

**General Scheme**

**of**

**PATIENT SAFETY BILL 2018**

**A Bill to provide for mandatory open disclosure of serious reportable patient safety incidents, notification of reportable incidents, clinical audit to improve patient care and outcomes and extend the Health Information Quality Authority remit to private health services**

**5 July 2018**

## **ARRANGEMENT OF HEADS**

### **Part 1: Preliminary Matters**

1. Short title and commencement
2. Interpretation –General
3. Regulations
4. Expenses

### **Part 2: Patient Safety Incidents**

5. Mandatory open disclosure
6. Mandatory open disclosure procedure of a patient by a health services provider
7. Mandatory open disclosure: information and apology not to invalidate insurances; constitute admission of liability or fault; or not be admissible in proceeding
8. Reportable incidents
9. Notification of reportable incidents
10. Standards set by the Authority and Commission on notification of patient safety incidents
11. Notification of patient safety incidents
12. Functions of the Agency under this Part
13. Information on the functions of the Agency under this Part
14. Freedom of Information
15. Patient safety incidents notifications not admissible in certain civil proceedings.
16. Saver

### **Part 3: Clinical Audit**

17. Interpretation – Part 3
18. Minister shall issue guidance for the purposes of this Part
19. Publication of aggregate clinical audit results
20. Freedom of Information
21. Evidence
22. Saver for this Part

### **Part 4: Amendment of Health Act 2007 (HIQA Remit Extension)**

23. Amendment of section 2 of the Act of 2007 (Interpretation)
24. Amendment of section 8 of the Act of 2007 (Functions of Authority)
25. Amendment of section 9 of the Act of 2007 (Investigations by Authority)
26. Amendment of section 10 of the Act of 2007 (Standards set by Authority)
27. Amendment of section 12 of the Act of 2007 (Provision of Information to the Authority)
28. Amendment of section 73 of the Act of 2007 (Right of entry and inspection by authorised person or Chief Inspector)
29. Amendment of section 74 of the Act of 2007 (Requirement for consent of occupier or District Court warrant to enter dwelling)
30. Amendment of section 78 of the Act of 2007 (Reports of authorised person, the Chief Inspector and inspectors)
31. Insertion of section 98A in the Act of 2007 – new regulation making power to prescribe privately provided services to come within HIQA’s standard setting, monitoring and investigative remit.

### **Part 5: Offences**

### **Part 6: Miscellaneous**

## **PART 1: PRELIMINARY MATTERS**

### **Short title and commencement**

#### **Head 1. Provide that:**

(1) This Act may be cited as the Patient Safety Act 201X.

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

#### ***Explanatory Note***

This is a standard provision.

### **Interpretation -General**

#### **Head 2. Provide that:**

In this Act-

“*Act of 1988*” means the Data Protection Act 1988;

“*Act of 2000*” means State Claims Agency under National Treasury Management Agency (Amendment) Act 2000;

“*Act of 2007*” means the Health Act 2007;

“*Act of 2014*” means the Freedom of Information Act 2014;

“*Act of 2017*” means Civil Liability (Amendment) Act 2017;

“*Act of 2018*” means the Data Protection (Amendment) Act 2018;

“*Authority*” means the Health Information and Quality Authority established by the Health Act 2007;

“*Agency*” means the State Claims Agency under the National Treasury Management Agency (Amendment) Act 2000;

“*apology*”, in relation to open disclosure if a patient safety incident, means an expression of sympathy or regret as in the Act of 2017;

“*Chief Inspector of Social Services*” means the person who is appointed to the office of the Chief Inspector of Social Services in accordance with section 40 of the Act of 2007;

“*Child and Family Agency*” means the Child and Family Agency established in accordance with section 7 of the Child and Family Agency Act 2013;

“*Commission*” means the Mental Health Commission established under section 32 of the Mental Health Act 2001;

“*Commissioner*” has the meaning assigned to it by section 9 of the Act of 1988;

“*designated centre*” means a designated centre as defined in section 2(1) of the Act of 2007;

“*Executive*” means the Health Service Executive established by the Health Act 2004;

“*health practitioner*” means-

- (a) a registered medical practitioner within the meaning of the Act 2007 or a medical practitioner practising medicine pursuant to section 50 of that Act,
- (b) a registered dentist within the meaning of the Dentists Act, 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 Nurses and Midwives Act, 2011,
- (f) a registrant within the meaning of section 3(1) of the Health and Social Care Professionals Act, 2005, or
- (g) a person whose name is entered in the register referred to in Article 4(s) of the Pre-Hospital Emergency Care Council (Establishment) Order, 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- by or under the direction of a health services provider for-

- (a) for-
  - (i) the screening, preservation or improvement of 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 the purpose-
  - (i) employs a health practitioner for the provision (weather 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 (weather for, or on behalf of, that person) by the 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, 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 a mandatory open disclosure” shall be construed in accordance with section 9 of the Civil Liability (Amendment) Act 2017;

“*mandatory open disclosure*” means the required disclosures of any serious patient safety incident that is any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service;

“*mental health services*” means mental health services as defined in section 2(1) of the Mental Health Act 2001;

“*Minister*” means the Minister for Health;

“*open disclosure*” means as detailed in the Civil Liability (Amendment) Act 2017;

“*patient safety incident*” shall be construed in accordance with section 8 of the Civil Liability (Amendment) Act 2017;

“*personal data*” has the same meaning as in the Data Protection Act 2018;

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

“*record*” has the same meaning as in the Act of 2014;

“*registered provider*” means a registered provider as defined in section 2(1) of the Act of 2007;

“*relevant body*” means-

- (a) the Executive,
- (b) the Child and Family Agency,

(c) a service provider who is a State authority under the National Treasury Management (Amendment) Act 2000;

“*relevant provider*” means-

- (a) a relevant body,
- (b) a person providing mental health services,
- (c) a registered provider;

“*reportable incident*” means a patient safety incident prescribed by the Minister under Head 5 of the Act;

“*service provider*” means a service provider as defined in section 2(1) of the Act of 2007;

“*service user*” means a person who receives or received a health service;

“*standards*” means standards jointly set by the Authority and the Commission and approved by the Minister as referred to in *Head 10* of the Act;

“*State authority*” means a State authority as defined in section 7(1) of the National Treasury Management (Amendment) Act 2000.

### ***Explanatory Note***

The Commission on Patient Safety and Quality Assurance provided a framework for the improvement of patient safety and quality in the Irish health service. In this respect, a number of its recommendations focus on the development of quality improvement learning systems. The Commission recommended that provision should be made for the mandatory reporting of adverse events which result in death or serious harm to the appropriate regulatory body. In addition, the Commission recommended that provision be made for (voluntary) reporting of other less serious adverse events and ‘near-misses.’ Many adverse events and poor outcomes in healthcare arise from several service wide factors acting together, with such incidents rarely attributable to shortcomings or failures on the part of particular individuals. However, the Commission recognised that fear of litigation and damage to professional reputation presents a significant challenge for professionals in engaging with incident reporting, open disclosure and audit processes. This is supported by international experience.

To build a positive culture of participation that would benefit patients and the health services as a whole, the Commission recommended that legislation should be introduced providing for (a) exemptions from FOI legislation for records arising from these specific activities and (b) protections for these records from admissibility as evidence in civil proceedings. These protections do not preclude the taking of disciplinary or regulatory proceedings through other routes. Criminal proceedings are not affected. Part 4 of the Civil Liability (Amendment) Act 2017 provides legal and liability protections for health service staff engaging in the open disclosure of patient safety incidents. That in relation to information and / or an apology by the health service provider, sets out that, it shall not constitute an expressed or implied admission of fault or liability.

Access by individuals, under FOI, to their own medical records is unaffected, as is the use of medical records in civil liability cases.

Part 2 (Head 5) of the current Bill provides for the mandatory open disclosure of serious patient safety incidents. In addition, it defines a patient safety incident as an unintended or unexpected incident of harm that occurred in the provision of a health service. Under Head 5(3), the Minister is empowered to prescribe by regulation those serious patient safety incidents that are subject to mandatory open disclosure.

Part 2 of the Bill, in addition provides that health service providers (public and private) must also notify those serious patient incidents and reportable incidents, which require mandatory open disclosure, occurring in their services to the State Claims Agency and either to the Health Information and Quality Authority (HIQA) or the Mental Health Commission, as appropriate. The Child and Family Agency (Tusla) will also notify the State Claims Agency of reportable incidents it becomes aware of occurring in services provided on behalf of Tusla.

Any private health service providers regulated by HIQA/the Chief Inspector of Social Services (e.g. private nursing homes) must notify the Chief Inspector of serious incidents. Private providers of mental health services will be required to notify the Mental Health Commission of serious incidents.

Less serious incidents and near misses may also be reported by public providers to the State Claims Agency. In the case of Tusla, this will also include less serious incidents and near misses it becomes aware of in services provided on its behalf.

HIQA and the Mental Health Commission will jointly set standards for notifications and the intention is that notifications made in line with these standards will have the protections recommended by the Commission on Patient Safety and Quality Assurance.

Requirements in this Part of the Bill supplement existing obligations by State authorities (including the public health service) to report adverse incidents to the State Claims Agency under section 11 of the National Treasury Management (Amendment) Act 2000 and arrangements for incident reporting by providers to the Chief Inspector of Social Services or the Mental Health Commission arising from the Health Act 2007 and the Mental Health Act 2001.

Head 2 sets out key definitions. “Patient safety Incident” in relation to a relevant provider is defined to include unintended or unanticipated injury or harm to a service user, incidents that could have caused harm, but did not (no harm incidents) and incidents that were prevented from happening due to timely intervention or chance (near misses).

“Relevant provider” is intended to cover public and private health service providers. It means a relevant body (the public health service providers), public and private providers of mental health services regulated by the Mental Health Commission and registered providers of residential services under the Health Act 2007. These registered providers would include the HSE, voluntary bodies and providers of private nursing homes.

As outlined above, “relevant body” is designed to encompass public health service providers and means the HSE, Tusla and service providers as defined in the Health Act 2007 (i.e.



persons providing services on behalf of the HSE or Tusla) but only those service providers which are also within the remit of the State Claims Agency.

The definition of “designated centre” relates to residential services for older people (including private nursing homes), children and people with disabilities. The Health Act 2007 provides for the registration and inspection of these services.

“Mental health services” has the same meaning as it does under the Mental Health Act 2001 and includes public and private providers.

“Health service” is broadly defined.

“Health services provider” is intended to cover public and private health services and those who operate in both the private and public sides whether providing health services through a company, partnership or on their own. For example, it includes the HSE, section 38 service providers, private hospitals and a general practitioner with an exclusively private practice or a mix of private and public patients.

## **Regulations**

### **Head 3. Provide that:**

(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 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 has sat after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done under the regulation.

### ***Explanatory Note***

This is a standard provision.

## **Expenses**

### **Head 4. Provide that:**

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, be paid out of moneys provided by the Oireachtas.

### ***Explanatory Note***

This is a standard provision.

## PART 2: PATIENT SAFETY INCIDENTS

This Part of the Bill is concerned with the mandatory open disclosure and notification of serious patient safety incidents.

### Mandatory open disclosure

#### Head 5. Provide that:

- (1) Serious patient safety incidents that shall be subject to “mandatory open disclosure”.
- (2) In this Section serious patient safety incidents means any unintended or unexpected incident or harm that occurred in the provision of a health service including:
  - (a) the death of the person,
  - (b) a permanent lessening of bodily, sensory, motor, physical or intellectual functions (including removal of the wrong limb or organ or brain damage) (“severe harm”),
  - (c) harm which is not severe harm but which results in—
    - (i) an increase in the person’s treatment,
    - (ii) changes to the structure of the person's body,
    - (iii) the shortening of the life expectancy of the person,
    - (iv) an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days,
    - (v) the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days,
  - (d) the person requiring treatment by a health practitioner in order to prevent—
    - (i) the death of the person, or
    - (ii) any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned in paragraph (b) or (c).
- (3) Serious patient safety incidents shall include, but not be limited to, such serious patient safety incidents as may be prescribed by the Minister by regulation under this section.

#### *Explanatory Note*

Head 5(1) provide that serious patient safety incidents will be subject to mandatory open disclosure. Mandatory open disclosure will be made in line with the provisions for open disclosure as set out in Part 4 of the Civil Liabilities (Amendment) Act 2017, following the same procedures and providing the same protections to create a culture of openness, transparency and an opportunity for learning across the whole health system. Head 5 (2, a, b, c, d) is modelled on the approach taken by the UK Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 (Duty of Candour) and within Scottish Legislation, the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016.

Examples of serious patient safety incidents include wrong site surgery, patient death or serious disability associated with a medication error, death or associated disability associated with a diagnostic error, serious errors that emerge in screening programmes, maternal death, perinatal death of a neonate occurring in a term infant, stillbirths, patient death or serious disability due to the administration of incompatible blood or blood products etc.

Note: The list in Head 5 (2) is not limited to this list and the Minister will have the ability to prescribe, address or modify any Regulations to detail those serious incidents requiring mandatory open disclosure that may evolve over time.

Head 5 gives the Minister the power to prescribe patient safety incidents that require “mandatory open disclosure”. These will be actual events of a serious nature or no harm events that potentially could have been serious. They will not include near misses although they may be reported to the State Claims Agency.

### **Mandatory open disclosure procedure of a patient safety incident by health services provider**

#### **Head 6. Provide that:**

The procedure for making an open disclosure as provided for in Part 4 of the Act of 2017 shall apply to the making of a mandatory open disclosure under this Act and references to open disclosure procedures in that Part shall be construed as a reference to mandatory open disclosure for the purposes of this Section.

#### **Explanatory Note**

Head 6 provides that the procedure for making a mandatory open disclosure of a serious patient safety incident is to be in line with the Civil Liabilities (Amendment) Act 2017. The Civil Liabilities (Amendment) Act 2017 provides that when a health services provider discloses an incident in accordance with the Act, information and / or an apology where made does not invalidate insurance, constitute admission of liability or fault, nor is it admissible in proceedings. These same protections in Head 7 of the Act of 2017, will therefore apply to occasions requiring mandatory open disclosure.

### **Mandatory open disclosure: information and apology not to invalidate insurance; constitute admission of liability or fault; or not be admissible in proceeding.**

#### **Head 7. Provide that:**

Section 10 of the Act of 2017 shall apply to the making of a mandatory open disclosure under this Act and references to open disclosure in that Section shall be construed as a reference to mandatory open disclosure for the purposes of this Section.

#### **Explanatory Note**

The Civil Liabilities (Amendment) Act 2017 (Prescribed Forms) Regulations 2018 are currently being drafted. The Minister has the power to prescribe new regulations for mandatory open disclosure or adapt the current regulations for open disclosure. Part 4 of the Civil Liabilities Act 2017 covers, for example, notification by a health practitioner, the apology to be provided, actions taken by the responsible person, meetings with the patient and the provision of information, the form and manner of the information provided, training to be undertaken etc.

## **Reportable incidents**

### **Head 8. Provide that:**

(1) Serious patient safety incidents prescribed by the Minister under Section 5 (3) shall be reportable incidents.

### ***Explanatory Note***

The Madden Commission Report on Patient Safety and Quality Assurance considered that the system for reporting adverse events must clearly delineate the events which must be reported. This will be done through Ministerial regulations which will specify “reportable incidents” which must be reported to the relevant reporting authority. This detailed listing will make it clear what must be reported.

Head 8 gives the Minister the power to prescribe those patient safety incidents which are also to be reportable incidents. These will be actual events of a serious nature or no harm events that potentially could have been serious. They will not include near misses although as indicated earlier these may be reported to the State Claims Agency (Head 11).

## **Notification of reportable incidents**

### **Head 9. Provide that:**

(1) A relevant body shall notify the Agency of a reportable incident as soon as the body becomes aware of the incident and, in any event, not later than 7 days after becoming so aware and, in the case of the Child and Family Agency, this shall include a reportable incident occurring in a service provided by a service provider on behalf of the Child and Family Agency.

(2) The Executive shall notify the Authority of a reportable incident (not being a reportable incident relating to services at a designated centre) as soon as the Executive become becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(3) A registered provider of a designated centre shall notify the Chief Inspector of Social Services of a reportable incident relating to services at a designated centre as soon as the registered provider becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(4) A person providing mental health services shall notify the Commission of a patient safety incident relating to mental health services as soon as the person becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(5) A notification under this Head shall be made in accordance with standards set by the Authority and the Commission under *Head 10*.

(6) A reporting authority shall acknowledge receipt of a notification under this Head.

(7) In this Head, reporting authority means-

- (a) the Agency,
- (b) the Authority,
- (c) the Chief Inspector of Social Services,
- (d) the Commission.

### ***Explanatory Note***

Through Ministerial regulations, those “reportable incidents” which must be reported to the relevant reporting authority and those that require “mandatory open disclosure” will be specified. This detailed listing will make it clear what must be reported under “mandatory open disclosure”. A patient safety incident in relation to a relevant provider, means-

- (a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service,
- (b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm,

Head 9 places obligations on persons to notify “reportable incidents”. The authorities to which incidents must be notified are the State Claims Agency and the relevant regulator. These are HIQA, the Chief Inspector of Social Services in the case of residential services and, in the case of mental health services, the Mental Health Commission. Where a notification is received under this Head, the regulator will be in a position to take action as it considers appropriate under its own legislation.

Notifications must be made within seven days of the provider becoming aware of the incident.

Under subhead (1), the HSE, Tusla and service providers who are State authorities under the National Treasury Management (Amendment) Act 2000 must notify the State Claims Agency of a reportable incident. Tusla must also notify the State Claims Agency of reportable incidents occurring in services provided on its behalf, where it becomes aware of the incident. Under subhead (3), the HSE must notify HIQA of reportable incidents other than reportable incidents in designated centres or in mental health services. These will be reported to the Chief Inspector of Social Services and the Mental Health Commission respectively. Under subhead (4), registered providers of designated centres (these providers may be the HSE, service providers under the Health Act 2007 or owners of private nursing homes), must notify the Chief Inspector of Social Services of reportable incidents in designated centres.

Under subhead (5) persons providing mental health services must notify reportable incidents to the Mental Health Commission.

Subhead (6) provides that notifications must be made in line with standards set by HIQA and the Commission.

Subhead (7) requires reporting authorities to acknowledge receipt of notifications under this Head.

Subhead (8) defines the reporting authorities as the State Claims Agency, HIQA, the Chief Inspector of Social Services and the Mental Health Commission.

### **Standards set by the Authority and the Commission on notification of patient safety incidents.**

#### **Head 10. Provide that:**

- (1) The Authority and the Commission shall jointly set standards-

(a) for relevant bodies in relation to the notification of patient safety incidents to the Agency pursuant to *Head 7 or Head 8*,

(b) for relevant providers in relation to the notification of reportable incidents to the Authority, the chief inspector of social services and the Commission pursuant to *Head 7*,

and different standards may be set in relation to different types of incidents.

(2) Without limiting the generality of *Head 3*, the Minister may make regulations respecting procedures to be followed by the Authority and the Commission in setting standards under this Head including but not limited to regulations respecting-

(a) publication of any proposed standards,

(b) consultations in relation to the standards,

(c) the consultation period, and

(d) the publication of the standards after their approval by the Minister.

(3) After considering any representations made in relation to any standards proposed by the Authority and Commission and after making any changes the Authority and Commission think fit, they shall submit the proposed standard to the Minister for approval.

### ***Explanatory Note***

The Bill envisages that there will be two standard setting bodies for this Part of the Bill: HIQA and the Mental Health Commission. *Head 10* provides for HIQA and the Mental Health Commission to jointly set standards on the notification of reportable incidents and other patient safety incidents. Standards will require Ministerial approval.

Subhead (2) provides that without limiting the generality of Head 3 of the Bill – the Head that deals with the making of regulations under the Patient Safety Bill - the Minister may make regulations respecting procedures to be followed by the Authority and Commission in setting standards under this Head including but not limited to regulations respecting-

(a) publication of any proposed standards,

(b) consultations in relation to the standards,

(c) the consultation period, and

(d) the publication of the standards after their approval by the Minister.

Under subhead (3), HIQA and the Commission will submit the proposed standards to the Minister for approval after they have considered any representations made making any changes they consider appropriate.

### **Notification of patient safety incidents**

#### **Head 11. Provide that:**

Without prejudice to section 11 of the National Treasury Management (Amendment) Act 2000, a relevant body may notify the Agency of a patient safety incident that is not a reportable incident, and in the case of the Child and Family Agency, this may include a reportable incident occurring in a service provided by a service provider on behalf of the Child and Family Agency.

#### ***Explanatory Note***

As set out earlier, in addition to events causing injury or harm, patient safety incident is defined to include near misses and no harm incidents. Learning can be gained from these. Head 11 in association with Heads 14 and 15 is designed to support notifications of these incidents to the State Claims Agency. In this way, information will be available on serious incidents, incidents that are less serious, no harm incidents and near misses.

### **Functions of the Agency under this Part.**

#### **Head 12. Provide that:**

(1) The functions of the Agency, under this Part, are to-

(a) promote, through such measures as it thinks appropriate, patient safety awareness in relevant bodies,

(b) compile, analyse, disseminate and publish information derived from patient safety incidents notified to it under *Head 10(1)* or *Head 11*, including extracting and analysing trends of any matter that appears relevant to patient safety,

(c) disseminate or publish, as it sees fit, information and analysis on specific or general issues of patient safety.

(2) In disseminating or publishing information under *subhead (1)*, the Agency shall not disclose personal data relating to any individual without the consent of the individual concerned.

(3) This Head is without prejudice to any functions and powers of the Agency under the National Treasury Management Agency (Amendment) Act 2000 and any other enactments.

#### ***Explanatory Note***

Head 12 is concerned with ensuring that learning from patient safety incidents notified to the State Claims agency under Heads 10 and 11 is disseminated.

Subhead (1) sets out the functions of the Agency under this part. The Agency will (a) promote patient safety awareness in relevant bodies, (b) compile, analyse, disseminate and

publish information derived from patient safety incidents notified to it, including extracting and analysing trends of any matter that appears relevant to patient safety and (c) disseminate or publish, as it sees fit, information and analysis on specific or general issues of patient safety.

Subhead (2) provides that in disseminating or publishing information, under subhead (1), the Agency shall not disclose personal data relating to any individual without consent.

The Agency already has functions under section 8 of the National Treasury Management Agency (Amendment) Act 2000 in relation to advising and assisting State authorities. Subhead (3) provides that this Head is without prejudice to the State Claims Agency in regard to their functions and powers under the National Treasury Management Agency (Amendment) Act 2000 and any other enactments.

### **Information on the functions of the Agency under this Part**

#### **Head 13. Provide that:**

(1) Subject to *subhead (2)*, the Agency shall publish information in relation to the performance of its functions under this Part.

(2) Information on patient safety incidents notified to the Agency pursuant to *Head 8* and *Head 9* may not be published in a manner that particulars relating to any identifiable individual are ascertainable without the consent of the individual concerned.

#### ***Explanatory Note***

This Head provides for the State Claims Agency to make information available on the performance of its functions. Information relating to an identifiable individual will not be published unless the individual has given his or her consent.

### **Freedom of Information**

#### **Head 14. Provide that:**

(1) Subject to *subhead (2)*, section 6 of the Act of 2014 shall not apply to a record that is a notification under *Head 10* or *Head 11* made in accordance with standards set under *Head 69*.

(2) *Subhead (1)* shall not apply where the request for access under section 6 is by an individual whose personal information is contained in a notification.

#### ***Explanatory Note***

Head 14 provides that the provisions of the FOI legislation (including Access to Records under section 6) will apply to records created under this Part of the Bill with one exception: namely, that third party access (where it might otherwise arise), for example, the media, will not be available in respect of notifications made under Heads 13 or 14, where the notification is made in accordance with standards set under Head 12. This provision is intended to ensure that the rights of individuals to access information relating to them under FOI will continue to apply fully while at the same time incentivising, from a public interest perspective, healthcare providers to notify patient safety incidents so that greater knowledge can be gained about the number and nature of such incidents.



## **Patient safety incident notifications not admissible in certain civil proceedings**

### **Head 15. Provide that:**

A notification under *Head 9* or *Head 11* made in accordance with standards set under *Head 10* is not admissible in evidence in any civil proceedings (whether by discovery or otherwise) as evidence of the liability of a health and social care provider (including any employee or agent of the provider acting in the capacity of employee or agent) in connection with any injury, harm or death alleged to have been caused by the health and social care provider.

### ***Explanatory Note***

The intention here is to provide that notifications under Head 9 (reportable incidents) or Head 11 (other patient safety incidents) made in accordance with joint HIQA/MHC standards are not admissible as evidence in civil proceedings relating to liability for injury or death. They would be admissible in evidence for other civil proceedings and in criminal proceedings.

This provision has the same purpose as the FOI provision in Head 14: that is to encourage notification of patient safety incidents. Any documents or reports created in the course of investigating an incident are not covered by the exemption and will be subject to the normal rules of evidence.

## **Saver**

### **Head 16. Provide that:**

- (1) Nothing in this Part shall be construed as-
  - (a) diminishing or removing any obligations on a person who makes a notification under *Head 9* or *11* to comply with any other laws,
  
  - (b) limiting or removing any other protection available in law for the reporting of matters covered by this Part.

### ***Explanatory Note***

Provisions in this Part are not intended to interfere with other obligations by persons to notify incidents to the State Claims Agency, the Mental Health Commission or to the Chief Inspector of Social Services. Nor are they intended to interfere with obligations to make reports to any other agencies.

Head 16 is therefore intended to prevent the reduction or removal of any obligations on a person who makes a notification under Head 9 or 11 to comply with any other laws. It is also intended to prevent the limiting or removal of any other protection available in law for the reporting of matters covered by this Bill.

## **PART 3: CLINICAL AUDIT**

Clinical Audit is a process to improve patient care and outcomes.

### **Interpretation – Part 3**

#### **Head 17. Provide that:**

For the purposes of this Part:

“*clinical audit*” means a process to improve patient care and outcomes-

- (a) involving a documented, structured and systematic review and evaluation, against clinical standards, or clinical guidelines, referred to in *Head 18(3)(c)*, of clinical care, and, where necessary, actions to improve clinical care, and
- (b) carried out by or on behalf of or in association with one or more health services providers;

“*guidance*” means guidance issued *Head 18*;

“*record*” has the same meaning as in the Act of 2014.

#### ***Explanatory Note***

Head 2 defines terms used in this Part of the Bill.

Clinical audit is part of the clinical governance agenda and is intended to provide the evidence for assuring the quality of clinical care and helping to bring about improvements where necessary.

Clinical care should be interpreted in its broadest sense, providing for specific clinical circumstances across the entire clinical system. Accordingly, clinical care is not confined to the care delivered at the hospital bedside but includes, for example, diagnostic laboratory services or health promotion services provided by public health nurses in the community.

Clinical audit can look at the structures of care, the processes of delivering care (including, for example, clinical handover arrangements) or the outcome for individuals having received that care. Ultimately, it is about improving care or outcomes through review, evaluation and action for improvement in clinical practice, where indicated.

Clinical audit is a cyclical process, recognised as having the following elements:

- a commitment to quality improvement and learning,
- measurement - measuring a specific element of clinical practice,
- comparison - comparing results with an accepted benchmark, these are national or international clinical standards, or clinical guidelines
- evaluation and action - reflecting the outcome of audit and where indicated, changing practice accordingly (sometimes referred to as “closing the loop”).

The definition in Head 17 envisages clinical audit undertaken by a health services provider (for example, a hospital) either alone or with other providers and also envisages that the

clinical audit may be carried out “in association with” meaning by other persons on behalf of the provider(s). Such other persons may consist, for example, of an academic partner institution or one of the professional colleagues.

The definitions of health services and health services provider set out in Head 2 are applicable to this Part.

**Minister shall issue guidance for the purposes of this Part**

**Head 18. Provide that:**

(1) The Minister shall establish a process for consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, the Minister shall issue guidance applicable to clinical audit to which this Part applies.

(2) Different guidance may be issued in relation to different categories of health service providers.

(3) Without prejudice to the generality of *subhead (1)*, such guidance shall cover-

(a) the governance framework to be adopted for clinical audit,

(b) the methodology to be used in carrying out clinical audit,

(c) (i) the identification of the relevant clinical standard, or clinical guideline to be used in carrying out clinical audit, or (ii) in the absence of such a clinical standard, or guideline, in any case, the process to be followed by the persons intending to carry out the clinical audit in setting the clinical standard, or clinical guideline that should be used in carrying out the clinical audit concerned.

(4) The Minister shall establish a process for consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, the Minister may amend or withdraw any guidance issued under *subhead (1)*.

(5) The Minister, where he or she issues guidance under *subhead (1)* or amends or withdraws any guidance issued under *subhead (3)*, shall publish on an internet website that he or she maintains-

(a) the guidance issued and any amendments thereto, and

(b) where the guidance or amended guidance has been withdrawn, a notification to that effect.

***Explanatory Note***

Subhead (1) requires the Minister to issue guidance on carrying out clinical audit and to establish a process for consulting with such persons, if any, as he or she considers appropriate. Later Heads provide that FOI exemptions and legal protections will not apply to clinical audit which has not been carried out in accordance with Ministerial guidance and other requirements under this Part.

It is expected that the National Clinical Effectiveness Committee (NCEC) will play an important role in advising the Minister on guidance to be issued and updated. The NCEC is a

group of key stakeholders which was established on a non-statutory basis as part of the Patient Safety First Initiative and its mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise patient and service user care.

Under subhead (2), the Minister may issue different guidance in relation to different categories of health services provider.

While not limiting guidance that may be issued, subhead (3) provides that guidance may encompass the governance framework (see below), the methodology to be used in carrying out the audit, and the identification of relevant clinical standards, or clinical guidelines (including the process for establishing such a standard, or guideline, where one does not exist) –the purpose of the guidance is to ensure quality and consistency of the audit.

The governance framework will detail the necessary structure, process and outcome criteria that are required for formalised oversight, accountability and compliance of the clinical audit with the guidance to achieve its objectives. The process for identifying potential clinical standards and determining the most appropriate clinical standards, or clinical guidelines to use in the audit will also be explicit in the guidance. In limited cases where there is an absence of clinical standard(s) for the topic of interest, the guidance will make explicit how the clinical standard(s), or clinical guideline (s) can be established.

Guidance can be amended or withdrawn, in the light of experience gained with issued guidance or evolving national or international evidence – subhead (4).

Subhead (5) requires the Minister to publish any guidance and any changes to the guidance on the Internet – this will be the Department of Health website.

## **Publication of aggregate clinical audit results**

### **Head 19. Provide that:**

(1) The Minister shall, after consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, specify the timing, frequency, format and method of publication of aggregate results of clinical audit to which this Part applies.

(2) The timing, frequency, format or method of publication specified under *subhead (1)* may differ in relation to different categories of health service providers.

(3) A publication under this Head shall not contain personal data.

(4) The Minister may, after consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, amend or withdraw a specification referred to in *subhead (1)*.

(5) The Minister, where he or she specifies a matter under *subhead (1)* or amends or withdraws any specification under *subhead (4)*, shall publish on an internet website that he or she maintains-

- (a) the specification and any amendments thereto, and
- (b) where the specification or amended specification has been withdrawn, a notification to that effect.

### ***Explanatory Note***

The Commission on Patient Safety and Quality Assurance said that if clinical audit is to be granted FOI exemption or legal privilege, aggregated information must be published on the results of the audit. Later Heads therefore provide for this publication requirement if the FOI exemption and legal protection are to be given.

Aggregate results are essentially findings from the clinical audit presented in a statistical format.

Subhead (1) requires the Minister to specify the timing, frequency format and method of publication of aggregate information after having consulted with such persons as he or she deems appropriate. The intention is that published information on the results could cover a number of providers, giving a national, regional or local picture of the outcome of the audit.

The information would give an overview of performance and show how any deficits are addressed. However, given that clinical audit is a cyclical process, the specifications in relation to timing, frequency format and method of publication of aggregate information is to ensure that publication does occur within the cycle.

Subhead (2) allows the Minister to specify different arrangements for different categories of providers. As this Head is concerned with aggregate data, subhead (3) provides that publications under this Head cannot contain personal data. It will separately be open to a person carrying out a clinical audit to publish information in relation to a clinical audit that identifies an individual in line with the Data Protection Acts and the General Data Protection Regulation.

Subheads (4) and (5) deal with publication by the Minister of his or her specifications on the timing, frequency and format of clinical audit aggregated data, and any amendments to those specifications.

### **Freedom of Information**

#### **Head 20. Provide that:**

(1) Subject to *subhead (2)*, the Act of 2014 shall not apply to a record that is created solely for the purpose of clinical audit where-

(a) the clinical audit is carried out in accordance with all elements of the guidance issued by the Minister under *Head 18*,

(b) aggregate results of the clinical audit are published in accordance with *Head 19*.

(2) This Head does not apply to a publication under *Head 19*.

### ***Explanatory Note***

The purpose of this Head is to provide for an FOI exemption for clinical audit in line with Madden Commission Report on Patient Safety and Quality Assurance.

Subhead (1) provides for a FOI exemption for a record (up to and including the audit report) created solely for the purpose of clinical audit where the following requirements are met: the clinical audit is carried out in accordance with all the elements of the guidance issued under Head 15, and the results of the clinical audit are published in accordance with Head 19.

It is envisaged that where a person makes an FOI request to a (public) health service provider in regard to a clinical audit, the provider, where he or she considers that they have carried out the audit in line with the requirements of this Part, will cite the exemption in Head 20 to the FOI requester. If the requestor wishes to pursue the matter, he or she can do so under the mechanisms set out in the FOI Act 2014 involving internal reviews (under chapter 3 of that Act) and reviews by the Information Commissioner (under chapter 4 of that Act). Documents published under Head 19 will be in the public domain so they do not need to be FOI exempted under this Head. Accordingly, subhead (2) provides that this Head does not apply to a publication under Head 19.

### **Evidence**

#### **Head 21. Provide that:**

(1) Subject to *subhead (2)*, a record created solely for the purposes of clinical audit will not be admissible in evidence (whether by discovery or otherwise) in civil proceedings where-

(a) the clinical audit is carried out in accordance with all elements of the guidance issued by the Minister under *Head 79*, and

(b) aggregate results of the clinical audit are published in accordance with *Head 80*.

(2) This Head does not apply to a publication under *Head 19*.

### ***Explanatory Note***

Like Head 20, this provision gives effect to a recommendation in the Madden Commission Report on Patient Safety and Quality Assurance. This Head provides that a record created solely for the purposes of a clinical audit will not be admissible as evidence (whether by discovery or otherwise) in civil proceedings.

Specifically, subhead (1) provides for the civil admissibility exemption for a record (document etc) created solely for the purpose of clinical audit where the clinical audit is carried out in accordance with all the elements of the guidance issued under Head 18 and the clinical audit are published in accordance with Head 19 .

Documents published under Head 19 will be in the public domain. Subhead (2) therefore provides that this Head does not apply to a publication under Head 19.

Records created as part of a clinical audit will be admissible in evidence in criminal proceedings.

Separately, the medical records of a patient would, of course, continue to be admissible in civil proceedings including in relation to personal injury or death.

The Bill does not contain provisions on monitoring of clinical audit to assess if it is being carried out in accordance with the requirements set out in this Part. If the matter of the admissibility in evidence of clinical audit documents is raised in civil proceedings, it will be for the Court to determine, on the basis of the arguments made by the parties to the proceedings and the facts of the situation, whether the documents in question are ones that fall within the exemption in Head 19 or not.

**Saver for this Part**

**Head 22. Provide that:**

(1) Nothing in this Part shall be construed as-

(a) diminishing or removing any obligations on health services providers to comply with any other laws,

(b) limiting or removing any protection available in law for the reporting of matters covered by this Part.

***Explanatory Note***

This is intended to prevent the reduction or removal of any obligations on health services providers, carrying out clinical audit to comply with any other laws e.g. arrangements for the reporting of deaths to the coroner under the Coroners Acts or statutory obligations to report to the Health and Safety Authority or the State Claims Agency. It also addresses not limiting or removing any protections available in law for the reporting of matters covered by this Part.

## **Part 4: AMENDMENT OF HEALTH ACT 2007**

(Extending HIQA's remit to the private health service)

### **Amendment of section 2 of the Act of 2007**

#### **Head 23. Provide that:**

Section 2 of the Act of 2007 is amended in subsection (1) –

(a) by inserting the following after the definition of “local authority”:

““medical speciality” for the purposes of the definition of private hospital means a medical speciality recognised by the Medical Council under section 89 of the Medical Practitioners Act 2007;”

(c) by inserting the following definitions after the definition of “prescribed”:

“prescribed private health service” means a private health service prescribed by the Minister under section 98A;

“private hospital” means an establishment carried on by a person other than the Executive or a service provider at which medical or surgical treatment for illness, injury, or palliative or obstetric care is provided to an individual under the direction of registered medical practitioners from at least 3 medical specialties and which is being held out by the person carrying on the business of the private hospital as being capable of accommodating one or more such individuals for continuous periods of 24 hours or longer but does not include any part of the institution that is a centre registered by the Mental Health Commission or a designated centre.

#### ***Explanatory note***

Section 2 of the Health Act 2007 is the Interpretation section for that Act. This Head amends section 2 to include new terms.

The definition of private hospital and related definition of “medical specialty” is intended to describe private hospitals where medical or surgical treatment for illness or injury, palliative care or obstetric care is provided under the direction of registered medical practitioners from at least 3 of the specialties recognised by the Medical Council in accordance with section 89 of the Medical Practitioners Act 2007. Current recognised medical specialities are:

- anaesthesia
- emergency medicine
- general practice
- medicine
  - cardiology
  - clinical genetics
  - clinical neurophysiology
  - clinical pharmacology and therapeutics
  - dermatology
  - endocrinology and diabetes mellitus
  - gastroenterology
  - general (internal) medicine
  - genito-urinary medicine
  - geriatric medicine
  - infectious diseases



- medical oncology
- nephrology
- neurology
- palliative medicine
- pharmaceutical medicine
- respiratory medicine
- rheumatology
- tropical medicine
- obstetrics and gynaecology
- ophthalmology
- paediatrics
  - paediatric cardiology
  - paediatrics
- pathology
  - chemical pathology
  - haematology (clinical and laboratory)
  - histopathology
  - immunology (clinical and laboratory)
  - microbiology
  - neuropathology
- psychiatry,
  - child and adolescent psychiatry
  - psychiatry
  - psychiatry of learning disability
  - psychiatry of old age
- public health medicine
- radiology
  - radiation oncology
  - radiology
- sports and exercise medicine
- surgery
  - cardiothoracic surgery
  - general surgery
  - neurosurgery
  - ophthalmic surgery
  - oral and maxilla-facial surgery
  - otolaryngology
  - paediatric surgery
  - plastic, reconstructive and aesthetic surgery
  - trauma and orthopaedic surgery
  - urology
  - vascular surgery.

For the avoidance of any doubt, the definition of “private hospital” excludes residential centres for children, older people and people with disabilities and also excludes psychiatric hospitals and units.

*Other private health services*

As indicated earlier, the intention is that HIQA's functions on setting standards, monitoring compliance with standards and undertaking investigations will also extend to other private services in addition to private hospitals. Information on this is in Head 31 which inserts a new regulation making provision in the Health Act 2007 – section 98A – to enable the Minister to prescribe a private health service to come within HIQA's remit. As mentioned, if a service is prescribed by the Minister, HIQA's functions will apply to all private providers of that service. A prescribed service is intended to include particular high risk services currently provided in the private health service where the use of a general anaesthetic is required to be administered to the patient.

### **Amendment of section 8 of the Act of 2007 (Functions of HIQA)**

#### **Head 24. Provide that:**

(1) Section 8 of the Act of 2007 is amended in subsection (1)–

(a) by inserting the following after paragraph (b):

“(bb) to set standards on safety and quality in relation to-

(i) private hospitals,

(ii) prescribed private health services,

and advise the Minister accordingly;”,

(b) in paragraph (c), by deleting “referred to in paragraph (b)” and substituting “referred to in paragraph (b) and paragraph (bb)”,

(c) in paragraph (g), by inserting “or services referred to in paragraph (bb)” after “the services”.

(2) Section 8 of the Act of 2007 is amended by the insertion of the following after subsection (2):

“(2A) (a) The Authority, in setting standards under subsection (1)(b) or subsection (1)(bb), may set different standards in relation to different categories of services.”.

#### ***Explanatory note***

HIQA's current functions are set out in section 8 of the Health Act 2007. This Head amends section 8 of the Health Act 2007 to allow for HIQA standards to apply to both the public and private healthcare services. The standards will apply to services provided by private hospitals and to such other services as prescribed by the Minister. HIQA also operates schemes aimed at ensuring safety and quality in the provision of public services and this function is now extended to the private hospitals and prescribed private services.

It is not expected that HIQA will set standards specifically for private hospitals or prescribed private health services but is instead envisaged that HIQA will instead apply existing standards e.g. the Safer Better Healthcare Standards to those services. However, to provide flexibility generally in regard to different categories of services, both public and private, a new subsection - subsection (2A) - provides that HIQA may set different standards for

different categories of services. Where services are provided in the private health service and not in the public health service, HIQA may set specific standards relevant to that service. In the event that the service should be provided by the public health service in the future the same standards will apply.

Currently, HIQA standards must be approved by the Minister and this will not change.

**Amendment of section 9 of the Act of 2007 (Investigations by the Authority)**  
**Head 25. Provide that:**

Section 9 of the Act of 2007 is amended by substituting the following for subsections (1), (2) and (2A):

“(1) 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 8 (1) (bb) if the Authority believes on reasonable grounds that-

(a) there is a serious risk-

(i) to the health or welfare of a person receiving those services, or

(ii) of a failure to comply with the provisions of the Act of 2013, and

(b) the risk may be the result of any act, failure to act or negligence on the part of—

(i) the Executive,

(ii) the Agency,

(iii) a service provider to which paragraphs (a) or (b) of the definition of service provider applies,

(iv) a service provider to which paragraph (c) of the definition of service provider applies,

(v) the registered provider of a designated centre to which paragraphs (a)(ii), (iii) or (c) of the definition of designated centre applies,

(vi) the registered provider of a designated centre to which paragraphs (a)(i) or (b) of the definition of designated centre applies,

(vii) the person in charge of a designated centre referred to in subparagraph (v), if other than its registered provider,

(viii) the person in charge of a designated centre referred to in subparagraph (vi), if other than its registered provider,

(ix) a person carrying on the business of a private hospital,

(x) a person carrying on the business of a prescribed private health service”;

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

(2) The Minister may, if he or she believes on reasonable grounds that—

(a) there is a serious risk of the kind mentioned in paragraph (a) of subsection (1), and

(b) the risk may be the result of any act, failure or negligence of the kind mentioned in paragraphs (b)(i), (iii), (v), (vii), (ix) or (x) of subsection (1),

require the Authority to undertake an investigation in accordance with this section.

(2A) The Minister for Children and Youth Affairs may, if he or she believes on reasonable grounds that-

(a) there is a serious risk of the kind mentioned in paragraph (a) (i) of subsection (1), and

(b) the risk may be the result of any act, failure or negligence mentioned in paragraph

(b)(ii), (iv), (vi) or (viii) of subsection (1),

require the Authority to undertake an investigation in accordance with this section.

(2AB) On undertaking an investigation, the Authority shall—

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

(b) give the person referred to in paragraph (a) copies of any documents relevant to the investigation.

### ***Explanatory note***

Section 9 of the Health Act 2007 deals with investigations by HIQA where HIQA believes there is a serious risk to the health or welfare of people receiving a particular service. Investigations under section 9 may be carried out by HIQA on its own initiative or when required by the Minister or the Minister for Children and Youth Affairs as the case may be. Currently, section 9(1)(b) applies to the HSE, the Child and Family Agency, service providers under the Act, registered providers of designated centres and persons in charge of designated centres. This Head amends section 9 to take account of investigations into services provided by other healthcare providers. It also provides for HIQA to notify the Minister in advance where it proposes to undertake an investigation. Head 90 also includes a new subsection in section 9 (subsection (2AB) in regard to procedures to be followed. HIQA must give written notification to the public or private provider concerned when undertaking the investigation and give relevant documentation to the provider.

### **Amendment of section 10 of the Act of 2007 (Standards set by Authority)**

#### **Head 26. Provide that:**

The Act of 2007 is amended by substituting the following for section 10:

“”Standards set by Authority”

**10.** (1) In this section, —standards means standards set by the Authority under section 8(1).

(2) Subject to subsection (4), before submitting a draft standard to the Minister for approval the Authority shall-

(a) publish the proposed draft on the Internet website of the Authority and in such other manner as the Authority may determine, and

(b) issue a notice on the Internet website of the Authority to the public seeking written comment on the draft before a date as specified by the Authority in the notice, and in accordance with any requirement prescribed by the Minister for

this purpose.

(3) The Authority shall consult with such other persons on the draft standard referred to in subsection (2) in accordance with any requirements prescribed for this purpose by the Minister.

(4) The Authority shall notify the Minister before undertaking a consultation under this section.

(5) Following consideration of any comments received under subsection (2) and consultation under subsection (3), and where the Authority proposes to proceed with the draft standard, the Authority shall submit to the Minister for approval the draft standard either in the form in which it was published or with such other changes as the Authority may determine.

(6) Where the standards referred to in subsection (5) relate to services provided under the Child and Family Agency Act 2013, the Minister shall not approve the proposed standards without the consent of the Minister for Children and Youth Affairs.

(7) As soon as practicable after a standard is approved by the Minister, the Authority shall publish the standard on the Internet website of the Authority and in any other manner as may be prescribed by the Minister, and shall publish a note on the standard in Iris Oifigiuil.

(8) A note referred to in subsection (7) shall identify the standard and specify the date on which the standard comes into operation."

### ***Explanatory note***

Section 10 of the Health Act 2007 sets out arrangements in relation to standard setting. Currently, after considering any representation made during consultation on a proposed standard, and after making any changes HIQA thinks fit, HIQA submits the proposed standard to the Minister for approval. If a proposed standard relates to a function of the Child and Family Agency, the Minister cannot approve the proposed standard without the consent of the Minister for Children and Youth Affairs. This Head amends section 10 and sets out requirements for publishing and consulting on draft standards.

Under subhead (2), before submitting a standard to the Minister for approval, HIQA must publish a draft standard on the Internet and by any other means that HIQA thinks appropriate and invite written comment from the public on the draft before a date as specified by HIQA in the notice and in line with any requirements prescribed by the Minister.

Under subhead (3), HIQA must also consult with other persons in accordance with requirements prescribed by the Minister. These for example could be the HSE, organisations representing private providers and organisations representing service users.

Subhead (4), requires HIQA to notify the Minister prior to undertaking a consultation. Following consideration of any comments received under subhead (2) and consultation under subhead (3), and where HIQA decides to proceed with the draft standard, it shall submit it to the Minister for approval in its published form or with other changes as HIQA consider necessary - Subhead (5).

Subhead (6) replicates the current role of the Minister for Children and Youth Affairs. Under subhead (7), once a standard is approved by the Minister, HIQA must publish the standard on the Internet and in any other form the Minister may prescribe. HIQA must also publish a note on the standard in Iris Oifigiuil. Subhead (8) provides that this note must identify the standard and indicate the date on which the standard comes into operation.

**Amendment of section 12 of the Act of 2007 (Provision of Information to the Authority)  
Head 27. Provide that:**

The Act of 2007 is amended by substituting the following for section 12:  
““Provision of information to Authority”

**12.-**The Authority may require -

- (a) the Executive,
  - (b) the Agency,
  - (c) a service provider,
  - (d) a person carrying on the business of a private hospital, and
  - (e) a person carrying on the business of a prescribed private health service
- to provide it with any information or statistics the Authority needs in order to determine the level of compliance by-
- (i) the Executive,
  - (ii) the Agency,
  - (iii) a service provider,
  - (iv) a person carrying on the business of a private hospital, and
  - (v) a person carrying on the business of a prescribed private health Service with the standards set by the Authority in accordance with section 8(1).l.

***Explanatory note***

Section 12 of the Health Act 2007 provides that HIQA may require the HSE, the Child and Family Agency, or a service provider to give HIQA any information or statistics HIQA needs in order to determine the level of compliance by these organisations with standards set by HIQA. Head 27 amends section 12 to include private healthcare providers. Detailed powers in relation to monitoring compliance and investigations are in Part 9 of the Health Act 2007.

**Amendment of section 73 of the Act of 2007 (Right of entry and inspection by authorised person or Chief Inspector)**

**Head 28. Provide that:**

(1) Section 73 (1) of the Act of 2007 is substituted by the following:

- “73. (1) If an authorised person considers it necessary or expedient for the purposes of-
- (a) monitoring compliance with standards in accordance with section 8(1)(c),
  - or
  - (b) an investigation referred to in section 8 (1)(d),

the authorised person may enter and inspect at any time any premises-

- (i) owned or controlled by-
  - (A) the Executive,
  - (B) the Agency,
  - (C) a service provider,
  - (D) a person carrying on the business of a private hospital or
  - (E) a person carrying on the business of 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 (bb).

(2) Section 73 of the Act of 2007 is amended in paragraph (a) of subsection (4) by inserting-

“a person carrying on the business of a private hospital, or a person carrying on the business of a prescribed private health service” after “service provider”.

***Explanatory note***

Section 73 provides for the right of entry and inspection by authorised person or chief inspector for the purposes of monitoring compliance with HIQA standards and investigations. Currently, section 73(1) provides that where an authorised person considers it necessary for the purposes of monitoring compliance of HIQA standards or an investigation as referred to under section 8 of the Act, he or she may enter and inspect premises owned by the HSE, the Child and Family Agency, or a service provider or used or proposed to be used for the purposes of providing services described in section 8 (1) (c).

This Head amends subsection (1) of section 73 to also apply to premises owned, used or proposed to be used by persons carrying on a private hospital or a prescribed private health service.

Subparagraph (a) of subsection (4) is also amended under this Head to take account of private hospitals or prescribed private health services.

## **Amendment of section 74 of the Act of 2007 (Requirement for consent of occupier or District Court warrant to enter dwelling)**

### **Head 29. Provide that:**

The Act of 2007 is amended by substituting the following for section 74:

“”Requirement for consent of occupier or District Court warrant to enter dwelling”

**74. (1)** In this section, “dwelling” includes any part of a designated centre, private hospital, or premises used to carry on the business of a prescribed private health service occupied as a private residence.

(2) Notwithstanding section 73, an authorised person or the chief inspector, in the performance of functions under that section, may not enter a dwelling other than—

- (a) with the consent of the occupier, or
- (b) in accordance with a warrant from the District Court issued under section 75(2) authorising the entry.”.

### ***Explanatory note***

Section 74 of the Health Act 2007 provides that, notwithstanding the right of entry under section 73 of that Act, the Chief Inspector of Social Services or an authorised person cannot enter a dwelling other than with the consent of the occupier, or in accordance with a warrant from the District Court authorising such an entry. “Dwelling” includes any part of a designated centre occupied as a private residence by the registered provider of the designated centre or by a member of staff of the registered provider. Head 94 amends the definition of “dwelling” in subsection (1) to include any part of a private hospital or premises used to carry on a prescribed health service that is used as a private residence.

## **Amendment of section 78 of the Act of 2007 (Reports of authorised person, the Chief Inspector and inspectors)**

### **Head 30. Provide that:**

The Act of 2007 is amended by substituting the following for section 78:

“”Reports of Authority, authorised persons, the chief inspector and inspectors.

**78.—**

(1) The Authority and the chief inspector may prepare and may publish reports related to activities and functions of the Authority or the chief inspector as the case may be, including reports—

- (a) on compliance by a person with standards monitored in accordance with section 8(1)(c),
- (b) on investigations referred to in section 8(1)(d),
- (c) arising from the performance by the chief inspector of his or her functions under section 41,
- (d) arising from the performance of functions under section 43 by an inspector appointed under that section, or
- (e) arising from the performance of functions under section 70 by an authorised person or other person appointed under that section.



(2). Where the Authority or the chief inspector proposes to prepare a report referred to in subsection (1) and the report is in relation to compliance by a person with standards set under *section 8*, regulations applicable to designated centres or investigations under section 8(1)(d), the Authority or the chief inspector, as the case may be, shall—

(a) prepare a draft of the report, and

(b) give to the person concerned—

(i) a copy of the draft of the report, and

(ii) a notice in writing stating that the person concerned 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 submissions in writing to the Authority on the draft.

(3) The Authority shall, as soon as is practicable after—

(a) the expiration of the period referred to in subsection (2)(b)(ii), and

(b) having—

(i) considered the submissions (if any) referred to in subsection (2)(b)(ii) made before the expiration of that period on the draft report concerned, and

(ii) made any revisions to the draft of the investigation report which, in the opinion of the Authority, are warranted following such consideration,

prepare the final form of the report.

(4) The Authority shall give a copy of the final report to the person referred to in subsection (2)(b) before publishing the report.

(5) The Authority, an authorised person, the chief inspector, an inspector or a person appointed under section 72 is not liable in damages arising from any—

(a) report or other document prepared, or

(b) report published, or

(c) communication made,

in good faith.

### ***Explanatory note***

Section 78 is about reports of HIQA, authorised persons and the Chief Inspector. It currently provides that HIQA, authorised persons, the Chief Inspector or people appointed to assist the Chief Inspector are not liable in damages arising from reports or other documents prepared or communications made in good faith for the purposes of or in connection with monitoring compliance with standards, investigations or, in the case of the Chief Inspector, inspections. This Head amends section 78 by including procedures to be followed by HIQA in preparing reports.

Subhead (1) provides that HIQA and the Chief Inspector may prepare and may publish reports related to their activities and functions including reports on compliance with standards or investigations and reports arising from the performance of their functions and the functions of authorised persons. Subhead (2) provides for a situation where HIQA or the Chief Inspector proposes to prepare a report on monitoring compliance or on an investigation,

HIQA or the Chief Inspector, as applicable, must prepare a draft report and give a copy of it to the provider concerned, together with a notice stating that submissions can be made on the draft within a stated time period. The intention is that the provider will have the opportunity to correct any factual statements or clarify an issue by giving additional information. It is not intended that submissions would challenge any regulatory judgements by HIQA or the Chief Inspector.

Subhead (3) provides that HIQA prepares the final draft having considered any submissions made. Subhead (4) requires HIQA to provide the final version to the provider before publication. Subhead (5) deals with qualified privilege.

### **Insertion of section 98A in the Act of 2007**

#### **Head 31. Provide that:**

The Act of 2007 is amended by inserting the following section after section 98:

“**98A.** (1) Without limiting the generality of section 98, the Minister, after consultation with the Authority and any other person whom the Minister considers appropriate, may make regulations for the purposes of *section 8* prescribing a private health service.

(2) A private health service may be prescribed under this section only if the service falls within the definition of a private health service set out in subsection (3).

(3) In this section, “private health service” means—

(a) a service offered or provided by a person other than the Executive or a service provider for-

(i) the screening, preservation or improvement of health and wellbeing,

or

(ii) the prevention, diagnosis, treatment or care of illness or injury, or

(b) any procedure offered or provided by a person other than the Executive or a service provider that is similar to forms of medical or surgical care but is not provided in connection with a medical condition,

but does not include any of the following-

(i) services provided at a centre registered by the Mental Health Commission or any other service regulated by the Mental Health Commission under the Mental Health Act 2001,

(ii) services provided at a designated centre,

(iii) a retail pharmacy business, or

(iv) complementary and alternative medicine;

“retail pharmacy business” has the meaning assigned to it by *section 2 (1)* of the Pharmacy Act 2007.”.

#### ***Explanatory note***

Regulations under the Health Act 2007 are provided for in Part 13 of the Act – sections 98 to 102. Head 31 inserts a new section in the Act, section 98A, allowing the Minister to prescribe private health services for the purposes of the Act. HIQA may then set standards for these

services, can monitor compliance with standards set and can, if necessary, undertake investigations into these services. The Minister will make a regulation prescribing a health service only after consultation with HIQA and any other person or group the Minister thinks appropriate.

For a service to be prescribed by regulation it must be a service coming within the definition of private health service. Private health service is defined in subhead (3) as:

- (a) a service offered or provided by a person other than the Executive or a service provider for-
  - (i) the screening, preservation or improvement of health and wellbeing,
- or
- (ii) the prevention, diagnosis, treatment or care of illness or injury, or
- (b) any procedure offered or provided by a person other than the Executive or a service provider that is similar to forms of medical or surgical care but is not provided in connection with a medical condition.

As set out earlier, prescribed services are likely to be those higher risk services sometimes provided outside of a hospital setting, for example the provision of services involving the use of a general anaesthetic. The necessary related services associated with the prescribed service would also be encompassed.

For the avoidance of any doubt, the definition of private health service in subhead (3) excludes services that are already regulated. The definition also excludes alternative and complementary therapies.

## **Part 5**

### **Offences**

#### **Head 32. Provide that:**

- (1) A registered health service provider shall be guilty of an offence if the health service provider fails to make a mandatory open disclosure in accordance with Section 5 of the Act or fails to notify a reportable incident in accordance with Section 10.
  
- (2) A registered health service provider guilty of an offence under subsection 1 is liable to:
  - (a) on summary conviction to a fine not exceeding €5,000 or imprisonment not exceeding 3 months or both,
  - or
  - (b) on conviction on indictment to a fine not exceeding €7,000 or imprisonment for a term not exceeding 6 months or both.

#### ***Explanatory Note***

If the registered health service provider fails to notify the Agency of a mandatory disclosure or a serious reportable incident as prescribed by the Minister, the provider will be guilty of an offence in failing to discharge their duty. A registered health service provider guilty of an offence will be subject to the penalties as outline in section 79 of the Health Act 2007.

## **Part 6**

### **Miscellaneous Provisions**

Any miscellaneous provisions if any will be included in this Part.