a health practitioner or otherwise),

(iii) a health practitioner who provides, or provided, a health service—

(I) for, or on behalf of, that provider pursuant to a contract referred to in *subparagraph (ii)* of *paragraph (a)*, *(b)* or *(c)* of the definition of "health services provider", or

(II) for, or on behalf of, or through or in connection with, that provider pursuant to an arrangement referred to in *subparagraph (iv)* of *paragraph (a)* of that definition,

(iv) an agency health practitioner who provides, or provided, a health service for, or on behalf of, that provider,

(v) a health practitioner including, in the case of a health services provider which is a partnership, a partner of a health practitioner, providing a health service for that provider,

(vi) an agency worker assigned to that provider pursuant to an agency contract,

(vii) a person who enters into a contract or arrangement, referred to in—

(I) *paragraph (a)(v)* of the definition of "health services provider", or

(II) *paragraph (b)(iv)*, or as the case may be *paragraph (c)(iv)*, of that definition,

with a health services provider,

(viii) by another health services provider where the open disclosure of the notifiable incident is, pursuant to *section 5(1)*, made by the health services provider in respect of a notifiable incident which did not occur when it was providing a health service to the patient, or

(ix) a person referred to in *subparagraph (ii)* to *(vii)* who is an employee of, a health practitioner who provides a health service referred to in *subparagraph (iii)* to *(vi)* for, an agency health practitioner who provides a health service for, and a person who enters into a contract with, a health services provider referred to in *subparagraph (viii)*,

in relation to that notifiable incident or a clinical negligence action which arises (whether in whole or in part) from the consequences of that notifiable incident,

(b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability of—

(i) that health services provider,

(ii) an employee of that provider (whether the employee is a health practitioner or otherwise),

(iii) a health practitioner referred to in *paragraph (a)(iii)*,

(iv) an agency health practitioner referred to in *paragraph (a)(iv)*,

(v) a health practitioner referred to in *paragraph (a)(v)*,

(vi) an agency worker referred to in *paragraph (a)(vi)*,

(vii) a person who enters into a contract or arrangement, referred to in—

(I) *paragraph (a)(v)* of the definition of "health services provider", or

(II) *paragraph (b)(iv)*, or as the case may be *paragraph (c)(iv)*, of that definition,

with a health services provider,

(viii) a health services provider referred to in *paragraph (a)(viii)*, or

(ix) a person referred to in *paragraph (a)(ix)*,

in a court in relation to that notifiable incident or a clinical negligence action which arises (whether in whole or in part) from the consequences of that notifiable incident, and

(c) shall not, notwithstanding—

(i) any provision to the contrary in—

(I) a policy of professional indemnity insurance,

(II) any documentation that comprises an offer, or evidence, of an arrangement for indemnity between a medical defence organisation and a member of that organisation, or

(III) a contract of insurance providing insurance cover for claims in respect of civil liability or clinical negligence actions,

or

(ii) any other enactment or rule of law,

invalidate or otherwise affect the cover provided by such policy or contract of insurance that is, or but for such information and such apology would be, available in respect of the notifiable incident concerned or any matter alleged which arises (whether in whole or in part) from that notifiable incident. 5

(2) Information provided, and an apology where it is made, to a patient or a relevant person (or both of them) by a health services provider at a notifiable incident disclosure meeting in respect of a notifiable incident or pursuant to the provisions specified in *subsection (3)*, the statement referred to in *section 18(5)* and the statements referred to in the provisions specified in *subsection (3)*— 10

(a) shall not 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 the determination of—

(i) a complaint under section 57 of the Medical Practitioners Act 2007, 15

(ii) an application under section 38 of the Act of 1985,

(iii) a complaint within the meaning of section 33 of the Pharmacy Act 2007,

(iv) a complaint under section 55 of the Act of 2011,

(v) a complaint under section 52 of the Act of 2005, or

(vi) an allegation referred to in Article 37 of the Order of 2000, that is made in respect of the health practitioner and which arises (whether in whole or in part) from the consequences of that notifiable incident, 20

and

(b) are not, notwithstanding any other enactment, admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation referred to in *paragraph (a)*. 25

(3) This section shall—

(a) in accordance with *section 22(7)*, apply to—

(i) additional notifiable information provided, and an apology where it is made, at the additional notifiable information meeting, and 30

(ii) a statement referred to in *section 22(3)*,

and

(b) in accordance with *section 23(8)*, apply to information and statements provided in a clarification referred to in, and given under, that section. 35

(4) Information provided by a health practitioner to a health services provider under *section 6*—

(a) shall not constitute an express or implied admission of fault by—

(i) that health practitioner,

(ii) that health services provider,

(iii) a health services provider referred to in *subsection (1)(a)(viii)*, or

(iv) a person referred to in *subsection (1)(a)(ix)*,

whether the health practitioner is a practitioner referred to in *subparagraph (iii)* or *(v)* of *subsection (1)(a)* or an agency practitioner referred to in *subsection (1)(a)(iv)*, 5

(b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability of—

(i) that health practitioner, 10

(ii) that health services provider, or

(iii) a health services provider referred to in *paragraph (a)(iii),*

whether the health practitioner is a practitioner referred to in *subparagraph (iii)* or *(v)* of *subsection (1)(a)* or an agency practitioner referred to in *subsection (1)(a)(iv)*, 15

(c) shall not, notwithstanding—

(i) any provision to the contrary in—

(I) a policy of professional indemnity insurance,

(II) any documentation that comprises an offer, or evidence, of an arrangement for indemnity between a medical defence organisation and a member of that organisation, or 20

(III) a contract of insurance providing insurance cover for claims in respect of civil liability or clinical negligence actions,

or

(ii) any other enactment or rule of law, 25

invalidate or otherwise affect the cover provided by such policy or contract of insurance that is, or but for such information would be, available in respect of the notifiable incident concerned or any matter alleged which arises (whether in whole or in part) from that notifiable incident,

(d) shall not constitute an express or implied admission, by that health practitioner, of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in the determination of— 30

(i) a complaint under section 57 of the Medical Practitioners Act 2007,

(ii) an application under section 38 of the Act of 1985,

(iii) a complaint within the meaning of section 33 of the Pharmacy Act 2007, 35

(iv) a complaint under section 55 of the Act of 2011,

(v) a complaint under section 52 of the Act of 2005, or

(vi) an allegation referred to in Article 37 of the Order of 2000, that is made in respect of the health practitioner and which arises (whether in whole or in part) from the consequences of that notifiable incident,

and

(e) is not, notwithstanding any other enactment, admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation referred to in *paragraph (d)*.

(5) This section is in addition to, and not in substitution for, any enactment or rule of law relating to the disclosure of information in respect of the provision of a health service.

(6) In this section—

"clinical negligence" means anything done or omitted to be done in the provision of a health service by a health services provider in circumstances which could give rise to liability for damages for negligence in respect of personal injury or death;

"clinical negligence action" means an action for the recovery of damages brought—

(a) by or on behalf of a person alleging that he or she, or a deceased person of whom he or she is a personal representative, has suffered personal injury or death as a result of clinical negligence, and

(b) against the health services provider alleged to have committed the act or omission giving rise to liability or any other person alleged to be liable in respect of that act or omission;

"medical defence organisation" means a body corporate, or an unincorporated body, which provides professional indemnity insurance, on a discretionary or other basis, to a member of that body in relation to an incident of clinical negligence which gives rise to a claim against a member of that body;

"professional indemnity insurance" means a policy of indemnity insurance to cover claims by or on behalf of a patient (or a relevant person) in respect of any description of civil liability for injury, harm or death that is incurred in the provision of a health service (including the carrying on of the business of the provision of a health service).

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

11. (1) A health services provider shall prepare a statement in writing of—

(a) its procedure for making an open disclosure of a notifiable incident pursuant to, and in accordance with this Part, and

(b) the manner in which *section 10* applies to the restrictions on the use, pursuant to this Act, of information provided, and any apology made, at the notifiable incident disclosure meeting, the additional notifiable information meeting, or the information provided in a clarification under *section 23* and any statements in writing provided in respect of those meetings or that clarification.

(2) Without prejudice to the generality of *section 50*, the Minister may make guidelines in respect of the form of the statement referred to in *subsection (1)*.

Chapter 2

Open disclosure: openness and transparency

Disclosure of information by health services provider and health practitioner

12. (1) When making an open disclosure of a notifiable incident under this Act, a health services provider shall provide all relevant information in relation to the provision of a health service to the patient (or relevant person as the case may be) that is being provided by that provider to the patient and where appropriate any other health service that is to be, or may be provided, to address the consequences of that incident.

(2) When making an open disclosure of a notifiable incident under this Act, a health practitioner shall provide all relevant information in relation to the provision of a health service to the patient (or relevant person as the case may be) that is being provided by that provider to the patient and where appropriate any other health service that is to be, or may be provided, to address the consequences of that incident.

PART 3

Procedure for Making Open Disclosure of Notifiable Incident

Making of open disclosure of notifiable incident by health services provider

13. (1) For the purposes of *section 5*, the open disclosure of a notifiable incident shall be made on behalf of a health services provider by—

(a) the principal health practitioner, in relation to the patient to whom, or in respect of whom, the open disclosure of the notifiable incident is to be made, or

(b) where the conditions specified in *subsection (2)* are satisfied, a health practitioner referred to in that subsection.

(2) Where, for the purposes of *subsection (1)*—

(a) the principal health practitioner referred to in *paragraph (a)* of that subsection is not available or otherwise not in a position to make the open disclosure of the notifiable incident, or

(b) having had regard to the circumstances of the notifiable incident, the health services provider, or the principal health practitioner referred to in *paragraph (a)* of that subsection, is satisfied that the open disclosure of that incident should be made by another health practitioner,

the open disclosure of that notifiable incident shall be made by a health practitioner whom the health services provider, having considered the incident concerned, considers appropriate.

Time of making of open disclosure

14. (1) For the purposes of making an open disclosure of a notifiable incident pursuant to *section 5*, the health services provider shall make the open disclosure of that notifiable incident at a time when it considers to be appropriate having regard to—

(a) the desirability, subject to *paragraphs (b)* and *(c)*, of making the open disclosure as soon as practicable notwithstanding that—

(i) as referred to in *section 5(2)*, some, or all, of the likely consequences of the notifiable incident are not present or have not developed,

(ii) as referred to in *section 5(2)*, the health services provider does not have all of the information relating to the notifiable incident available to it when the open disclosure of the incident is made, or

(iii) without prejudice to *subparagraph (ii)*, the health services provider does not have all, or any, of the information in respect of the cause of the incident available to it when the open disclosure of the incident is made,

(b) all the circumstances of the patient and the nature, and consequences, of the notifiable incident concerned, and

(c) the requirements of *section 15.*

(2) Having considered the appropriate time for making the open disclosure of the notifiable incident, the health services provider shall take all steps reasonably open to it to make the open disclosure as soon as practicable following that consideration.

(3) Where an open disclosure of a notifiable incident is not made as soon as practicable after the consideration referred to in *subsection (2)*, nothing in this Act shall be construed as preventing *section 10* from having effect in respect of that open disclosure of that incident.

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

15. (1) Before making an open disclosure of a notifiable incident, a health services provider shall—

(a) in order to determine the appropriate time at which to make the open disclosure to the patient or the relevant person (or both of them) and having regard to *section 14(1)(a)*—

(i) make an assessment of all the circumstances of the patient and the nature of the notifiable incident, and

(ii) consult, having had regard to the circumstances referred to in *subparagraph (i)*, with such other person (if any) as the health services provider considers appropriate,

(b) determine, subject to *subsection (2)*, whether the open disclosure of the notifiable incident is to be made to the patient or the relevant person (or both of them) having had regard to—

(i) the assessment referred to in *paragraph (a)(i)*,

(ii) the nature of the notifiable incident, and

(iii) consultations, if any, referred to in *paragraph (a)(ii)*,

(c) determine whether, having regard to the nature and circumstances of the notifiable incident concerned, it is appropriate for an apology to be made to the

patient or the relevant person (or both of them) at the notifiable incident disclosure meeting,

(d) consider the information relating to the notifiable incident and, having regard to the complexity of that information, take all steps as are reasonably open to the health services provider to present that information in as clear a manner as is possible having regard to that complexity,

(e) designate, in accordance with *section 16*, a person to liaise with 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*, and

(f) having regard to the information available, make arrangements for the preparation of the statement in writing, referred to in *section 18(5)*, that is to be provided, in accordance with *section 18(2)(c)* to the patient or relevant person (or both of them).

(2) *Subsection (1)(b)* shall not apply where an open disclosure of a notifiable incident is made to a relevant person pursuant to *section 7(1)(b)(ii)*, *(iii)* or *(1)(c)* as the case may be.

Designated person

16. (1) For the purpose of making a designation under *section 15(1)(e)*, where the health services provider making the designation is a health services provider referred to in—

(a) *paragraph (a)* of the definition of "health services provider", that health services provider may designate—

(i) an employee of that provider, including an employee who is a health practitioner,

(ii) a health practitioner who provides a health service for that provider pursuant to a contract referred to in *paragraph (a)(ii)* of that definition,

(iii) a person with whom that provider has entered into a contract referred to in *paragraph (a)(v)(II)* of that definition,

(iv) an agency health practitioner who provides a health service for that provider pursuant to an agency contract referred to in *paragraph (a)(iii)* of that definition, or

(v) an agency worker,

as the designated person for the purposes of *section 15(1)(e)*, or

(b) *paragraph (b)* of the definition of "health services provider", that provider may designate—

(i) himself or herself,

(ii) the health practitioner providing the clinical care and treatment to the patient concerned,

(iii) an employee of that provider, including an employee who is a health practitioner,

(iv) a health practitioner who provides a health service for that provider pursuant to a contract referred to in *paragraph (b)(ii)* of that definition,

(v) a person with whom that provider has entered into a contract referred to in *paragraph (b)(iv)(II)* of that definition,

(vi) an agency health practitioner who provides a health service for that provider pursuant to an agency contract referred to in *paragraph (b)(iii)* of that definition, or

(vii) an agency worker,

as the designated person for the purposes of *section 15(1)(e)*, or

(c) *paragraph (c)* of the definition of health services provider, that provider may designate—

(i) the partner who is the health practitioner providing the health service to the patient concerned,

(ii) any other partner who is a health practitioner in the partnership concerned,

(iii) an employee of that provider, including an employee who is a health practitioner,

(iv) a health practitioner who provides a health service for that provider pursuant to a contract referred to in *paragraph (c)(ii)* of that definition,

(v) a person with whom that provider has entered into a contract referred to in *paragraph (c)(iv)(II)* of that definition,

(vi) an agency health practitioner who provides a health service for that provider pursuant to an agency contract referred to in *paragraph (c)(iii)* of that definition, or

(vii) an agency worker,

as the designated person for the purposes of *section 15(1)(e)*.

(2) A designation under this section shall be in writing and shall be kept in the records, referred to in *section 25*, relating to the open disclosure of the notifiable incident made under this Act.

Notifiable incident disclosure meeting generally to be held in person

17. (1) A notifiable incident disclosure meeting shall, subject to *subsection (2)*, be held in person with the patient or relevant person (or both of them).

(2) A patient or a relevant person (or both of them) may, when contacted by a health services provider pursuant to *section 18* to make arrangements to meet with it for the purpose of making an open disclosure, request the provider that the proposed meeting be held by telephone (or other similar method of communication) ("other than in person").

(3) A request under *subsection (2)* may be made orally.

(4) Where a request is made orally, the health services provider shall make a record of the request in writing and maintain it with the records referred to in *section 25*.

Notifiable incident disclosure meeting

18. (1) A health services provider shall, subject to *section 14*, make arrangements—

(a) to meet with the patient or relevant person (or both of them), or

(b) where the patient or a relevant person has (or both of them have) made a request under *section 17*, to hold the meeting other than in person, 5

for the purpose of making an open disclosure of a notifiable incident in respect of which the patient, or patient to whom the relevant person is connected, is the subject of the notifiable incident (in this Act referred to as an "notifiable incident disclosure meeting").

(2) When making an open disclosure of a notifiable incident at a notifiable incident disclosure meeting, a health services provider— 10

(a) shall provide the patient, or the relevant person (or both of them), with the information specified in *subsection (3)*, which, having regard to *section 14*, the health services provider has in its possession, at the time the notifiable incident disclosure meeting is held, 15

(b) may provide the information specified in *subsection (3)*—

(i) orally, and

(ii) in the order in which the health services provider considers appropriate, having regard to all the circumstances of the patient or the relevant person (or both of them) and the notifiable incident concerned, 20

(c) may—

(i) in accordance with *section 24*, give the patient or the relevant person (or both of them) a copy of the statement in writing referred to in *subsection (5)* or inform him or her (or both of them) that it will provide the statement in accordance with that section, or 25

(ii) in the case of a meeting referred to in *subsection (1)(b)*, shall give a copy of that statement to the patient or relevant person (or both of them) in accordance with *section 24*,

and

(d) shall give the statement referred to in *section 11(1)* to the patient or relevant person (or both of them) at the same time that it provides the statement referred to in *paragraph (c)* to him or her (or them) or, in the case of a meeting referred to in *subsection (1)(b)*, shall give that statement to the patient or relevant person (or both of them) in accordance with *section 24*. 30

(3) The information, referred to in *subsection (2)*, that is to be provided in accordance with that subsection shall be as follows: 35

(a) the names of the persons present at the notifiable incident disclosure meeting;

(b) a description of the notifiable incident concerned;

(c) the date on which—

(i) the notifiable incident occurred (if known), and 40

(ii) the notifiable incident came to the notice of the health services provider;

(d) the manner in which the notifiable incident came to the notice of the health services provider;

(e) where, in the opinion of the health services provider, physical or psychological consequences of the notifiable incident which, at the time of the notifiable incident disclosure meeting is held, are present or have developed, information in respect of those consequences;

(f) where the health services provider has reasonable grounds for believing that, in addition to the consequences referred to in *paragraph (e)*—

(i) physical or psychological consequences which, at the time of the notifiable incident disclosure meeting is held, have not presented, or developed, but which, notwithstanding such absence, 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, and

(ii) physical or psychological consequences which, at the time of the notifiable incident disclosure meeting have not presented, or developed, and which 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, information in respect of those consequences;

(g) where 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, a statement to that effect;

(h) where, at the time of the notifiable incident disclosure meeting—

(i) any physical or psychological consequences arising from the notifiable incident have presented, or developed, and

(ii) 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;

(i) having regard to the consideration, by the health services provider, of the notifiable incident—

(i) the actions the health services provider has taken, or proposes to take, and

(ii) procedures or processes to be implemented,

in order to, in so far as it is reasonably open to that provider to do so, address the knowledge the provider has obtained from its consideration of that incident and the circumstances giving rise to it.

(4) Where, pursuant to *section 15(1)(c)*, the health services provider has determined that an apology is to be made to the patient or the relevant person (or both of them), that health services provider may, at the notifiable incident disclosure meeting, make the

apology to the patient or the relevant person (or both of them) in respect of the notifiable incident.

(5) The statement in writing referred to in *subsection (2)(c)* that is to be given to the patient or the relevant person (or both of them) in accordance with that subsection shall—

(a) be in writing,

(b) set out the information, specified in *subsection (3)*, provided to the patient or the relevant person (or both of them) in accordance with *subsection (2)*,

(c) contain an apology referred to in *subsection (4)* where such apology was made,

(d) state that the open disclosure of the notifiable incident was made pursuant to *section 5(1)*,

(e) specify the date on which the open disclosure of the notifiable patient safety incident was made,

(f) state that the notifiable incident disclosure meeting was held in compliance with *section 5(1)*, and

(g) be signed in accordance with *subsection (6)*.

(6) The statement in writing referred to in *subsection (5)*, shall be signed by—

(a) the principal health practitioner, or

(b) the health practitioner referred to in *section 13(2)*,

who made the open disclosure of the notifiable incident on behalf of the health services provider.

(7) The health services provider shall keep, in the records referred to in *section 25*, the statement referred to in *subsection (5)*.

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

19. (1) Nothing in this Act shall require a patient to engage with the health services provider in the open disclosure of a notifiable incident and—

(a) a patient may authorise a relevant person not to attend the notifiable incident disclosure meeting, and

(b) where a relevant person refuses to attend the notifiable incident disclosure meeting, the health services provider shall inform the patient of the refusal and the patient may specify another relevant person to attend that meeting.

(2) Where a health services provider informs a patient or a relevant person that the provider proposes to hold a notifiable incident disclosure meeting in order to make an open disclosure of the notifiable incident and the patient or relevant person does not want to have the open disclosure made to him or her and refuses to attend that notifiable incident disclosure meeting, the patient, or a relevant person, shall inform the provider that he or she—

(a) will not attend the notifiable incident disclosure meeting,

(b) does not want to receive the information which is to be provided at that meeting, and

(c) does not want to receive, having regard to *section 5(2)* and *section 14*, any additional notifiable information that may be provided (or apology that may be made) pursuant to *section 21*.

(3) Where a patient or a relevant person informs a health services provider of the matters specified in *subsection (2)*, the provider shall—

(a) set out a statement in writing of those matters,

(b) include, in the statement referred to in *paragraph (a)*, a reference to the entitlement under *subsection (7)* for the patient to make a later request for a notifiable incident disclosure meeting despite the refusal referred to in *subsection (2)*,

(c) sign that statement and specify the date on which it was signed,

(d) give the patient or relevant person a copy of that statement which has, in accordance with *paragraph (c)*, been signed by the provider, as soon as practicable,

(e) maintain the statement which has, in accordance with *paragraph (c)*, been signed by the provider, in the records referred to in *section 25*, and

(f) pursuant to that statement, not proceed to hold the notifiable incident disclosure meeting.

(4) Where *section 7(1)(c)* applies and a health services provider informs both a patient and a relevant person that the provider proposes to hold a notifiable incident disclosure meeting in order to make an open disclosure of the notifiable incident and both the patient and relevant person do not want to have the open disclosure made to them and refuse to attend that notifiable incident disclosure meeting, the patient and relevant person shall inform that provider that—

(a) they will not attend the notifiable incident disclosure meeting,

(b) they do not want to receive the information which is to be provided at that meeting, and

(c) they do not want to receive, having regard to *section 5(2)* and *section 14*, any additional notifiable information that may be provided (or apology that may be made) pursuant to *section 21*.

(5) Where a patient and a relevant person informs a health services provider of the matters specified in *subsection (4)*, the provider shall—

(a) set out a statement in writing of those matters,

(b) include, in the statement referred to in *paragraph (a)*, a reference to the entitlement under *subsection (7)* for the patient to make a later request for a notifiable incident disclosure meeting despite the refusal referred to in *subsection (2)*,

(c) sign the statement referred to in *paragraph (a)* and specify the date on which it was signed,

(d) provide the patient and the relevant person who has informed the provider of those matters with a copy of the statement which has, in accordance with *paragraph (c)*, been signed by the provider, as soon as practicable,

(e) maintain the statement which has, in accordance with *paragraph (c)*, been signed by the provider, in the records referred to in *section 25*, and

(f) pursuant to that statement, not proceed to hold the notifiable incident disclosure meeting.

(6) Where a patient, or a relevant person, refuses to accept receipt of the statement referred to in *subsection (3)(d)*, or *subsection (5)(d)*, the provider shall—

(a) make a note in writing of that refusal,

(b) include, in the note referred to in *paragraph (a),* the incident to be disclosed and the date of the incident (if known),

(c) sign the note referred to in *paragraph (a)* and specify the date of signing, and

(d) keep, in the records referred to in *section 25*, the note referred to in *paragraph (a)*, which has been signed in accordance with *paragraph (c)*.

(7) Where a patient or a relevant person has, or as the case may be both of them have, refused to engage with the health services provider in the making of an open disclosure of a notifiable incident, the patient may, within 5 years from the date of the refusal, request the health services provider to make the open disclosure.

(8) A request referred to in *subsection (7)* may be made orally and the provider shall keep a note of the request in writing specifying the date of the request and the person who made it.

(9) Where the health services provider receives a request under *subsection (7)*, it shall hold a notifiable incident disclosure meeting.

(10) The health services provider shall keep, in the records referred to in *section 25*, the note referred to in a request under *subsection (8)*.

(11) Nothing in *subsection (1)* to *(5)* shall operate to prevent the making of a notification under *Part 4* in respect of that notifiable incident.

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

20. (1) Where for the purposes of *section 5(1)*, and arranging a notifiable incident disclosure meeting, the health services provider concerned is unable to contact a patient on the basis of the contact information provided to it by the patient, the provider shall take all steps reasonably open to it to establish contact with the patient in order to comply with *section 5(1)*.

(2) Where for the purposes of *section 5(1)*, and arranging a notifiable incident disclosure meeting with a relevant person, the health services provider concerned is unable to contact him or her on the basis of the contact information provided to it by the patient or the relevant person, the provider shall take all steps reasonably open to it to establish contact with the relevant person in order to comply with *section 5(1)*.

(3) Where for the purposes of *section 5(1)*, and arranging a notifiable incident disclosure meeting with a patient and a relevant person, the health services provider concerned is unable to contact either or both of them on the basis of the contact information provided to it by the patient or the relevant person, the provider shall take all steps reasonably open to it to establish contact with either or both of them in order to comply with *section 5(1)*.

(4) A health services provider shall—

(a) set out, in a statement in writing, the steps taken by it to establish contact with a patient, a relevant person or, as the case may be, both of them,

(b) include, without prejudice to the generality of *paragraph (a)*, the contact information, referred to in *subsection (1)*, or as the case may be *subsection (2)*, provided to the provider,

(c) sign the statement referred to in *paragraph (a)* and shall specify the date of signing, and

(d) keep, in records referred to in *section 25*, the statement referred to in *paragraph (a)*, which has been signed in accordance with *paragraph (c)* together 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) and any record of the steps referred to in *paragraph (a)*.

(5) Where, at any time after the signing of the statement referred to in *subsection (4)*—

(a) the health services provider makes contact with the patient or relevant person, or as the case may be, both of them, or

(b) the patient or relevant person makes, or as the case may be both of them make, contact with the health services provider,

the health services provider shall hold a notifiable incident disclosure meeting in order to make the open disclosure of the notifiable incident after that contact has been made.

(6) Nothing in this section shall operate to prevent the making of a notification under *Part 4* in respect of the notifiable incident concerned.

(7) In this section "contact information" means information provided to a health services provider by the patient or a relevant person (or both of them) for the purpose of permitting the provider to contact the patient or relevant person (or both of them) as it may require when the patient is no longer in the care of the provider or has left the premises on which the health service concerned is provided to that patient.

Additional notifiable information

21. (1) A health services provider may, at any time after the holding of the notifiable incident disclosure meeting, provide information that is additional to the information which was, in accordance with *section 18(2)(a)*, provided to the patient or relevant person (or both of them) at the notifiable incident disclosure meeting ("additional notifiable information") that, having regard to—

(a) *section 5(2)*, and

(b) *subparagraphs (i)* to *(iii)* of *section 14(1)(a)*,

was not available to the health services provider at the time of the notifiable incident disclosure meeting and which, after that meeting has become available and may, having regard to that additional notifiable information, make an apology.

(2) An additional notifiable information meeting shall, subject to *subsection (3)*, be held in person with the patient or relevant person (or both of them).

(3) A patient or a relevant person (or both of them) may, when requesting the holding of an additional notifiable information meeting, request the provider that the proposed meeting be held other than in person.

(4) A request under *subsection (3)* may be made orally.

(5) A health services provider shall make arrangements—

(a) to meet with a patient or a relevant person (or both of them), or

(b) where the patient or relevant person has made a request under *subsection (3)* to hold the meeting other than in person,

for the purpose of providing that additional notifiable information (in this Act referred to as an "additional notifiable information meeting").

(6) Additional notifiable information and an apology (if any) shall be provided, or made—

(a) by the principal health practitioner who made the open disclosure of the notifiable incident in accordance with *section 13*,

(b) where, pursuant to *section 13(1)(b)*, the open disclosure of the notifiable incident was made by a health practitioner referred to in *section 13(2)*, by that health practitioner, or

(c) by a health practitioner referred to in *subsection (7)*.

(7) Where additional notifiable information referred to in *subsection (1)* is to be provided (and an apology, if any, to be made), to a patient or relevant person (or both of them) and the person who, in accordance with *section 13*, made the open disclosure of the notifiable incident—

(a) is not available to provide that additional notifiable information (or make an apology), or

(b) is otherwise not in a position to provide that information (or make an apology),

that additional notifiable information (and apology, if any), shall be provided, or made, by a health practitioner whom the health services provider considers appropriate.

(8) Nothing in this Act shall operate to prevent an apology being made on behalf of a health services provider at the additional notifiable incident meeting whether an apology was made (or was not made) at the notifiable incident disclosure meeting having regard to the additional notifiable information which has become available since that meeting.

(9) Where a request is made orally under *subsection (4)*, the health services provider shall make a note, in writing, of the request and it shall be kept in the records referred to in *section 25*.

Additional notifiable information to be provided at additional notifiable information meeting 5

22. (1) When providing the additional notifiable information referred to in *section 21* at an additional notifiable information meeting, a health services provider—

(a) shall provide the additional notifiable information in accordance with *subsection (2)*,

(b) may provide the additional notifiable information— 10

(i) orally, and

(ii) in the order in which the health services provider considers appropriate, having regard to all the circumstances of the patient or the relevant person (or both of them) and the incident concerned, and

(c) may— 15

(i) in accordance with *section 24*, give the patient or the relevant person (or both of them) a copy of the statement in writing referred to in *subsection (3)* or inform him or her (or both of them) that it will provide the statement in accordance with that section, or

(ii) in the case of an additional notifiable information meeting referred to in *section 21(5)(b)*, shall give a copy of that statement to the patient or relevant person (or both of them) in accordance with *section 24*. 20

(2) When providing the additional notifiable information referred to in *subsection (1)*—

(a) the health services provider shall provide the names of the persons present at the additional notifiable information meeting, 25

(b) the health services provider shall have regard to the provisions of *section 18(3)* and shall specify the provisions of that section to which the additional notifiable information, provided at the additional notifiable information meeting refers,

(c) without prejudice to *paragraph (b)*, where having regard to the additional notifiable information provided, the health services provider has reasonable grounds for believing that further physical or psychological consequences referred to in *section 18(3)(f)*, are likely to present or develop, the health services provider shall provide further information in respect of— 30

(i) any physical or psychological consequences which, at the time the additional notifiable information meeting is held, have not presented, or developed, but which, notwithstanding such absence, the health services provider reasonably believes are likely to present or develop at any time after that meeting, and 35

(ii) any physical or psychological consequences which, at the time of the additional notifiable information meeting, have not presented, or developed, and which the health services provider reasonably believes are less likely or unlikely to present or develop at any time after the holding of that meeting, 40

(d) without prejudice to *paragraph (b)* and having regard to the additional notifiable information, where, at the time the additional notifiable information meeting is held—

(i) any physical or psychological consequences arising from the notifiable incident have presented, or developed, 5

(ii) the patient is under the clinical care of the health services provider concerned,

(iii) having regard to the information referred to in *section 18(3)(h)* which was provided at the notifiable incident disclosure meeting, and

(iv) the health services provider proposes to make changes to the treatment, and relevant clinical care, that the provider is providing to the patient to address those consequences, 10

the health services provider shall provide information relating to those changes to the treatment and clinical care.

(3) The statement referred to in *subsection (1)(c)*, that is to be given to the patient or the relevant person (or both of them) by the health services provider in accordance with that subsection, shall— 15

(a) be in writing,

(b) set out the additional notifiable information, specified in *subsection (2)*, provided to the patient or the relevant person (or both of them) in accordance with that subsection, 20

(c) contain an apology referred to in *section 21* where such apology was made,

(d) specify the date on which the additional notifiable information was provided to the patient or the relevant person (or both of them), and

(e) be signed in accordance with *subsection (4)*. 25

(4) The statement referred to in *subsection (3)* shall be signed by—

(a) the principal health practitioner referred to in *section 21(6)(a)*, or

(b) the health practitioner referred to in *section 21(6)(b)* or *(c)*, who provided the additional notifiable information to the patient or relevant person (or both of them) in accordance with this section. 30

(5) The health services provider shall keep, in the records referred to in *section 25*, the statement referred to in *subsection (3)*.

(6) Nothing in this Act shall operate to prevent the additional notifiable information being provided (and an apology, if any, being made), at the additional notifiable information meeting, to— 35

(a) both the patient and the relevant person where the open disclosure of the notifiable incident (and an apology, if any) was made to either of them at the notifiable incident disclosure meeting, and

(b) a relevant person where—

(i) the open disclosure of the notifiable incident (and an apology, if any) was made to the patient concerned at the notifiable incident disclosure meeting, and

(ii) the patient died after the notifiable incident disclosure meeting was held.

(7) *Section 10* shall apply to— 5

(a) any information provided (or apology made) to the patient or the relevant person (or both of them) at the additional notifiable information meeting, in the same way as *section 10* applies to information provided, and an apology where it is made, at a notifiable incident disclosure meeting, and

(b) the statement referred to in *subsection (3)* in the same way as it applies to the statement referred to in *section 18(5)*. 10

Clarification of information provided at notifiable incident disclosure meeting or additional notifiable information provided at additional notifiable information meeting

23. (1) A patient or relevant person (or both of them) to whom an open disclosure of a notifiable incident was made, may, at any time after the notifiable incident disclosure meeting, or the additional notifiable information meeting as the case may be, make a request, to the designated person, for the clarification of— 15

(a) any information provided to the patient or relevant person (or both of them) at the notifiable incident disclosure meeting, or

(b) any additional notifiable information provided to the patient or relevant person (or both of them) at the additional notifiable information meeting, 20

and may request that the clarification be made other than in person.

(2) Where a request is made under *subsection (1)*—

(a) in the case of a request for clarification of the information provided at the notifiable incident disclosure meeting, the designated person shall— 25

(i) as soon as practicable, inform the person who, pursuant to *section 13*, made the open disclosure of the notifiable incident, or where the conditions in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, of the request, and

(ii) liaise with the person, or the health practitioner, referred to in *subparagraph (i)* in relation to the provision of a response to the request, 30

(b) in the case of a request for clarification of the additional notifiable information provided at the additional notifiable information meeting, the designated person shall—

(i) as soon as practicable, inform the person who, pursuant to *section 21*, provided the additional notifiable information at that meeting or, where the conditions in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, of the request, and 35

(ii) liaise with the person, or the health practitioner, referred to in *subparagraph (i)* in relation to the provision of a response to the request, 40

(c) in the case of a request for clarification of the information provided at the notifiable incident disclosure meeting, the person who, pursuant to *section 13*, made the open disclosure of the notifiable incident at the notifiable incident disclosure meeting, or where the conditions referred to in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, shall— 5

(i) provide the clarification to the patient or relevant person (or both of them), in so far as it is reasonably open to him or her to do so having regard to the information available to him or her at the time at which he or she provides the clarification, and

(ii) liaise with the designated person in relation to the provision of the clarification referred to in *subparagraph (i)*, 10

(d) in the case of a request for clarification of additional notifiable information provided at an additional notifiable information meeting, the person who, pursuant to *section 21*, provided the additional notifiable information at that meeting, or where the conditions in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, shall— 15

(i) provide the clarification to the patient or relevant person (or both of them) in so far as it is reasonably open to him or her to do so having regard to the information available to him or her at the time at which he or she provides the clarification, and 20

(ii) liaise with the designated person in relation to the provision of the clarification referred to in *subparagraph (i)*,

and

(e) the designated person shall—

(i) set out, in a statement in writing— 25

(I) the request for clarification made under *subsection (1)*, and

(II) the date on which the clarification requested under *subsection (1)* was provided,

and

(ii) keep, in the records referred to in *section 25*, the statement referred to in *subparagraph (i)*. 30

(3) For the purposes of providing the clarification requested under *subsection (1)*, the person who, pursuant to *section 13*, made the open disclosure of the notifiable incident at the notifiable incident disclosure meeting, the person who, pursuant to *section 21*, provided the additional notifiable information at the additional notifiable information meeting, or, where the conditions referred to in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, as the case may be— 35

(a) may provide that clarification orally, and

(b) shall, in accordance with *section 24*, give a copy of the statement in writing referred to in *subsection (5)* to— 40

(i) the designated person, and

(ii) the patient or relevant person (or both of them) who made the request under *subsection (1)*.

(4) Where a request is made under *subsection (1)* and the person who—

(a) pursuant to *section 13*, made the open disclosure of the notifiable incident at the notifiable incident disclosure meeting, or

(b) pursuant to *section 21*, provided the additional notifiable information at the additional notifiable information meeting,

is not available to provide the clarification requested under *subsection (1)*—

(i) the designated person shall notify the health services provider, and

(ii) the clarification shall be provided by a health practitioner whom the health services provider, having considered the notifiable incident concerned, considers appropriate.

(5) The statement referred to in *subsection (3)(b)* that is to be given, in accordance with that subsection, to the persons specified in that subsection, shall—

(a) set out the information provided in the clarification,

(b) specify the date on which the clarification was provided to the persons referred to in *subsection (3)*, and

(c) be signed in accordance with *subsection (6)*.

(6) The statement referred to in *subsection (5)* shall be signed by the person who provided the clarification.

(7) The health services provider shall keep, in the records referred to in *section 25*, the statement referred to in *subsection (5)*.

(8) *Section 10* shall apply to—

(a) information provided in a clarification made to a patient or relevant person (or both of them) pursuant to a request made under *subsection (1)* in the same way as that section applies to information provided to a patient or relevant person (or both of them) at a notifiable incident disclosure meeting or an additional notifiable information meeting as the case may be, and

(b) the statement in writing referred to in—

(i) *subsection (2)(e)*, and

(ii) *subsection (5)*,

in the same way as that section applies to the statement referred to in *section 18(5)*.

Statements specifying information given at certain meetings

24. (1) *Subsection (2)* shall apply for the purposes of—

(a) a notifiable information disclosure meeting that is held in person and the provision of the statement referred to in *section 18(5)* to a patient or relevant person (or both of them) in accordance with *section 18(2)(c)* and the statement referred to in *section 18(2)(d)*,

(b) an additional notifiable information meeting that is held in person and the provision of the statement referred to in *section 22(3)* to a patient or relevant person (or both of them) in accordance with *section 22(1)(c)*, and

(c) a clarification provided under *section 23* and the provision of the statement referred to in *section 23(3)(b)* to a patient or relevant person (or both of them) in accordance with that section.

(2) A health services provider—

(a) may give the statements referred to in *subsection (1)(a)* to the patient or relevant person (or both of them) at the meeting referred to in *subsection (1)(a)* and shall, in any event, give such statements to him or her (or them) not later than 5 days from the date on which that meeting was held, and

(b) may give the statement referred to in *subsection (1)(b)* or *(1)(c)* to the patient or relevant person (or both of them) at the meeting referred to in *subsection (1)(b)* or as the case may be at a clarification referred to in *subsection (1)(c)* and shall, in any event, give such statements to him or her (or them) not later than 5 days from the day on which that meeting or as the case may be clarification was held.

(3) *Subsection (4)* shall apply for the purposes of—

(a) a notifiable information disclosure meeting that is held other than in person and the provision of the statement referred to in *section 18(5)* to a patient or relevant person (or both of them) in accordance with *section 18(2)(c)* and the statement referred to in *section 18(2)(d)*,

(b) an additional notifiable information meeting that is held other than in person and the provision of the statement referred to in *section 22(3)* to a patient or relevant person (or both of them) in accordance with *section 22(1)(c)*, and

(c) a clarification provided under *section 23* that is made other than in person and the provision of the statement referred to in *section 23(3)(b)* to a patient or relevant person (or both of them) in accordance with that section.

(4) A health services provider shall give—

(a) the statements referred to in *subsection (3)(a)* to the patient or relevant person (or as the case may be both of them) not later than 5 days from the day on which that meeting was held, and

(b) the statement referred to in *subsection (3)(b)* or *(c)* to the patient or relevant person (or as the case may be both of them) not later than 5 days from the day on which the meeting referred to in *subsection (3)(b)*, or as the case may be the clarification referred to in *subsection (3)(c)*, was held.

Records relating to open disclosure of notifiable incident

25. (1) A health services provider shall keep and maintain records in relation to—

(a) a copy of the designation referred to in *section 16(2)*,

(b) the statement in writing referred to in *section 18(7)*,

(c) the statement referred to in *section 19(3)(e)* or *section 19(5)(e)*, as the case may be,

(d) the note referred to in *section 19(6)(b)(iii)*,

(e) the request referred to in *section 19(8)*,

(f) the statement referred to in *section 20(4)(d)*, 5

(g) the statement in writing referred to in *section 22(5)*, and

(h) the statement in writing—

(i) of a request referred to in *section 23(2)(e)*, and

(ii) referred to in *section 23(7)*.

(2) The Minister may prescribe the form of the records to be kept and maintained by a health services provider under this section and any matter relating to the keeping and maintenance of such records. 10

PART 4

NOTIFICATION TO CERTAIN BODIES OF NOTIFIABLE INCIDENTS

Interpretation for Part 15

26. In this Part—

"additional Part 4 information" shall be construed in accordance with *section 31*;

"chief inspector" has the meaning assigned to it by section 40 of the Act of 2007;

"further Part 4 information" shall be construed in accordance with *section 31*;

"National Treasury Management Agency incident management system" means the system established pursuant to, and in accordance with, the Act of 2000 that is, from time to time, used pursuant to that Act 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). 20

Notification to Authority by health services providers of notifiable incident

27. (1) Where a health services provider, other than a health services provider referred to in *section 28* or *section 29* is satisfied that a notifiable incident, specified in *subsection (2)* has occurred in the course of the provision by the health services provider of a health service to a patient, it shall notify the Authority of that notifiable incident— 25

(a) as soon as practicable, and

(b) in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred. 30

(2) For the purposes of *subsection (1)*, all of the following shall be notified in accordance with that subsection:

(a) each notifiable incident specified in *Part 1* of *Schedule 1*;

(b) each notifiable incident specified in *Part 2* of *Schedule 1*;

(c) in the case of a notifiable incident specified in regulations made under *section 8*, each such incident specified in any regulations made under that section.

(3) A notification under this section shall specify the following information:

(a) the name of the health services provider;

(b) identification of the type of notifiable incident, specified in *Part 1* or *2* of *Schedule 1* or, as the case may be, specified in regulations made under *section 8*, into which the notifiable incident concerned falls;

(c) the date the notifiable incident occurred if, having regard to *section 5(2)*, the date is known at the time the notification under this section is made;

(d) the date the notifiable incident came to the notice of the health services provider;

(e) having regard to the notifiable incident and the causes of the notifiable incident insofar as they are known at the time of the notification is made under this section—

(i) the action the health services provider has taken in response to that incident, or proposes to take, to prevent reoccurrence, or mitigate the consequences of any similar such incident should there be a reoccurrence, and

(ii) a statement of any action taken, or proposed to be taken, for the purpose of sharing what has been learnt, and knowledge obtained, from the occurrence of the notifiable incident.

(4) The Authority shall acknowledge receipt, in writing, of a notification made to it under this section not later than 21 days from receipt of the notification.

(5) An acknowledgement made under *subsection (4)* may be made electronically.

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

28. (1) Where a health services provider carries on the business of a designated centre and it is satisfied that a notifiable incident, specified in *subsection (2)*, has occurred in the course of the provision by it of a health service to a patient, the health services provider shall notify the chief inspector of that notifiable incident—

(a) as soon as practicable, and

(b) in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred.

(2) For the purposes of *subsection (1)*, all of the following shall be notified in accordance with that subsection:

(a) each notifiable incident specified in *Part 1* of *Schedule 1*;

(b) in the case of a notifiable incident specified in regulations made under *section 8*, each such incident specified in any regulations made under that section.

(3) A notification under this section shall specify the information that is set out in *section 27(3)*.

(4) The chief inspector shall acknowledge receipt, in writing, of a notification made to it under this section not later than 21 days from receipt of the notification.

(5) An acknowledgement made under *subsection (4)* may be made electronically.

(6) In this Part, "designated centre" means—

(a) a designated centre within the meaning of section 2 of the Act of 2007, and

(b) which is registered in accordance with section 49 of the Act of 2007 and includes—

(i) a designated centre whose registration has been cancelled under section 51 of that Act where an appeal against the cancellation has been made and has not been determined or withdrawn or in respect of which an appeal has been made under section 62 of that Act and that appeal has not been determined or withdrawn, and

(ii) a designated centre in respect of which an application was made to the District Court under section 59 of the Act of 2007 and the application has not been determined or withdrawn or in respect of which an appeal has been made under section 62 of that Act and that appeal has not been determined or withdrawn.

Notification to Commission of notifiable incident by certain health services providers

29. (1) Where a health services provider, which provides a health service in an approved centre, is satisfied that a notifiable incident, specified in *subsection (2)*, has occurred in the course of the provision by it of a health service to a patient, it shall notify the Commission of that notifiable incident—

(a) as soon as practicable, and

(b) in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred.

(2) For the purposes of *subsection (1)*, all of the following shall be notified in accordance with that subsection:

(a) each notifiable incident specified in *Part 1* of *Schedule 1*;

(b) in the case of a notifiable incident specified in regulations made under *section 8*, each such incident specified in any regulations made under that section.

(3) A notification under this section shall include the information specified in *section 27(3)* for the notifiable incident concerned.

(4) The Commission shall acknowledge receipt, in writing, of a notification made to it under this section not later than 21 days from receipt of the notification.

(5) An acknowledgement made under *subsection (4)* may be made electronically.

(6) In this Part, "approved centre" shall be construed in accordance with section 63 of the Mental Health Act 2001 and, in accordance with section 65(4)(a) of that Act, or as the case may be, section 64(10)(a) of that Act, and references to an approved centre include a reference to an approved centre to which section 65(4)(a) of that Act, or as the case may be, section 64(10)(a)(iii) of that Act, refers.

Method of making notifications under *sections 27*, *28* and *29*

30. For the purposes of making a notification under *section 27*, *28* or *29*, the health services provider shall make the notification by means of the National Treasury Management Agency incident management system.

Provision of additional and further information by health services provider 5

31. (1) Where, following a notification under *section 27*, *28* or *29*—

(a) the Authority,

(b) the chief inspector, or

(c) the Commission,

has had regard to the notifiable incident concerned and requires additional 10 information in respect of the notifiable incident concerned, it, or he or she, may request the health services provider concerned to furnish it, or him or her, with additional information that is additional to the information specified in the notification, and where it, or he or she, considers it appropriate with the further information referred to in *subsection (2)* (in this Part referred to as "additional Part 4 15 information").

(2) The further information referred to in *subsection (1)* (in this Part referred to as "further Part 4 information") is information which—

(a) arises from the consideration by the Authority, chief inspector or Commission of the nature of the notifiable incident concerned, and 20

(b) having had regard to the safety of patients, and the performance by the Authority, chief inspector or Commission, it, or him or her, of its, or his or her, functions the Authority, chief inspector or Commission considers necessary for the performance of those functions.

(3) Additional Part 4 information or further Part 4 information, provided pursuant to a 25 request under this section shall be provided in such manner as the Authority, chief inspector or Commission specifies in the request.

Sharing information

32. (1) Where, in the opinion of the Authority, chief inspector or the Commission, having had regard to— 30

(a) the information, specified in *section 27(3)*, *28(3)* or as the case may be *section 29(3)*, provided in respect of the notifiable incident, additional Part 4 information and further Part 4 information provided under *section 31*,

(b) the issues arising from that information in relation to the safety of patients, and

(c) the functions of a relevant body including functions relating to the provision, or 35 regulation, of a health service or the regulation of a health practitioner,

it is necessary for the purposes of the safety of patients that such information be shared with one or more relevant bodies for the performance by any such relevant body of its functions, the Authority, the chief inspector or the Commission may share

information (including additional Part 4 information and further Part 4 information referred to in *paragraph (a)*) provided to it, or as the case may be, to him or her under, and in accordance with, this Part with any such relevant body.

(2) A relevant body shall use any information provided to it under this section solely for the purpose of the performance by it of its functions.

(3) In this section—

"Act of 1962" means the Coroners Act 1962;

"relevant body" means all or any of the following:

(a) the coroner (within the meaning of the Act of 1962) for the coroner's district (within the meaning of the Act of 1962) in which a notifiable incident has occurred;

(b) the Health Products Regulatory Authority;

(c) the Health and Safety Authority;

(d) the Child and Family Agency;

(e) a body established by or under any enactment (other than the Companies Act 2014) whose functions include the regulation of any matter relating to a health service or the regulation of a health practitioner.

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

33. (1) Information provided in a notification under this Part (including additional Part 4 information and further Part 4 information) and any such information that is, pursuant to *section 32*, shared under that section—

(a) shall not constitute an express or implied admission of fault or liability by—

(i) that health services provider, or

(ii) a person specified in *subparagraphs (ii)* to *(ix)* of *section 10(1)(a)*,

in relation to the notifiable incident which is the subject of the notification or a clinical negligence action which arises (whether in whole or in part) from the consequences of that notifiable incident,

(b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability of—

(i) that health services provider, or

(ii) a person specified in *subparagraphs (ii)* to *(ix)* of *section 10(1)(b)*,

in a court in relation to the notifiable incident which is the subject of the notification or a clinical negligence action which arises (whether in whole or in part) from the consequences of that notifiable incident, and

(c) shall not, notwithstanding—

(i) any provision to the contrary in—

(I) a policy of professional indemnity insurance,

(II) any documentation that comprises an offer, or evidence, of an arrangement for indemnity between a medical defence organisation and a member of that organisation, or

(III) a contract of insurance providing insurance cover for claims in respect of civil liability or clinical negligence actions,

or

(ii) any other enactment or rule of law,

invalidate or otherwise affect the cover provided by such policy or contract of insurance that is, or but for such information would be, available in respect of the notifiable incident which is the subject of the notification or any matter alleged which arises (whether in whole or in part) from that notifiable incident.

(2) Information provided in a notification under this Part—

(a) shall not 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 the determination of any matter specified in *subparagraphs (i)* to *(vi)* of *section 10(2)(a)*, or

(b) are not, notwithstanding any other enactment, admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation referred to in *paragraph (a)*.

(3) This section is in addition to, and not in substitution for, any enactment or rule of law relating to the disclosure of information in respect of the provision of a health service.

(4) In this section—

"clinical negligence" has the meaning assigned to it by *section 10*;

"clinical negligence action" has the meaning assigned to it by *section 10*;

"medical defence organisation" has the meaning assigned to it by *section 10*;

"professional indemnity insurance" has the meaning assigned to it by *section 10*.

Restriction of Act of 2014 in respect of notification made under this Part

34. (1) The Act of 2014 shall not apply to a record of, or relating to, a notification made under *sections 27*, *28* and *29*, additional Part 4 information provided under *section 31*, further Part 4 information provided under *section 31* or any other provision of this Part which is held—

(a) pursuant to *section 27*, by the Authority,

(b) pursuant to *section 28*, by the chief inspector,

(c) pursuant to *section 29*, by the Commission, or

(d) pursuant to *section 30*, by the State Claims Agency (within the meaning of section 8(6) of the Act of 2000).

(2) Where information obtained from a notification referred to in *subsection (1)* (including additional Part 4 information and further Part 4 information) is shared under *section 32*, the Act of 2014 shall not apply to a record of, or relating to, that notification (or that additional and further information) which is held by the relevant body referred to in *section 32* with which it was shared. 5

PART 5

CLINICAL AUDIT

Interpretation for Part

35. In this Part—

"aggregated information", in relation to data, means the absence of information in the data that prevents a person in the clinical audit from being identified; 10

"clinical audit" shall be construed in accordance with *section 36*;

"clinical guideline" shall be construed in accordance with *section 36*;

"clinically-led" means carried out by a health practitioner;

"clinical standard" means a statement which— 15

(a) specifies a level of healthcare outcome that is required to contribute to patient quality and safety,

(b) sets out the care that patients should, having regard to a specific clinical condition, be offered by, or receive from, a health practitioner or health care provider (or both) for— 20

(i) such specific clinical condition, or

(ii) the treatment and prevention of different diseases and conditions,

(c) is consistent with current evidence-based best practice, and

(d) is measurable,

and includes any such statement that is agreed for use, from time to time, at a national level or in respect of any region or other specific geographical area. 25

Clinical audit and clinical guideline

36. (1) In this Part—

"clinical audit" means a clinically-led quality improvement process in healthcare—

(a) for the purpose of improving patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and taking action to improve care when clinical standards or clinical guidelines are not met, and 30

(b) which selects aspects of the structure, processes and outcomes of care for systematic evaluation against explicit specific clinical standards or clinical guidelines;

"improving patient care and outcomes", in relation to a clinical audit, includes the contribution to the improvement of the safety and quality of care for patients by— 5

(a) facilitating greater self-evaluation for health services providers and health practitioners, and

(b) measuring clinical practice against evidence-based clinical standards or clinical guidelines,

which provides information for health services providers and health practitioners for 10 learning from the documented conclusions required for, and provided by, the clinical audit thereby improving patient care and outcomes.

(2) In this Part, "clinical guideline" means a statement relating to clinical care—

(a) that is used to assist in making decisions in relation to appropriate health care for specific clinical circumstances by— 15

(i) a health services provider or a health practitioner (or both of them), and

(ii) the patient and the health practitioner or the health services provider (or as the case may be, both of them) where a decision is made in consultation with a patient,

and 20

(b) which is repeatedly subjected to systematic review and evaluation.

(3) In respect of a reference to clinical standards or clinical guidelines that are evaluated in a clinical audit, a clinical audit may be carried out for the purpose of establishing a new clinical standard or clinical guideline that will in turn be used for the carrying out of the clinical audit or be evaluated in a subsequent clinical audit and references to— 25

(a) clinical audit,

(b) clinical guideline, and

(c) clinical standards,

shall be construed accordingly.

Clinical audit to which Part applies 30

37. This Part applies to a clinical audit that is carried out by a health services provider or a health practitioner (or both of them), where the data obtained from that audit is, or has been—

(a) collected solely for the purpose of improving patient safety and quality improvement in healthcare of patients, 35

(b) collected by the health services provider or the health practitioner (or both of them) or more than one health services provider or more than one health practitioner and analysed by the health services provider or the health practitioner (or both of them) or more than one health services provider or health practitioner,

(c) published as aggregated information, and

(d) used by that health services provider or health practitioner—

(i) solely for the purpose referred to in *paragraph (a)* in relation to the manner in which that provider or the health practitioner provides, and improves, clinical care to patients, 5

(ii) for sharing with another health services provider or health practitioner solely for the purpose referred to in *paragraph (a)*, to provide information in respect of the provision and improvement of clinical care for the purpose of improving patient safety and quality in healthcare, or

(iii) for the purpose and use referred to in *subparagraph (i)* and *(ii)*. 10

Restriction of Act of 2014

38. (1) A record referred to in *subsection (2)* shall not be disclosed under the Act of 2014.

(2) A record—

(a) of—

(i) a clinical audit to which this Part applies, or 15

(ii) a component of, or information provided in respect of, a clinical audit to which this Part applies,

and

(b) which is held by a health services provider or health practitioner.

(3) In this section, "record" has the meaning assigned to it by the Act of 2014. 20

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

39. (1) Information provided in a clinical audit, including data, referred to in *section 37*, collected solely for the purpose referred to in *section 37(a)* or provided for, or contained in, documentation or information derived from a clinical audit— 25

(a) shall not constitute an express or implied admission of fault or liability by—

(i) that health services provider, or

(ii) a person specified in *subparagraphs (ii)* to *(ix)* of *section 10(1)(a)*,

in relation to any matter which arises (whether in whole or in part) from the circumstances with which the data is connected or the clinical audit is conducted, 30 including a clinical negligence action which arises (whether in whole or in part) from the consequences of any such matter or circumstances,

(b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability of—

(i) that health services provider, or 35

(ii) a person specified in *subparagraphs (ii)* to *(ix)* of *section 10(1)(b)*,

in a court in relation to a matter or circumstances referred to in *paragraph (a)* which is the subject of a clinical negligence action which arises (whether in whole or in part) from the consequences of that matter or those circumstances, and

(c) shall not, notwithstanding— 5

(i) any provision to the contrary in—

(I) a policy of professional indemnity insurance,

(II) any documentation that comprises an offer, or evidence, of an arrangement for indemnity between a medical defence organisation and a member of that organisation, or 10

(III) a contract of insurance providing insurance cover for claims in respect of civil liability or clinical negligence actions,

or

(ii) any other enactment or rule of law,

invalidate or otherwise affect the cover provided by such policy or contract of 15 insurance that is, or but for such information would be, available in respect of a matter or circumstances referred to in *paragraph (a)* which is, or are, the subject of that data or clinical audit or any matter alleged which arises (whether in whole or in part) from that matter or those circumstances.

(2) Information provided in data referred to in *subsection (1)* or a clinical audit referred to 20 in that subsection—

(a) shall not 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 the determination of any matter specified in *subparagraphs (i)* to *(vi)* of *section 10(2)(a)*, and 25

(b) are not, notwithstanding any other enactment, admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in proceedings to determine a complaint, application or allegation referred to in *paragraph (a)*.

(3) This section is in addition to, and not in substitution for, any enactment or rule of law 30 relating to the disclosure of information in respect of the provision of a health service.

(4) In this section—

"clinical negligence" has the meaning assigned to it by *section 10*;

"clinical negligence action" has the meaning assigned to it by *section 10*;

"medical defence organisation" has the meaning assigned to it by *section 10*; 35

"professional indemnity insurance" has the meaning assigned to it by *section 10*.

Amendment of section 2 of Act of 2007

40. Section 2 of the Act of 2007 is amended, in subsection (1)—

(a) by the insertion of the following definitions: 5

" 'Act of 2004' means the Health Act 2004;

'health service' has the same meaning as it has in *section 2* of the *Patient Safety (Notifiable Patient Safety Incidents) Act 2019*;

'medical speciality' means a medical speciality recognised by the Medical Council under section 89 of the Medical Practitioners Act 2007; 10

'prescribed private health service' means a health service that is prescribed under section 101A;

'private hospital' means a hospital under the management or control of a person (other than the Executive)— 15

(a) at which—

(i) medical or surgical treatment for illness, injury, disability, palliative, obstetric or gynaecological care, or

(ii) a health service,

is provided to a person which provision of treatment is under the direction of registered medical practitioners from at least 3 different medical specialities who are registered in the Specialist Division of the register of medical practitioners, and 20

(b) which is capable of accommodating one or more persons in that hospital when providing the treatment under paragraph (a), for a minimum period of 24 hours, but does not include— 25

(i) a designated centre,

(ii) a centre registered by the Mental Health Commission,

(iii) a service provider to which paragraph (a) of the definition of service provider applies, or 30

(iv) a hospital which is in receipt of assistance under section 39 of the Act of 2004;

'register of medical practitioners' has the same meaning as it has in the Medical Practitioners Act 2007;

'registered medical practitioner' has the same meaning as it has in the Medical Practitioners Act 2007; 35

'Specialist Division' has the same meaning as it has in the Medical Practitioners Act 2007.",

and

(b) by the substitution of the following definition for the definition of "service provider": 5

" 'service provider' means—

(a) a person who enters into an arrangement under section 38 of the Act of 2004 to provide a health or personal social service on behalf of the Executive,

(b) a person who is in receipt of assistance under section 39 of the Act of 2004 in an amount that exceeds an amount prescribed for the purpose of this subparagraph, 10

(c) a service provider under the Child and Family Agency Act 2013, or

(d) a private hospital;".

Amendment of section 8 of Act of 2007 15

41. Section 8 of the Act of 2007 is amended—

(a) in subsection (1)—

(i) in paragraph (b)—

(I) in subparagraph (i), by the substitution of "a service provider to which paragraph (a), (b) or (c) of the definition of service provider applies" for "service provider", and 20

(II) by the substitution of "and advise the Minister, the Minister for Children and Youth Affairs" for "in this section called the 'services', and advise the Minister, the Minister for Children and Youth Affairs",

(ii) by the insertion of the following paragraph after paragraph (b): 25

"(ba) to set standards on safety and quality in relation to services provided by a service provider to which paragraph (d) of the definition of service provider applies or a person carrying on the business of providing prescribed private health services;",

(iii) in paragraph (c), by the substitution of "paragraphs (b) and (ba)" for "paragraph (b)", 30

(iv) in paragraph (e), by the substitution of "services referred to in paragraph (b)" for "services",

(v) in paragraphs (f), (g) and (i), by the substitution of "services referred to in paragraph (b) or (ba)" for "services" in each place that it occurs, 35

(vi) by the substitution of the following paragraph for paragraph (k):

"(k) to set standards as the Authority considers appropriate for the Executive, the Agency, service providers or a person carrying on

the business of providing prescribed private health services respecting data and information in their possession in relation to services and the health and welfare of the population;",

and

(vii) in paragraph (l), by the substitution of "the Executive, the Agency, service providers and persons carrying on the business of providing prescribed private health services" for "the Executive and service providers",

and

(b) by the insertion of the following subsection after subsection (1):

"(1A) The Authority may, in setting standards referred to in subsections (1)(b), (1)(ba) or (1)(k), set different standards for different categories of services referred to in those subsections.".

Amendment of section 9 of Act of 2007

42. Section 9 of the Act of 2007 is amended—

(a) in subsection (1)—

(i) by the substitution of "Subject to subsection (1A), the Authority may undertake an investigation as to the safety, quality and standards of the services described in section 8(1)(b) or (1)(ba)" for "The Authority may undertake an investigation as to the safety, quality and standards of the services described in section 8(1)(b)", and

(ii) in paragraph (b)—

(I) by the insertion of the following subparagraph after subparagraph (iv):

"(iva) a service provider to which paragraph (d) of the definition of service provider applies,",

(II) in subparagraph (viii), by the substitution of "registered provider, or" for "registered provider.", and

(III) by the insertion of the following subparagraph after subparagraph (viii):

"(ix) a person carrying on the business of providing a prescribed private health service.",

(b) by the insertion of the following subsection after subsection (1):

"(1A) The Authority shall notify the Minister in writing before undertaking an investigation under subsection (1).",

(c) in subsection (2)(b), by the substitution of "paragraph (b) (i), (iii), (iva), (v), (vii), or (ix)" for "paragraph (b) (i), (iii), (v) or (vii)",

(d) in subsection (2A)(b), by the substitution of "paragraph (b)(ii), (iv), (iva), (vi), (viii) or (ix) of subsection (1)" for "paragraph (b)(ii), (iv), (vi) or (viii) of subsection (1)",

(e) by the insertion of the following subsection after subsection (3):

"(3A) Where an investigation under this section is being undertaken in respect of the services specified in section 8(1)(b) or (1)(ba), the Authority shall—

(a) give notice in writing to the relevant person of the matters to which the investigation relates, and 5

(b) give the relevant person a copy of any document which in the reasonable opinion of the Authority is relevant to the investigation.",

and

(f) in subsection (6), by the insertion of the following definition: 10

" 'relevant person' means a person or body referred to in subparagraphs (i) to (ix) of subsection (1)(b);".

Standards set by Authority

43. (1) The Act of 2007 is amended by the substitution of the following section for section 10: 15

"10. (1) The Authority shall, prior to submitting a draft standard to the Minister for approval, publish a notice on the website of the Authority stating that—

(a) it proposes to set a standard,

(b) a draft of the proposed standard is available on that website for the period specified in the notice, and 20

(c) submissions in relation to the draft standard may be made in writing to the Authority on or before that date.

(2) Subject to subsection (3), the Authority may consult with such other persons on the draft standard referred to in subsection (1), as the Authority thinks fit. 25

(3) The Authority shall notify the Minister and the Minister for Children and Youth Affairs, where appropriate, before undertaking a consultation under subsection (2).

(4) After considering any representations made to it under subsection (1) or (2) on the draft standard and making any changes to the draft standard that the Authority thinks fit in view of those representations or otherwise, the Authority shall submit the draft standard to the Minister for approval and, where the standard relates to services provided under the Child and Family Agency Act 2013, the Minister shall not approve the draft standard without the prior consent of the Minister for Children and Youth Affairs. 30 35

(5) Where the Minister approves a standard under this section, he or she shall cause a notice of the approval to be published in *Iris Oifigiúil* and the notice shall specify the date from which the standard shall come into operation. 40

(6) Subject to subsection (7), the Authority may revoke or amend a standard approved under subsection (5).

(7) Subsections (1) to (5) shall, with all necessary modifications, apply to a standard that the Authority proposes to amend or revoke under subsection (6) as those subsections apply to a standard that the Minister approved under subsection (5).

(8) In this section, 'standard' means the standards set by the Authority under section 8(1).".

(2) Notwithstanding the amendment of section 10 of the Act of 2007 by *subsection (1)*, a standard set by the Authority before the coming into operation of *subsection (1)* and which is in force immediately before that commencement shall continue in force after such amendment unless revoked or amended by the Authority.

Provision of information to Authority

44. The Act of 2007 is amended by the substitution of the following section for section 12:

"12. The Authority may require—

(a) the Executive,

(b) the Agency,

(c) a service provider, or

(d) a person carrying on the business of providing a prescribed private health service,

to provide it with any information or statistics that the Authority needs in order to determine the level of compliance by the Executive, Agency, service provider or the person carrying on the business of providing a prescribed private health service, as the case may be, with the standards set by the Authority in accordance with section 8(1).".

Amendment of section 73 of Act of 2007

45. Section 73 of the Act of 2007 is amended—

(a) in subsection (1)(b), by the substitution of the following subparagraphs for subparagraphs (i) and (ii):

"(i) owned or controlled by the Executive, the Agency, a service provider, or a person carrying on the business of providing a prescribed private health service, or

(ii) used or proposed to be used, for any purpose connected with the provision of services described in section 8(1)(b) or (1)(ba).",

and

(b) in subsection (4)(a), by the substitution of "a service provider, a person carrying on the business of providing a prescribed private health service," for "a service provider".

Reports of Authority or chief inspector

46. The Act of 2007 is amended by the insertion of the following section after section 77:

"77A. (1) The Authority or the chief inspector may prepare and publish a report relating to the functions and activities of the Authority, or the chief inspector, as the case may be. 5

(2) A report prepared under subsection (1) may include information on the monitoring of compliance with standards under section 8(1)(c).

(3) Where preparing a report providing information in relation to subsection (2), the Authority or the chief inspector as the case may be, shall give to a service provider or a person carrying on the business of 10 providing a prescribed private health service a draft of the report (in this section referred to as a 'draft report') along with a written notice stating that the person may, not later than 21 days from the date on which the notice was received by him or her, or such further period as the Authority allows, make written submissions to the Authority or the 15 chief inspector on the draft report.

(4) As soon as practicable after the expiration of the period referred to in subsection (3) and, having considered any submissions made pursuant to that subsection, the Authority or the chief inspector as the case may be, may amend the draft report and shall furnish the final report to— 20

(a) the Executive,

(b) the Agency,

(c) a service provider, or

(d) a person carrying on the business of providing a prescribed private health service. 25

(5) Without limiting the generality of section 78, the Authority or the chief inspector is not liable in damages arising from any report or communication made in good faith for the purposes of, or in the performance of, the functions under this section.".

Prescribed private health services 30

47. The Act of 2007 is amended by the insertion of the following section after section 101:

"101A.(1) Without limiting the generality of section 98, the Minister, having consulted the Authority and any other person as he or she considers appropriate, may prescribe a health service to be a prescribed private health service for the purposes of this Act. 35

(2) For the purposes of subsection (1), the Minister shall have regard to the following matters:

(a) whether the service is provided on an in-patient, day-patient or out-patient basis;

(b) whether the service is provided in a hospital (other than a private hospital) where medical or surgical treatment for illness or injury, disability, palliative, obstetric or gynaecological care is provided;

(c) whether a general anaesthetic is administered to a patient in the provision of that service;

(d) whether the service is provided in a hospital (other than a private hospital) where the provision of the service is under the direction of registered medical practitioners from at least 3 different medical specialities who are registered in the Specialist Division of the register of medical practitioners;

(e) whether the service that is being provided is arranged by the National Treatment Purchase Fund Board under the National Treatment Purchase Fund Board (Establishment) Order 2004 (S.I. No. 179 of 2004);

(f) whether the service that is being provided includes the performance of surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-clinical purposes, that involves instruments or equipment being inserted into the body of the patient.

(3) When prescribing a health service to be a prescribed private health service under subsection (1), the Minister shall not prescribe health services provided—

(a) at a designated centre,

(b) at a centre registered by the Mental Health Commission, or

(c) at a retail pharmacy business.

(4) In this section, 'retail pharmacy business' has the same meaning as it has in the Pharmacy Act 2007.".

Repeal

48. Section 100 of the Act of 2007 is repealed.

PART 7

Offences and Penalties

Offences

49. (1) A person who fails to comply with *section 5(1)* without reasonable excuse shall be guilty of an offence and shall be liable on summary conviction to a class A fine.

(2) A person who fails to comply with *section 19(9)* without reasonable excuse shall be guilty of an offence and shall be liable on summary conviction to a class A fine.

(3) A person who fails to comply with *section 20(5)* without reasonable excuse shall be guilty of an offence and shall be liable on summary conviction to a class A fine.

(4) A person who fails to comply with *section 27*, *28* or *29* shall be guilty of an offence and shall be liable on summary conviction to a class A fine.

(5) In proceedings for an offence under this Act, it shall be a defence for a person against whom such proceedings are brought to show that the person made all reasonable efforts to ensure compliance with such provisions of this Act as are alleged to have been contravened.

(6) Where an offence under *subsection (1)*, *(2)*, *(3)* or *(4)* is committed by a body corporate and it is proved that the offence was committed with the consent or connivance, or was attributable to any wilful neglect, of a person who was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person shall, as well as the body corporate, be guilty of an offence and may be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(7) Where the affairs of a body corporate are managed by its members, *subsection (6)* applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

PART 8

Miscellaneous and General

Guidelines

50. (1) The Minister may, after consultation with the Authority, the chief inspector (within the meaning of *Part 4*), the Commission and the State Claims Agency (within the meaning of *Part 4*), and such other persons as he or she considers appropriate, prepare and issue guidelines for the purpose of providing practical guidance as regards the operation of, and compliance with, this Act and any regulations made under it.

(2) The Minister shall publish guidelines made under this section.

Regulations

51. (1) The Minister may by regulations provide for any matter referred to in this Act as prescribed or to be prescribed.

(2) Regulations under this Act may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary or expedient for the purposes of the regulations.

(3) Every regulation made by the Minister under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the regulation is passed by either such House within the next 21 days on which that House sits after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done thereunder.

Amendment of Act of 2000

52. The Act of 2000 is amended by the insertion of the following section after section 11:

"Notifications under *Act of 2019*

11A. (1) The Agency may provide the National Treasury Management Agency incident management system (within the meaning of the *Act of 2019*) as the means for making a notification under *section 27*, *28* or *29* of the *Act of 2019*. 5

(2) Subsection (1) shall apply whether the health services provider (within the meaning of the *Act of 2019*) making a notification referred to in that subsection is a State authority or otherwise. 10

(3) In this section, '*Act of 2019*' means the *Patient Safety (Notifiable Patient Safety Incidents) Act 2019*.".

Amendment of Act of 2017

53. The Act of 2017 is amended in the manner specified in *Schedule 2*.

Savings and transitional provisions in respect of open disclosure under Part 4 of the Act of 2017 15

54. (1) Where, before the coming into operation of this section, a health services provider had, under, and in accordance with, Part 4 of the Act of 2017 made an open disclosure of an incident (within the meaning of the Act of 2017) that is a notifiable incident specified in *Schedule 1*, that Part of the Act of 2017 shall continue to apply to that open disclosure of that incident. 20

(2) Where, on or after the coming into operation of *section 8*, a notifiable incident is specified in regulations under that section and a health services provider had, under, and in accordance with, Part 4 of the Act of 2017 made an open disclosure of an incident (within the meaning of the Act of 2017) that is a notifiable incident specified in those regulations made under *section 8*, that Part of the Act of 2017 shall continue to apply to that open disclosure of that incident. 25

SCHEDULE 1

Section 2

NOTIFIABLE INCIDENTS

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.
1.8	Patient death associated with a medication error and the death was unintended and unanticipated as it did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.9	An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to, or aggravated by, the management of the pregnancy, and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient.
1.10	An unanticipated and unintended stillborn child where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child.

Item	Notifiable Incident
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.

SCHEDULE 2

Section 51

AMENDMENTS OF ACT OF 2017

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
1.	Section 7(1)	The deletion of the definition of "Act of 2010".
2.	Section 7(1)	The substitution for the definition of "relevant person" of the following definition: " 'relevant person' means— (a) a person specified in paragraphs (a) to (f) of section 12A(1), or (b) a person nominated pursuant to section 12A(2);".
3.	Section 7(1)	The insertion of the following definition: " 'notifiable incident' has the meaning assigned to it by the *Patient Safety (Notifiable Patient Safety Incidents) Act 2019*;"
4.	Section 8(a)	The insertion of ", other than a notifiable incident," after "an incident".
5.	Section 8(b)	The insertion of ", other than a notifiable incident," after "an incident".
6.	New section 9A inserted	The insertion of the following new section after section 9: **"Disclosure of information by health services provider and health practitioner** **9A.** (1) When making an open disclosure of a patient safety incident under this Act, a health services provider shall provide all relevant information in relation to the provision of a health service to the patient (or relevant person as the case may be) that is being provided by that provider to the patient and where appropriate any other health service that is to be, or may be provided to address the consequences of that incident.

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
		(2) When making an open disclosure of a patient safety incident under this Act, a health practitioner shall provide all relevant information in relation to the provision of a health service to the patient (or relevant person as the case may be) that is being provided by that provider to the patient and where appropriate any other health service that is to be, or may be provided to address the consequences of that incident.”.
7.	Section 12(b)	The substitution of the following paragraph for paragraph (b): “(b) a relevant person where— (i) in the opinion of the principal health practitioner providing clinical care to the patient, having regard to the clinical circumstances of the patient, who is the subject of the patient safety incident, the capacity of the patient is such that he or she is unable to— (I) participate in that open disclosure, and (II) consent to that open disclosure being made to a relevant person, and that capacity is unlikely to be of a temporary duration, and the health services provider is satisfied that a patient safety incident has occurred, it is appropriate the open disclosure of that incident is made to a relevant person, (ii) the patient has died, or (iii) the patient has requested the health services provider to make the open disclosure of the patient safety incident to a person whom the patient has nominated as a relevant person for the purposes of this Part and not the patient, or”.

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
8.	Section 12(c)	The substitution of the following paragraph for paragraph (c): "(c) both the patient and a relevant person where, before the open disclosure meeting is held, the patient has requested that a person whom the patient has nominated as a relevant person for the purposes of this Part, attends that meeting to assist the patient and that in addition to making the open disclosure to the patient that the health services provider makes the open disclosure of the patient safety incident to that relevant person.".
9.	New section 12A inserted	By the insertion of the following new section after section 12: **"Section 12: supplemental provisions** **12A.** (1) For the purposes of section 12(b)(i), and making an open disclosure of a patient safety incident to a relevant person, the health services provider shall make the open disclosure— (a) 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, to the person appointed, (b) 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, (c) where the patient is a ward of court, to the Committee of the Person of that ward, duly authorised in that behalf, (d) where the patient has nominated, in writing, a person to whom his or her clinical information may be disclosed, to that person, (e) where the patient is a child, to the parent or guardian of that child or where—

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
		(i) an order in respect of the child made under section 18 of the Act of 1991, (ii) the child has been taken into the care of the Agency under section 4 of the Act of 1991, or (iii) an order in respect of the child has been made under section 13, 17 or 20 of the Act of 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 Act of 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), or (f) where the patient does not fall within the categories specified in paragraphs (a) to (e), to— (i) the spouse, civil partner or cohabitant of the patient, (ii) an adult son or daughter of the patient, or (iii) the mother, father, brother or sister of the patient. (2) For the purposes of a request referred to in— (a) section 12(b)(iii), and (b) section 12(c), without prejudice to subsection (1)(d), where a patient makes a request referred to in paragraph (a) or (b), the patient shall nominate the person in writing (including a person referred to in subsection (1)) as a person to whom clinical information may be disclosed in respect of information to be provided in an open disclosure of a patient safety incident. (3) For the purposes of section 12(b)(ii), and making an open disclosure of a patient safety incident, the open disclosure shall be made to a person specified in subsection (1).

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
		(4) Where an open disclosure of a patient safety incident is made pursuant to— (a) section 12(b)(i) or (b)(iii), to a relevant person, or (b) section 12(c), to both the patient and the relevant person, the relevant person shall consult with the patient in respect of the information provided at the open 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. (5) Where, after a health services provider has, in accordance with section 12(b)(i), held the open disclosure meeting with the relevant person and after that meeting was held the patient regains capacity, 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. (6) In this section— 'Act of 1991' means the Child Care Act 1991; 'authorised person' in relation to a child referred to in subsection (1)(e) who is— (a) placed in residential care pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children in Residential Care) Regulations 1995 (S.I. No. 259 of 1995), (b) placed in foster care pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children in Foster Care) Regulations 1995 (S.I. No. 260 of 1995), or (c) placed with a relative pursuant to the Act of 1991, has the same meaning as it has in the Child Care (Placement of Children with Relatives) Regulations 1995 (S.I. No. 261 of 1995);

Item	Provision of Act of 2017	Amendment to provision of Act of 2017
		'civil partner' has the meaning assigned to it by the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010; 'cohabitant' means one of 2 adults (whether of the same or opposite sex) who live together as a couple in an intimate and committed relationship and who are not married to each other or civil partners of each other.".
10.	Section 17(1)	The substitution for subsection (1) of the following subsection: "(1) Nothing in this Part shall require a patient to engage with the health services provider in the open disclosure of a patient safety incident and— (a) a patient may authorise a relevant person not to attend the open disclosure meeting, and (b) where a relevant person refuses to attend the open disclosure meeting, the health services provider shall inform the patient of the refusal and the patient may specify another relevant person to attend that meeting.".

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

BILLE

(mar a tionscnaíodh)

dá ngairtear

Acht do dhéanamh socrú maidir le soláthraithe seirbhísí sláinte do dhéanamh nochtadh oscailte sainordaitheach i leith teagmhais áirithe a tharlóidh i gcúrsa seirbhís sláinte a sholáthar do dhuine; do dhéanamh socrú, ar mhaithe le leas an phobail, maidir le srianta áirithe leis an bhfaisnéis a úsáid a sholáthraítear i nochtaí den sórt sin arna ndéanamh de réir an Achta seo agus le haon leithscéalta a úsáid a ghabhtar i gcúrsa nochtaí den sórt sin agus le haon fhaisnéis eile a úsáid a bhaineann leis an nochtadh oscailte a sholáthraítear, agus leis an leithscéal a ghabhtar, tar éis an chruinnithe faoi nochtadh teagmhais infhógartha; do dhéanamh socrú maidir le nósanna imeachta i leith iniúchadh cliniciúil, agus leis na sonraí a fhaightear in iniúchtaí cliniciúla; do dhéanamh socrú maidir le fógra faoi theagmhais áirithe a thabhairt do dhaoine áirithe; do leasú an Achta um Ghníomhaireacht Bainistíochta an Chisteáin Náisiúnta (Leasú), 2000; do leasú Chuid 4 den Acht um Dhliteanas Sibhialta (Leasú), 2017; do leasú an Achta Sláinte, 2007 chun socrú a dhéanamh maidir le caighdeáin arna leagan síos ag an Údarás um Fhaisnéis agus Cáilíocht Sláinte a fheidhmiú maidir le hospidéil phríobháideacha agus leis an Aire d'fhorordú seirbhísí sláinte áirithe mar sheirbhís sláinte phríobháideach fhorordaithe; agus do dhéanamh socrú i dtaobh nithe gaolmhara.

An tAire Sláinte a thíolaic,

5 *Nollaig,* 2019

Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

BILL

(as initiated)

entitled

An Act to provide for the mandatory open disclosure, by health services providers of certain incidents occurring in the course of the provision, to a person, of a health service; to provide, in the interest of the common good, for certain restrictions on the use of the information provided in such disclosures that are made in accordance with this Act and of any apologies made in the course of such disclosures and the use of any other information relating to the open disclosure provided, and apology made, after the notifiable incident disclosure meeting; to make provision for procedures in respect of clinical audit, and the data obtained in clinical audits; to provide for the notification of certain incidents to certain persons; to amend the National Treasury Management Agency (Amendment) Act 2000; to amend Part 4 of the Civil Liability (Amendment) Act 2017; to amend the Health Act 2007 to provide for the application of standards set by the Health Information and Quality Authority to private hospitals and for the Minister to prescribe certain health services as a prescribed private health service; and to provide for related matters.

Presented by the Minister for Health,

5*th December,* 2019

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