



Number 30 of 2017

Civil Liability (Amendment) Act 2017



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CIVIL LIABILITY (AMENDMENT) ACT 2017

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Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 (No. 24)
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Health and Social Care Professionals Act 2005 (No. 27)
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Medical Practitioners Act 2007 (No. 25)
National Treasury Management Agency (Amendment) Act 2000 (No. 39)
Nurses and Midwives Act 2011 (No. 41)
Pharmacy Act 2007 (No. 20)
Taxes Consolidation Act 1997 (No. 39)



Number 30 of 2017

CIVIL LIABILITY (AMENDMENT) ACT 2017

An Act to amend the Civil Liability Act 1961 to provide for the award of damages by way of a periodic payments order in certain circumstances where a plaintiff has suffered catastrophic injuries; to amend the Insurance Act 1964; to amend the Bankruptcy Act 1988; to amend the Taxes Consolidation Act 1997; to amend the Civil Liability and Courts Act 2004; to make provision for the making, by health services providers, of the open disclosure of patient safety incidents; to provide, in the interest of the common good, for certain restrictions on the use of information provided in an open disclosure of a patient safety incident that is made by a health services provider in accordance with this Act, the use of any apologies made in that open disclosure and the use of any other information relating to the open disclosure provided, and apology made, after the open disclosure meeting; and to provide for related matters. [22nd November, 2017]

Be it enacted by the Oireachtas as follows:

PART 1

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Civil Liability (Amendment) Act 2017.
- (2) The Civil Liability Acts 1961 and 1964, Part 2 of the Civil Liability and Courts Act 2004 and *Part 2* of this Act may be cited together as the Civil Liability Acts 1961 to 2017.
- (3) This Act, other than *Part 4*, shall come into operation on such day or days as the Minister for Justice and Equality 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.
- (4) *Part 4* shall come into operation on such day or days as the Minister for Health 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.

PART 2

AMENDMENT OF CIVIL LIABILITY ACT 1961

Periodic payments orders - insertion of Part IVB in Civil Liability Act 1961

2. The Civil Liability Act 1961 is amended by the insertion of the following Part after Part IVA (inserted by section 4 of the Civil Law (Miscellaneous Provisions) Act 2011):

“PART IVB

PERIODIC PAYMENTS ORDERS

Interpretation (Part IVB)

51H. In this Part—

‘Act of 2004’ means the Civil Liability and Courts Act 2004;

‘activities of daily living’ includes dressing, eating, walking, washing and bathing;

‘catastrophic injury’ means, in relation to a person, a personal injury which is of such severity that it results in a permanent disability to the person requiring the person to receive life-long care and assistance in all activities of daily living or a substantial part thereof;

‘child’ means a person under the age of 18 years;

‘Clinical Indemnity Scheme’ means the scheme established by the State under which the State Claims Agency manages clinical negligence claims taken against certain State Authorities and other parties indemnified by the scheme;

‘General Indemnity Scheme’ means the scheme established by the State under which the State Claims Agency manages negligence claims, other than clinical negligence claims to which the Clinical Indemnity Scheme applies, taken against certain State Authorities;

‘Insurance Compensation Fund’ means the fund established under section 2 of the Insurance Act 1964;

‘Minister’ means the Minister for Justice and Equality;

‘paying party’ means the party who is responsible for making payments to a plaintiff under a periodic payments order;

‘periodic payments order’ has the meaning assigned to it by section 51I;

‘State Authority’ has the same meaning as it has in section 7 of the National Treasury Management Agency (Amendment) Act 2000;

‘stepped payment’ has the meaning assigned to it by section 51I.

Award of damages by periodic payments

51I. (1) Subject to subsection (2) and section 51J, where a court awards damages for personal injuries to a plaintiff who has suffered a catastrophic injury, the court may order that the whole or part of such damages which relate to—

- (a) the future medical treatment of the plaintiff,
- (b) the future care of the plaintiff,
- (c) the provision of assistive technology or other aids and appliances associated with the medical treatment and care of the plaintiff, and
- (d) where the parties consent in writing, damages in respect of future loss of earnings,

be paid by a defendant in the proceedings concerned in the form of periodic payments to the plaintiff in such amounts as the court may determine (in this Part referred to as a ‘periodic payments order’).

(2) In deciding whether or not to make a periodic payments order, a court shall have regard to—

- (a) the best interests of the plaintiff, and
- (b) the circumstances of the case, including:
 - (i) the nature of the injuries suffered by the plaintiff; and
 - (ii) the form of award that would, in the court’s view, best meet the needs of the plaintiff having regard to—
 - (I) the amount of any payments proposed to be made to the plaintiff,
 - (II) whether the court has made an order in the proceedings concerned expressed to be one of an interim nature with respect to the payment of damages to the plaintiff, and where such an order has been made, the amount of such damages,
 - (III) the form of award preferred by the plaintiff and the reasons for that preference,
 - (IV) any financial advice received by the plaintiff in respect of the form of the award, and
 - (V) the form of award preferred by the defendant and the reasons for that preference.

(3) Where the parties to an action to which this Part applies agree to the payment of damages wholly or partly by way of periodic payments to the plaintiff in relation to any matter referred to in paragraphs (a), (b), (c) and (d) of subsection (1)—

- (a) the parties may apply to the court for a periodic payments order in accordance with the terms which have been agreed by the parties, and
- (b) the court may, subject to subsection (2)—
 - (i) make a periodic payments order in accordance with the terms which have been agreed by the parties,
 - (ii) refuse the application, or
 - (iii) refuse the application and make a periodic payments order under subsection (1).
- (4) Where it is anticipated that there will be changes in a plaintiff's circumstances during his or her life which are likely to have an effect on his or her needs, a court may make provision in a periodic payments order that a payment under the order shall, from a specified date, increase or decrease by a specified amount (in this Part referred to as a 'stepped payment').
- (5) The changes in circumstances which may form the basis of a stepped payment include:
 - (a) a plaintiff reaching 18 years of age;
 - (b) a plaintiff entering primary or secondary school;
 - (c) a plaintiff entering third level education; and
 - (d) anticipated changes in the care needs of a plaintiff, including a requirement that the plaintiff move into residential care.
- (6) Where a court makes a periodic payments order under this section, the order shall specify—
 - (a) the annual amount awarded to the plaintiff,
 - (b) the frequency of the payments that are to be made to the plaintiff from the annual amount by the paying party,
 - (c) the amount awarded for damages in respect of the matters referred to in paragraphs (a), (b) and (c) of subsection (1),
 - (d) where, further to subsection (1)(d), the periodic payments order includes damages in respect of future loss of earnings by the plaintiff, the amount awarded for such loss of earnings,
 - (e) the method by which payments are to be made by the paying party to the plaintiff,
 - (f) that the payments under the order are to be made to the plaintiff during his or her lifetime,
 - (g) that the annual amount awarded to the plaintiff will be adjusted in accordance with the Harmonised Index of Consumer Prices as

published by the Central Statistics Office or such other index as may be specified by the Minister under section 51L,

- (h) where a stepped payment is provided for—
 - (i) the change in circumstances on which an increase or decrease in the amount of a payment (referred to subsequently in this paragraph as ‘the relevant increase or decrease’) is based,
 - (ii) the date on which the relevant increase or decrease shall take effect,
 - (iii) the amount of the relevant increase or decrease at current value, and
 - (iv) that the amount of the relevant increase or decrease shall, on the date that it takes effect, be applied to the annual amount awarded to the plaintiff as adjusted in accordance with the Harmonised Index of Consumer Prices as published by the Central Statistics Office or such other index as may be specified by the Minister under section 51L,
- and
- (i) any other matter that the court considers appropriate.

(7) Where—

- (a) a court provides in a periodic payments order for a stepped payment, and
- (b) prior to the date that the stepped payment is due to take effect, it is evident to the plaintiff that the anticipated change in the plaintiff’s circumstances on which that stepped payment was based will not arise,

the plaintiff shall, as soon as practicable and not later than 10 working days before the date on which the stepped payment is due to take effect, notify the court that made the periodic payments order and the paying party in writing that the anticipated change in the plaintiff’s circumstances which formed the basis for the stepped payment concerned will not arise.

- (8) Where a court receives a notification under subsection (7) from a plaintiff in relation to a stepped payment specified in a periodic payments order, the court shall amend the periodic payments order concerned by making such adjustments to the order as it considers appropriate.
- (9) Where a periodic payments order is amended under subsection (8), the court shall cause a copy of the order as amended to be sent to the plaintiff and the paying party.

Security of periodic payments order

- 51J.** (1) A court may make a periodic payments order where it is satisfied that continuity of the payments under the order is reasonably secure.
- (2) In considering whether continuity of the payments under a periodic payments order is reasonably secure, a court shall have regard to the following matters:
- (a) whether the payments under the order are guaranteed under the Clinical Indemnity Scheme or the General Indemnity Scheme;
 - (b) whether the payments under the order are eligible for payment—
 - (i) from the Insurance Compensation Fund, or
 - (ii) by the Motor Insurers' Bureau of Ireland;
 - (c) whether continuity of the payments under the order can be guaranteed by other means.
- (3) In considering whether other means for guaranteeing payments referred to in subsection (2)(c) are such that continuity of the payments under a periodic payments order would be reasonably secure, a court shall have regard to whether the proposed means for guaranteeing payments under the order—
- (a) are such as to be capable of making the proposed payments to a plaintiff during his or her lifetime, and
 - (b) are capable of being adjusted in accordance with the Harmonised Index of Consumer Prices as published by the Central Statistics Office or such other index as may be specified by the Minister under section 51L.

Alteration of method of payment

- 51K.** (1) A paying party may apply to the court to alter the method of payment specified in a periodic payments order.
- (2) An application under subsection (1) shall be on notice to—
- (a) the plaintiff, or
 - (b) where the plaintiff has assigned his or her right to payments under a periodic payments order pursuant to section 51M(1), the person to whom the right is assigned.
- (3) A court may, on application to it under subsection (1), approve an alteration to the method of payment specified in a periodic payments order where—
- (a) the plaintiff consents to the altered method of payment,
 - (b) the court is satisfied that continuity of the payments under the order is reasonably secure notwithstanding the alteration to the method of payment, and

- (c) the alteration to the method of payment concerned is capable of adjustment in accordance with the Harmonised Index of Consumer Prices as published by the Central Statistics Office or such other index as may be specified by the Minister under section 51L.

Indexation of periodic payments

- 51L.** (1) A periodic payments order shall provide for the amount of a payment under the order to be adjusted annually by reference to the Harmonised Index of Consumer Prices as published by the Central Statistics Office or such other index as may be specified under this section.
- (2) The Minister shall, not less than 5 years after the commencement of this Part, carry out a review of the application of the index referred to in subsection (1) (in this section referred to as an ‘initial review’) in order to determine the suitability of that index for the purposes of the annual adjustment of the amount of payments provided for under periodic payments orders.
 - (3) The Minister shall, 5 years after the initial review and every 5 years thereafter, carry out a review of the application of the index referred to in subsection (1) or such other index as may be specified by him or her under this section, in order to determine the suitability of the index concerned for the purposes of the annual adjustment of the amount of payments provided for under periodic payments orders.
 - (4) Subject to subsection (5), where, pursuant to an initial review or a review under subsection (3), the Minister is of the opinion that an alternative index would be more suitable for the purpose of the annual adjustment of the amount of payments provided for under periodic payments orders, he or she shall, subject to the consent of the Minister for Finance, make regulations specifying the index to be used for that purpose.
 - (5) In forming an opinion for the purpose of subsection (4), the Minister shall have regard to—
 - (a) the relevance of the goods and services on which an index is based to the loss or expenditure, including cost of care and medical expenses, for which plaintiffs who are the subject of periodic payments orders are compensated,
 - (b) the body calculating the index,
 - (c) whether or not the index is accessible at the same time or times each year,
 - (d) the reliability of the index over time, and
 - (e) the reproducibility of the index in the future.

- (6) The index specified in regulations under subsection (4) shall apply to an annual adjustment of the amount of a payment to be made under a periodic payments order where the annual adjustment is made after—
 - (a) the date of the making of the regulations, or
 - (b) such later date as may be specified in the regulations.
- (7) Regulations under this section shall be laid before each House of the Oireachtas as soon as may be after they are made and if a resolution annulling the regulations is passed by either such House within the next 21 days on which that House has sat after the regulations are laid before it, the regulations shall be annulled accordingly but without prejudice to the validity of anything previously done under the regulations.

Assignment, commutation or charging of right to periodic payments

- 51M.** (1) Where a plaintiff has a right to receive payments under a periodic payments order, the plaintiff may apply to the court that made the order for approval to assign, commute or charge the right.
- (2) A right to receive payments under a periodic payments order may not be assigned, commuted or charged without the approval of the court that made the order.
 - (3) Where a plaintiff, without the approval of the court, purports to—
 - (a) assign, commute or charge his or her right to receive payments under a periodic payments order, or
 - (b) enter into an agreement to assign, commute or charge such a right, the assignment, commutation or charge, as the case may be, shall be void.
 - (4) In considering whether or not to approve a proposed assignment, commutation or charge of a plaintiff's right to receive payments under a periodic payments order, a court shall have regard to—
 - (a) whether the capitalised value of the assignment, commutation or charge represents value for money,
 - (b) whether the assignment, commutation or charge is in the plaintiff's best interests, and
 - (c) how the plaintiff will be financially supported following the assignment, commutation or charge, as the case may be.

Appeals

- 51N.** An appeal shall lie from a decision of the High Court under section 51I, 51J or 51M to the Court of Appeal on a point of law only.

Application of this Part

- 51O.** This Part applies to personal injuries actions relating to catastrophic

injuries—

- (a) that are brought on or after the commencement of *section 2* of the *Civil Liability (Amendment) Act 2017*, or
- (b) that have been initiated, and have not been concluded, prior to such commencement, and the actions to which this paragraph applies include an action in which the court has made an order of the interim nature referred to in clause (II) of section 51I(2)(b)(ii).”.

PART 3

AMENDMENTS TO OTHER ACTS

Amendment of section 3 of Insurance Act 1964

3. Section 3 of the Insurance Act 1964 is amended—

- (a) by the insertion of the following subsection after subsection (4):

“(4A) Where a sum is due to a person under a policy by reason of a periodic payments order, the limitation prescribed by subsection (4) on payment out of the Fund shall not apply to the sum required to meet the liability of the insured under the periodic payments order.”,

- (b) in subsection (5), by the substitution of “Subject to subsection (4A), where” for “Where”, and

- (c) by the substitution of the following for subsection (8):

“(8) In this section—

‘insurer in liquidation’ means an insolvent insurer or an insolvent insurer authorised in another Member State in respect of which a liquidator, or a person who performs the equivalent function to a liquidator in the Member State concerned, has been appointed;

‘periodic payments order’ has the same meaning as it has in Part IVB of the Civil Liability Act 1961.”.

Amendment of Bankruptcy Act 1988

4. The Bankruptcy Act 1988 is amended—

- (a) in section 3, by the insertion of the following definitions:

“ ‘Act of 2010’ means the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

‘periodic payments order’ has the same meaning as it has in Part IVB of the Civil Liability Act 1961;”,

- (b) in section 44—

- (i) in subsection (3)—
 - (I) in paragraph (b), by the substitution of “by those sections; and” for “by those sections.”, and
 - (II) by the insertion of the following paragraph after paragraph (b):
 - “(c) any sum paid to the bankrupt under a periodic payments order, which relates to damages in respect of future loss of earnings.”,
 - (ii) in subsection (4)—
 - (I) in paragraph (a), by the deletion of “or”,
 - (II) in paragraph (b), by the substitution of “Central Bank Act 1971, and” for “Central Bank Act, 1971.”, and
 - (III) by the insertion of the following paragraph after paragraph (b):
 - “(c) any sum paid to the bankrupt under a periodic payments order, other than a sum referred to in subsection (3)(c).”,
- and
- (iii) by the insertion of the following subsection after subsection (5):
 - “(6) Subsection (5) shall not apply to any sum paid to a bankrupt under a periodic payments order before the discharge or annulment of the adjudication order, other than any part of such sum which relates to damages in respect of future loss of earnings.”,
- (c) in section 45—
 - (i) by the substitution of the following for subsection (1):
 - “(1) (a) Subject to paragraph (b), a bankrupt shall be entitled to retain as excepted articles—
 - (i) any assistive technology or other aids and appliances associated with the medical treatment and care of the bankrupt, his or her spouse or civil partner within the meaning of the Act of 2010, his or her children and any dependent relative residing with him or her, and
 - (ii) such articles of clothing, household furniture, bedding, tools or equipment of the bankrupt’s trade or occupation or other like necessaries for the bankrupt, his or her spouse or civil partner within the meaning of the Act of 2010, his or her children and any dependent relatives residing with him or her, as the bankrupt may select.
 - (b) The total value of articles selected by a bankrupt under paragraph (a)(ii) shall not exceed €6,000 or such further amount as the Court may, on an application by the bankrupt, allow.”,

and

- (ii) in subsection (2), by the substitution of “subsection (1)(a)(ii)” for “subsection (1)”,
- (d) in section 47—
 - (i) by the substitution of “Subject to subsection (2), notwithstanding” for “Notwithstanding”,
 - (ii) by the designation of that section as subsection (1), and
 - (iii) by the addition of the following subsection:
 - “(2) Money or securities referred to in subsection (1), which derive from—
 - (a) payments to a bankrupt, before or after adjudication, made under a periodic payments order, other than any part of such payments which relates to damages in respect of future loss of earnings, or
 - (b) damages or compensation otherwise paid to a bankrupt, before or after adjudication, for a personal injury or loss suffered by him or her, other than any part of such damages or compensation which relates to damages in respect of future loss of earnings,
 shall not vest in the Official Assignee.”,
- and
- (e) in section 85D, by the insertion of the following subsection after subsection (7):
 - “(8) A payment which a bankrupt receives, or is entitled to receive, under a periodic payments order, other than any part of such payment that relates to damages in respect of future loss of earnings, shall not be regarded as income or an asset for the purposes of this section.”.

Amendment of Taxes Consolidation Act 1997

5. The Taxes Consolidation Act 1997 is amended by the insertion of the following section after section 189A:

“Exemption in respect of periodic payments for personal injuries

189B. (1) This section shall apply to any payment made to or in respect of an individual—

- (a) pursuant to a periodic payments order within the meaning of Part IVB of the Civil Liability Act 1961, or
 - (b) pursuant to any order or other instrument that corresponds to an order referred to in paragraph (a) which is made in accordance with the law of a territory other than the State.
- (2) Where, for any year of assessment, an individual is in receipt of a payment to which this section applies, such payment shall be exempt from income tax and shall not be reckoned in computing income for the purposes of the Income Tax Acts.”.

Amendment of section 17 of Civil Liability and Courts Act 2004

6. Section 17 of the Civil Liability and Courts Act 2004 is amended—

(a) by the insertion of the following subsection after subsection (2):

“(2A) Where a formal offer is made in respect of a personal injuries action relating to a catastrophic injury, the formal offer shall specify the proportion of the amount of the formal offer that is attributable to—

- (a) the future medical treatment of the plaintiff,
- (b) the future care of the plaintiff,
- (c) the provision of assistive technology or other aids and appliances associated with the medical treatment and care of the plaintiff, and
- (d) future loss of earnings of the plaintiff.”

(b) in subsection (5), by the substitution of “Subject to subsection (5A), the court” for “The court”,

(c) by the insertion of the following subsection after subsection (5):

“(5A) (a) Where a court has made a periodic payments order in a personal injuries action, the court shall, when considering the making of an order as to the payment of the costs in the personal injuries action, have regard to—

- (i) the terms of any formal offer, other than those terms which relate to the matters referred to in paragraphs (a), (b), (c) and (d) of subsection (2A), and
- (ii) the reasonableness of the conduct of the parties to the personal injuries action concerned in making any formal offers.

(b) In determining liability for the part of the costs of the personal injuries action relating to the matters referred to in paragraphs (a), (b), (c) and (d) of subsection (2A), the court shall have regard to—

- (i) any offers not expressed to be without prejudice or in terms having like effect, and
- (ii) any offers made without prejudice save as to the issue of costs which were made by or on behalf of a party to the personal injuries action after the commencement of the trial of the action, to effect a settlement of that action.”

and

(d) by the insertion of the following definitions in subsection (7):

“ ‘catastrophic injury’ has the same meaning as it has in Part IVB of the Civil Liability Act 1961;

‘periodic payments order’ has the same meaning as it has in Part IVB of the Civil Liability Act 1961;”

PART 4

OPEN DISCLOSURE OF PATIENT SAFETY INCIDENTS

CHAPTER 1

*General***Interpretation**

7. (1) In this Part—

“Act of 1985” means the Dentists Act 1985;

“Act of 2005” means the Health and Social Care Professionals Act 2005;

“Act of 2007” means the Medical Practitioners Act 2007;

“Act of 2010” means the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

“Act of 2011” means the Nurses and Midwives Act 2011;

“additional information” shall be construed in accordance with *section 18(1)*;

“additional information meeting” has the meaning assigned to it by *section 18*;

“agency contract”, in relation to a health services provider, means a contract between an employment agency and a health services provider by virtue of which an agency worker or an agency health practitioner—

(a) is assigned to work for the health services provider, and in the case of an agency health practitioner, to provide a health service, for (or on behalf of) the health services provider, and

(b) remains under the direction and supervision of the health services provider;

“agency health practitioner”, in relation to a health services provider, means an agency worker who—

(a) is a health practitioner, and

(b) under an agency contract, is assigned to work for the health services provider, and the work to be carried out is to provide a health service for (or on behalf of) the health services provider,

and a reference to an agency health practitioner, in relation to a health services provider, shall be construed as a reference to an agency health practitioner who provides a health service for the health services provider and is under the direction and supervision of that health services provider;

“agency worker”, in relation to a health services provider, means a person who is employed by an employment agency under a contract of employment by virtue of which that person may be assigned to work for the health services provider, and a reference to an agency worker, in relation to a health services provider, shall be

construed as a reference to an agency worker who works for a health services provider and is under the direction and supervision of that provider;

“apology”, in relation to an open disclosure of a patient safety incident, means an expression of sympathy or regret;

“designated person” means a person designated under *section 15(1)(e)*;

“employee”, in relation to a health services provider, means—

(a) a person who—

- (i) has entered into, or works under (or where the employment has ceased, had entered into or worked under), a contract of employment, with the health services provider, or
- (ii) is (or was) placed for the purpose of vocational training with the health services provider,

and

(b) a fixed-term employee of the health services provider,

and a reference to an employee, in relation to a health services provider, shall be construed as a reference to an employee employed by that health services provider;

“employment agency” has the meaning assigned to it by the Employment Agency Act 1971;

“fixed-term employee” means an employee of a health services provider whose employment is governed by a contract of employment for a fixed-term or for a specified purpose, being a purpose of a kind that the duration of the contract was limited but was, at the time of its making, incapable of precise ascertainment;

“health practitioner” means—

- (a) a registered medical practitioner within the meaning of the Act of 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 a health or personal social service (including personal care and any ancillary matter relating to the health or personal social service) provided to a patient—

(a) for—

- (i) the screening, preservation or improvement of the health of the patient, or
- (ii) the prevention, diagnosis, treatment or care of an illness, injury or health condition of the patient,

and

- (b) by or under the direction of a health services provider;

“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,

or

- (b) a health practitioner who, or a partnership which, 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, or a partnership which—
- (i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner of a health service,
 - (ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner, of a health service,
 - (iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner or the partnership, or
 - (iv) insofar as it relates to the carrying on of the business of providing a health service—
 - (I) employs one or more persons,
 - (II) enters into a contract for services with one or more persons,
 - (III) enters into an agency contract for the assignment of an agency worker, or
 - (IV) enters into an arrangement with one or more persons,in respect of the carrying on of that business;

“making an open disclosure” shall be construed in accordance with *section 9*;

“Minister” means the Minister for Health;

“open disclosure meeting” has the meaning assigned to it by *section 16*;

“open disclosure of a patient safety incident” shall be construed in accordance with *section 9* and references to the open disclosure of a patient safety incident or open disclosure, in relation to a patient safety incident, shall be construed accordingly;

“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);

“partnership” means 2 or more health practitioners who provide a health service in common;

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

“patient safety incident” shall be construed in accordance with *section 8*;

“prescribed” means prescribed by regulations made by the Minister under this Part;

“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;

“relevant person”, in relation to a patient, means a person—

- (a) who is—
 - (i) a parent, guardian, son or daughter,
 - (ii) a spouse, or
 - (iii) a civil partner (within the meaning of the Act of 2010), of the patient,
- (b) who is cohabiting with the patient (including a cohabitant within the meaning of Part 15 of the Act of 2010), or
- (c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed.

(2) References in this Part to—

- (a) “information provided”, or an “apology made”, at an open disclosure meeting,
- (b) “additional information provided”, or “apology made”, at an additional information meeting, or
- (c) information provided in a clarification under *section 19*,

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

(3) For the purposes of *paragraph (b)* of the definition of “health services provider”, references in that paragraph to “through or in connection with” do not include the use by a health services provider referred to in that paragraph of a health service (or processes related to a health service) provided—

- (a) by a health services provider referred to in *paragraph (a)* of that definition, and
- (b) for the purpose of the provision, by a health services provider referred to in *paragraph (b)* of that definition, of health services on its own behalf (including, as the case may be, on behalf of a partnership).

Meaning of “patient safety incident”

8. In this Part, “patient safety incident”, in relation to the provision of a health service to a patient by a health services provider, means—

- (a) an incident which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient,
- (b) an incident—
 - (i) which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and

(ii) in respect of which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm,

or

(c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient.

CHAPTER 2

Open disclosure of a patient safety incident

Open disclosure of patient safety incident

9. Where a health services provider discloses, in accordance with this Part, at an open disclosure meeting, to—

- (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her,
- (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or
- (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient,

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

- (i) the information, in respect of the patient safety incident, provided to the patient or relevant person (or both of them) at the open disclosure meeting, additional information provided at the additional information meeting and information provided in a clarification under *section 19*,
- (ii) an apology, in respect of the patient safety incident, where an apology is made at that meeting, or the additional information meeting.

Open disclosure: 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 an open disclosure meeting in respect of a patient safety incident, or pursuant to the provisions specified in *subsection (3)*, the statement referred to in *section 16(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)* or *(b)* 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, or
- (vii) a person who enters into a contract or arrangement, referred to in—
 - (I) *subparagraph (v)* of *paragraph (a)* of the definition of “health services provider”, or
 - (II) *subparagraph (iv)* of *paragraph (b)* of that definition,
 with a health services provider,

in relation to that patient safety incident or a clinical negligence action which arises (whether in whole or in part) from the consequences of that patient safety 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)*, or
 - (vii) a person who enters into a contract or arrangement, referred to in—
 - (I) *subparagraph (v)* of *paragraph (a)* of the definition of “health services provider”, or
 - (II) *subparagraph (iv)* of *paragraph (b)* of that definition,

with a health services provider,

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

and

(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 patient safety incident concerned or any matter alleged which arises (whether in whole or in part) from that patient safety incident.

(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 an open disclosure meeting in respect of a patient safety incident or pursuant to the provisions specified in *subsection (3)*, the statement referred to in *section 16(5)* and the statements referred to in the provisions specified in *subsection (3)*—

(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 Act of 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,

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

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

(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 patient safety incident, 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)*.

(3) This section shall—

(a) in accordance with *section 18(10)*, apply to—

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

(ii) a statement referred to in *section 18(6)*,

and

(b) in accordance with *section 19(8)*, apply to information and statements provided in a clarification referred to in, and given under, that section.

(4) 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 open disclosure procedure and application of *section 10* to information and apology

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

(a) the procedure for making an open disclosure of a patient safety 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 Part, of information provided, and any apology made, at the open disclosure meeting, the additional information meeting, or the information provided in a

clarification under *section 19* and any statements in writing provided in respect of those meetings or that clarification.

- (2) The Minister may make guidelines in respect of the form of the statement referred to in *subsection (1)*.

CHAPTER 3

Making of open disclosure of patient safety incident

Voluntary open disclosure of patient safety incident

- 12.** Where a patient safety incident occurs in the course of the provision by a health services provider of a health service to a patient, the health services provider may make, in accordance with this Part, an open disclosure of the patient safety incident to—

- (a) the patient concerned,
 - (b) a relevant person where—
 - (i) in the opinion of the health services provider, having had regard to the age, capacity or health of the patient who is the subject of the patient safety incident, it is appropriate 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 patient safety incident to the relevant person and not to the patient,
- or
- (c) both the patient and a relevant person where—
 - (i) in the opinion of the health services provider, having had regard to the age or capacity of the patient who is the subject of the patient safety incident, it is appropriate that the open disclosure of that incident is made to both the patient and a relevant person, or
 - (ii) before the open disclosure meeting is held, the patient has requested that the health services provider makes the open disclosure of the patient safety incident to a relevant person as well as that patient.

Making of open disclosure of patient safety incident by health services provider

- 13.** (1) The open disclosure of a patient safety 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 patient safety 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 patient safety incident, or
 - (b) having had regard to the circumstances of the patient safety 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 patient safety incident shall be made by a health practitioner whom the health services provider, having considered the patient safety incident concerned, considers appropriate.

Time of making of open disclosure

- 14.** (1) Where a health services provider has reasonable grounds for believing that a patient safety incident has occurred, the health services provider concerned shall make the open disclosure of that patient safety incident at a time 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) some, or all, of the likely consequences of the patient safety incident are not present or have not developed, and
 - (ii) the health services provider does not have all of the information relating to the patient safety 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 patient safety incident concerned, and
 - (c) the requirements of *section 15*.
- (2) Having considered the appropriate time for making the open disclosure of the patient safety 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 patient safety incident is not made as soon as practicable after the consideration referred to in *subsection (2)*, nothing in this Part shall be construed as preventing *section 10* from having effect in respect of that open disclosure of the patient safety incident.
- (4) Nothing in this Part shall be construed as preventing a health services provider from making an open disclosure of a patient safety incident if none, or not all, of the likely consequences of the patient safety incident have presented or have developed.

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

15. (1) Before making an open disclosure of a patient safety 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 relevant person (or both of them) and having regard to *paragraph (a) of section 14(1)*—
 - (i) make an assessment of all the circumstances of the patient and the nature of the patient safety incident concerned, 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 (4)*, whether the open disclosure of the patient safety incident concerned 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 patient safety incident, and
 - (iii) consultations, if any, referred to in *paragraph (a)(ii)*,
 - (c) determine whether, having regard to the nature and circumstances of the patient safety incident concerned, it is appropriate for an apology to be made to the patient or the relevant person (or both of them) at the open disclosure meeting,
 - (d) consider the information relating to the patient safety 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, subject to *subsection (2)*, 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 patient safety incident (in this Part referred to as “designated person”) and in respect of a request for clarification under *section 19*, and
 - (f) make arrangements for the preparation of the statement in writing, referred to in *section 16(5)*, that is to be provided to the patient or relevant person (or both of them) at the open disclosure meeting.
- (2) For the purpose of making a designation under *subsection (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 *subparagraph (ii)* of *paragraph (a)* of that definition,
 - (iii) a person with whom that provider has entered into a contract referred to in *subparagraph (v)(II)* of *paragraph (a)* of that definition,
 - (iv) an agency health practitioner who provides a health service for that provider pursuant to an agency contract referred to in *subparagraph (iii)* of *paragraph (a)* of that definition, or
 - (v) an agency worker,
- as the designated person in relation to the patient safety incident concerned, 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 *subparagraph (ii)* of *paragraph (b)* of that definition,
 - (v) a person with whom that provider has entered into a contract referred to in *subparagraph (iv)(II)* of *paragraph (b)* of that definition,
 - (vi) an agency health practitioner who provides a health service for that provider pursuant to an agency contract referred to in *subparagraph (iii)* of *paragraph (b)* of that definition,
 - (vii) an agency worker, or
 - (viii) a partner of the health practitioner referred to in *subparagraph (i)*,

as the designated person for the purposes of *subsection (1)(e)*.
 - (3) A designation under *subsection (1)(e)* shall be in writing and shall be kept in the records, referred to in *section 21*, relating to the open disclosure of the patient safety incident made under this Part.
 - (4) *Paragraph (b)* of *subsection (1)* shall not apply where an open disclosure of a patient safety incident is made to a relevant person pursuant to *section 12(b)(ii)* or *12(b)(iii)*, as the case may be.

Open disclosure meeting

- 16. (1) A health services provider shall, subject to *section 15*, make arrangements—
 - (a) to meet with a patient or a relevant person (or both of them), or

- (b) where it is not practicable for a patient or a relevant person (or both of them) to attend at a meeting with the provider, for that patient or person (or both of them) to be contacted by telephone (or other similar method of communication),
- for the purpose of making an open disclosure of a patient safety incident in respect of which the patient, or patient to whom the relevant person is connected, is the subject (in this Part referred to as an “open disclosure meeting”).
- (2) When making an open disclosure of a patient safety incident at an open disclosure meeting, a health services provider—
- (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 open disclosure meeting is held,
- (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 patient safety incident concerned,
- (c) shall give the patient or the relevant person (or both of them) a copy of the statement in writing referred to in *subsection (5)* or, in the case of an open disclosure meeting referred to in *subsection (1)(b)*, shall deliver a copy of that statement to the patient or relevant person (or both of them) as soon as practicable after the meeting, and
- (d) shall provide the statement referred to in *section 11(1)* to the patient or relevant person (or both of them) or, in the case of an open disclosure meeting referred to in *subsection (1)(b)*, shall deliver that statement to the patient or relevant person (or both of them) as soon as practicable after the meeting.
- (3) The information referred to in *subsection (2)* to be provided in accordance with that subsection shall be as follows:
- (a) the names of the persons present at the open disclosure meeting;
- (b) a description of the patient safety incident concerned;
- (c) the date on which—
- (i) the patient safety incident occurred, and
- (ii) the patient safety incident came to the notice of the health services provider;
- (d) the manner in which the patient safety 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 patient safety incident which, at the time the open 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)*, further physical or psychological consequences of the patient safety incident are likely to present or develop, information in respect of—
 - (i) the physical or psychological consequences which, at the time the open disclosure 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 the open disclosure meeting, and
 - (ii) the physical or psychological consequences which, at the time of the open disclosure 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 the open disclosure meeting;
- (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 patient safety incident, a statement to that effect;
- (h) where, at the time of the open disclosure meeting—
 - (i) any physical or psychological consequences arising from the patient safety 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, the provider is providing to the patient to address those consequences;
- (i) having regard to the consideration, by the health services provider, of the patient safety 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 it to do so, address the knowledge the provider has obtained from its consideration of the patient safety incident and the circumstances giving rise to that incident.
- (4) Where, pursuant to *paragraph (c)* of *section 15(1)*, the health services provider has determined that an apology is to be made to the patient or the relevant person (or both of them), the health services provider concerned may, at the open disclosure meeting, make the apology to the patient or the relevant person (or both of them) in respect of that patient safety 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 the prescribed form,

- (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) specify the day on which the open disclosure of the patient safety incident was made, and
 - (e) 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 patient safety incident on behalf of the health services provider.
- (7) The health services provider shall keep, in the records referred to in *section 21*, the statement referred to in *subsection (5)*.

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

17. (1) Nothing in this Part shall require a patient or a relevant person, or where *section 12(c)* applies, both of them, to engage with the health services provider in the open disclosure of a patient safety incident.
- (2) Where a health services provider informs a patient or a relevant person that the provider proposes to hold an open disclosure meeting and the patient or relevant person does not want to attend that open disclosure meeting, the patient or relevant person shall inform that provider that he or she—
- (a) will not attend the open disclosure meeting,
 - (b) does not wish to receive the information which is to be provided at that meeting, and
 - (c) does not wish to receive, having regard to *section 14(1)(a)* and *section 14(4)*, any additional information that may be provided (or apology that may be made) pursuant to *section 18*.
- (3) Where a patient or a relevant person, or as the case may be both of them, informs a health services provider of the matters specified in *subsection (2)*, the provider shall—
- (a) set out a statement in writing, in the prescribed form, of those matters,
 - (b) sign that statement and specify the date on which it was signed,
 - (c) provide the patient, relevant person or, as the case may be, both of them with a copy of that statement which has, in accordance with *paragraph (b)*, been signed by the provider, as soon as practicable,
 - (d) maintain the statement which has, in accordance with *paragraph (b)*, been signed by the provider, in the records referred to in *section 21*, and

- (e) pursuant to that statement, not proceed to hold the open disclosure meeting.
- (4) Where, in accordance with *section 12(c)*, a health services provider informs both a patient and a relevant person that the provider proposes to hold an open disclosure meeting and both the patient and relevant person do not want to attend that open disclosure meeting, the patient and relevant person shall inform that provider that—
- (a) they will not attend the open disclosure meeting,
 - (b) they do not wish to receive the information which is to be provided at that meeting, and
 - (c) they do not wish to receive, having regard to *section 14(1)(a)* and *section 14(4)*, any additional information that may be provided (or apology that may be made) pursuant to *section 18*.
- (5) Where, in accordance with *subsection (4)*, a patient and a relevant person informs a health services provider of the matters specified in that subsection, the provider shall—
- (a) set out a statement in writing, in the prescribed form, of those matters,
 - (b) sign that statement and specify the date on which it was signed,
 - (c) provide the patient and the relevant person who has informed the provider of those matters with a copy of that statement which has, in accordance with *paragraph (b)*, been signed by the provider, as soon as practicable,
 - (d) maintain the signed statement which has, in accordance with *paragraph (b)*, been signed by the provider, in the records referred to in *section 21*, and
 - (e) pursuant to that statement, not proceed to hold the open disclosure meeting.
- (6) Where a patient, or a relevant person, refuses to accept the statement referred to in—
- (a) *paragraph (c)* of *subsection (3)*, or
 - (b) *paragraph (c)* of *subsection (5)*,
- the provider shall—
- (i) make a note in writing, in the prescribed form, of that refusal,
 - (ii) sign the note referred to in *paragraph (i)* and specify the date of signing, and
 - (iii) keep, in the records referred to in *section 21*, the note referred to in *subparagraph (i)*, which has been signed in accordance with *subparagraph (ii)*.

Provision of additional information at additional information meeting

- 18.** (1) A health services provider may, at any time after the holding of the open disclosure meeting, provide information that is additional to the information, specified in *section 16(3)*, which was, in accordance with *section 16(2)(a)*, provided to the patient or relevant person (or both of them) at the open disclosure meeting (“additional information”) that, having regard to—

- (a) *subparagraphs (i) and (ii) of paragraph (a) of section 14(1), and*
- (b) *section 14(4),*

was not available to the health services provider at the time of the making of the open disclosure of the patient safety incident and which, after that open disclosure of that incident was made, has become available and may, having regard to that additional information, make an apology, and such additional information and apology (if any) shall be provided, or made—

- (i) by the principal health practitioner who made the open disclosure of the patient safety incident in accordance with *section 13*,
 - (ii) where, pursuant to *section 13(1)(b)*, the open disclosure of the patient safety incident was made by a health practitioner referred to in *section 13(2)*, by that health practitioner, or
 - (iii) by a health practitioner referred to in *subsection (2)*.
- (2) Where additional information referred to in *subsection (1)* is, in accordance with that subsection, 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 patient safety incident—
- (a) is not available to provide that additional information (or make an apology), or
 - (b) is otherwise not in a position to provide that information (or make an apology),
- that additional information (and apology, if any) shall be provided, or made, by a health practitioner whom the health services provider considers appropriate.
- (3) A health services provider shall make arrangements—
- (a) to meet with a patient or a relevant person (or both of them), or
 - (b) where it is not practicable for a patient or a relevant person (or both of them) to attend at a meeting with the provider, for that patient or person (or both of them) to be contacted by telephone (or other similar method of communication),
- for the purpose of providing that additional information (in this Part referred to as an “additional information meeting”).
- (4) When providing the additional information referred to in *subsection (1)* at an additional information meeting, a health services provider—
- (a) shall provide the additional information in accordance with *subsection (5)*,
 - (b) may provide the additional information—
 - (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 patient safety incident concerned,
- and

- (c) shall give the patient or the relevant person (or both of them) a copy of the statement in writing referred to in *subsection (6)* or, in the case of an additional information meeting referred to in *subsection (3)(b)*, shall deliver a copy of that statement to the patient or relevant person (or both of them) as soon as practicable after the meeting.
- (5) When providing the additional information referred to in *subsection (1)*—
- (a) the health services provider shall provide the names of the persons present at the additional information meeting,
- (b) the health services provider shall have regard to the provisions of *section 16(3)* and shall specify the provisions of that section to which the additional information, provided at the additional information meeting, refers,
- (c) without prejudice to *paragraph (b)*, where having regard to the additional information provided, the health services provider has reasonable grounds for believing that further physical or psychological consequences referred to in *section 16(3)(f)*, are likely to present or develop, the health services provider shall provide further information in respect of—
- (i) any physical or psychological consequences which, at the time the additional 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
- (ii) any physical or psychological consequences which, at the time of the additional 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,
- (d) without prejudice to *paragraph (b)* and having regard to the additional information, where, at the time the additional information meeting is held—
- (i) any physical or psychological consequences arising from the patient safety incident have presented, or developed,
- (ii) the patient is under the clinical care of the health services provider concerned,
- (iii) having regard to the information referred to in *section 16(3)(h)* which was provided at the open disclosure meeting, and
- (iv) the health services provider proposes to make changes to the treatment, and relevant clinical care, the provider is providing to the patient to address those consequences,
- the health services provider shall provide information relating to those changes to the treatment and clinical care.
- (6) The statement referred to in *subsection (4)(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—

- (a) be in the prescribed form,
 - (b) set out the additional information, specified in *subsection (5)*, provided to the patient or the relevant person (or both of them) in accordance with that subsection,
 - (c) contain an apology referred to in *subsection (1)* where such apology was made,
 - (d) specify the day on which the additional information was provided to the patient or the relevant person (or both of them), and
 - (e) be signed in accordance with *subsection (7)*.
- (7) The statement in writing referred to in *subsection (6)* shall be signed by—
- (a) the principal health practitioner referred to in *subsection (1)(i)*, or
 - (b) the health practitioner referred to in *subsection (1)(ii)* or *(1)(iii)*,
- who provided the additional information to the patient or relevant person (or both of them) in accordance with this section.
- (8) The health services provider shall keep, in the records referred to in *section 21*, the statement referred to in *subsection (6)*.
- (9) Nothing in this section shall operate to prevent the additional information being provided (and an apology, if any, being made), at the additional information meeting, to—
- (a) both the patient and the relevant person where the open disclosure of the patient safety incident (and an apology, if any) was made to either of them at the open disclosure meeting, and
 - (b) a relevant person where—
 - (i) the open disclosure of the patient safety incident (and an apology, if any) was made to the patient concerned at the open disclosure meeting, and
 - (ii) the patient died subsequent to the time at which the open disclosure meeting was held.
- (10) *Section 10* shall apply to—
- (a) any information provided (or apology made) to the patient or the relevant person (or both of them) at the additional information meeting, in the same way as *section 10* applies to information provided, and an apology where it is made, at an open disclosure meeting, and
 - (b) the statement referred to in *subsection (6)* in the same way as it applies to the statement referred to in *section 16(5)*.

Clarification of information provided at open disclosure meeting and additional information provided at additional information meeting

19. (1) A patient or relevant person (or both of them) to whom an open disclosure of a patient safety incident was made, may, at any time after the open disclosure meeting, or the

additional information meeting as the case may be, make a request, to the designated person, for the clarification of—

- (a) any information provided to the patient or relevant person (or both of them) at the open disclosure meeting, or
- (b) any additional information provided to the patient or relevant person (or both of them) at the additional information meeting.

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

- (a) in the case of a request for clarification of the information provided at the open disclosure meeting, the designated person shall—
 - (i) as soon as practicable, inform the person who, pursuant to *section 13*, made the open disclosure of the patient safety 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,
- (b) in the case of a request for clarification of the additional information provided at the additional information meeting, the designated person shall—
 - (i) as soon as practicable, inform the person who, pursuant to *section 18*, provided the additional 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
 - (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,
- (c) in the case of a request for clarification of the information provided at the open disclosure meeting, the person who, pursuant to *section 13*, made the open disclosure of the patient safety incident at the open disclosure meeting, or where the conditions referred to in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, shall—
 - (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 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)*,
- (d) in the case of a request for clarification of additional information provided at an additional information meeting, the person who, pursuant to *section 18*, provided the additional information at the additional information meeting, or where the conditions in *subsection (4)* are satisfied, a health practitioner referred to in that subsection, shall—

- (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 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)*,and
- (e) the designated person shall—
 - (i) set out, in a statement in writing, in the prescribed form—
 - (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 21*, the statement in writing referred to in *subparagraph (i)*.
- (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 patient safety incident at the open disclosure meeting, the person who, pursuant to *section 18*, provided the additional information at the additional 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—
 - (a) may provide that clarification orally, and
 - (b) shall give a copy of the statement in writing referred to in *subsection (5)* to—
 - (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 patient safety incident at the open disclosure meeting, or
 - (b) pursuant to *section 18*, provided the additional information at the additional 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 patient safety incident concerned, considers appropriate.

- (5) The statement in writing 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) be in the prescribed form,
 - (b) set out the information provided in the clarification,
 - (c) specify the date on which the clarification was provided to the persons referred to in *subsection (3)*, and
 - (d) be signed in accordance with *subsection (6)*.
- (6) The statement in writing 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 21*, the statement in writing 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 an open disclosure meeting or an additional 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 16(5)*.

Failure to contact patient for purpose of open disclosure of patient safety incident

20. (1) Where—

- (a) pursuant to *section 16(1)*, a health services provider is unable to contact a patient for the purpose of arranging an open disclosure meeting on the basis of the contact information provided to it by the patient, and
- (b) the open disclosure of the patient safety incident is to be made to the patient in accordance with *section 12(a)*,

the health services provider concerned shall take all steps reasonably open to the provider to establish contact with the patient for the purpose of arranging the open disclosure meeting.

(2) Where—

- (a) pursuant to *section 16(1)*, a health services provider is unable to contact a relevant person for the purpose of arranging an open disclosure meeting on the basis of the contact information provided to it by the patient or relevant person, and

(b) the open disclosure of the patient safety incident is to be made to the relevant person in accordance with *subparagraph (i), (ii) or (iii) of paragraph (b) of section 12*,

the health services provider concerned shall take all steps reasonably open to the provider to establish contact with the relevant person for the purpose of arranging the open disclosure meeting.

(3) Where—

(a) pursuant to *section 16(1)*, a health services provider is unable to contact a patient and relevant person for the purpose of arranging an open disclosure meeting on the basis of the contact information provided to it by the patient or relevant person, and

(b) the open disclosure of the patient safety incident is to be made to both the patient and the relevant person in accordance with *subparagraph (i) or (ii) of paragraph (c) of section 12*,

the health services provider concerned shall take all steps reasonably open to the provider to establish contact with the patient and relevant person for the purpose of arranging the open disclosure meeting.

(4) A health services provider shall—

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

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

(c) keep, in records referred to in *section 21*, the statement referred to in *paragraph (a)*, which has been signed in accordance with *paragraph (b)*.

(5) 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 having regard to the health service being provided to the patient 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.

Records relating to open disclosure of patient safety incident

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

(a) a copy of the designation referred to in *section 15(3)*,

(b) the statement in writing referred to in *section 16(7)*,

(c) the statement referred to in *section 17(3)(d) or section 17(5)(d)*, as the case may be,

(d) the note referred to in *section 17(6)(iii)*,

- (e) the statement in writing referred to in *section 18(8)*,
 - (f) the statement in writing—
 - (i) of a request referred to in *section 19(2)(e)*, and
 - (ii) referred to in *section 19(7)*,and
 - (g) the statement referred to in *section 20(4)(c)*.
- (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.

Regulations

- 22.** (1) The Minister may by regulations provide for any matter referred to in this Part as prescribed or to be prescribed.
- (2) Without prejudice to any provision of this Part, regulations under this section 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 Part 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.

Savings and transitional provisions for this Part

- 23.** (1) This Part shall apply to the making of an open disclosure of a patient safety incident by a health services provider on or after the coming into operation of this Part.
- (2) Where a patient safety incident occurred, or came to the notice of a health services provider, before the day on which this Part comes into operation, a health services provider may, on or after the coming into operation of this Part, make an open disclosure of that incident in accordance with this Part.
- (3) For the purposes of making an open disclosure of a patient safety incident pursuant to *subsection (2)*, the reference in *section 14(1)(a)* to “as soon as practicable” shall be construed as being as soon as practicable after the coming into operation of this Part.