

General Scheme of the Patient Safety (Licensing) Bill

Introduction

The draft general scheme sets out a licensing framework for hospitals and other services not already included in other licensing type legislation. The Health Information and Quality Authority (HIQA) will be the licensing authority.

Regulation of hospitals and other clinical services

Focus in the proposed licensing regime is on services that are potentially high risk if not provided to proper standards. Acute hospitals (as defined in the Bill) will be subject to licensing as by their nature they provide higher risk services. Higher risk clinical health services provided in other settings will also be licensed. These high risk activities provided outside of the hospital setting are referred to in the Bill as “designated activities”. Designated activities are likely to initially relate to cosmetic surgery services but other services may be added over time as the licensing system becomes embedded in the health system. This approach also allows the licensing framework to evolve in line with changes in healthcare. Designations of activities will be made by statutory instruments under the Bill. The Minister will consult with HIQA and other stakeholders before making these statutory instruments. It will be an offence to carry on the business of a hospital or a designated activity without a licence. The legislation includes transitional arrangements for pre-existing hospitals and pre-existing providers of designated activities.

Standards and other requirements for hospitals and clinical facilities

The objective of the proposed licensing system is to improve patient safety by ensuring that healthcare providers do not operate below the standard set by Ministerial regulations and applied in a consistent and systematic way. Before getting a licence, providers must satisfy HIQA that they can comply with these regulations and other requirements under the legislation. For example, to ensure effective governance, under the legislation HIQA must be satisfied that the provider is a fit and proper person to be a licensee – this covers partners in a partnership and company boards of directors. The provider must also identify an individual as the person with responsibility for managing the service on a day to day basis. This individual is referred to in the draft scheme as the person in charge. Again, HIQA must be satisfied that the person identified by the provider to be the person in charge is a fit and proper person for this role.

A licence application must include a statement of purpose. The statement of purpose for a hospital must set out the services to be provided at the hospital. A statement of purpose for a hospital or designated activity must also explain how the provider will ensure that services are delivered in line with the standards set by the regulations made under section 101A. Any proposed change to the services referred to in a statement of purpose must be notified to HIQA and approved by HIQA.

In line with the Report by the Chief Medical Officer on HSE Midland Regional Hospital, Portlaoise Perinatal Deaths, licensed providers must keep a patient safety statement containing up to date patient safety information on outcomes and also on adverse events.

Enforcement

If a licensed provider is not meeting licensing requirements, the ultimate sanction is the withdrawal of the licence but other options are also provided for in the Scheme to address failings where withdrawal of the licence is not the appropriate action, particularly as a first option of action.

General

HIQA was established under the Health Act 2007 and its regulatory functions are set out in that Act. Consequently, the general scheme amends the Health Act 2007, as necessary, to provide for functions in relation to licensing and to set out the licensing framework. The amendments to the Health Act 2007 are in Part 2 of this draft general scheme. In particular, Head 5 amends HIQA's functions and Head 9 inserts a new Part – Part 6A - in the Health Act 2007 which sets out the licensing framework.

As currently provided for under the Health Act 2007, HIQA will continue to set non mandatory standards for hospitals and other acute services provided by the HSE and public providers and will monitor compliance with those standards. Under separate new legislation - the Health Information and Patient Safety Bill - HIQA's remit will be extended to the private health service and HIQA will be given the function of setting standards for private hospitals and private acute services and monitoring compliance with standards in the same way as it does for the public health service. The general scheme of the licensing legislation reflects this.

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PATIENT SAFETY (LICENSING) BILL

LONG TITLE

AN ACT TO AMEND THE HEALTH ACT 2007 TO CONFER FUNCTIONS ON THE HEALTH INFORMATION AND QUALITY AUTHORITY IN RESPECT OF THE LICENSING OF HOSPITALS AND DESIGNATED ACTIVITIES, TO PROVIDE FOR A SCHEME OF LICENSING OF HOSPITALS AND DESIGNATED ACTIVITIES, AND TO PROVIDE FOR RELATED MATTERS.

PART 1

PRELIMINARY AND GENERAL

This part of the Scheme contains standard provisions such as setting out the short title of the Bill, definitions of specific words and terms used in the Bill and powers to bring the legislation into operation.

HEAD 1: SHORT TITLE

1. This Act may be cited as the Patient Safety Licensing Act 201__.

EXPLANATORY NOTE:

This is a standard provision giving the short title of the Bill.

HEAD 2: INTERPRETATION.

2.- (1) In this Act, unless the context otherwise requires-

“Act of 2007” means the Health Act 2007;

“Minister” means the Minister for Health;

HEAD 3: COMMENCEMENT

3. – This Act comes into operation on such day or days as the Minister may appoint by order or orders, either generally or with reference to any particular purpose or provision, and different days may be appointed for different purposes or different provisions of this Act.

EXPLANATORY NOTE:

This is a standard Head which provides for the making of orders by the Minister with regard to setting the day or days on which the provisions of the Bill will come into operation. Different days may be set for different purposes or different provisions of the Bill.

PART 2
AMENDMENTS TO THE ACT OF 2007

HEAD 4: AMENDMENT OF SECTION 2 OF THE ACT OF 2007

4. Section 2 of the Act of 2007 is amended –

(a) in subsection (1) by inserting the following definitions after the definition of “dependent person”:

““designated activity” shall be construed in accordance with section 39D (*Designation of activities*);

“director” in relation to a body corporate, includes-

- (a) any person occupying the position of director, by whatever name,
- (b) any person who effectively directs or has a material influence over the business of the body corporate,
- (c) any person who in accordance with whose directions or instructions the directors of the body corporate are accustomed to act, unless the directors are accustomed so to act by reason only that they do so on advice given by the person in a professional capacity, and
- (d) where the affairs of the body corporate are managed by its members, any of the members who exercises the functions of such management;

(b) in subsection (1) by inserting the following definitions after the definition of “financial year”:

““guidance” means any guidance issued with or pursuant to a standard set by the Authority under this Act;

"Health Products Regulatory Authority" means the body established by section 3 of the Irish Medicines Board Act 1995 as amended by section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013;

“health service” for the purposes of designating activities means-

(a) a service provided by -

- (i) the Executive,
- (ii) a service provider, or
- (iii) other person,

for -

- (I) the preservation or improvement of health and wellbeing, or
- (II) the prevention, diagnosis, treatment or care of illness or injury,

(b) procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition, including procedures which involve a (aesthetic) procedure or other invasive treatments, which may or may not involve breaching the skin, to correct a defect or deformity perceived by the patient, and deemed correctable by the provider;

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,

(iv) an activity requiring an authorisation granted by the Health Products Regulatory Authority under the -

(I) European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005), as amended,

(II) European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006),

(III) European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012), as amended,

(v) complementary and alternative medicine, or

(vi) an emergency Good Samaritan service;

“hospital” means an institution carried on by-

(a) the Executive,

(b) a service provider, or

(c) other person

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 of the specialties recognised by the Medical Council in accordance with section 89 of the Medical Practitioners Act 2007, and which is being held out by the person carrying on or intending to carry on the institution as being capable of accommodating one or more such individuals for continuous periods of 24 hours or longer but does not include

(I) any part of an institution that is a centre registered by the Mental Health Commission;

(II) a designated centre;

(III) any activity carried on at the institution that is an activity requiring an authorisation granted by the Health Products Regulatory Authority under the -

(i) European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005), as amended,

(ii) European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006),

(iii) European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012), as amended;"

(c) in subsection (1), by inserting the following definitions after the definition of "Irish Health Services Accreditation Board":

"“licence” means a licence in the specified form issued under section 39H (*Grant or refusal of licence*);

"licensed designated activity" means a designated activity in respect of which a licence is in force

"licensed hospital" means a hospital in respect of which a licence is in force;

"licensed provider" in relation to a licensed hospital or licensed designated activity, means a person whose name is entered on a licence as a person carrying on the business of the hospital or designated activity;

"licensed service" means a licensed hospital or licensed designated activity;"

(d) in subsection (1), by inserting the following after the definition of "ordinary member":

"“premises” includes any land, building, vehicle, or part thereof;"

(e) in subsection (1), by inserting the following definitions after the definition of "prescribed":

"“principal officer” –

(a) in relation to a body corporate, means any person who is—

- (i) a director, member of the committee of management or other controlling authority of the body concerned,
- (ii) the manager, secretary or other similar officer of the body concerned, or
- (iii) a person purporting to act in any such capacity,

or

(b) in relation to a partnership means any person who is—

(i) a partner in, or a manager or other similar officer, of the partnership, or

(ii) a person purporting to act in any such capacity;

(f) in subsection (1), by substituting the following for the definition of “register”:

““register” means:

(a) a register of designated centres established and maintained under section 41(b);

(b) a register of hospitals established and maintained under section 8(1A);

(c) a register of designated activities established and maintained under section 8(1A);”;

(g) in subsection (1), by inserting the following definition after the definition of “registered provider”:

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

EXPLANATORY NOTE:

Section 2 of the Health Act 2007 is the Interpretation section for that Act. Head 4 amends section 2 to include some of the key terms used in this general scheme, including the definition of hospital and designated activity.

Some further definitions in regard to licensing of hospitals and designated activities are in head 11 which inserts a new Part in the Health Act 2007 – Part 6A – setting out the licensing framework for hospitals and designated activities.

The licensing legislation is intended to add to current regulation of health services and will not duplicate existing controls. For the avoidance of doubt, services already regulated under other legislation are therefore excluded from the definitions of hospital and health service.

Psychiatric hospitals and units are already regulated by the Mental Health Commission under the Mental Health Act 2001 and the proposed licensing legislation will therefore not apply to these hospitals and units or to other mental health services regulated by the Mental Health Commission.

Legislative provision for the regulation of residential centres for children, older people and people with disabilities is already provided for in the Health Act 2007 (these residential centres are referred to as designated centres under the 2007 Act).

The Health Products Regulatory Authority is the regulatory authority for certain prescribed activities under Statutory Instruments transposing EU Directives on blood, human tissue and organs.

Under European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005), as amended, “prescribed activity” means any activity consisting of any aspect of—

- (a) the collection and testing of blood or blood components whatever their intended purpose, and
- (b) the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion.

Under the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006), a "prescribed activity" means any activity consisting of any aspect of -

- (a) the donation, procurement, testing, processing, preservation, storage or distribution of tissues or cells for human applications;
- (b) the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells for use in manufactured products, where these products are not covered by other Directives;
- (c) the donation, procurement and testing of tissues and cells for use in manufactured products, where those products are covered by other Directives.

Under the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012), as amended, “prescribed activity” means any activity relating to the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs intended for transplantation to the human body.

Hospitals

Hospitals are defined as institutions at or through which in-patient services – medical and surgery, or palliative or obstetric care¹ - are provided under the direction of registered medical practitioners from at least three of the specialities 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
 - rehabilitation medicine
 - respiratory medicine
 - rheumatology
 - tropical medicine

¹ Care of women before, during and after childbirth.

- obstetrics and gynaecology
- occupational medicine
- 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 maxillo facial surgery
 - otolaryngology
 - paediatric surgery
 - plastic, reconstructive and aesthetic surgery
 - trauma and orthopaedic surgery
 - urology
 - vascular surgery.

As mentioned above, the definition of hospital is intended to exclude services already regulated under other legislation.

Licensing will apply to all hospitals as defined in the General Scheme i.e. HSE hospitals, voluntary hospitals and private hospitals.

To facilitate the introduction of licensing on a phased basis, the definition of hospital has three categories of providers - (a) the HSE, (b) service providers as defined under the Health Act 2007 and (c) other providers i.e. any person who is neither the HSE nor a service provider as defined in the Health Act 2007.

The term “service provider” is defined in the Health Act 2007 as meaning a person who -

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

(b) is in receipt of assistance under section 39 of the Health Act 2004 in an amount that exceeds an amount prescribed for the purpose of this subparagraph, (under S.I. No. 366 of 2013, this is currently €10,000) or

(c) is a service provider under the Child and Family Agency Act 2013.

Voluntary hospitals are funded by the HSE to provide services on behalf of the HSE under section 38 of the Health Act 2004 and therefore fall within the definition of “service provider” in the Health Act 2007.

To facilitate the introduction of licensing on a phased basis, the definition of hospital has three categories of providers - (a) the HSE, (b) service providers as defined under the Health Act 2007 and (c) other persons.

Activities outside the hospital setting

As set out in page 1, activities designated by the Minister will also require a licence. Regulations designating activities for licensing may be made by the Minister under section 39D.

For an activity to be designated by regulation it must be an activity coming within the definition of health service. The Minister must also consider the level of risk attached to the activity in question and if other statutory safeguards exist for the activity as it is not the intention to duplicate existing controls.

Health service is defined as:

- a service provided for:
 - the preservation or improvement of health and wellbeing, or
 - the prevention, diagnosis, treatment or care of illness or injury, or
- a procedure that is similar to forms of medical or surgical care but is not provided in connection with a medical condition including procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition, including procedures which involve a (aesthetic) procedure or other invasive treatments, which may or may not involve breaching the skin, to correct a defect or deformity perceived by the patient, and deemed correctable by the provider.

As with the definition of hospital, the definition of health service is intended to exclude activities already regulated under other legislation.

Again, licensing of activities under the Bill will apply to all providers, public and private. The range and number of public and private providers who may be subject to licensing is potentially large. The categorising of providers in the definition of “health service” is intended to facilitate a phased introduction of the licensing system. The categorisation is the same as that used for hospitals, i.e. the HSE, service providers as defined in the Health Act 2007 and other providers.

The phrase “procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition” is intended to cover cosmetic surgery and invasive cosmetic procedures. However, the list of designated clinical activities is likely to include the provision of general anaesthetics so any cosmetic surgery or invasive procedure involving general anaesthesia will be covered there. Alternative and complementary therapies are not encompassed by the Bill.

HEAD 5: AMENDMENT OF SECTION 8 OF THE ACT OF 2007 (Functions of HIQA)

5.- Section 8 of the Act of 2007 is amended -

(a) in subsection (1) by substituting the following for paragraph (b):

“(b) subject to subparagraphs (ii) to (iv), to set standards on safety and quality in relation to—

(i) services provided by the Executive, the Agency or a service provider in accordance with—

(I) the Health Acts 1947 to 2011, except for services under the Mental Health Acts 1945 to 2011 that, under the Health Act 2004, are provided by the Executive,

(II) the Child Care Acts 1991 to 2013, and

(III) the Children Act 2001,

(ii) designated centres

(iii) hospital and

(iv) designated activities

in this section called the “services” and advise in writing or by electronic means, one or more of the following-

(I) the Minister,

(II) the Minister for Children and Youth Affairs,

(III) the Agency, or

(IV) the Executive,

as may be appropriate in relation to the particular service in respect of which the standards are set;”;

(b) in subsection (1) by inserting the following after paragraph (b):

“(ba) to issue guidance in accordance with section 10A; ”,

(c) in subsection (1) by substituting the following for paragraph (c):

“(c) subject to subsection (1A), to monitor compliance with the standards referred to in paragraph (b), except any standards in relation to designated centres and the performance of the Executive’s or the Agency’s functions referred to in section 41(1)(a), and to advise the Minister, the Minister for Children and Youth Affairs, the Executive and the Agency accordingly;”;

(d) in subsection (1) by substituting the following for paragraphs (e), (f) and (g):

“(e) at the request or with the approval of the Minister or the Minister for Children and Youth Affairs, to review and make recommendations as the Authority thinks fit in respect of any services referred to in paragraph (b) provided by the Executive, the Agency or a service provider, to ensure the best outcomes for the resources available to the Executive and the Agency;

(f) to operate accreditation programmes in respect of the services referred to in subparagraph (i) of paragraph (b) other than services that are hospitals or designated activities and to grant accreditation to any of them meeting standards set or recognised by the Authority,

(g) at the request or with the approval of the Minister or the Minister for Children and Youth Affairs, to operate such other schemes aimed at ensuring safety and quality in the provision of the services referred to in subparagraph (i) of paragraph (b), other than services that are hospitals or designated activities, as the Authority considers appropriate;”

(e) by inserting the following subsection after subsection (1)-

“(1A) In addition to the functions set out in subsection (1), the Authority shall have the following functions:

(a) to establish and maintain one or more registers of-

(i) hospitals, and

(ii) designated activities;

(b) to inspect hospitals to assess whether the licenced provider or person carrying on the business of a hospital pursuant to section 39AK (*Transitional arrangements*) is in compliance with regulations under section 101A and any other requirements under this Act;

(c) to inspect designated activities to assess whether the licenced provider or person carrying on the business of a designated activity pursuant to section 39AK (*Transitional Arrangements*) is in compliance with regulations under section 101A and any other requirements under this Act; and

(d) do all things necessary and reasonable in relation to the licensing of a hospital or a designated activity to further its objective under section 7;”

(f) in subsection (2) by inserting the following paragraphs after paragraph (d)-

“(e) the need to ensure that action by the Authority in relation to a licensed service is proportionate to the risks against which it would afford safeguards, and is targeted only where it is needed,

(f) best practice among persons performing functions comparable to those of the Authority, and

(g) the efficient and effective use of resources in the performance of its functions.”

(g) by inserting the following subsection after subsection 2:

“(2A) The Authority, in setting standards under subsection (1)(b)), may set different standards in relation to different classes of —

- (i) services referred to in subparagraph (i) of subsection (1)(b),
- (ii) designated centres,
- (iii) hospitals, whosoever carries on the business of the hospital, and
- (iv) designated activities, whosoever carries on the business of the activity.”,

(h) by substituting the following subsection for subsection (4):

“(4) (a) Subject to subparagraph (b) of this subsection, any directions given by the Minister under section 29 (*Directions to Authority*), or to any charges determined under section 39 (*Charges for services*), the Authority, in relation to health or personal social services may—

- (i) provide advice on safety, quality and standards, and
- (ii) operate accreditation programmes for and at the request of persons other than service providers as defined in section 2(1), the Executive or the Agency,

(b) health or personal social services under this subsection do not include hospitals, designated activities or designated centres.”.

EXPLANATORY NOTE:

HIQA’s current functions are set out in section 8 of the Health Act 2007. Head 5 amends section 8 of the Health Act 2007 to provide for the additional functions proposed for HIQA under the general scheme. Additional functions under section 8 include-

- establishing and maintaining registers of licensed hospitals and licensed designated activities
- inspecting hospitals and designated activities to assess compliance with regulations and other licensing requirements
- inspecting pre-existing hospitals and clinical activity businesses during transitional arrangements, when licensing is first commenced for hospitals or when a particular activity is designated under the legislation, to assess compliance by providers with regulations and other requirements
- doing all things necessary and reasonable in relation to the licensing of a hospital or a designated activity to further HIQA’s object as set out under section 7 of the Health Act 2007. Under that section, HIQA’s object is to promote safety and quality in the provision of health and personal social services for the benefit of the health and welfare of the public
- issuing guidance on compliance, in line with section 10A, with standards set under section 8 (1)(b).

In carrying its functions HIQA will be –

- balanced and targeted in its approach,
- have regard to best practice by others performing comparable functions to its own,
- effective and efficient in the use of resources required for the purpose of performing its functions.

As set out earlier, standards which providers must comply with to get and keep a licence will be set out in regulations made by the Minister. More information on these regulations is given in Head 20. In addition, HIQA will continue to set non mandatory standards for hospitals and designated activities and will monitor compliance with those standards. Providers are expected to be clear on their organisational response to complying with HIQA standards and be able to demonstrate the processes and governance arrangements used and actions taken to assure themselves of their compliance with standards relevant to their services.

HEAD 6: AMENDMENT OF SECTION 9 OF THE ACT OF 2007 (INVESTIGATIONS BY THE AUTHORITY)

6. Section 9 of the Act of 2007 is amended -

(a) in subsection (1), by the substitution of the following for paragraph (b):

“(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) the licensed provider of a hospital,
- (x) the person in charge of a hospital,
- (xi) the licensed provider of a designated activity,
- (xii) the person in charge of a designated activity,
- (xiii) a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional arrangements*).”

(b) by the substitution of the following for subsection (2):

“(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) or (ix) to (xiii) of subsection (1),

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

EXPLANATORY NOTE:

Section 9 of the Health Act 2007 deals with investigations by HIQA where HIQA, the Minister or the Minister for Children and Youth Affairs believes there is a serious risk to the health or welfare of people receiving a particular service. An investigation 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.

Head 6 amends section 9 to take account of the licensing system. HIQA will be empowered to investigate licensed hospitals and licensed designated activities and will also be able to investigate private hospitals and designated activities operating under the transitional arrangements at section 39AK.

Head 7: AMENDMENT OF SECTION 10 of the Act of 2007 (Standards set by the Authority).

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

““Standards set by Authority”

10.-(1) In this section,

"representatives of other providers" means persons who, in the opinion of the Authority, are representative of persons carrying on the business of hospitals or designated activities, other than the Executive, the Agency or service providers;

"standards" means standards set by the Authority under section 8(1)(b).

(2) Before submitting a draft standard to the Minister for approval the Authority shall -

- (a) publish the proposed draft on its Internet website and in such other manner as the Authority may determine,
- (b) issue a notice on its Internet website 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 requirements prescribed by the Minister for this purpose ,
- (c) consult with such other persons on the draft standard in accordance with any requirements prescribed for this purpose by the Minister, and
- (d) notwithstanding paragraph (c) of subsection (2) and subject to subsection (3), assess
 - (i) the likely costs associated with complying with the draft standard,
 - (ii) the likely benefits associated with the draft standard, and
 - (iii) the capacity of the Executive and the Agency to comply with the standard,

(3) In assessing the matters referred to in paragraph (d) in subsection (2), the Authority shall consult with

(a) the Executive, where the draft standard is in relation to -

- (i) services provided by the Executive or by service providers referred to in paragraphs (a) or (b) of the definition of "service provider",
- (ii) designated centres carried on by the Executive or service providers referred to in paragraphs (a) or (b) of the definition of "service provider", or
- (iii) hospitals or designated activities carried on by the Executive or service providers referred to in paragraphs (a) or (b) of the definition of "service provider" ,

(b) the Agency, where the draft standard is in relation to -

- (i) services provided by the Agency or service providers referred to in paragraph (c) of the definition of "service provider" , or
- (ii) designated centres carried on by the Agency or service providers referred to in paragraph (c) of the definition of "service provider,"

(4) In assessing the matters referred to in subparagraphs (i) and (ii) of paragraph (d) in subsection (2), the Authority shall consult with

(a) representatives of persons that are not service providers under this Act but who receive assistance under section 39 of the Health Act 2004 where the draft standard is in relation to designated centres carried on by such persons,

(b) representatives of other providers where the draft standard is in relation to hospitals or designated activities carried on by persons other than the Executive or service providers.

(5) Following consideration of any comments received under paragraph (b) of subsection (2), the consultation under paragraph (c) of subsection (2) and the assessment referred to in paragraph (d) of subsection (2), the Authority may –

(a) 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, or

(b) decide not to proceed further with the draft standard.

(6) The Authority shall prepare a report of the assessment referred to in paragraph (d) of subsection (2) and the findings of this assessment and shall provide a copy of the report when submitting a draft standard to the Minister for approval.

(7) Where the draft standard referred to in paragraph (a) of subsection (4) relate to services provided under the Child and Family Agency Act 2013, the Minister shall not approve the proposed standard without the consent of the Minister for Children and Youth Affairs.

(8) As soon as practicable after a standard is approved by the Minister, the Authority shall publish the standard and the report of the assessment referred to in subsection (6) on its Internet website and in any other manner as may be prescribed by the Minister."

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. Head 7 amends section 10 and sets out requirements for publishing and consulting on draft standards.

Subsection (1) explains that the term “standards” in this section refers to standards set by HIQA under section 8(1)(b). These would cover standards for services provided under specified Acts by the HSE, Tusla and their service providers, standards for residential centres for people with disabilities, standards for public and private residential centres for older people, standards for residential centres

for children, standards for special care units, standards for public and private hospitals and standards for public and private designated activities.

Subsection (1) also defines the terms "representatives of other providers" which are used in the amended section 10 in relation to the providers HIQA should consult with on likely costs and benefits and capacity to comply with a draft standard. These are providers other than the HSE or service providers.

Subsection (2) sets out the consultation and assessment that HIQA must carry out in regard to a draft standard before submitting the draft standard to the Minister for approval.

Under subsection (2)(a), HIQA must publish a draft standard on its Internet website and by any other means that HIQA thinks appropriate. Subsection (2)(b) requires HIQA to 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 subsection (2)(c), HIQA must also consult with other persons in accordance with requirements prescribed by the Minister. These for example could be the HSE, organisations representing providers and organisations representing service users.

Subsection (2)(d) requires HIQA to carry out an assessment of the likely costs and benefits of a draft standard and the capacity of the HSE and Tusla to comply with the standard. Subsection (3) provides that HIQA must consult with the HSE and Tusla in assessment.

Paragraph (a) of subsection (4) requires HIQA to consult on costs and benefits with representatives of persons that are not service providers under this Act but who receive assistance under section 39 of the Health Act 2004 where the draft standard is in relation to designated centres carried on by such persons. Paragraph (b) of subsection (4) requires HIQA to consult with private providers on the costs and benefits of a draft standard where the draft standard is in relation to hospitals or designated activities provided by private providers.

Having considered any comments received from the public, and after its consultation with other groups and its assessment of the costs and benefits and capacity issues, HIQA may then submit the draft standard to the Minister for approval or it may decide not to proceed any further with the draft standard - subsection (5).

Subsection (6) requires HIQA to prepare a report of its assessment of costs and benefits and capacity issues and its findings in regard to these and to give the Minister a copy of the report when submitting a draft standard to the Minister for approval.

Subsection (7) replicates the current role of the Minister for Children and Youth Affairs.

Subsection (8) provides that, as soon as practicable after a standard is approved by the Minister, the Authority must publish the standard and the report of the assessment referred to in subsection (6) on its Internet website and in any other manner as may be prescribed by the Minister.

HEAD 8: INSERTION OF SECTIONS 10A and 10B IN THE ACT OF 2007

8.-The Act of 2007 is amended by the insertion of the following sections after section 10:

“10A. AUTHORITY TO ISSUE GUIDANCE ON COMPLIANCE WITH STANDARDS.

10A.-(1) When publishing a standard in accordance with section 10(8), the Authority may issue guidance on compliance with the standard.

(2) The guidance may—

- (a) operate by reference to provisions of other documents specified in it (whether published by the Authority or otherwise),
- (b) provide for any reference in it to such a document to take effect as a reference to that document as revised from time to time, and
- (c) make different provision for different cases or circumstances.

(3) The Authority may revise any guidance prepared under this section and shall issue the revised guidance.

(4) The Authority shall publish guidance issued under this section on its Internet website and in any other manner as may be prescribed by the Minister.

10B. CONSULTATION BY AUTHORITY IN RELATION TO GUIDANCE ON COMPLIANCE WITH STANDARDS

10B.-Where the Authority proposes to issue guidance under section 10A(1) or revised guidance under section 10A(3), it shall —

- (a) prepare a draft of the guidance, and
- (b) consult such persons as the Authority considers appropriate in relation to the draft."

EXPLANATORY NOTE:

Head 8 inserts two new sections into the Health Act 2007 – section 10A and section 10B. These make provision regarding guidance on compliance with standards.

Section 10A (1) provides that HIQA may issue guidance on compliance with standards when publishing a standard so that providers may be clear on what is expected.

Under subsection (2), guidance may take account of other documents HIQA considers relevant and may refer to those documents as revised from time to time.

Under subsection (3), HIQA can revise any guidance. If the guidance is revised, the revised guidance must be issued.

Under subsection (4), guidance must be published on HIQA's Internet website and as prescribed by the Minister.

Section 10B sets out what HIQA should do before it issues guidance under section 10A. HIQA is to prepare a draft of the guidance and may to consult with relevant interested parties.

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HEAD 9: AMENDMENT OF SECTION 12 OF THE ACT OF 2007 – PROVISION OF INFORMATION TO THE AUTHORITY

9.-The Act of 2007 is amended by substituting the following for section 12.

“12.-The Authority may require -

- (a) the Executive,
- (b) the Agency,
- (c) a service provider, or
- (d) a person carrying on the business of a hospital or a designated activity other than the Executive or a service provider

to provide it with any information or statistics the Authority needs in order to determine the level of compliance by the Executive, the Agency, the service provider or the person referred to in paragraph (d) with the standards set by the Authority in accordance with section 8(1).”.

EXPLANATORY NOTE:

Section 12 of the Health Act 2007 currently provides that HIQA may require the HSE, the Child and Family Agency or someone providing a service on behalf of the HSE or the Agency, 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 9 amends section 12 to also include private hospitals and private providers of designated activities.

HEAD10: INSERTION OF SECTION 12A IN THE ACT OF 2007

10. The Act of 2007 is amended by the insertion of the following section after section 12:

“12A PROVISION OF INFORMATION TO THE AUTHORITY ON COMPLIANCE WITH REGULATIONS under section 101A

12A.-The Authority may require a licensed provider or a person who is carrying on the business of a hospital or designated activity in accordance with section 39AK(*Transitional arrangements for hospitals and designated activities*) to provide it with such information or statistics as it requires in order to determine the level of compliance with Ministerial regulations made under section 101A.”

EXPLANATORY NOTE:

This Head provides that HIQA may require licensed providers or providers of hospitals and designated activities under transitional arrangements to give HIQA any information HIQA needs to determine compliance with Ministerial regulations on standards. See also detailed powers in relation to inspections by HIQA and other requirements to provide information.

HEAD 11: INSERTION OF PART 6A IN THE ACT OF 2007.

11. The Act of 2007 is amended by inserting the following Part after Part 6:

“PART 6A

LICENSING OF HOSPITALS AND DESIGNATED ACTIVITIES

Section 39A Interpretation (Part 6A)

39A.-(1) In this Part:

“approved location” means a premises at or through which a licensed provider is licensed to carry on the business of-

- (a) a hospital, or part of a hospital, or
- (b) a designated activity;

“clinical claim” in relation to a licensed provider means a claim connected with the provision of or failure to provide a service which he or she is licensed to provide;

“improvement notice” means a notice issued by the Authority under section 39L (*Improvement notice*);

“improvement plan” means a plan under section 39K (*Improvement plan*);”,

““patient safety statement” shall be construed in accordance with section 39AC (*Patient safety statement*);

“person in charge” in relation to a hospital or designated activity means the person designated by the licensed provider to be the person in charge of the hospital or designated activity in accordance with section 39I (*Requirement for a licensed provider to designate an individual to be the person in charge*);

“policy of insurance” means a policy of insurance against losses from claims in respect of any description of civil liability incurred by a person arising from his or her-

- (a) carrying on a hospital or designated activity, or
- (b) being granted practicing privileges under section 39C;

“practising privileges” in relation to a health practitioner refers to the grant by a licensed provider of permission to practice as such a health practitioner, other than in the course of employment or engaged on a contract for services;

“prohibition notice” shall be construed in accordance with section 39M;

“statement of purpose” shall be construed in accordance with section 39AD.

(2) For the purposes of the definition of “practising privileges” -

- (a) reference to employing a person includes –
 - (i) a person employed under a contract of employment, or
 - (ii) a person placed for the purposes of vocational training whether paid or unpaid, and

(b) reference to a “health practitioner” means—

- (i) a registered medical practitioner within the meaning of section 2 of the Medical Practitioners Act 2007, or a medical practitioner practising medicine pursuant to section 50 of that Act,
 - (ii) a registered dentist within the meaning of section 2 of the Dentists Act 1985,
 - (iii) a registered pharmacist, or registered pharmaceutical assistant within the meaning of the Pharmacy Act 2007,
 - (iv) a registered nurse, or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011,
 - (v) a registrant within the meaning of section 3(1) of the Health and Social Care Professionals Act 2005, or
 - (vi) a person whose name is entered in the register of pre-hospital emergency care practitioners established under the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000).
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EXPLANATORY NOTE:

This section sets out the terms used in this Part of the general scheme. More detail is given where the terms appear in the relevant heads.

SECTION 39B: PROHIBITIONS IN RELATION TO UNLICENSED HOSPITALS AND UNLICENSED DESIGNATED ACTIVITIES

39B.-(1) A person shall not carry on the business of a hospital unless he or she is licensed to do so under this Act, or in accordance with section 39AK (*Transitional arrangements for hospitals and designated activities*).

(2) A person shall not carry on the business of a designated activity unless he or she is licensed to do so under this Act or in accordance with section 39AK.

(3) Where two or more persons-

- (a) use different parts of the same premises to carry on the business of a hospital or designated health activity, or
- (b) use the same premises [establishment] at different times,

each of the persons unless they are in partnership together shall be regarded as carrying on a separate hospital or designated activity, and each person shall be required to be licensed.

(4) A licensed provider or person appointed by or under the law in place of a licensed provider shall not carry on a hospital or designated activity at any location other than an approved location.

(5) A person shall not manage or participate in the management of a hospital or a designated health activity unless the hospital or activity is-

- (a) a hospital or designated activity licensed under this Act or being carried on by a person appointed by or under the law in place of its licensed provider, or
- (b) a hospital or designated activity being carried on in accordance with section 39AK.

(6) A person does not contravene the requirements of subsections (1) or (2) if the person is a person appointed by or under the law to carry on the business of a hospital or designated activity in place of its licensed provider.

EXPLANATORY NOTE:

The purpose of this section is to provide for compulsory licensing of hospitals and designated activities. Later provisions make it an offence to contravene any of the matters in this section.

Subsection (1) provides that a person must not carry on a hospital unless he or she is licensed to do so or in accordance with the transitional arrangements for existing providers which are set out in section 39AK.

Similar provision applies in relation to designated activities under subsection (2).

Under subsection (3), where two or more persons (outside of a partnership practice/business) are using different parts of the same premises to carry on the business of a hospital or designated activity, either at the same or different times, each of them is required to hold an individual licence.

Under subsection (4), hospitals or designated clinical activities must only be carried on at approved locations. “Approved location” is defined in section 39A and means the premises at or through which the health service provider is licensed to carry on the hospital/ part of the hospital or designated activity. Hospitals and designated activities may in some instances provide services to people at home. The term “approved location” is not intended to refer to private dwellings. However, a statement of purpose would be expected to indicate whether any services are to be provided on a domiciliary care basis.

The purpose of subsection (6) is to provide for circumstances where someone has been appointed by or under the law in place of a licensed provider. This would be in the event of the death of a licensed provider or the provider becoming bankrupt. See also section 39AA.

Subsection (5) provides that a person must not manage or participate in the management of a hospital or a designated activity unless the service is licensed or carried on by a person appointed by or under the law or the transitional arrangements for pre-existing services apply.

SECTION 39C: PRACTISING PRIVILEGES

39C.-(1) A licensed provider of a hospital or a designated activity or a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) shall not grant practising privileges to a health practitioner in respect of that hospital or designated activity unless he or she is satisfied that the requirements referred to in subsection (2) have been met in relation to that health practitioner and the granting of such privileges is consistent with the conditions of the provider's licence and with the statement of purpose.

(2) The requirements referred to in subsection (1) are that-

- (a) there is evidence that all professional registration requirements are met,
- (b) the health practitioner has the qualifications, skills and experience which are necessary for the work which he or she is to perform,
- (c) the health practitioner is a fit and proper person, and
- (d) there is evidence that the practitioner has an adequate policy of insurance relating to medical or clinical matters.

(3) Where a licensed provider of a hospital a designated activity or a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) grants practising privileges to a health practitioner, the licenced provider or person shall ensure that adequate arrangements are in place to ensure that the services provided by the health practitioner meet the requirements of the regulations made under section 101A.

(4) Where a licensed provider of a hospital or a designated activity or a person carrying on the business of a hospital or designated activity under section 39AK grants practising privileges to a health practitioner, the licenced provider or person carrying on the business of a hospital or designated activity under section 39AK shall ensure that, if requested by the Authority, evidence is available to demonstrate that the requirements set out in subsection (2) and subsection (3) are met.

EXPLANATORY NOTE:

Under the General Scheme, health practitioners are described as having 'practising privileges' in situations where, although there is no employment relationship, the licensed provider allows them to practise in the hospital, or as the case may be, in a premises in which a designated activity is carried on. (Section 39A(2) provides that a reference to employment includes persons under a contract of employment and persons receiving vocational training whether paid or unpaid).

"Health practitioner" is defined in section 39A(1) in the context of "practising privilege" to include a range of health professionals.

An example of practising privileges is where a doctor rents a room or suite of rooms from a licensed provider. If the practitioner has been granted practising privileges by the licensed provider, he or she is not seen as carrying on the business of a licensed service under the Bill and therefore does not need a separate licence from HIQA in respect of the licensed service. However, if the practitioner is

renting part of the premises but has not been granted practising privileges by the licensed provider, the practitioner is seen as a provider in his/her own right and must have a licence from HIQA.

The interpretation section for the licensing provisions (section 39A) defines “practising privileges” as meaning, the granting by a licensed provider of a hospital or designated activity to a health practitioner who is not his or her employee or under contract, of permission to practise as such a health practitioner in that hospital or in a premises in which the licensed designated activity is carried on.

For all intents and purposes a health practitioner who has been granted practising privileges would be subject to the policies and governance arrangements of the licensed service. For example, this would include arrangements concerning clinical governance and audit and the hospital’s policies and systems for dealing with complaints.

A licensed provider is ultimately responsible for the service provided under licence including that provided under practising privileges. As the licensed holder the onus rests with him or her to ensure that all licensing requirements and obligations under the legislation are being met in relation to the services for which the licence has been granted including those provided under practising privileges.

Subsection (1) provides that the licensed provider must not grant practising privileges to a health practitioner unless the provider is satisfied that the health practitioner meets specified requirements. These are set out in subsection (2).

Under subsection (2), specified requirements are that the health practitioner meets all registration requirements, has the qualifications, skills and experience which are necessary for the work which he or she is to perform, is a fit person and there is evidence of an adequate policy of insurance.

Subsection (3) provides that where a licensed provider or a person carrying on the business of a hospital or designated activity under section 39AK grants practising privileges, the provider must have adequate arrangements in place to ensure that the services provided by the meet the requirements of the regulations made under section 101A.

Subsection (4) provides that, if required by HIQA, a licensed provider of a hospital or a designated activity or a person carrying on the business of a hospital or designated activity under section 39AK must have evidence to demonstrate that the requirements set out in subsection (2) and subsection (3) are met.

SECTION 39D: DESIGNATION OF ACTIVITIES

39D.-(1) After consulting the Authority and such other persons as the Minister may determine, the Minister may prescribe an activity (referred to in this Act as a designated activity).

(2) An activity may be prescribed for the purposes of subsection (1) only if the activity involves the provision of a health service as defined in section 2.

(3) In considering the designation of an activity under this Act, the Minister shall-

(a) have regard to the degree of risk to the health, safety or welfare of the public associated with the activity after taking account of any protections offered by other statutory regulatory arrangements.

EXPLANATORY NOTE:

Changes in service delivery models and advances in healthcare have resulted in the potential for some high risk clinical activities to be provided in settings other than hospitals. For effective regulation, the legislative framework for licensing will need flexibility to keep pace with these developments.

Consequently, the proposed licensing legislation must apply to hospitals and to high risk healthcare activities carried out in other settings. A phased implementation is envisaged with licensing potentially being introduced for providers by category of provider. As set out earlier, providers are categorised into three – (1) the HSE, (2) service providers as defined under the Health Act 2007 i.e. persons receiving funding from the HSE under section 38 of the Health Act 2004, persons receiving funding from the HSE under section 39 of the Health Act 2004 above a prescribed amount (currently €10,000) and (3) other providers.

Under subsection (1) the Minister, having consulted with HIQA and relevant stakeholders, may prescribe an activity known as a designated activity for the purposes of this legislation.

Under subsection (2), an activity may only be prescribed if it involves the provision of a health service. Health service is defined in the Bill under Head 4 which amends the interpretation section for the Health Act of 2007.

Subsection (3) sets out what the Minister must take into account when considering whether to designate an activity. The Minister must consider the other protections in place to reduce the risks associated with the activity, how these may be reducing the risk associated with the activity. These would include other statutory protections or governance arrangements which are already in force. These might include for example the health practitioner regulatory bodies and the Health Products Regulatory Authority.

SECTION 39E: REGISTERS OF HOSPITALS AND DESIGNATED ACTIVITIES

39E.-(1) For each licensed hospital or person providing a licensed designated activity there shall be entered, where applicable, in the appropriate register established and maintained under section 8(1A)(*Functions of the Authority*) by the Authority —

- (a) the name of the licensed hospital and a description of the services provided at the hospital,
- (b) the name and type of licensed designated activity,
- (c) the name of —
 - (i) the licensed provider of the hospital or designated activity, and
 - (ii) the person in charge,
- (d) where a person has been appointed under the law to carry on the licensed hospital or designated activity, the name of the person who is appointed,
- (e) the location or locations at which the hospital or designated activity is carried on,
- (f) the date from which the licence for the hospital or designated-activity is to take effect,
- (g) any condition attached to the licence for the hospital or designated activity,
- (h) the date of issue of any improvement notice in force and the particulars of the notice,
- (i) the date of issue of any prohibition notice in force and the particulars of the notice, and
- (j) such other particulars as the Authority may decide.

(2) The registers referred to in subhead (1) shall be—

- (a) kept at the head office of the Authority,
- (b) open to inspection by members of the public free of charge, during normal business hours of the Authority, and
- (c) made available on its Internet website and by any other means that the Authority considers reasonable and appropriate to facilitate public availability of or access to the Registers.

(3) On request, a copy of an entry in any register maintained by the Authority shall be issued by the Authority on payment of a fee, if any, not exceeding the reasonable cost of making the copy, as may be determined by the Authority.

(4) The Authority shall amend the appropriate register as referred to in subhead (1) when it revokes a licence.

(5) The Authority shall ensure that the registers are accurate and, for that purpose, the Authority shall make any alteration requiring to be made in the information contained in an entry.

(6) As soon as is practicable after doing anything under subsection (5), the Authority shall inform the licensed provider to whom the alteration relates in writing of that fact.

(7) The licensed provider to whom an entry in a register relates shall inform the Authority of-

(a) any error that he or she knows of in the entry, or

(b) any matter that is likely to have a bearing on the accuracy of the entry,

as soon as may be after he or she becomes aware of that error or change in circumstances as the case may be.

EXPLANATORY NOTE:

Section 39E is modelled on section 49 of the Health Act, 2007 and section 29(7) – (9) of the Property Services (Regulation) Act 2011. It sets out under subsection (1) the details to be included in the register or registers established and maintained by HIQA. These include the name of the hospital or activity, a description of the services provided in the case of a hospital, the name of the licensed provider, the name of the person in charge, the location or locations at which the service is carried on, the date of which the licence is to take effect. Details in regard to any conditions attached to a licence, improvement notice or prohibition notice in force are also shown.

Under section 39AA, HIQA must also note the name of any person appointed under the law to take charge of a licensed hospital or licensed designated clinical activity in place of its licensed provider. Under subsection (2), registers will be held at HIQA's head office and will be accessible to the public for inspection, free of charge, during normal working hours. They will also be made available on the HIQA website and as the Authority so decides.

Under subsection (3), HIQA must provide a copy of an entry in a register, when requested, on payment of a fee, if any, which the Authority determines covers the reasonable cost of making a copy.

Under subsection (4), HIQA must amend the relevant register when a licence has been revoked.

Subsection (5) requires HIQA to keep the registers up to date, ensuring that the register is accurate and must make any necessary alteration to the information in the entry should the need arise.

Where an entry is altered, HIQA, under subsection (6), must write to the licensed provider concerned advising him or her of the alteration.

Subsection (7) places an obligation on licensed providers to inform HIQA of any entry errors that they are aware of, and of any change in circumstances that are likely to have a bearing on the accuracy of the entry.

SECTION 39F: APPLICATION FOR LICENCE OR RENEWAL OF LICENCE

39F.-(1) A person seeking a licence for a hospital or designated activity under this Act shall make an application to the Authority.

(2) A person who wishes to carry on more than one hospital shall make a separate application in respect of the licensing of each hospital.

(3) Subject to subsection (4), a person who wishes to carry on more than one designated activity shall make a separate application in respect of the licensing of each designated activity.

(4) A person seeking a licence in respect of two or more designated health activities to be provided at or through the same location may make a single application in respect of them.

(5) An application for a licence shall be made to the Authority in such form and manner as may be determined by the Authority from time to time.

(6) An application for a licence shall be accompanied by –

(a) evidence as to the character and competence of the intended licensed provider,

(b) in the case of an application by an individual (not being a partner in a partnership), a declaration of

(i) any capacity or former capacity as a provider of services regulated by any regulatory body performing functions comparable to those of the Authority in or outside the State,

(ii) the imposition of conditions on any licence or authorisation, the revocation, suspension, withdrawal or removal of any registration or licence or other authorisation, or the refusal to grant registration or a licence or other authorisation, by any regulatory body performing functions comparable to those of the Authority in or outside the State in respect of any capacity or former capacity of the applicant as a provider of services regulated by that body,

(c) in the case of an application by a partnership or a body corporate, a declaration by each principal officer of the partnership or body of

(i) any capacity or former capacity as a provider of services regulated by any regulatory body performing functions comparable to those of the Authority in or outside the State,

(ii) the imposition of conditions on any licence or authorisation, the revocation, suspension, withdrawal or removal of any registration or licence or other authorisation,

(iii) any refusal to grant registration or a licence or other authorisation, by any regulatory body performing functions comparable to those of the Authority in or outside the State in respect of any capacity or former capacity of the applicant as a provider of services regulated by that body,

(d) evidence of the availability to the intended licensed provider of appropriate insurance, indemnity provisions or other financial assurance instruments to cover liabilities potentially deriving from the carrying on of the hospital or activity or activities in question and in relation to clinical claims,

(e) in the case of a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*), a patient safety statement in accordance with section 39AC (*Patient safety statement*),

(f) a statement of purpose in accordance with section 39AD (*Statement of purpose*),

(g) the name of the person to be designated as the person in charge under section 39I (*Requirement for licensed provider or intended licensed provider to designate an individual to be the person in charge*),

(h) evidence as to the character and competence of the person to be designated as the person in charge relevant to his or her management role in the hospital or designated activity the subject of the application,

(i) other particulars as may be specified by the Authority in relation to the intended licensed provider, or person to be designated as the person in charge of the service the subject of the application,

(j) the prescribed application fee and

(k) in the case of an application by a person, other than the Executive or a person who will be providing the proposed services the subject of the application on behalf of the Executive pursuant to section 38 of the Health Act 2004, evidence as to the financial capability of the intended licensed provider to carry on the business of the hospital or designated activity in accordance with the statement of purpose referred to in paragraph (f),

(7) The Authority may request a person making an application under this section to provide additional information in relation to the application.

(8) An application under this section by a body corporate or a partnership shall be made by a principal officer of the body corporate or partnership.

(9) Where an application for a licence is not made in full compliance with requirements under this section, the Authority shall notify the applicant for the licence of a final date for the receipt of the complete application and the Authority will not be obliged to consider the application further if the full application is not received on or before that date.

(10) Different fee amounts may be prescribed in respect of applications under this section for hospitals and for designated activities and for different classes of hospitals and designated activities, having regard to the number of medical specialties provided or to be provided at the hospital, the medical complexity of the activity and the size and number of locations at which the hospital or activity is or will be carried on.

(11) Other than in the case of the Executive and a person providing services on behalf of the Executive pursuant to section 38 of the Health Act 2004, references in this section to an intended licensee's character and competence include, in the case of an applicant which is a body corporate or a partner in a partnership, references to the character, competence of any of the principal officers of the body corporate or partnership, as the case may be.

EXPLANATORY NOTE:

Section 39F sets out the detail on applications for a licence. It is part modelled on sections 48(2), (3) and (4), and 80(4) of the Health Act 2007. Subsection (9) is based on section 9(2) of the Public Transport Regulation Act 2009.

A separate application for a licence must be made in respect of each hospital. This will be reviewed when legislation is in place regarding hospital trusts. In the meantime, in advance of legislation to establish hospital trusts, acute hospitals – HSE and voluntary - have been configured on an administrative basis into a small number of Hospital Groups, each with its own governance and management. Pending the enactment of legislation to establish the Groups on a statutory basis, hospital groups continue to operate within the policy and accountability frameworks determined by the Department of Health and the HSE. Where hospitals are established as legal entities in their own right they remain responsible and accountable for the governance of their hospital, while operating within their Group. However, it is intended that the statement of purpose submitted with an application would give scope for information to be given by HSE and voluntary hospitals on their roles and linkages within a Hospital Group.

The composition of the Groups is as follows:

- RCSI Hospitals: Beaumont Hospital; Our Lady of Lourdes Hospital, Drogheda; Connolly Hospital; Cavan General Hospital; Rotunda Hospital; Louth County Hospital; Monaghan Hospital.
- Dublin Midlands: St James's Hospital; Tallaght Hospital; Midlands Regional Hospital, Tullamore; Naas General Hospital; Midlands Regional Hospital Portlaoise; the Coombe Women and Infant University Hospital.
- Ireland East: Mater Misericordiae University Hospital; St Vincent's University Hospital; Midland Regional Hospital, Mullingar; St Luke's General Hospital, Kilkenny; Wexford General Hospital; National Maternity Hospital; Our Lady's Hospital, Navan; St Columcille's Hospital; St Michael's Hospital, Dun Laoghaire; Cappagh National Orthopaedic Hospital; Royal Victoria Eye and Ear Hospital.
- South/South West: Cork University Hospital/CUMH; Waterford Regional Hospital; Kerry General Hospital; Mercy University Hospital; South Tipperary General Hospital; South Infirmary Victoria University Hospital; Bantry General Hospital; Mallow General Hospital, Lourdes Orthopaedic Hospital, Kilcreene, Kilkenny.
- Saolta: University Hospital Galway and Merlin Park University Hospital; Sligo Regional Hospital; Letterkenny General Hospital; Mayo General Hospital; Portiuncula Hospital; Roscommon County Hospital.
- University Limerick: Mid-Western Regional Hospital, Limerick; Ennis General Hospital; Nenagh General Hospital; St John's Hospital Limerick; Mid-Western Regional Maternity Hospital; Mid- Western Regional Orthopaedic.
- Children's: Our Lady's Children's Hospital Crumlin; Children's University Hospital Temple Street; paediatric service at Tallaght Hospital.

Returning to section 39F, subsection (1) requires a person seeking a licence for a hospital or designated activity to make an application to HIQA.

Under subsection (2), a separate application must be made in respect of each hospital.

Under subsection (3), a separate application must generally be made in respect of each designated activity.

However, under subsection (4), a single application may be made where a person wishes to carry on or manage more than one designated activity at or through the same location.

Subsection (5) provides that an application must be made in such form as specified by HIQA while subsection (6) specifies issues that must be covered in an application.

These are –

- evidence as to the character and competence of the intended licensee
- a declaration from the proposed provider including each principal officer in the case of a partnership or body corporate in regard to any capacity or former capacity as a provider of other services regulated in or outside the State, and any issues arising. The declaration should also refer to any unsuccessful applications to provide regulated services in Ireland or elsewhere. (The declaration covers similar information to that referred to in section 39AB which requires licensed providers to notify HIQA of material matters.)
- evidence of the availability of appropriate insurance, indemnity provisions or other financial assurance instruments to cover liabilities potentially deriving from the carrying on of the hospital or activity or activities in question and in relation to clinical claims. A clinical claim is defined in section 39A as “in relation to a licensed provider means a claim connected with the provision of or failure to provide a service which he or she is licensed to provide”.
- a patient safety statement in the case of an application by a provider operating under the transitional arrangement
- a statement of purpose setting out the services intended to be provided
- the name of the person to be designated as the person in charge under section 39I
- evidence as to the character and competence of the person to be designated as the person in charge relevant to the service to be provided
- any other particulars as specified by HIQA relating to the intended licensed or intended person in charge and
- the prescribed application fee.

In the case of private providers, evidence of financial capability to undertake the licensed service must also be submitted. This applies to providers other than the HSE or persons providing services on behalf of the HSE under section 38 of the Health Act 2004 as the HSE and organisations it funds under section 38 to provide services on its behalf are resourced by the State.

The intention is that evidence of financial capability may include business plans, annual audited accounts, bank account statements cash flow projections and details of capital on hand etc. Subsection (7) allows HIQA to look for additional information in relation to an application. Under

subsection (8), applications by a corporate body or by a partnership must be made by a principal officer of the body or partnership concerned. The definition of a principal officer is under Head 4 which amends section 2(1) of the Health Act 2007.

Under subsection (9), if an application is not compliant in full with this section, HIQA will notify the applicant of a final date for receipt of the completed application and it is not obliged to consider the application further if the full application is not received on or before that date.

The purpose of subsection (10) is to enable the Minister to prescribe different levels of application fees for hospitals and for designated activities and to prescribe different levels of fees for different types of hospitals and designated activities. Fees will be determined having regard to the range and medical complexity of the services to be provided and the size of the hospital or activity business. A standardised framework will be established under the regulations.

Subsection (11) provides that in this section, references to the character and competence of an intended licensed provider is included, in the case of intended licensees which are body corporates or partnerships, references to the character, competence of any of the principal officers of the body corporate or partnership. The exceptions are the HSE and hospitals funded by the HSE under section 38 of the Health Act 2004.

It should be noted that subsection (11) is concerned with individuals rather than the corporate level governance which is required of all organisations under the draft general scheme. In addition, provisions in regard to the person in charge apply to all organisations. The person in charge may be in charge of more than one hospital or designated activity and the information provided on the character and competence should demonstrate how the person in charge will deal with the management of a service in more than one location including where a person is in charge of more than one hospital or designated activity.

PROHIBITION AGAINST FALSE OR MISLEADING APPLICATION FOR LICENCE

39G.-A person shall not in, or in respect of, an application for a licence under this Part, knowingly make a statement or representation, whether orally or in writing, that is false or misleading in a material respect, knowing the statement or representation, as the case may be, to be so false or misleading or being reckless as to whether it is so false or misleading.

EXPLANATORY NOTE:

Section 39G states that in applying for a licence, a person must not knowingly make a statement which is false. This is an offence under the offences and penalties provisions. See also section 39N which relates to information concerning an application for variation or removal of a condition.

SECTION 39H: GRANT OR REFUSAL OF LICENCE

39H.-(1) Where an application is made in accordance with section 39F (*Application for a licence* -for a licence and the Authority is satisfied that the person who is the intended licensed provider and the person who is to be designated as the person in charge –

(a) is a fit and proper person to be the licensed provider of the hospital or designated activity, or to be the person in charge,

(b) will comply with

(i) regulations made by the Minister for the category of hospital or designated activity under section 101A,

(ii) any other requirement imposed under this Act,

(iii) any other enactment which appears to the Authority to be relevant, and is cited to the applicant in writing by the Authority,

(c) will comply with the statement of purpose, and

(d) in the case of an intended licensed provider other than the Executive or a person who will be providing the proposed services the subject of the application on behalf of the Executive pursuant to section 38 of the Health Act 2004, the intended licensed provider has the financial capability to carry on the hospital or the designated activity,

the Authority shall grant the application and if not so satisfied shall refuse it.

(2) The Authority in granting an application under this section may attach to the licence conditions that the Authority considers fit in relation to the hospital or designated activity concerned.

(3) A licence issued under this section is non-transferable.

(4) A licence issued under this section shall contain –

(a) the information referred to in paragraphs (a) to (j) in section 39E(1) (*Registers of hospitals and designated activities*),

(b) the enactments, if any, cited to the applicant under subsection (1)(b)(iii), and

any other particulars as the Authority may decide.

(5) When assessing the financial capability of an intended licensed provider to carry on a hospital or designated activity under paragraph (d) of subsection (1), the Authority shall consider the ability of the intended licensed provider -

(i) to meet the costs of carrying on the hospital or designated activity or activities in question,

(ii) to have or to put in place appropriate insurance, indemnity provisions or other financial assurance instruments to cover liabilities potentially deriving from the carrying on of the hospital or activity or activities in question and in relation to clinical claims.

(6) subject to subsection (8), the Authority shall not grant an application for a licence under section 39F (*Application for a licence*), if –

- (a) in the case of an application individual (not being a partner in a partnership), the applicant is an undischarged bankrupt,
- (b) in the case of a partner in a partnership, any principal officer of the partnership is an undischarged bankrupt, or
- (c) in the case of a body corporate (not being a partner in a partnership), any principal officer of the body corporate is an undischarged bankrupt.

(7) Subsection (6) does not apply to the Executive or a person providing services on behalf of the Executive pursuant to section 38 of the Health Act 2004.

EXPLANATORY NOTE:

Section 39H is modelled in part on section 50 of the Health Act 2007. Provisions on financial capability in paragraph (d) of subsection (1) and in subsection (5) are modelled in part on section 9A of the Petroleum and Other Minerals Development Act 1960 as amended by the Petroleum (Exploration and Extraction) Safety Act 2015.

Compliance with standards set under regulations and other governance issues is central to the licensing system. Subsection (1) provides that HIQA will grant an application for a licence if satisfied that the intended licensed provider and intended person in charge are fit for their role. HIQA must also be satisfied that the provider and person in charge will comply with regulations made by the Minister under section 101A and other licensing requirements set out under the legislation.

In the case of private providers, HIQA must also be satisfied that the intended licensee has the financial capability to carry on the hospital or designated activity. (Evidence in this regard must be submitted with the application under section 39F.) Information on how HIQA will make this assessment is in subsection (5).

Subsection (2) provides that HIQA may attach conditions to a licence.

Under subsection (3), a licence is non transferrable.

Subsection (4) provides for the information to be included on a licence. This information is the information shown on the relevant register of providers maintained by HIQA.

Subsection (5) relates to paragraph (d) of subsection (1). As outlined above, HIQA must be satisfied that a prospective licensee in the private health service must have the financial capability to carry on the service to be licensed. Subsection (5) provides that when assessing the financial capability of an intended licensed provider to carry on a hospital or designated activity, HIQA should consider the ability of the intended licenced provider to meet the costs of carrying on the hospital or designated activity.

Other financial issues are referred to in subsections (6) and (7). Subsection (6) provides that HIQA shall not grant an application for a licence where an applicant or one of the applicants is an undischarged bankrupt. Under subsection (7), subsection (6) does not apply to members of the governing bodies of the HSE or of health agencies funded by the HSE under section 38 of the Health Act 2004 to provide services on behalf of the HSE as the individual's financial solvency to provide a service does not arise.

SECTION 39I: REQUIREMENT FOR LICENSED PROVIDER TO DESIGNATE AN INDIVIDUAL TO BE THE PERSON IN CHARGE

39I.- (1) A licensed provider of a hospital or designated activity shall designate an individual to be the person in charge of that hospital or designated activity with responsibility for the management of the hospital or designated activity.

(2) An individual designated pursuant to this section may be-

(a) the licensed provider or one of the licensed providers of the hospital or designated activity, or

(b) another individual,

(3) An individual designated pursuant to this section shall be the person named in accordance with Section 39F(6)(e) in an application for a licence.

(4) A licensed provider shall notify the Authority of any proposed change in the identity of the person in charge.

(5) A notification under subsection (3) shall include the information referred to in section 39F (*Application for a licence*) in respect of the individual intended to be designated as the person in charge.

(6) A notification under subsection (3) shall be made in such form and manner as may be determined from time to time by the Authority and, in addition to the information described in subsection (4), shall include such particulars as may be determined by the Authority from time to time.

EXPLANATORY NOTE:

This section sets out an important accountability arrangement for licensed services.

Subsection (1) requires a licensed provider to designate an individual to be the person in charge of the hospital or designated activity with responsibility for the management of that hospital or activity.

The person in charge is the person with management responsibility for the hospital or designated activity as a whole. Information on the character and competence of the proposed person in charge must be included with an application for licence under section 39F. Section 39H(1) (*Grant or refusal of a licence*) makes it clear that HIQA must be satisfied that the person in charge is a fit and proper person for this role.

It would be expected that information required to be provided as set out in section 39F on the person in charge would set out the various locations where the service is provided/will be provided and how the person in charge will deal with the day to day management of a service provided at more than one location.

An individual may be in charge of more than one hospital or designated activity. Again, it would be expected that information on the person in charge would set out the management arrangements where a person is to be in charge of more than one hospital or designated activity.

The licensed provider is ultimately responsible for the service. However, as in section 80(4) of the Health Act 2007, the Bill provides that where an offence committed by a body corporate is proved to have been committed with the consent or approval of, or was attributable to any wilful neglect, of a

person who was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person, as well as the body corporate, shall be guilty of an offence.

Subsection (2) provides that the person in charge may be the licensed provider/one of the licensed providers or another individual. In some small businesses, the licensed provider himself/herself may be directly involved in the day to day management and operation of the service. Similarly, where the licensed provider is a partnership, one of the partners may be directly involved in the day to day management of the service. In those circumstances, the provider may wish to designate himself/herself or one of the partners as being in charge of the licensed service. However, in hospitals and in large organisations, the licensed provider may not have day to day involvement in the management of the service and in those circumstances would designate a very senior employee, for example the chief executive, as the person in charge.

Subsection (3) states that a licensed provider must notify HIQA of any proposed change in the identity of the person in charge.

Subsection (4) requires that when notifying HIQA of a proposed change in the identity of the person in charge under subsection (3), information concerning evidence of good character and competence must be provided as set out in section 39F (*Application for licence*).

A notification to HIQA must be made in the form and manner determined by HIQA and, in addition to the information required under this section must include any other information decided on by HIQA.

SECTION 39J: REVOKING A LICENCE, VARYING CONDITIONS OF A LICENCE OR IMPOSING NEW CONDITIONS, FOR CAUSE

39J.-(1) At any time, the Authority, on one or more of the grounds specified in subsection (2), may-

- (a) revoke a licence issued in relation to a hospital or designated activity,
- (b) vary or remove any condition of the licence of a hospital or designated activity, or
- (c) attach an additional condition to the licence of a hospital or designated activity.

(2) The following are the grounds referred to in subsection (1)–

- (a) that the licensed provider, the person in charge or any other person who participates in the management of the licensed service has been convicted of one or more of the following-
 - (i) an offence under this Act,
 - (ii) an offence under an enactment cited by the Authority in accordance with section 39H(1)(b)(iii) (*Grant or refusal of licence*) and noted on the licence in accordance with section 39H(4), or
 - (iii) an offence against the person,
 - (b) that, in the opinion of the Authority, the licensed provider, the person in charge or any other person who participates in the management of the licensed service is not a fit and proper person to be the licensed provider of the service, the person in charge or to participate in its management,
 - (c) that the licensed service is being, or has at any time been, carried on otherwise than in accordance with—
 - (i) any requirements or conditions imposed by or under this Act, or
 - (ii) any other statutory provision which the Authority considers to be relevant,
 - (d) that the annual fee (and any levy in regard to late payment) payable under this Act in respect of the licensed service has not been paid within 3 months after the due date, or
 - (e) subject to subsection (7) of section 39H, that a licensed provider who is a person referred to in section 39H (6) (*Grant or refusal of licence*) is an undischarged bankrupt.
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EXPLANATORY NOTE:

This section is modelled in part on section 51 of the Health Act 2007 (*Cancelling registration, varying conditions of registration or imposing new conditions for cause*). It sets out the circumstances whereby HIQA may revoke a licence, vary a condition attached to a licence or attach a new condition to a licence.

Under subsection (1), HIQA has the power to revoke a licence, vary a condition attached to a licence or attach a new condition to a licence. The criteria for doing so are set out in subsection (2). HIQA may take these steps –

- (a) where the licensed provider, the person in charge or other person involved in management of a licensed service have been convicted of an offence under the Bill, under other legislation

(b) previously signalled by HIQA as relevant, or an offence against the person,

(c) where HIQA believes that the licensed provider, the person in charge or other person involved in the management of the service is not fit to hold such a position in relation to the licensed service,

(d) where HIQA believes that the licensed service is being, or has at any time been, carried on otherwise than in accordance with any requirements or conditions under this Act, or other statutory provision which the Authority considers to be relevant. The reference to requirements under the Act includes improvement notices and prohibition notices,

(e) the annual fee (and any levy payable for late payment) has not been paid,

(f) or where a licensed provider is an undischarged bankrupt. As set out previously, this provision in regard to bankruptcy does not apply to the HSE or to persons providing services on behalf of the HSE pursuant to section 38 of the Health Act 2004.

Provisions in regard to notification by HIQA of proposed decisions, right to respond and rights of appeal are in later sections.

SECTION 39K: IMPROVEMENT PLAN FOR HOSPITAL OR DESIGNATED ACTIVITY

39K.-(1) If the Authority believes on reasonable grounds that a hospital or designated activity is not being, or has at any time been carried on otherwise than in accordance with-

- (a) any requirement or any condition imposed by or under this Act, or
- (b) any other statutory provision which the Authority considers to be relevant,

the Authority may give a direction in writing to the licensed provider concerned, or, as the case may be, the person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) requiring the provider to submit to the Authority within the time period stated in the direction, a plan, in this Act referred to as an “improvement plan”, specifying the remedial action proposed to be taken by the provider to rectify the matters set down in the direction.

(2) If an improvement plan is submitted in accordance with a direction issued under subsection (1) or re-submitted under paragraph (b), the Authority shall, not later than 28 days after receipt of the plan, write to the licensed provider or, as the case may be, the person carrying on the business of the hospital or designated activity under section 39AK, stating that –

- (a) the Authority is satisfied with the remedial action proposed to be taken, or
- (b) the Authority is not satisfied that the remedial action proposed to be taken is adequate and directing that the improvement plan be revised and re-submitted to the Authority within a specified time period.

(3) The Authority may withdraw a direction under this section before a date specified in the direction or may extend and further extend such date.

EXPLANATORY NOTE:

Section 39K is based on section 13Y of the Electricity Regulation Act 1999 as amended by the Petroleum (Exploration and Extraction) Safety Act 2010. Section 39K allows HIQA to issue a direction to a licensed provider or person carrying on a hospital or designated activity under transitional arrangements for pre-existing hospitals or pre-existing providers of designated activities to submit an improvement plan where it considers that the licensed provider is non-compliant with the Bill or other relevant legislation. Note: see section 39AA in relation to persons appointed by or under the law to take charge of a licensed service in place of its licensed provider and the making of regulations prescribing for specified provisions of this legislation to apply with prescribed modifications, if any, in cases where a person is appointed by or under the law to take charge of a hospital or designated activity in place of its licensed provider.

Under subsection (1) where HIQA believes that a licensed provider or person carrying on the business of a hospital or designated activity under transitional arrangements is not conducting the licensed service in line with the requirements or conditions under this Bill or any other statutory provision which it considers to be relevant, HIQA may issue a written direction requiring the provider to submit an improvement plan within a specified timeframe. The submitted plan must set out the specific measures to be taken by the provider to rectify the matters set out in the direction.

Subsection (2) provides that, within 28 days of receiving an improvement plan, HIQA must let the provider know whether HIQA is satisfied or not with the proposed remedial actions set out in the plan. If not satisfied with the proposed actions HIQA must instruct the provider concerned to revise the plan and resubmit it within a given timeframe.

Under subsection (3) HIQA may withdraw a direction prior to the date indicated in the direction, or it may extend and further extend the date as it sees fit.

SECTION 39L: IMPROVEMENT NOTICE FOR HOSPITAL OR DESIGNATED ACTIVITY BUSINESS

39L.-(1) Where the Authority believes on reasonable grounds that a licensed provider of a hospital or designated activity or, as the case may be, a person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) -

(a) has failed to comply with a direction under section 39K(1) (*Improvement plan for hospital or designated activity business*) to submit an improvement plan,

(b) has failed to comply with a direction under section 39K(2)(b) to submit a revised improvement plan,

(c) has failed to implement an improvement plan following notification by the Authority under section 39K(2)(a), or

(d) is not carrying on the business of a hospital or designated health activity in accordance with -

(i) the requirements of this Act, or

(ii) any other statutory provision which the Authority considers to be relevant,

the Authority may, in writing, serve an improvement notice on the licensed provider or person carrying on the business of the hospital or designated activity under section 39AK.

(2) An improvement notice shall -

(a) state that the Authority is of an opinion referred to in subsection (1),

(b) state the reason for that opinion,

(c) direct the licensed provider to remedy the matters occasioning that notice by a date specified in the notice, which shall not be earlier than the period within which an appeal may be brought under section 39R (*Appeal to District Court of Certain Decisions of the Authority in relation to Licensing*),

(d) set out of the actions that the Authority may take as a consequence of a failure to comply with the notice, including amending or revoking of the licence,

and

(e) include any other matter or requirement that the Authority considers appropriate.

(3) An improvement notice may include directions as to the measures to be taken to-

(a) remedy any matter to which the notice relates, or

(b) otherwise comply with the notice.

(4) The Authority may withdraw an improvement notice at any time before the date specified in it under subsection (2)(c), and the Authority may extend or further extend that date at any-time when an appeal against the notice is not pending.

(5) A failure to comply with an improvement notice, within the specified time, may lead to the Authority taking one or more of the actions specified in accordance with subsection (2)(d).

(6) Where an improvement notice has been issued, the licensed provider shall display it on his or her Internet website even when an appeal under section 39R (*Appeal to District Court of certain decisions of the Authority in relation to licensing*) has been lodged.

EXPLANATORY NOTE:

This section is part modelled on section 65 of the Safety, Health and Welfare at Work Act 2006 and on section 13Z of the Electricity Regulation Act 1099 as amended by the Petroleum (Exploration and Extraction) Safety Act 2010.

It provides for HIQA to serve an improvement notice in certain circumstances.

Under subsection (1), HIQA may serve an improvement notice in writing on the provider where it considers that the provider-

- has failed to submit an improvement plan or revised improvement plan as set out in section 39K (*Improvement plan for hospital or designated activity business*), or
- has failed to implement an improvement plan following notice by HIQA under section 39K that HIQA is satisfied with the plan.
- is not operating the licensed service in line with requirements of this legislation or any other statutory provision which HIQA considers to be relevant.

Subsection (2) sets out what must be contained in an improvement notice. The notice -

- must state HIQA's opinion and give the reason for this opinion.
- must direct the licensed provider to resolve within a given timeframe the issue which led to the notice
- must set out the actions that HIQA can take as a consequence of non-compliance with the notice
- may contain any other requirement HIQA thinks appropriate.

Subsection (3) provides that an improvement notice may include directions on the measures to be taken to resolve matters referred to in the notice or otherwise comply with the notice.

Subsection (4) provides that HIQA may withdraw an improvement notice any time before the date specified to the provider for resolving matters or may extend or further extend that date at any time when an appeal against the notice is not pending.

Subsection (5) states that failure to comply with the notice within the given timeframe may lead to HIQA taking any of the actions indicated to the provider under subsection 2(d).

Under subsection (6), a licensed provider must display an improvement notice on his or her website even when an appeal under section 39R has been lodged.

SECTION 39M: PROHIBITION NOTICE

39M.-(1) Where the Authority is of the opinion that a service provided at a hospital, is being carried on, was carried on, or is likely to be carried on otherwise than in accordance with-

- (a) any requirement or any condition imposed by or under this Act, or
- (b) any other statutory provision which the Authority considers to be relevant,

the Authority may serve a notice (in this Act referred to as a 'prohibition notice') on the licensed provider of that hospital or, as the case may be, the person carrying on the business of that hospital under section 39AK (*Transitional arrangements for hospitals and designated activities*).

(2) Where the Authority is of the opinion that part of a designated activity is being carried on, was carried on, or is likely to be carried on otherwise than in accordance with-

- (a) any requirement or any condition imposed by or under this Act, or
- (b) any other statutory provision which the Authority considers to be relevant,

the Authority may serve a notice (in this Act referred to as a 'prohibition notice') on the licensed provider of that designated activity or, as the case may be, the person carrying on the business of that activity under section 39AK (*Transitional arrangements for hospitals and designated activities*).

(3) A prohibition notice shall—

- (a) state that the Authority is of the opinion referred to in subsection (1),
- (b) specify the service or part of the activity in respect of which that opinion is held,
- (c) where, in the opinion of the Authority, the matter involves a contravention, or is likely to involve a contravention, of any requirement or condition imposed by or under this Act, specify the requirement or condition concerned and the reasons for that opinion,
- (d) where, in the opinion of the Authority, the matter involves a contravention, or is likely to involve a contravention, of any other statutory provision which the Authority considers relevant, specify the provision concerned and the reasons for that opinion,
- (e) prohibit the carrying on of the service or part of the activity until the matter which gives rise to the notice is remedied,
- (f) contain details of the consequences under this Act of a failure to comply with the notice.

EXPLANATORY NOTE:

This section provides for HIQA to serve a prohibition notice on a licensed provider of a hospital or a provider carrying on the business of a hospital under the transitional arrangements for pre-existing providers. It is intended to allow the closure of a service within a hospital without closing all of the hospital services. A prohibition notice may also be served in respect of part of a designated activity. As with some other actions by HIQA, later sections provide for HIQA to give the licensee advance notice of the proposed prohibition notice or restriction notice and to outline the rights of appeal. Later sections also provide for HIQA to make an *ex parte* application to the District Court in relation to a prohibition notice or restriction notice.

Under subsection (1) a prohibition notice can be served in regard to a service within a hospital where HIQA is of the opinion that the service was, is or is likely to be carried on otherwise than as required by the legislation or any other statutory provision which HIQA considers relevant.

Subsection (2) provides, in regard to a designated activity that a prohibition notice can be served in regard to part of a designated activity where HIQA holds the opinion that part of the designated activity was, is or is likely to be carried on otherwise than as required by the legislation or any other statutory provision which HIQA considers relevant.

Under subsection (3), the notice served under subsections (1) or (2) must state the opinion specify the hospital service or part of the designated activity concerned and specify the relevant provision or provisions involved and the reason why HIQA holds such an opinion. The prohibition notice prohibits the provision of that service or that part of the designated activity until matters are remedied. The notice must refer to the consequences of non-compliance – other provisions in the General Scheme make it an offence not to comply with a prohibition notice and non-compliance could also potentially result in losing a licence.

SECTION 39N: APPLICATION BY LICENSED PROVIDER FOR VARIATION OR REMOVAL OF A CONDITION

39N.-(1) A licensed provider carrying on the business of a hospital or designated activity may apply to the Authority for the variation or removal of any condition of the licence of the hospital or designated activity.

(2) The Authority may grant an application under subsection (1) if satisfied that the variation or removal of the condition is—

(a) appropriate in the circumstances, and

(b) will not adversely affect the individuals, who are receiving services at or from the hospital or designated activity,

and if not so satisfied shall refuse the application.

(3) An application under subsection (1) shall be made in the form determined by the Authority and be accompanied by the prescribed application fee.

(4) For the purposes of subsection (3), different amounts may be prescribed for different classes of hospital or designated activity and different circumstances and regulations may provide for the Authority to determine which of the different amounts prescribed is payable in a particular case.

(5) A licensed provider shall not, in, or in respect of, an application under this section for the variation or removal of any condition of the licence of a hospital or designated activity, knowingly make a statement or representation, whether orally or in writing which is false or misleading in a material respect, knowing the statement or representation, as the case may be, to be so false or misleading or being reckless as to whether it is so false or misleading.

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EXPLANATORY NOTE:

Section 39N is partly modelled on Section 52 of the Health Act 2007 (Application by registered providers).

Subsection (1) provides that a licensed provider may apply to HIQA for the removal of or change to a condition attached to the licence of a hospital or designated activity.

Under subsection (2) HIQA may grant the application if satisfied that it is appropriate to do so and having regard to the safety of the people receiving the service. It will refuse the application if it is not satisfied.

Subsection (3), requires that an application must be made in the form specified by HIQA and must include the relevant fee. (Section 52 of the Health Act 2007 provides for the Minister to prescribe the manner in which an application may be made.)

Subsection (4) allows for different amounts to be prescribed for different classes of licensed services and different circumstances and may also allow HIQA to decide which fees apply in a particular case. In this way, application fees to change conditions attached to a licence can be tailored as appropriate. The objective of the fee system is to cover the costs incurred by HIQA in considering the application.

Under subsection (5), a licensed provider making an application for the variation or removal of any condition of the licence of a licensed service shall not knowingly make a statement which is false or misleading in a material respect.

See also section 39G (*Prohibition against false or misleading application for a licence*).

SECTION 39O: NOTICE OF CERTAIN PROPOSED DECISIONS OF AUTHORITY

390.- (1) If the Authority proposes -

- (a) under section 39H (*Grant or refusal of a licence*) to refuse an application for a licence in respect of a hospital or designated activity,
- (b) under section 39H to grant an application subject to any conditions,
- (c) under section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions, for cause*) to -
 - (i) revoke the licence of a hospital or designated activity,
 - (ii) vary or remove any condition of the licence of a hospital or designated activity, or
 - (iii) attach an additional condition to the licence of a hospital or designated activity,
- (d) under section 39L (*Improvement notice for hospital or designated activity business*) to serve an improvement notice, or
- (e) under section 39M to serve a prohibition notice (*Prohibition Notice*),

the Authority shall give the applicant, the licensed provider of the hospital or designated activity, or the person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) as the case may be, written notice of the proposal, stating the particulars.

EXPLANATORY NOTE:

This section is part of the decision making process for HIQA. Section 39O is partly modelled on section 53 of the Health Act 2007 and sets out that HIQA must give written notice to those concerned where HIQA proposes to do any of the following-

- refuse an application for a licence,
- grant a licence subject to any conditions,
- revoke a licence,
- vary or remove a condition, or attach a new condition to a licence, or
- serve an improvement notice
- serve a prohibition notice.

The written notice must set out HIQA's reasons for the proposed decision.

SECTION 39P: RIGHT TO RESPOND TO NOTICE OF PROPOSED DECISION OF AUTHORITY

39P.- (1) A written notice of a proposal under section 39O (*Notice of certain proposed decisions of the Authority*) shall state that, within a time limit of 28 days after the notice is given, the applicant, licensed provider or the person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*), as the case may be, may make written representations to the Authority concerning the matter which is the subject matter of the proposal.

(2) Where written notice of a proposal has been given under section 39O (*Notice of certain proposed decisions of the Authority*), the Authority shall not decide the matter that is the subject of the proposal until—

(a) the person to whom the notice was given has—

(i) made written representations to the Authority concerning the proposal, or

(ii) notified the Authority in writing that the person does not intend to make representations,

or

(b) the time limit of 28 days referred to in subsection (1) has elapsed.

EXPLANATORY NOTE:

This section is modelled on section 54 of the Health Act 2007 and concerns the right to respond to proposed decision of HIQA under section 39O.

Under subsection (1) the applicant, the licensed provider, or the person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*), as the case may be, who has been notified under section 39O (*Notice of certain proposed decisions of HIQA*), may write to HIQA regarding the matter within 28 days after the notice is given.

Subsection (2) provides that HIQA will not proceed with its proposals until -

(a) the person to whom the notice was given-

(i) has made either written representations, or

(ii) has indicated that he or she will not be making representations, or

(b) the 28 days allowed for the process in subsection (1) has elapsed.

SECTION 39Q: NOTICE OF CERTAIN DECISIONS OF AUTHORITY

39Q.-(1) The Authority shall give written notice to the applicant of a decision under –

- (a) under section 39H (*Grant or refusal of a licence*) to refuse an application,
- (b) under section 39H to grant an application subject to any conditions,
- (c) under section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions, for cause*) to –
 - (i) revoke the licence of a hospital or designated activity,
 - (ii) vary or remove any condition of the licence of a hospital or designated activity,
 - (iii) attach an additional condition to the licence of a hospital or designated activity,
- (d) under section 39L (*Improvement notice for hospital or designated activity*) to serve an improvement notice,

or

- (e) under section 39M to serve a prohibition notice (*Prohibition Notice*).

(2) A written notice under this section shall inform the applicant of the right of appeal conferred by section 39R (*Appeal to District Court of certain decisions of the Authority in relation to licensing*).

(3) Subject to subsection (4), a decision referred to in subsection (1) does not take effect—

- (a) if no appeal from the decision is brought, until the expiration of 28 days, or a longer period determined by the Authority, after the receipt by the applicant of written notice under this section, or
- (b) if an appeal to the District Court from the decision is brought, until the determination or withdrawal of that appeal.

(4) If the applicant—

- (a) informs the Authority in writing that the applicant he or she accepts the decision concerned of the Authority and does not intend to appeal that decision to the District Court, and
- (b) requests the Authority in writing that the decision concerned of the Authority take effect on a date that is earlier than that specified in subsection (3)(a),

that decision shall take effect on such date that is earlier than the expiration of a period of 28 days after the receipt by the applicant or licensed provider, as the case may be, of written notice under this section, as may be determined by the Authority.

(5) Notwithstanding section 39R (*Appeal to District Court of certain decisions of the Authority in relation to licensing*), an appeal to the District Court may not be brought from a decision of the Authority that takes effect under subsection (4).

EXPLANATORY NOTE:

This section is modelled on section 55, as amended, of the Health Act 2007. Under subsection (1), HIQA is required to give notice of its decision-

- to refuse a licence,
- to grant a licence subject to conditions,
- to revoke a licence, or
- vary or remove any condition or attach additional conditions to a licence
- serve an improvement notice or
- serve a prohibition notice.

Under subsection (2) HIQA must inform the person concerned of the right to appeal such a decision to the District Court under section 39R (*Appeal to District Court of certain decisions of HIQA in relation to licensing*).

Subject to subsection (4), subsection (3) puts a stay on the implementation of a HIQA decision for 28 days or a longer period decided by HIQA. If an appeal is brought to the District Court, the decision does not take effect until the appeal is determined or withdrawn.

Under subsection (4), the decision may take effect from an earlier date if the person concerned (a) informs HIQA in writing that he or she accepts HIQA's decision and does not intend to appeal that decision to the District Court, and (b) requests that the decision take effect on an earlier date.

Subsection (5) provides that an appeal to the District Court may not be brought from a decision that takes effect under subsection (4).

SECTION 39R: APPEAL TO DISTRICT COURT OF CERTAIN DECISIONS OF THE AUTHORITY IN RELATION TO LICENSING

39R.-(1) A licensed provider, a person applying for a licence in respect of a hospital or designated activity or as the case may be, a person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) may appeal to the District Court from a decision of the Authority made under section 39H (*Grant or refusal of a licence*), section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions, for cause*), section 39L (*Improvement notice for hospital or designated activity business*), section 39M (*Prohibition notice*) or section 39N (*Application by licensed provider for variation or removal of a condition*).

(2) A person who appeals to the District Court under subsection (1)—

(a) shall bring the appeal within 28 days after the receipt by the person of written notice under section 39Q (*Notice of certain decisions of Authority*), of the decision, and

(b) at the same time as the appeal is brought, shall give to the Authority written notice of the appeal.

(3) A licensed provider carrying on the business of a hospital or a designated activity who appeals to the District Court under this section may continue to carry on that business until the determination or withdrawal of that appeal or of a further appeal under section 39W (*Appeals to the Circuit Court from decision of the District Court*).

(4) On an appeal under subsection (1), the District Court, as it considers appropriate, may confirm the decision of the Authority or direct the Authority to—

(a) grant the licence of the hospital or designated activity,

(b) restore the licence of the hospital or designated activity,

(c) cancel an improvement notice,

(d) cancel a prohibition notice,

(e) vary or remove a condition of the licence, or

(f) attach an additional condition to the licence.

(5) An appeal under subsection (1) shall be made to a District Court judge assigned to the district in which the hospital or designated activity is located or the principal location of the hospital or designated activity.

EXPLANATORY NOTE:

Section 39R is modelled on section 57 of Health Act 2007.

This section allows the licensed provider, person applying for a licence or person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) to make an appeal to the District Court on decisions made by HIQA in relation to granting a licence with conditions, refusing a licence, revoking a licence, varying conditions or attaching new conditions, serving an improvement notice or serving a prohibition notice.

It sets out the procedures to be followed in making an appeal. Subsection (1) provides that the licensed provider, person applying for a licence or person carrying on the business of the hospital or designated activity under section 39AK may make an appeal to the District Court from certain decisions made by HIQA under this Part.

Subsection (2) provides that the appeal must be brought within 28 days, and HIQA must be notified in writing at the same time as the appeal is brought.

Subsection (3) allows a licensed provider to carry on the licensed service until an appeal under this specific section is either decided or withdrawn, or a further appeal to the Circuit Court arising from an appeal under this section is decided or withdrawn. However, subsection (3) would not apply in circumstances where HIQA believes on reasonable grounds that there is a risk to the life, or a serious risk to the health or welfare of patients and applies to the District Court for an order – see section 39T.

Subsection (4) provides that the District Court may confirm HIQA's decision or direct HIQA to-

- grant the licence,
- restore the licence,
- cancel an improvement notice,
- cancel a prohibition notice,
- vary or remove a condition, or
- attach an additional condition to the licence.

Under subsection (5), the appeal must be made to a District Court judge assigned to the district in which the hospital or designated activity is situated or the principal location of the hospital or designated activity.

SECTION 39S: AUTHORITY MAY SEEK DISTRICT COURT ORDER ENFORCING CERTAIN DECISIONS IN RELATION TO LICENSING

39S. -(1) If the Authority believes on reasonable grounds that any person is carrying on a hospital or designated activity in contravention of a decision—

- (a) under section 39H (*Grant or refusal of a licence*), to refuse an application,
- (b) under section 39H, to grant an application subject to any conditions,
- (c) under section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions, for cause*), to -
 - (i) revoke the licence of a hospital or designated activity,
 - (ii) vary or remove any condition of the licence of a hospital or designated activity,
 - or
 - (iii) attach an additional condition to the licence of a hospital or designated activity,
- (d) under section 39L (*Improvement Notice*) in relation to directions in an improvement notice,
- or
- (e) under section 39M (*Prohibition Notice*) in relation to a prohibition notice,

the Authority may apply to the District Court for an order to enforce the decision.

(2) The District Court on hearing an application under this section may make an order—

- (a) in the terms sought by the Authority in the application, or
- (b) in such other terms as the Court considers appropriate.

(3) An application under subsection (1) shall be made to the District Court judge assigned to the district in which the hospital or designated activity is located.

EXPLANATORY NOTE:

Section 39S is based on section 58 of the Health Act 2007.

Under subsection (1), HIQA may apply to the District Court to enforce a decision made by HIQA under this Part where HIQA believes that a hospital or designated clinical activity is being carried on in contravention of a decision to refuse a licence or revoke a licence or in contravention of any decisions on conditions, directions in an improvement notice or a prohibition notice.

Subsection (2) provides that the District Court may make an order either on the terms sought by HIQA in its application or on other terms as the Court sees fit.

Under subsection (3) an application must be made in the District Court area in which the hospital or designated activity is located.

SECTION 39T: AUTHORITY MAY SEEK DISTRICT COURT ORDER FOR REVOCATION A LICENCE, VARIATION OF, REMOVAL OF OR ATTACHING NEW CONDITIONS TO LICENCE, IMPROVEMENT NOTICE OR PROHIBITION NOTICE

39T.-(1) If the Authority believes on reasonable grounds that there is a risk to the life, or a serious risk to the health or welfare, of the persons receiving a hospital service or designated activity service because of any act, failure to act or negligence on the part of-

- (a) the licensed provider carrying on the hospital or designated activity,
- (b) a person carrying on the business of a hospital or designated activity in accordance with section 39AK (*Transitional arrangements for hospitals and designated activities*), or
- (c) a person acting on behalf of the licensed provider or person referred to in paragraph (b),

the Authority may apply to the District Court for an order—

- (i) revoking the licence of the hospital or designated activity,
- (ii) varying or removing any condition attached to the licence of hospital or designated activity,
- (iii) attaching an additional condition to the licence of the hospital or designated activity,
- (iv) serving an improvement notice, or
- (v) serving a prohibition notice.

(2) Notice of an application for a final determination of the matters that are the subject of the application shall be given by the Authority to the licensed provider.

(3) The District Court, on hearing an application under this section, may make an order—

- (a) in the terms sought by the Authority in the application, or
- (b) in other terms as the Court considers appropriate.

(4) An application under subsection (1) shall be made to a District Court judge assigned to the district in which the hospital or designated activity is located.

EXPLANATORY NOTE:

Section 39T is modelled on section 59 of the Health Act 2007. It provides for HIQA to apply to the District Court in certain circumstances for an order to revoke a licence, vary or remove any condition of a licence or attach additional conditions to the licence. It also provides for HIQA to apply for an order in relation to an improvement notice or prohibition notice - improvement notices and prohibition notices would be applicable to providers providing services under the transitional arrangements for pre-existing providers as well as for licensed providers.

Under subsection (1), HIQA can apply to the District Court for an order to revoke a licence, vary or remove any condition of a licence, attach additional conditions to the licence, serve an improvement notice or a prohibition notice where it believes that there is a risk to life, or a serious risk to the health or welfare of persons receiving a service due to any act, failure to act, or negligence on the part of the licensed provider, a person acting on behalf of the licensed provider or, as the case may be, a person providing services under transitional arrangements or someone acting on behalf of a person providing services under transitional arrangements.

Under subsection (2), HIQA must notify the licensed provider or person providing services under transitional arrangements of the application.

Subsection (3) provides that the District Court may make an order on the terms sought by HIQA, or as the Court so decides.

Under subsection (4), the application must be made to the District Court judge assigned to the district in which the hospital or designated activity is located.

SECTION 39U: *Ex Parte* INTERIM ORDER IN PROCEEDINGS UNDER SECTION 39T

39U.-(1) An application under section 39T (*Authority may seek District Court order for revocation or variation of licence, improvement notice or prohibition notice*) by the Authority may be made *ex parte* and without notice for an interim order (in this section and section 39V (*Final determination of matters dealt with in an ex parte interim order under section 39T*) called an “*ex parte* interim order” and, on that application, an *ex parte* interim order may be made-

- (a) in the terms sought by the Authority in the application, or
- (b) in other terms as the District Court considers appropriate,

if, having regard to the circumstances of the particular case, the court considers it necessary or expedient to make the order immediately in the best interests of persons receiving the service.

(2) The application for an *ex parte* interim order shall be grounded on an affidavit sworn by the Authority.

(3) The *ex parte* interim order has effect for a period, to be specified in the order, not exceeding 28 days and ceases to have effect at the end of that period unless—

- (a) by consent of the parties, or
- (b) on application by the Authority on notice to the person who was the licensed provider at the time of the application made *ex parte* under section 39T(*Authority may seek District Court order for revocation or variation of licence, improvement notice or prohibition notice*),

the District Court within that period confirms the *ex parte* interim order with effect for a specified further period.

(4) Subsection (3) does not affect any right of a party to proceedings commenced under section 39T to apply to the District Court in the proceedings.

(5) The Authority, as soon as practicable, shall serve on the person who was the licensed provider at the time of the *ex parte* application a copy of—

- (a) the *ex parte* interim order, and
- (b) the affidavit referred to in subsection (2).

(6) If an *ex parte* interim order ceases to have effect because of the operation of subsection (3) then, effective on the next day after that order ceases to have effect—

- (a) the licence of the hospital or designated activity and the status as licensed provider of the person who was the hospital’s or designated activity’s licensed provider at the time of the *ex parte* application under subsection (1) are reinstated, and
- (b) the hospital or the designated activity and the licensed provider are restored to the same status under this Act as they had immediately before the date of the *ex parte* application under section 39T(*Authority may seek District Court order for revocation or variation of licence, improvement notice or prohibition notice*).

EXPLANATORY NOTE:

This section is based on section 60 of the Health Act 2007.

Subsection (1) provides that an application by HIQA under section 39T (*Authority may seek District Court order for revocation or variation of licence, improvement notice or prohibition notice*) may be made to the District Court *ex parte* and without notice for an interim order. This interim order is known in section 39U and section 39V as an *ex parte* interim order.

The Court may make an *ex parte* interim order in the terms sought by HIQA in the application, or in other terms as the District Court considers appropriate if, having regard to the particular circumstances of the case, the Court deems it necessary or expedient to make the order immediately in the best interest of patients.

Subsection (2) provides that application to the Court for an *ex parte* interim order must be grounded in an affidavit sworn by HIQA.

Subsection (3) sets out the length of time for which the *ex parte* interim order will have effect. The period shall not exceed 28 days and ceases to have effect at the end of that period unless the Court confirms the *ex parte* interim order for a further specified period either with the parties consent or on application by HIQA.

Under subsection (4), the rights of a party to proceedings taken under section 39T will not be affected as a consequence of subsection (3).

Subsection (5) requires HIQA, as soon as practicable, to serve a copy of the *ex parte* interim order and the copy of the affidavit in question (as referred to above in subsection 2) on the licensed provider who was the licensed provider at the time of the *ex parte* application.

Under subsection (6), in a situation where an *ex parte* interim order ceases to have effect as a consequence of subsection (3), the day after the order ceases to have effect –

- the hospital or designated activity licence and the status as licensed provider of the person who was the licensed provider at the time of the *ex parte* application are reinstated, and
- the status of the hospital or designated activity and the licensed provider who was the licensed provider at the time of the *ex parte* application are restored to what they were prior to the date of the *ex parte* order.

SECTION 39V: FINAL DETERMINATION OF MATTERS DEALT WITH IN AN *EX PARTE* INTERIM ORDER UNDER SECTION 39T

39V.-(1) Within 42 days after the date of an *ex parte* interim order, the Authority may apply to the District Court for a final determination of the matters dealt with in the order.

(2) Notice of an application under this section shall be given by the Authority to the person who was the licensed provider of the hospital or designated activity or the person carrying on the business of the hospital or designated activity under section 39AK at the time of the *ex parte* application made under section 39T (*Authority may seek district court order for revocation or variation of licence, improvement notice or prohibition notice*).

(3) On the hearing of the application for a final determination of the matters dealt with in the *ex parte* interim order, the District Court may make an order—

(a) confirming, varying or setting aside the *ex parte* interim order,

(b) reinstating -

(i) the licence of the hospital or designated activity, and

(ii) the person who was the licensed provider at the time of the *ex parte* application made under section 39W (*Appeals to Circuit Court from decision of District Court in relation to licensing*), if the licence was revoked under the *ex parte* interim order, or

(c) make any other order the Court considers appropriate.

(4) If the Authority does not apply, within the 42 days set out in subsection (1), for a final determination of the matters dealt with in the *ex parte* interim order, then, effective on the next day after expiry of the 42 days—

(a) the *ex parte* interim order ceases to have effect,

(b) the licence of the hospital or designated activity and the person who was the licensed provider at the time of the *ex parte* application under section 39W (*Appeals to Circuit Court from decision of District Court in relation to licensing*) are reinstated, and

(c) the hospital or designated activity and the licensed provider are restored to the same status under this Act as they had immediately before the date of the *ex parte* application under section 39W (*Appeals to Circuit Court from decision of District Court in relation to licensing*).

EXPLANATORY NOTE:

This section is modelled on section 61 of the Health Act 2007. It provides for the final determination of matters dealt with in *ex parte* interim orders.

Subsection (1) provides that HIQA may apply to the District Court within 42 days of the grant of the *ex parte* interim order for a final decision of the matters dealt with in the interim order. The 42 day period is to limit the time in which HIQA can go to Court for a final determination of the matters in the interim order. If HIQA does not apply for a final decision within the 42 days, the *ex parte* order – if still in force – ceases to have effect.

Subsection (2) requires HIQA to give notice of an application under this section to the person who was the licensed provider at the time of the *ex parte* application was made under section 39T.

Subsection (3) provides that, on the hearing of the application for a final determination of matter/s dealt with in the *ex parte* interim order, the District Court may make an order to:

- confirm, vary or set aside the *ex parte* interim order,
- reinstate-
 - (i) the licence of the hospital or designated activity, and
 - (ii) the person who was the licensed provider of the hospital or designated activity at the time of the *ex parte* application made under Section 39W(*Appeals to Circuit Court from Decision of District Court in relation to licensing*) if the licence had been revoked under the *ex parte* interim order, or
- make any other order the Court considers appropriate.

Under subsection (4), as mentioned above, if HIQA does not apply within the 42 day timeframe for a final determination, the following takes effect from the day following the expiry of the 42 days:

- the *ex parte* interim order ceases to have effect
- the licence of the hospital or designated activity is reinstated and the status of the licensed provider of the person who was the licensed provider at the time of the *ex parte* application made under section 39T(Authority may seek district court order for revocation or variation of licence, improvement notice or prohibition notice) is also reinstated, and
- the hospital or designated activity and the licensed provider are restored to the same status under the Bill as they had immediately before the date of the *ex parte* application made under section 39T.

SECTION 39W: APPEALS TO CIRCUIT COURT FROM DECISION OF DISTRICT COURT IN RELATION TO LICENSING

39W.-An appeal lies to the Circuit Court from a decision of the District Court under section 39R(4) (*Appeal to District Court of certain decisions of the Authority in relation to licensing*), section 39T(3) (*Authority may seek District Court order for revocation or variation of licence, improvement notice or prohibition notice*), or 39V(3) (*Final determination of matters dealt with in an ex parte interim order under section 39T*).

EXPLANATORY NOTE:

This section provides for appeals to the Circuit Court from District Court decisions under sections 39R(4), 39T(3), or 39V(3). As set out earlier, section 39R provides for a licensed provider, person applying for a licence or person carrying on the business of the hospital or designated activity under section 39AK (*Transitional arrangements for hospitals and designated activities*) to make an appeal to the District Court from decisions made by HIQA in relation to granting a licence with conditions, refusing a licence, revoking a licence, varying conditions or attaching new conditions, serving an improvement notice or serving a prohibition notice. The licensed provider or person applying for a licence may then appeal the decision of the District Court to the Circuit Court. Section 39T provides for HIQA to seek a District Court order to revoke a licence, to vary or remove a condition of a licence, attach an additional condition to a licence, serve an improvement notice or serve a prohibition notice and appeals from the District Court decision may be made to the Circuit Court. Section 39V provides for a final determination of matters dealt with in *ex parte* interim order under section 39T.

SECTION 39X: STATUS OF AUTHORITY IN COURT PROCEEDINGS

39X.-The Authority is a party to any court proceedings under this Part and is entitled in any such proceeding to appear, be heard, adduce evidence and give evidence.

EXPLANATORY NOTE:

Section 39X provides that HIQA is a party to any court proceedings in relation to licensing.

It is based on section 63 of the Health Act 2007 which provides that the Chief Inspector of Social Services is a party to any court proceedings under Part 8 of the Act. (The Chief Inspector is responsible for inspecting and registering designated centres (residential centres) under the Health Act 2007 and Part 8 of the Act is concerned with the regulation of those centres.)

SECTION 39Y: NOTIFICATION OF INTENDED CESSATION OF A LICENSED SERVICE.

39Y.-(1) If a licensed provider proposes to cease to carry on the business of a hospital or designated activity for which a licence has been granted under section 39H (*Grant or refusal of a licence*), he or she shall notify the Authority of-

- (a) the date on which it is intended that the licensed service will cease to be provided, and
- (b) any arrangements that he or she is proposing to make concerning persons currently receiving licensed services or scheduled to receive such services.

(2) The Authority may require such information from a licenced provider under this section as appears necessary to it to assess the impact of the intended cessation on the persons referred to in subsection (1)(b).

EXPLANATORY NOTE:

Section 39Y is part based on section 67 of Health Act 2007.

Subsection (1) provides that where a licensed provider intends to cease the business of a hospital or designated activity for which a licence has been granted under section 39H he or she must notify HIQA of -

- the date on which it is intended to cease providing the licensed service, and
- any arrangements he or she proposes to put in place for persons currently receiving or scheduled to receive the licensed service.

Under subsection (2) HIQA may require information from a licensed provider under this section to allow it to assess the likely impact of the intended cessation on patients receiving or scheduled to receive care from the hospital or designated activity business in question.

SECTION 39Z: CANCELLATION OF A LICENCE ON CLOSURE OF A HOSPITAL OR DESIGNATED CLINICAL ACTIVITY.

To provide that-

39Z.-If a licensed provider ceases to carry on the business of a hospital or designated activity for which a licence has been granted under section 39H (*Grant or refusal of a licence*) and closes the service, the Authority shall—

- (a) make a note to that effect in the appropriate register, and
- (b) cancel the licence of the hospital or designated activity.

EXPLANATORY NOTE

Section 39Z provides that where a licensed provider discontinues the business of a hospital or designated activity for which a licence has been granted under section 39H, and closes it, HIQA must make a note to that effect in the appropriate register, and cancel the licence of the hospital or designated activity concerned.

SECTION 39AA: NOTICE OF APPOINTMENT UNDER LAW TO TAKE CHARGE OF A HOSPITAL OR DESIGNATED ACTIVITY

39AA.-(1) A person appointed by or under the law to take charge of a licensed service in place of its licensed provider (whether the licensed provider is an individual or a body corporate) shall give notice of the appointment to the Authority, as soon as practicable, but no later than 48 hours after the appointment.

(2) The Authority may accept a later notification where the Authority is of the opinion that it would be right and proper to do so.

(3) Notification made under subsection (1) shall be made in the form determined by the Authority and be accompanied by such information as may be required by the Authority.

(4) The Authority shall note in the appropriate register the name of the person notified under subsection (1) as being appointed by or under law to take charge of a licensed hospital or designated activity.

(5) The Minister may make regulations in respect of the carrying on by a person referred to in subsection (1) of a hospital or designated activity.

(6) Without limiting the generality of subsection (5) regulations may –

(a) prescribe for specified provisions of this Act to apply with prescribed modifications, if any, in cases where a person is appointed by or under the law to take charge of a hospital or designated activity in place of its licensed provider,

(b) provide for a hospital or designated activity referred to in paragraph (a) to be carried on for a prescribed period by a person who is not licensed in respect of it, and

(c) include provision for the prescribed period referred to in paragraph (b) to be extended by a further period the Authority may allow.

EXPLANATORY NOTE:

This section is modelled in part on sections 68 and 101(3)(b) of the Health Act 2007.

Subsection (1) provides that HIQA must be notified when a person has been appointed under the law to take charge of a hospital or designated activity. As indicated earlier, this is intended to cover circumstances where a licensed provider has died or is bankrupt.

Notifications should be made within 48 hours of the appointment but subsection (2) allows for the acceptance of notifications outside of this timeframe where HIQA considers appropriate.

Subsection (3) provides that notification together with whatever information as HIQA may require must be in the form decided by HIQA.

Under subsection (4), HIQA must make a note in the register where there has been a change in the person appointed to take charge of a hospital or designated activity.

Subsection (5) provides for the Minister to make regulations in relation to carrying on the hospital or designated activity by a person appointed by or under the law to take charge of a hospital or designated activity.

Subsection (6) provides that such regulations may—

- provide for specific provisions of this Act to apply with particular modifications in cases where a person has been appointed by or under the law to take charge of a licensed service in place of the licensed provider
- provide for the hospital or designated activity concerned to be carried on for a specific period of time by a person other than its licensed provider, and
- provide for that time period to be extended.

SECTION 39AB: NOTIFICATION OF MATERIAL MATTER TO AUTHORITY

39AB.— (1) A licensed provider shall give notice in writing to the Authority as soon as is practicable but, in any case, not later than 30 days after that matter comes to the knowledge of the licensed provider, of any material matter which would be likely to affect the validity of the licensee’s licence.

(2) In this Head—

“change in the principal officers”, in relation to a body corporate or a partnership, means a person becoming or ceasing to be, by whatever means, a principal officer of the body corporate or the partnership, as the case may be,

“material matter”, includes, any change to the information contained in the statement of purpose and, in relation to a licensed provider, includes—

- (a) a change in the principal officers, and
- (b) the imposition of conditions on any licence or authorisation, the revocation, suspension, withdrawal or removal of any registration or licence or other authorisation, or the refusal to grant registration or a licence or other authorisation, by any regulatory body performing functions comparable to those of the Authority in or outside the State in respect of any capacity or former capacity of the licensed provider, as the case may be, as a provider of services regulated by that body.

EXPLANATORY NOTE:

This section is partly modelled on Section 41 of Property Services (Regulation) Act 2011. Section 39AB requires a licensed provider or an applicant for a licence to notify HIQA of a ‘material matter’ which would be likely to affect the validity of the licence.

Under subsection (1) a licensed provider must notify HIQA not later than 30 days of a material matter which would be likely to affect the validity of the licence.

Subsection (2) defines particular terms used in this Head, namely “change in the principal officers” and “material matter”.

Where the licensed provider is a company or a partner in a partnership HIQA must be informed of any change in the principal officers of the company or partnership, as the case may be.

A licensed provider must inform HIQA of certain changes to licences or authorisations made by bodies – in this country or abroad – performing functions comparable to HIQA’s.

This is intended to include for example the Mental Health Commission in this country and the Care Quality Commission in England. A licensed provider for a licence must also inform HIQA of any unsuccessful applications to such bodies.

This section also requires providers to inform HIQA of any change to the information given in the statement of purpose. Section 39AD requires a licensed provider to inform HIQA of any proposed changes to a statement of purpose and the statement cannot be changed with HIQA's approval.

SECTION 39AC: PATIENT SAFETY STATEMENT

39AC.-(1) A licensed provider or a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional Arrangements*), shall prepare a patient safety statement each month in relation to the hospital or activity.

(2) The Minister may make regulations specifying -

- (a) the form of a patient safety statement,
- (b) such matters as the Minister considers appropriate to be contained in the statement

(3) Without limiting the generality of subhead (2), regulations may in particular provide for the inclusion in a patient safety statement of information on -

- (a) clinical activity,
- (b) clinical outcomes, and
- (c) patient safety incidents

in respect of the hospital or designated activity.

(4) The Minister may specify different matters in relation to the form of a patient safety statement and the matters to be contained in a patient safety statement for -

- (a) different classes of hospitals, and
- (b) different classes designated activities.

(5) A person required to have a patient safety statement under this section shall publish it on his or her Internet website and in accordance with such other arrangements as the Minister may prescribe.

(6) A person required to have a patient safety statement under this section shall comply with a request from the Authority for any information on any matter relevant to the patient safety statement.

(7) In this section;

“patient safety incident” in relation to the provision of health service to a patient by a licensed provider or a person carrying on the business of a hospital or designated activity under section 39AK, 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 licensed provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm.

EXPLANATORY NOTE:

This section sets out one of the key oversights and clinical governance requirements for licensed services and concerns the preparation, update and publication of patient safety statements by providers.

Under subsection (1) a licensed provider or a person carrying on the business of a hospital or designated activity under the transitional arrangements for pre-existing providers must prepare a patient safety statement in respect of the service each month.

Subsection (2) provides for the Minister to make regulations prescribing the form and contents of patient safety statements.

Under subsection (4), the Minister may specify different matters for different kinds of hospitals and different kinds of designated activities.

However, subsection (3) sets out particular matters that may be required to be included: these are clinical activity, clinical outcomes and patient safety incidents. Patient safety incident is defined in subsection (7) and is based in part on the meaning of "patient safety incident" in Part 4 (Open Disclosure of Patient Safety Incidents) of the Civil Liability (Amendment) Act 2017 .

Subsection (5) requires the publication of patient safety statements.

Subsection (6) requires providers to provide information to HIQA on any matter relevant to the patient safety statement where HIQA asks for information.

Head 39AD: STATEMENT OF PURPOSE

39AD. (1) The Authority shall specify-

- (a) the form of a statement of purpose to be submitted by an applicant for a licence in accordance with section 39F, and
- (b) such matters, as it considers appropriate, to be contained in the statement.

(2) The Authority may specify different matters in relation to the form and contents of a statement of purpose in relation to

- (a) different classes of hospitals, and
- (b) different classes of designated activities.

(3) Without prejudice to subsections (1) and (2), a statement of purpose submitted by an applicant for a licence in accordance with section 39F shall contain –

- (a) a statement of the aims and objectives of the hospital or designated activity the subject of the application,
- (b) a statement of the facilities and services to be provided,
- (c) information on how regulations under section 101A and other requirements of the Act will be complied with, including -
 - (i) a description of the policies, clinical standards, clinical guidelines, clinical audit processes or other means which the applicant proposes to employ for the purpose of improving quality and safety, with particular reference to those policies, clinical standards, clinical guidelines and clinical audit processes endorsed by the Minister, and
 - (ii) information on the formal clinical governance arrangements that are in place to ensure accountability within the hospital, including in relation to services provided in conjunction with other hospitals, either through a clinical network or any other means,
- (d) the procedures to be put in place to respond to a patient safety incident, including in relation to the escalation of the issue to appropriate senior managerial or clinical levels, and
- (e) information concerning the granting of any practising privileges in relation to the hospital or designated activity the subject of the application.

(4) Where the Authority gives written notice to an applicant under section 39Q(1)(a), (*Notice of certain decisions of Authority*) of a decision under section 39H to grant an application subject to any conditions, and the applicant informs the Authority in writing that he or she accepts the decision concerned of the Authority, and does not intend to appeal that decision to the District Court, the Authority shall request the applicant to amend the statement of purpose where the Authority believes the statement of purpose is not consistent with a condition to be attached to the licence.

(5) An applicant for a licence shall comply with a request from the Authority under subsection (4) and shall submit an amended statement of purpose to the Authority.

(6) On being granted a licence by the Authority under section 39H, a licensed provider shall publish, on his or her website or in accordance with such other arrangements as the Authority may agree, the statement of purpose submitted with an application under section 39F or, where the statement of purpose was amended pursuant to subsection (4), that statement of purpose.

(7) Where a licenced provider proposes to amend a statement of purpose referred to in subsection (6) the licensed provider shall advise the Authority of-

- (a) the intention to amend,
- (b) the intended amendments, and
- (c) the reasons for and purpose of the intended amendments

and shall not amend the statement of purpose without the approval of the Authority.

(8) Where the Authority approves an amendment referred to in subsection (7) of a statement of purpose, the licenced provider concerned shall publish the amended statement of purpose on his or her website or in accordance with such other arrangements as HIQA may agree.

(9) An applicant or licensed provider shall comply with any request from the Authority for any information on any matter relevant to the statement of purpose.

EXPLANATORY NOTE:

A key objective of the proposed legislative framework is to improve patient safety and quality of services by ensuring that healthcare providers do not operate below core standards set under regulations and ensuring that services are provided within an appropriate framework or setting. A statement of purpose is a mechanism for measuring if this is being achieved. The statement is a requirement of an application for a licence. Such a statement will be set out in written form and relate to the hospital or designated activity the subject of an application for a licence. As mentioned in the explanatory note for section 39F (*Application for licence*), there would also be scope for information in the statement on participation in Hospital Groups.

Section 39AD sets out the provisions for the statement of purpose. The statement must contain the information set out in subsection (3) and any other information determined by HIQA.

If a license is issued, the statement of purpose must be consistent with the licence. A licenced provider is required to publish the statement of purpose when granted a licence. Any subsequent changes a licensed provider may wish to make to the statement of purpose would require HIQA's approval. (Section 39AB requires a licensed provider to notify HIQA of any material matter. This includes any change to the information contained in the statement of purpose.)

Subsection (1) provides that HIQA shall specify both the form of the statement and others matters which HIQA considers appropriate to be contained in the statement.

Under subsection (2), HIQA may specify different matters for different kinds of hospitals and different kinds designated activities.

However, subsection (3) sets out specific matters that must be included in the statement-

(a) a statement of the aims and objectives of the hospital or designated activity the subject of the application,

(b) a statement of the facilities and services to be provided,

(c) information on how regulations under section 101A and other requirements of the Act will be complied with, including -

(i) a description of the policies, clinical standards, clinical guidelines, clinical audit processes or other means which the applicant proposes to employ for the purpose of improving quality and safety, with particular reference to those policies, clinical standards, clinical guidelines and clinical audit processes endorsed by the Minister, and

(ii) information on the formal clinical governance arrangements that are in place to ensure accountability within the hospital, including in relation to services provided in conjunction with other hospitals, either through a clinical network or any other means,

(d) the procedures to be put in place to respond to a patient safety incident, including in relation to the escalation of the issue to appropriate senior managerial or clinical levels, and

(e) information concerning the granting of any practising privileges in relation to the hospital or designated activity the subject of the application.

The proposed regulations under this legislation will be closely based on existing HIQA National Standards for Safer Better Healthcare. As such, there will be a requirement to set out the governance arrangements that have been put in place by the provider to ensure the delivery of safe and high quality healthcare, to facilitate appropriate accountability at all levels of the hospital, and to respond appropriately to adverse events when they occur. The demonstration by an applicant of how it was planning to meet the regulatory requirements in relation to audit, or the use of appropriate and relevant clinical standards and guidelines, so as to ensure the provision of safe and effective care is a key element of the licensing framework.

The use of clinical networks to deliver healthcare services, whereby clinicians employed by one hospital also provide a service in a second hospital, will also need to be referred to by applicants in the Statement of Purpose to ensure that an appropriate governance structure has been put in place by the relevant parties.

It is also to be expected that the National Clinical Effectiveness Committee (NCEC) will play an important role in this area, given that it already advises the Minister in relation to clinical effectiveness, of which policies, standards, guidelines and audit are a part.

The NCEC is a group of key stakeholders which was established on a non-statutory basis to improve quality and safety. Its mission is to provide leadership for clinical effectiveness and a framework for endorsing national clinical guidelines and national clinical audit. Ministerial endorsement requires national implementation. Therefore, a hospital's statement of purpose could be expected to set out how the hospital will take into account the relevant NCEC national clinical guidelines and national clinical audit provisions that are applicable to the services it is providing.

Subsection (4) provides for changes to an applicant's statement of purpose where HIQA proposes to grant a licence subject to conditions and HIQA believes that the statement of purpose submitted with the application is not consistent with those conditions.

(Earlier sections concerning proposed decisions by HIQA and notification of decisions are also relevant here. Under section 39O, HIQA must give notice to an applicant for a licence notice of a proposed decision to grant an application subject to conditions. There is a right to respond under section 39P. Section 39Q provides for HIQA then to give written notice to the applicant of a decision and the applicant may accept the decision or appeal the decision to the District Court.) Under subsection (4) of section 39AD, where the applicant informs HIQA under section 39Q that he or she accepts the decision, HIQA must request the applicant to amend the statement of purpose where the HIQA believes the statement of purpose is not consistent with a condition to be attached to the licence.)

Under subsection (5), an applicant for a licence shall comply with a request from the Authority under subsection (4) and shall submit an amended statement of purpose to the Authority.

Subsection (6) requires a licenced provider to publish the statement of purpose when granted the licence.

Under subsection (7), a licensed provider will need HIQA's approval to any proposed changes to the statement of purpose.

Subsection (8) requires a licensed provider to publish any amended statement of purpose.

Subsection (9) provides that an applicant for a license or a licensed provider must provide HIQA with any information relating to the statement when requested to do so by HIQA.

SECTION 39AE: NOTIFICATION OF EXECUTIVE AND MINISTER UNDER THIS PART

39AE.- (1) The Authority shall notify the Executive where, under section 39O, the Authority gives a licenced provider of a hospital written notice of a proposal to revoke the licence of the hospital and the licensed provider is providing services on behalf of the Executive pursuant to section 38 of the Health Act 2004.

(2) The Authority shall notify the Executive where, in respect of a person who provides a service on behalf of the Executive pursuant to section 38 of the Health Act 2004, the Authority-

(a) revokes a licence under section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions, for cause*),

(b) varies or removes a condition, or attaches a new condition to a licence under section 39J (*Revoking a licence, varying conditions of a licence or imposing new conditions*),

(c) issues a direction in regard to an improvement plan (*Improvement plan*) under section 39K,

(d) serves an improvement notice under section 39L (*Improvement notice*),

(e) serves a prohibition notice under section 39M (*Prohibition notice*),

(g) varies or removes a condition under section 39N (*Application by licensed provider for variation or removal of a condition*),

(h) makes an application under section 39T (*Authority may seek District Court Order for revocation of a licence, variation of, removal or attaching new conditions to a licence, improvement notice, or prohibition notice*) or an *ex parte* application in accordance with section 39U (*Ex parte Interim Order in proceedings under section 39T*),

(i) obtains an order under section 39T (*Authority may seek District Court Order for revocation of a licence, variation of, removal or attaching new conditions to a licence, improvement notice or prohibition notice*), or an *ex parte* interim order under section 39U (*Ex parte Interim Order in proceedings under section 39T*),

(j) obtains a final determination of matters dealt with in *ex parte* interim order under section 39T,

(k) receives notification of intended cessation of a hospital or designated activity under section 39Y (*Notification of intended cessation of a hospital or designated activity*),

(l) cancels a licence in accordance with section 39Z(1) (*Cancellation of a licence on closure of a hospital or designated activity*),

(m) receives a notification under section 39AA (*Notice of appointment under law to take charge of a hospital or designated activity*) of an appointment under the law to take charge of a hospital or a designated activity,

(n) receives a notification of a material matter under section 39AB (*Notification of material matter to Authority*), or

(3) The Authority shall, where it deems it to be in the public interest, notify the Executive where in respect of a provider other than a provider referred to in subsection (1), the Authority-

- (a) obtains an order under section 39T (*Authority may seek District Court Order for revocation, variation of, removal of, or attaching new conditions to a licence, improvement notice, or prohibition notice*), or an *ex parte* interim order under section 39U (*Ex parte Interim Order in Proceedings under Section 39T*),
- (b) obtains a final determination of matters dealt with in an *ex parte* interim order issued under section 39T,
- (c) receives notification of intended cessation of a hospital or designated activity under section 39Y (*Notification of intended cessation of a hospital or designated activity*),
- (d) cancels a licence in accordance with *section 39Z(1)(b) (Cancellation of a licence on closure of a hospital or designated activity)*.

(4) The Authority shall notify the Minister where, under section 39O, the Authority gives a licenced provider of a hospital written notice of a proposal to revoke the licence of the hospital and the licensed provider is the Executive or a person providing services on behalf of the Executive pursuant to section 38 of the Health Act 2004.

(5) The Authority shall inform the licensed provider concerned of a notification to the Executive under subsection (1) or a notification to the Minister under subsection (4).

EXPLANATORY NOTE:

This section deals with notifications by HIQA to the HSE and to the Minister.

Section 39O(1)(c) provides for HIQA to give written notice to a licensed provider where HIQA proposes to revoke the licence of a hospital. Under section 39P the licensed provider may make written representations to HIQA concerning this matter.

To allow the health system to prepare for the possible revocation of the licence of a public hospital, subsection (1) of section 39AE requires HIQA to notify the HSE where, under section 39O, the Authority gives a licenced provider of a hospital written notice of a proposal to revoke the licence of the hospital and the licensed provider is providing services on behalf of the HSE pursuant to section 38 of the Health Act 2004. Similarly, subsection (4) requires HIQA to notify the Minister in the case of a notification under section 39O in the case of an HSE hospital or a hospital carried on by a person providing services on behalf of the HSE pursuant to section 38 of the Health Act 2004.

Subsection (2) also has requirements for HIQA to notify the HSE of particular actions HIQA takes in relation to providers who provide services on behalf of the HSE.

The actions which require such notification are where HIQA:

- revokes a licence under section 39J
- varies or removes a condition, or attaches a new condition to a licence under section 39J
- issues a direction to submit an improvement plan under section 39K
- serves an improvement notice under section 39L
- serves a prohibition notice under section 39M

- at the request of a provider, varies or removes a condition attached to a licence under section 39N
- makes an application to the court for an order under section 39T or an ex parte application for an interim order in accordance with section 39U to revoke a licence, or vary, remove or add a condition to a licence, or serve an improvement notice or prohibition notice
- obtains a court order under section 39T or an ex parte interim order under section 39U to revoke a licence, vary or remove a condition of a licence or attach an additional condition to a licence, serve an improvement notice or prohibition notice
- obtains, a final determination of matters dealt with in *ex parte* interim order under section 39T
- receives notification of an intended cessation of a hospital or designated activity under section 39Y
- cancels a licence under section 39Z when a hospital or designated activity closes
- receives a notification of an appointment under the law to take charge of a hospital or a designated activity under section 39AA
- receives notification of material matters under section 39AB.

Sudden closure of health services delivered by other providers could have a significant impact on the health system. Subsection (2) therefore provides that where HIQA considers it to be in the public interest, HIQA must notify the HSE where HIQA has-

- obtained a court order under section 39T or an ex parte interim order under section 39U to revoke a licence, vary or remove a condition of a licence or attach an additional condition to a licence, serve an improvement notice or prohibition notice
- obtained a final determination of matters dealt with in *ex parte* interim order under section 39T
- received notification of an intended cessation of a hospital or designated activity under section 39Y
- cancelled a licence under section 39Z when a hospital or designated activity has closed.

As set out above, subsection (4) requires HIQA to notify the Minister where HIQA has given written notice under section 39O that HIQA proposes to revoke the licence of an HSE hospital or the licence of a person providing services on behalf of the HSE pursuant to section 38 of the Health Act 2004.

Subsection (5) provides that HIQA must inform the licensed provider concerned of a notification to the HSE under subsection (1) or to the Minister under subsection (4).

SECTION 39AF: SUBMISSION OF INFORMATION BY LICENSED PROVIDERS AND OTHER PERSONS

39AF.-(1) Without prejudice to section 12A (*Provision of information to the Authority on compliance with regulations under section 101A*), a licensed provider or a person carrying on the business of a hospital or designated activity under section 39AK (*Transitional arrangements*) shall submit to the Authority such information or documents at such time and in such form as the Authority may require to perform its functions under this Act.

(2) A licensed provider or other person shall not give, or cause or knowingly allow to be given any information whether orally or in writing, in purported compliance with a provision of this Act, that is false or misleading in a material particular, knowing the information to be so false or misleading or being reckless as to whether it is so false or misleading, to the Authority.

EXPLANATORY NOTE:

Subsection (1) obliges a licensed provider or person providing services under the transitional arrangements to give HIQA the information or documents HIQA requires to perform its functions. Under subsection (2) a provider or any other person shall not knowingly supply information to HIQA that is false or misleading. (See also section 39G in regard to false or misleading applications for a licence and provisions to prohibit the giving of false or misleading information to an authorised officer conducting an inspection of a hospital or designated activity in section 77 of the Health act 2007.)

In addition, there is provision for giving information under section 12A.

SECTION 39AG: DISPLAY OF LICENCE AND ISSUE OF REPLACEMENT LICENCE

39AG.-(1) A licensed provider carrying on a licensed hospital or designated activity shall ensure that a licence issued by the Authority for the licensed service is affixed in a conspicuous place at the main place of business for that hospital or activity.

(2) The Authority, if satisfied that a licence has been lost or destroyed, may issue a replacement licence on payment of a fee prescribed by the Minister for this purpose.

EXPLANATORY NOTE:

This section deals with the display of a licence and issuing a replacement licence.

Under subsection (1), a licensed provider must display the licence at the main offices of the licensed hospital or designated activity.

Subsection (2) is modelled on section 39 of the Property Services (Regulation) Act 2011.

Under subsection (2), HIQA, if satisfied that a licence has been lost or destroyed, may issue a replacement licence on payment of the appropriate fee.

SECTION 39AH: PROHIBITED CONDUCT IN RELATION TO LICENCE

39AH.- (1) In this section “licence” includes a duplicate of a licence.

(2) A licensed provider issued with a licence under this Act shall not allow the licence to be used by any other person.

(3) A person shall not forge a licence, or utter a licence knowing it to be forged, (in this section referred to as a “forged licence”).

(4) A person shall not alter a licence, or utter a licence knowing it to be altered, with intent to defraud or deceive (in this section referred to as an “altered licence”).

(5) A person shall not without lawful authority, have in his or her possession a forged licence or an altered licence.

EXPLANATORY NOTE:

Section 39AH sets out prohibitions concerning the use of a licence.

Under subsection (1), the term “licence” includes a duplicate of a licence.

Under subsection (2), a licensed provider cannot allow the licence to be used by anyone else.

Under subsection (3), a person must not forge a licence or knowingly use a forged licence.

Under subsection (4), a licence may not be altered for the purposes of defrauding or deceiving others and an altered licence may not be used.

Under subsection (5), a person shall not, without lawful authority, have in his or her possession a forged licence or an altered licence.

SECTION 39AI: PROHIBITED CONDUCT IN RELATION TO HOSPITAL OR DESIGNATED ACTIVITY

39AI. (1) Unless licensing as a hospital or designated activity of a particular description has been effected under this Part in respect of a premises, undertaking or organisation, a person shall not, with intent to deceive another person-

(a) apply a name to the premises, undertaking or organisation that in any way describes it as a hospital or designated activity of that description, or

(b) hold out the premises, undertaking or organisation as a hospital or designated activity of that description.

(2) A person shall not make any statement or representation, whether oral or written, that he or she knows to be false or misleading in any material respect, including by knowingly concealing any material fact regarding -

(a) whether he or she has a licence under this Part, or

(b) any condition attached to such a licence,

(3) A licensed provider carrying on a hospital or designated activity shall not describe or hold out the hospital or activity as able to—

(a) provide a service, the provision of which would be in contravention of

(i) the licence issued to the provider under section 39H in respect of the hospital or designated activity

(ii) a condition of the licence of the hospital or designated activity or

(iii) a prohibition notice served in respect of the hospital or activity or

(b) do anything else, the doing of which would be in contravention of

(i) the licence issued to the provider under section 39H in respect of the hospital or designated activity

(ii) a condition of the licence, of the hospital or designated activity or

(iii) a prohibition notice served in respect of the hospital or activity.

EXPLANATORY NOTE:

This section is modelled in part on the provisions in sections 56(3) and (4) of the Health Act 2007. It sets out prohibitions concerning specific conduct in relation to a hospital or designated activity.

Under subsection (1) a person must not with the intention to deceive apply a name to a premises, undertaking or organisation, or hold out premises, undertaking or organisation as a hospital or designated activity unless the premises, undertaking or organisation in question has been licensed accordingly.

Subsection (2) deals with false or misleading representation by a person. Under subsection (2) a person must not make any statement or representation be it oral or written that they know to be false or misleading regarding–

- (a) whether they hold a licence, or
- (b) the terms or conditions associated with the licence.

Under subsection (3), a licensed provider must not describe or hold out the licensed hospital or designated activity as able to provide a service, or do anything else which would in any way contravene the licence, a condition of the licence for the hospital or designated activity or a prohibition notice served in respect of the hospital or activity.

SECTION 39AJ: PAYMENT OF ANNUAL FEE AND LATE LEVY IN RELATION TO HOSPITALS AND DESIGNATED ACTIVITIES

39AJ.-(1) A licensed provider of a hospital or designated activity shall, on or before 1 June in each year, or such other date as may be notified to the licensed provider in writing by the Authority, pay to the Authority the annual fee (if any), prescribed by the Minister, in relation to the type and category of hospital or designated activity.

(2) A person carrying on the business of a hospital or designated activity under section 39AK (*Transitional Arrangements*) shall, on or before 1 June in each year, or such other date as may be notified to the person in writing by the Authority, pay to the Authority the annual fee (if any), prescribed by the Minister, in relation to the type and class of hospital or designated activity.

(3) The Authority may accept a late payment of an annual levy under subsection (1) or (2) within 3 months of the due date but only if an additional late levy (if any) prescribed by the Minister is paid at the same time as the annual fee.

EXPLANATORY NOTE:

Subsection (1) of section 39AJ requires a licensed provider to pay an annual fee to HIQA on xxxxx day or on another date as may be notified by HIQA. The fee will be set down by the Minister and will take into account the type and category of hospital or designated activity. This fee is to contribute to the costs incurred by HIQA in the performance of its inspection and monitoring functions.

Subsection (2) has similar provisions for a person providing services under transitional arrangements.

Subsection (3) provides that HIQA may accept a late payment of the annual fee within three months of the due date only if an additional charge, as set down by the Minister, is paid at the same time as the annual fee.

SECTION 39AK: TRANSITIONAL ARRANGEMENTS FOR HOSPITALS AND DESIGNATED ACTIVITIES

39AK (1) Notwithstanding section 39B(1) (*Prohibitions in relation to unlicensed hospitals or unlicensed designated activities*) but subject to this section, a person who immediately before the date section 39B(1) comes into operation was carrying on the business of a hospital and who has made an application for a licence in accordance with subsection (3) may continue to carry on that business until notified by the Authority of a decision under section 39Q (*Notice of certain decisions of Authority*) to refuse an application under section 39H (*Grant or refusal of a licence*) for a licence in respect of the hospital.

(2) No later than three months after the commencement of section 39B(1) (*Prohibitions in relation to unlicensed hospitals or unlicensed designated activities*), a person who immediately before that date was carrying on the business of a hospital, shall notify the Authority that the person is carrying on the hospital.

(3) No later than three months after the commencement of section 39B(1), a person referred to in subsection (1) shall make an application to the Authority for a licence in accordance with section 39F (*Application for a licence*).

(4) During the period referred to in subsection (1) in which a person, in accordance with that subsection, may carry on the business of the hospital, this Act applies to the person and to the hospital as if the hospital were a licensed hospital under this Act with the person as its licensed provider.

(5) Notwithstanding section 39B(2) (*Prohibitions in relation to unlicensed hospitals or unlicensed designated activities*) but subject to this section, a person who immediately before an activity is designated under this Act is carrying on the business of that activity and who has made an application for a licence in accordance with subsection (7) may continue to do so until notified by the Authority of a decision under section 39Q (*Notice of certain decisions of Authority*) to refuse an application under section 39H (*Grant or refusal of a licence*) for a licence in respect of the activity.

(6) No later than three months after an activity becomes a designated activity under this Act, a person who immediately before that date was carrying on the business of the designated activity shall notify the Authority that the person is carrying on the activity.

(7) No later than three months after an activity has been designated under this Act, a person referred to in subsection (5) shall make an application to the Authority for a licence in accordance with section 39F (*Application for licence*).

(8) During the period described in subsection (5) in which a person, in accordance with that subsection, may carry on the business of a designated activity, this Act applies to the person and to the activity as if the activity were a licensed designated activity under this Act with the person as its licensed provider.

EXPLANATORY NOTE:

When the licensing legislation comes into effect for hospitals or for a designated activity, a hospital provider and a provider of a designated activity will have to be licensed by HIQA in respect of that hospital or activity. In the case of a new hospital or a new provider of an activity or an activity being carried on in a new location, a licence will be needed before the hospital may open or before the provider may start to carry on the designated activity. While licensing will also apply to pre-existing hospitals and to pre-existing providers of designated activities, transitional arrangements will be put in place for those pre-existing hospitals and providers of pre-existing designated activities. These transitional arrangements are intended to facilitate the smooth transfer over to a licensing system. The arrangements are set out in section 39AK and allow a lead in period for HIQA and pre-existing providers.

Once licensing comes into operation for hospitals, a person already carrying on a hospital has up to three months to notify HIQA about the hospital. Elsewhere in the general scheme, provision is made for non-notification to be an offence. Within the same time period, the person must apply for a licence if the intention is to continue on with the hospital. The hospital may continue without a licence up until the outcome of the licence application is known. Although not licensed under the Bill, during this transition time i.e. pending the outcome of an application for a licence, other aspects of the licensing legislation will apply to pre-existing providers. For example, the hospital must comply with regulations made by the Minister and will be subject to monitoring and inspection by HIQA, the annual levy will be payable and improvement plans and notices will apply as appropriate.

The same arrangements are proposed for designated activities. Once the licensing legislation is brought into operation for a particular activity, any new provider will need a licence from HIQA prior to carrying on the activity and existing providers will need a licence in regard to an activity being carried on in a new location. Providers carrying on an activity immediately before the activity is designated must notify HIQA of their existence and must apply for a licence within three months of licensing coming into effect for that activity.

As with hospitals, the provider may continue to provide the service until the outcome of the application is known. Again, as with hospitals, the provisions of the legislation will apply.

Under subsection (1), a person carrying on a hospital prior to section 39B coming into force may continue the business of the hospital without a licence until the outcome of his or her application, including any appeals of decisions by HIQA in relation to the application.

Under subsection (2), a person carrying on a hospital has up to three months to notify HIQA about the hospital.

Subsection (3) requires providers of pre-existing hospitals to apply for a licence within three months.

Subsection (4) provides that during this transition period i.e. until the outcome of the licence application, the Act will apply to these providers and their services as if they were licensed. As mentioned earlier, this would include for example inspections and payment of the annual levy to HIQA.

Arrangements for pre-existing providers of designated activities are set out in subsections (5), (6), (7) and (8). These are similar to subsections (1), (2), (3) and (4).

SECTION 39AL: SERVICE OF DOCUMENTS

39AL. (1) A notice or other document that is required to be served on or given to a person under this Act shall be addressed to the person concerned by name, and may be so served on or given to the person in one of the following ways:

- (a) by delivering it to the person;
- (b) by leaving it at the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, at that address; or
- (c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, to that address.

(2) For the purpose of this section, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.

EXPLANATORY NOTE:

This section sets out the administrative arrangements for the serving of documents to a person under this Bill. It also clarifies the residency of a company within the meaning of the Companies Acts.

Subsection (1) provides that any notice or document that is required to be served or given to a person under the Bill must be addressed in name to the person concerned and it may be served or given to the person by one of the following means:

- delivering it to the person concerned;
- leaving it at the address at which the person ordinarily resides or an address provided for that purpose; or
- prepaid registered post to the address at which a person ordinarily resides or an address provided for that purpose.

Subsection (2) provides that the residency of a company, within the meaning of the Companies Acts, shall be that of its registered office, and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.

SECTION 39AM: AMENDMENT OF LICENCE

39AM.-(1) Where the certain particulars referred to in section 39H(4)(*Grant or refusal of licence*) change, the Authority may amend a licence by-

- (a) endorsing the licence with the amendment, or
- (b) revoking the licence and issuing a new licence incorporating the amendment.

(2) The particulars referred to in subsection (1) are –

- (a) the name of the licensed hospital and a description of the services provided at the hospital,
- (b) the name of the designated activity,
- (c) the name of the person in charge,
- (d) the appointment of a person by or under the law to carry on the hospital or designated activity in place of its licensed provider,
- (e) the location or locations at which the hospital or designated activity is carried on,
- (f) a condition attached to the licence,
- (g) where an improvement notice has been served or is no longer in force,
- (h) where a prohibition notice has been served or is no longer in force.

EXPLANATORY NOTE:

Under section 39H(4)(*Grant or refusal of licence*), various matters must be set out in a licence. Some of these may be subject to change and the licence may have to be amended or a new licence issued. The changes concerned are a change in the name of the hospital or activity, a change in the name of the person in charge, the appointment of a person under the law to take charge of a hospital or designated activity, a change in location, when an improvement notice has been served or when an improvement notice is no longer in force and when a prohibition notice has been serviced or is no longer in force. information on where an improvement notice has been served or is no longer in force.

SECTION 39AN: AUTHORITY TO ISSUE INFORMATION ON INSPECTION AND MONITORING FUNCTIONS

To provide that-

39AN.-(1) The Authority may from time to time, for the information of -

- (a) licensed providers,
- (b) applicants for a licence, and
- (c) the public,

prepare and issue information on the manner in which it proposes to perform its monitoring and inspection functions in accordance with section 8(1)(c), 8(1A)(b), or (c)(*Functions of the Authority*) in relation to hospitals and designated activities.

(2) The Authority shall publish information issued under this section on its Internet website and in any other manner as may be prescribed by the Minister."

EXPLANATORY NOTE:

The aim of this section is to facilitate HIQA in its work with providers and to inform providers and the public on how HIQA carries out its licensing role.

Subsection (1) provides that HIQA may prepare and issue information on how it will inspect and monitor licensed services.

Subsection (2) requires HIQA to publish any information issued on its Internet website and in any other form as may be required by the Minister.

HEAD 12: AMENDMENT OF SECTION 70 OF THE ACT OF 2007 – (APPOINTMENT BY THE AUTHORITY OF AUTHORISED PERSONS)

12. The Act of 2007 is amended by substituting the following for section 70:

“70.—(1) The Authority shall appoint, with the approval of the Minister given with the consent of the Minister for Public Expenditure and Reform, one or more persons with appropriate qualifications and experience for the purposes of—

- (a) monitoring compliance with standards in accordance with section 8(1)(c) (*Functions of the Authority*),
- (b) an investigation referred to in section 8(1)(d) undertaken by the Authority,
- (c) an inspection referred to in section 8(1A)(b), or
- (d) an inspection referred to in section 8(1A)(c),

and a person so appointed shall be known as an authorised person.

(2) At the request of an authorised person, the Authority may appoint such other number of persons that the Authority may determine, to assist that authorised person in the performance of the authorised person’s functions and the persons appointed shall be authorised persons for the purposes of—

- (a) monitoring compliance with standards in accordance with section 8(1)(c),
- (b) an investigation referred to in section 8(1)(d),
- (c) an inspection referred to in section 8(1A)(b), or
- (d) an inspection referred to in section 8(1A)(c).

(3) An authorised person shall be paid the remuneration and allowances for expenses that the Authority may determine with the approval of the Minister given with the consent of the Minister for Public Expenditure and Reform.

(4) Each authorised person shall be given a certificate of his or her appointment and, when exercising any power conferred on the Authority, shall produce, on request by any person affected, the certificate or a copy of the certificate, together with a form of personal identification.”.

EXPLANATORY NOTE:

Section 70 allows HIQA to appoint persons known as “authorised persons” to monitor compliance with standards and to carry out investigations into services. Provisions on right of entry and other powers of authorised persons are set out in later sections. Head 12 amends section 70 to take account of the licensing system and inspections against the Minister's regulations.

HEAD 13: AMENDMENT OF SECTION 73 OF THE ACT OF 2007 (RIGHT OF ENTRY AND INSPECTION BY AUTHORISED PERSON OR CHIEF INSPECTOR)

To provide that-

13. Section 73 of the Act of 2007 is amended -

(a) by substituting the following for subsection (1):

“(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)(*Functions of the Authority*),
- (b) an investigation referred to in section 8(1)(d),
- (c) an inspection referred to in section 8(1A)(b), or
- (d) an inspection referred to in section 8(1A)(c),

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

- (i) owned or controlled by the Executive, the Agency or a service provider, or
- (ii) used or proposed to be used, for any purpose connected with the provision of services described in section 8(1)(b) or
- (iii) used or proposed to be used, or which the authorised person reasonably believes is being used as a hospital or designated activity.”,

(b) in subsection (3), by substituting “of an investigation referred to in section 8(1)(d), of an inspection referred to in section 8(1A)(b), or of an inspection referred to in section 8(1A)(c),” for “or an investigation referred to in section 8(1)(d),” ,

(c) in subsection (4)(c)(i), by substituting “of an investigation referred to in section 8(1)(d), of an inspection referred to in section 8(1A)(b), or of an inspection referred to in section 8(1A)(c),” for “or of an investigation referred to in section 8(1)(d),” ,

(d) by substituting the following for subsection (5):

“(5) At any time, an authorised person, in respect of premises referred to in subsection (1), may require any person who—

- (a) is in charge of the premises or of services provided at the premises, or
- (b) possesses or is in charge of any records held at the premises or in respect of any services provided at the premises, even if the records are held elsewhere,

to furnish the authorised person with the information—

- (i) the authorised person reasonably requires for the purposes of monitoring compliance with standards in accordance with section 8(1)(c), of an investigation referred to in section 8(1)(d), of an inspection referred to in section 8(1A)(b) or of an inspection referred to in section 8(1A)(c)

and to make available to the authorised person any document or record in the power or control of the person described in paragraph (a) or (b) of this subsection that, in the opinion of the authorised person, is relevant to the monitoring of compliance with the standards, to the investigation, to the inspection referred to in section 8(1A)(b) or to the inspection referred to in section 8(1A)(c).” ,

(e) to insert the following after subsection (5):

“(5A) At any time, the chief inspector, in respect of premises referred to in subsection (2), may require any person who—

(a) is in charge of the premises or of services provided at the premises, or

(b) possesses or is in charge of any records held at the premises or in respect of any services provided at the premises, even if the records are held elsewhere,

to furnish the chief inspector with the information the chief inspector reasonably requires for the purposes of an inspection referred to in section 41 and to make available to the chief inspector any document or record in the power or control of the person described in paragraph (a) or (b) of this subsection that, in the opinion of the chief inspector, is relevant to the inspection.”.

EXPLANATORY NOTE:

Section 73 of the Health Act 2007 sets out the powers of entry and other powers of authorised persons when monitoring compliance with standards or carrying out investigations and the similar powers of the Chief Inspector of Social Services when carrying out inspections of designated centres. This Head amends section 73 to include powers for authorised persons in relation to inspecting hospitals and premises where designated clinical activities are carried on. As with section 73 as it currently stands, the amended section 73 sets out certain powers of authorised persons in regard to inspections and also sets out some obligations of people who are in charge of the premises or have control of relevant records.

HEAD 14: AMENDMENT OF SECTION 74 OF THE ACT OF 2007 (REQUIREMENT FOR CONSENT OF OCCUPIER OR DISTRICT COURT WARRANT TO ENTER DWELLING).

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

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

74.-(1) In this section, “dwelling” includes any part of a designated centre, hospital, or premises used to carry on the business of a designated activity occupied as a private residence by the registered provider of the designated centre, licensed provider of the hospital or designated activity or by a member of staff of the registered provider or licensed provider as the case may be.

(2) Notwithstanding section 73(*Right of entry & inspection by authorised person or chief inspector*), 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)(*Further circumstances in which District Court may issue warrant*) authorising the entry.”.

EXPLANATORY NOTE:

Section 74 of the Health Act 2007 provides that, notwithstanding the right of entry under section 73 (*Right of entry & inspection by authorised person or chief inspector*) of that Act, the Chief Inspector of Social Services cannot enter a dwelling other than with the consent of the occupier, or in accordance with a warrant from the District Court authorising such entry. Head 14 amends section 74 to include similar provision in regard to authorised persons in relation to hospitals and designated clinical activities –subsection (2).

The definition of “private dwelling” is amended under subsection (1) to include any part of a hospital premises or designated activity premises that is used as a private residence.

HEAD 15: AMENDMENT OF SECTION 75 OF THE ACT OF 2007 (FURTHER CIRCUMSTANCES IN WHICH DISTRICT COURT MAY ISSUE A WARRANT).

To provide that –

15. The Act of 2007 is amended by substituting the following for section 75:

“75.—(1) Where—

- (a) in relation to any premises referred to in section 73(1)(*Right of entry and inspection by authorised person or chief inspector*), an authorised person-
 - (i) monitoring compliance with the standards in accordance with section 8(1)(c)(*Functions of the Authority*), or conducting an investigation referred to in section 8(1)(d),
 - (ii) conducting an inspection referred to in section 8(1A)(b),
 - (iii) conducting an inspection referred to in section 8(1A)(c), or
- (b) in relation to any premises referred to in section 73(2), the chief inspector conducting an inspection referred to in section 41(*Functions of the Chief Inspector*),

is prevented or has reasonable cause to believe there is a likelihood that he or she will be prevented from entering the premises, an application may be made to the District Court for a warrant under subsection (2) authorising the entry.

(2) If a judge of the District Court is satisfied on the sworn information of an authorised person or the chief inspector that there are reasonable grounds for believing—

- (a) that there are any records (including records stored in a non-legible form) relating to a service, a hospital, a designated activity, a licensed provider or to a registered provider or designated centre, or that there is anything being used at the premises referred to in section 73(1) or (2), which—
 - (i) the authorised person considers it necessary to inspect for the purposes of monitoring compliance with standards in accordance with section 8(1)(c) or an investigation referred to in section 8(1)(d),
 - (ii) the authorised person considers it necessary to inspect for the purposes of an inspection referred to in section 8(1A)(b) or (c), or
 - (iii) the chief inspector considers it necessary to inspect for the purposes of an inspection referred to in section 41,
- (b) in the case of an inspection referred to in paragraph (a)(ii), that there is, or such an inspection is likely to disclose, evidence of a contravention of this Act or regulations under section 101A,

or

(c) in the case of an inspection referred to in paragraph (a)(iii), that there is, or such an inspection is likely to disclose, evidence of a contravention of—

(i) this Act or the regulations,

(ii) the provisions, specified in section 41(1)(a), of this Act, of the other Acts referred to in section 41(1)(a), or

(iii) the regulations or standards referred to in section 41(1)(c) or (d),

the judge may issue a warrant permitting the authorised person, accompanied by other persons with appropriate qualifications, or by members of the Garda Síochána as may be necessary, at any time or times, within one month after the date of issue of the warrant, on production of the warrant if requested, to enter the premises, if need be by reasonable force, and to perform the functions conferred by or under section 73.”.

EXPLANATORY NOTE:

Section 75 of the Health Act 2007 provides for other circumstances where the District Court may issue a warrant for entry to an authorised person monitoring compliance with HIQA standards or conducting an investigation or to the Chief Inspector carrying out an inspection of a designated centre. This Head amends section 75 of the Health Act 2007 to take account of licensing and include authorised persons inspecting in regard to compliance with regulations and other issues in hospitals and premises where designated activities are carried on.

Subsection (1) provides that, if an authorised person or Chief Inspector of Social Services is prevented from entering a premises or believes he or she may be prevented from entering a premises, the authorised person or Chief Inspector may apply to the District Court for a warrant authorising entry.

Under subsection (2) the judge may issue a warrant permitting the authorised person or the chief inspector or an inspector, accompanied by other persons with appropriate qualifications, or by members of the Garda Síochána as may be necessary, at any time or times, within one month after the date of issue of the warrant, on production of the warrant if requested, to enter the premises, if need be by reasonable force, and to perform the functions conferred by or under section 73)(*Right of entry and inspection by authorised person or chief inspector*).

HEAD 16: AMENDMENT OF SECTION 78 OF THE ACT OF 2007

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

“Reports of 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 of the chief inspector including reports –

(a) on compliance by a person with standards monitored in accordance with section 8(1)(c)(*Functions of the Authority*),

(b) on investigations referred to in section 8(1)(d),

(c) arising from the performance by the Authority of its functions under section 8(1)A,

(d) arising from the performance by the chief inspector of his or her functions under section 41,

(e) arising from the performance of functions under section 43(*Inspector of Social Services*) by an inspector appointed under that section, or

(f) arising from the performance of functions under section 70(*Appointment by the Authority of authorised persons*) 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), the Authority or the chief inspector, as the case may be, shall prepare a draft of the report, and give a person concerned -

(a) a copy of the draft report, and

(b) 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 or the chief inspector shall, as soon as is practicable after the expiration of the period referred to in subsection (2)(b), having—

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

(b) 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 or the chief inspector shall give a copy of the final report to a person concerned before publishing the report.

(5) The Authority, an authorised person, the chief inspector, an inspector or a person appointed under section 72 (*Appointment of qualified persons to assist chief inspector & inspectors in an inspection*) is not liable in damages arising from any—

(a) report or other document prepared, or

(b) communication made,

in good faith, for the purposes of, or in connection with, the performance of the functions—

(i) under section 70 of an authorised person appointed under that section,

(ii) under section 41(*Functions of the Chief Inspector*) of the chief inspector, or

(iii) under section 43 of an inspector appointed under that section.

(6) The Authority or the chief inspector is not liable in damages arising from reports published pursuant to subsection (1).

(7) In this section ‘person concerned’ means –

(a) in the case of a report arising from the performance of the functions of the Authority under section 8 (1)(c) relating to a service, the person providing the service,

(b) in the case of a report arising from the performance of the functions of the Authority under section 8(1)(d) relating to an investigation, the person providing the service the subject of the investigation or in the case of a designated centre, the registered provider and the person in charge of the designated centre,

(c) in the case of a report arising from the performance of the functions of the Authority in relation to a licensed hospital or a licensed designated activity under section 8(1)A, the licensed provider and the person in charge,

(d) in the case of a report arising from the performance of the functions of the Authority under section 8(1)A relating to a hospital or a designated activity carried on pursuant to section 39AK, the person providing the service and the person in charge.".

EXPLANATORY NOTE:

This Head concerns the publication of reports by HIQA and the Chief Inspector of Social Services. Qualified privilege is provided for in section 78(*Reports of authorised persons, the chief inspector and inspectors*) of the Health Act 2007. The amendments to section 78 in this Head set out the procedures to be followed in regard to reports.

Under subsection (1), HIQA and the Chief Inspector of Social Services may prepare and publish reports related to their activities and functions including reports on compliance with standards, investigations, inspections by the Chief Inspector and other inspectors of designated centres (residential centres) and other services and inspections by authorised persons of hospitals and designated activities under licensing.

Under subsection (2), a draft of a report must be given to a person concerned who has an opportunity to make a submission on the draft within 21 days. The definition of "person concerned" is in subsection (7) and is intended to cover the relevant person in each instance i.e. the provider of the service, the registered provider of a designated centre and the person in charge of the centres and the provider of the hospital or designated activity

Subsection (3) requires HIQA and the Chief Inspector as the case may be to consider any submission made. Revisions may be made and a final version is prepared.

Under subsection (4), a copy of the final version must be given to a person concerned before the report is published.

Subsections (5) and (6) contain provisions similar in nature to the current section 78.

HEAD 17: INSERTION OF SECTION 79A IN THE ACT 2007 (LICENSING OFFENCES).

17. The Act of 2007 is amended by inserting the following after section 79(*Offences*):

““**Licensing offences**

79A. – (1) A person is guilty of an offence if the person—

(a) fails to discharge a duty to which the person is subject under section 39AB (*Notification of material matter to Authority*), or section 39AK(2), (3), (6) or (7) (*Transitional arrangements for hospitals and designated activities*), or

(b) contravenes sections 39B(1), (2), (4) or (5) (*Prohibitions in relation to unlicensed hospitals or unlicensed designated activities*), section 39G (*Prohibition against false or misleading application for licence*), section 39AF(2), (*Submission of information under this Part by licensed providers and other persons*), section 39AH(3), (4), or (5) (*Prohibited conduct in relation to licence*), or section 39AI(1) (*Prohibited conduct in relation to hospital or designated activity*),

(c) fails to comply with an improvement notice,

(d) fails to comply with a prohibition notice,

(e) fails to discharge a duty to which the person is subject under a provision of the regulations under section 101A, or

(f) contravenes a provision of the regulations under section 101A.

(2) A licensed provider carrying on the business of a hospital or designated activity is guilty of an offence if the licensed provider—

(a) fails to discharge a duty to which the licensed provider is subject under section 39AG(1) (*Display of licence and issue of replacement licence*),

(b) contravenes section 39C(1) (*Practising privileges*), section 39N(5) (*Application by licensed provider for variation or removal of a condition*), section 39AH(2) (*Prohibited conduct in relation to licence*), or section 39AI(2) (*Prohibited conduct in relation to hospital or designated activity*),

(c) fails to comply with a condition of the licence.

(3) A person guilty of an offence under subsection (1) is liable—

(a) on summary conviction to a Class A fine or imprisonment for a term not exceeding 12 months or both, or

(b) on conviction on indictment to a fine not exceeding €70,000 or imprisonment for a term not exceeding 2 years or both.

(4) A licensed provider guilty of an offence under subsection (2) is liable—

(a) on summary conviction to a class A fine or imprisonment for a term not exceeding 12 months or both, or

(b) on conviction on indictment to a fine not exceeding €70,000 or imprisonment for a term not exceeding 2 years or both.”

EXPLANATORY NOTE:

Head 17 inserts a new section – section 79A – in the Health Act 2007 to set out offences and resulting penalties in regard to licensing under the Bill. These offences are partly modelled on section 79 of the Health Act 2007.

Subsection (1)(a) provides that a person will be guilty of an offence if he or she fails to discharge a duty to which the person is subject to:

- under section 39AB (*Notification of Material Matter to Authority*) by failing to notify HIQA of a material matter which would likely effect the validity of the licence,
- under section 39AK(2), (3), (6) or (7) (*Transitional Arrangements for hospitals and designated activities*)
 - by failing to notify HIQA that he or she is carrying on a hospital or designated activity
 - by failing to apply to HIQA for a licence to carry on a hospital or designated activity if the person intends to continue the business.

Subsection (1)(b) creates offences which arise where a person contravenes:

- section 39B(1), (2), (4) or (5) (*Prohibitions in relation to unlicensed hospitals or unlicensed designated activities*). A person is guilty of an offence if he or she has contravened section 39B(1) or (2), by carrying on a hospital or designated activity without a valid licence, unless the hospital or activity is being carried on in line with the transitional arrangement under section 39AK. A licensed provider or person appointed under the law in place of a licensed provider is guilty of an offence if he or she has contravened section 39B(4) by carrying on a licensed service at a location other than an approved location. A person will also be guilty of an offence if he or she has contravened section 39B(5) by managing or participating in the management of a hospital or designated activity which is not licensed or carried on under transitional arrangements for pre-existing services
- section 39G (*Prohibition against false or misleading application for licence*). A person is guilty of an offence if he or she has contravened section 39G by making a misleading or false statement when making an application for a licence
- section 39AF(2) (*Submission of information under this Part by licenced providers and other persons*). A person is guilty of an offence if he or she contravenes section 39AF(2) by knowingly supplying false or misleading information to HIQA
- section 39AH(3), (4), or (5) (*Prohibited conduct in relation to licence*). A person is guilty of an offence where he or she has contravened section 39AH(3), (4) or (5) by forging a licence or knowingly using a forged licence, altering a licence or knowingly using an altered licence with intent to defraud or deceive or, being in unlawful possession of a forged or altered licence or

- section 39AI(1) (*Prohibited conduct in relation to hospital or designated activity*). A person is also guilty of an offence where he or she contravenes section 39AI(1) by applying a name to a premises, undertaking or organisation that describes it as a licensed hospital or designated activity in order to deceive another person, or holding out the premises or undertaking or organisation as a hospital or designated activity in order to deceive another person and

Under subsections (1) (c) or (d), it is an offence not to comply with an improvement notice or a prohibition notice.

Subsections (1)(e) provides for an offence where a person fails to discharge a duty to which the person is subject under a provision of the regulations under section 101A, and subsection (1)(f) provides for an offence where a person contravenes a provision of the regulations under section 101A.

Subsection (2)(a) provides that a licensed provider is guilty of an offence if he or she fails to discharge a duty to which he or she is subject to under section 39AG(1) (*Display of licence and issue of replacement licence*) by not displaying the licence in a conspicuous place at the main place of business of the licensed hospital or designated activity.

Subsection 2(b) creates offences where a licensed provider person contravenes section 39AI(2) (*Prohibited conduct in relation to hospital or designated activity*) by indicating that the licensed hospital or designated activity can provide a service in contravention of its licence or that would contravene a condition of the licence.

Under subsection (2)(c), a licensed provider is guilty of an offence where he or she fails to comply with a condition of the licence.

Subsections (3) and (4) set out the penalties for offences. These are similar to the penalties in section 79 of the Health Act 2007.

HEAD 18: AMENDMENT OF SECTION 80 OF THE ACT OF 2007. (PROCEEDINGS FOR OFFENCES)

18. The Act of 2007 is amended by substitution of the following for section 80:

“80. —(1) Subject to subsection (3), summary proceedings for an offence under section 79 (*Offences*) may be brought and prosecuted by the chief inspector.

(2) Summary proceedings for an offence under section 79A may be brought and prosecuted by the Authority.

(3) Where a person contravenes section 77 (*Prohibition against certain conduct in relation to inspections under section 73*) by refusing to allow -

(a) an authorised person to perform his or her functions in accordance with section 73(*Right of entry & inspection by authorised person or chief inspector*), or

(b) the chief inspector to perform his or her functions in accordance with section 73 (2), summary proceedings may be brought and prosecuted by the Authority in relation to paragraph (a) and by the chief inspector in relation to paragraph (b).

(4) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under this Act may be commenced any time within—

(a) 12 months after the date of the offence, or

(b) 6 months after the date on which evidence first comes to the knowledge of the Authority or the chief inspector that is sufficient, in the opinion of the Authority or the chief inspector, to justify the bringing of the proceedings, provided that the proceedings are commenced not later than 2 years after the date of the offence.

(5) A document, purporting to have been issued by the Authority or by the chief inspector certifying the date on which the evidence described in subsection (4) first came to the knowledge of the Authority or the chief inspector—

(a) is admissible without proof of the signature or official character of the person appearing to have signed the document,

(b) in the absence of evidence to the contrary, is proof of the matters certified in the document.

(6) Where an offence under this Act—

(a) is committed by a body corporate, by a person purporting to act on behalf of a body corporate or by an individual or an unincorporated body of persons, and

(b) is proved to have been committed with the consent or approval of, or to have been attributable to any neglect on the part of, any person who, when the offence was committed, was—

(i) a director, member of the committee of management or other controlling authority of the body concerned, or

(ii) the manager, secretary or other officer of the body concerned,

that person shall also be deemed to have committed the offence and may be proceeded against and punished accordingly.

(7) Where a person is convicted of an offence under section 79A (*Licensing offences*), the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority the costs and expenses, measured by the court, incurred by the Authority in relation to the prosecution of the offence.

(8) An order for costs and expenses under subsection (7) is in addition to, and not instead of, any fine or penalty the court may impose."

EXPLANATORY NOTE:

Section 80 of the Health Act 2007 deals with proceedings for the summary prosecution of offences. It is being amended under the Bill to take account of amendments to the 2007 Act in respect of licensing. Currently, section 80 provides that summary proceedings for an offence under the Health Act 2007 may be brought and prosecuted by the Chief Inspector of Social Services, except where a person contravenes section 77 (*Prohibition against certain conduct in relation to inspections under section 73*) by refusing to allow an authorised person to monitor compliance with standards or conduct an investigation. In those circumstances the proceedings are brought by HIQA. This Head amends section 80 to allow HIQA to bring summary proceedings in regard to offences under section 79A (*Licensing offences*) and to take account of changes to section 73 (*Right of entry & inspection by authorised person or chief inspector*). It also amends section 80 to include new provisions on the payment of costs incurred by HIQA in relation to successful prosecutions.

Subsection (1) refers to prosecutions by the Chief Inspector relating to offences under section 79.

Subsection (2) provides for summary proceedings for an offence under section 79A to be brought and prosecuted by the Authority.

Subsection (3) provides for summary proceedings where a person fails to comply with section 77.

Under subsection (4), summary proceedings for an offence under this Act may be instituted within—

- 12 months from the date of the offence, or
- 6 months after HIQA or the Chief Inspector as the case may be receives information which HIQA or the Chief Inspector consider sufficient to justify the bringing of court proceedings, provided that such proceedings are brought within two years following the date on which the offence took place.

Subsection (5) is a standard provision concerning documents.

Subsection (6) provides for circumstances relating to an offence committed under this Act where the licence provider or individual is a body corporate. Where an offence committed by a body corporate is proved to have been committed with the consent or approval of, or was attributable to any wilful neglect of a person who was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person, as well as the a body corporate person is guilty of an offence.

A similar provision is not currently in the 2007 Act.

HEAD 19: REPEAL OF SECTION 100 OF THE ACT OF 2007 (REGULATIONS RESPECTING PROCEDURES FOR SETTING STANDARDS)

19. (1) Section 100 of the Act of 2007 is repealed.

EXPLANATORY NOTE:

Section 100 of the Act of 2007 is repealed because the provisions relating to publication of proposed standards, consultations and consultation periods along with provisions relating to the publication of standards are now provided for under section 10 (*Standards set by the Authority*) as amended under Head 7.

HEAD 20: INSERTION OF SECTION 101A IN ACT OF 2007 (REGULATIONS)

20. The Act of 2007 is amended by the insertion of the following section after section 101 –

“101A. REGULATIONS RESPECTING HOSPITALS AND DESIGNATED ACTIVITIES

101A-(1) The Minister, after consulting with the Authority, for the purposes of ensuring proper standards including standard for systems for corporate and clinical governance in relation to a hospital or a designated activity -

- (a) shall make regulations as the Minister thinks appropriate, and
- (b) may make different regulations for different purposes and for different classes of hospitals or designated activities.

(2) Without limiting the generality of subsection (1), regulations under this section may require a licensed provider to make adequate arrangements for the putting in place of appropriate systems and processes for one or more of the following:

- (a) the provision of person-centred care,
- (b) the provision of effective care,
- (c) the provision of safe care,
- (d) the promotion of better health and wellbeing,
- (e) leadership, corporate and clinical governance and management,
- (f) planning, organising and managing the workforce,
- (g) the use of resources,
- (h) the use of information,
- (i) dealing with complaints made by or on behalf of a person who is or was receiving a service provided by a licensed provider or who is seeking or has sought any such service,
- (j) the management of patient safety incidents.

(3) Before making regulations under this Section, the Minister shall publish a draft of the proposed regulations on the internet stating that written representations may be made before a date as specified not less than 28 days from the date of publication on the internet."

EXPLANATORY NOTE

Under this Head the Minister is required to make regulations to ensure proper standards including systems for corporate and clinical governance, for hospitals or designated activities. The regulations have the capacity to be wide ranging, from the provision of person centred care to having proper arrangements for managing patient safety incidents.

Subsection (1) requires the Minister to make these regulations for the purposes of ensuring that proper standards are being met by licensed providers of both hospitals and designated activities.

Subsection (2) sets out some of the areas that may be covered by these regulations. It is intended that the regulations be closely aligned with the National Standards for Safer Better Healthcare, which have been in effect since 2012 and which were designed as the precursor to the introduction of the licensing system.

Subsection (2)(a) allows for regulations to require providers to have appropriate systems and process for patient centred care. The HIQA ‘National Standards for Safer Better Healthcare’ describe this as placing “service users at the centre of all that the service does. It does this by advocating for the needs of service users, protecting their rights, respecting their values, preferences and diversity and actively involving them in the provision of care. Person-centred care and support promotes kindness, consideration and respect for service users’ dignity, privacy and autonomy.” It requires that the planning, design and delivery of services are informed by patients identified needs and preferences and that they are enabled to participate in making informed decisions about their healthcare. This subsection would also require that appropriate processes for dealing with service users’ complaints are put in place.

Subsection (2)(b) allows for regulations to require providers to have appropriate systems and processes for the provision of effective care in a hospital or designated activity. The healthcare provided should reflect national and international evidence of what is known to achieve best outcomes for patients, e.g. National Clinical Guidelines and nationally agreed protocols. Care should be planned and delivered to meet the needs of individual patients, with appropriate coordination within and between services in order to ensure an adequate level of integrated care. An identified healthcare professional should have overall responsibility and accountability for an individual’s care during an episode of care. It considers that care should be provided through a suitable model of service, in a physical environment that supports the delivery of safe, high quality care. It also calls for the effectiveness of the healthcare being delivered to be monitored, evaluated and continuously improved through mechanisms such as National Clinical Audit.

Subsection (2)(c) allows regulations to require providers to have appropriate systems and processes for safer care. Service providers would be obliged to ensure the care is safe. This involves designing and delivering health services to protect service users from harm, and promoting learning relevant to the provision of safe services.

Subsection (2)(d) provides for regulations to have systems and processes to promote health and wellbeing among service users. This would involve putting in place programmes to promote better health and wellbeing among patients, taking account of national policies, best available evidence and stakeholders views. It would mean that advice, information and support is available to allow patients make healthier choices, participate in initiatives to improve health and wellbeing.

In line with recommendations relating to patient safety and clinical governance as contained in the Oireachtas Committee on the Future of Healthcare Sláintecare Report, (pp. 92), subsection (2) (e), relates to the putting in place by a hospital or designated activity of the necessary clinical and corporate governance arrangements. These would include -

- systems or processes to ensure clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare
- systems and processes for formal governance arrangements to assure the delivery of high quality, safe and reliable healthcare
- effective management arrangements to support and promote the delivery of high quality, safe and reliable healthcare services
- systems or processes to assess, monitor and improve the quality and safety of care

- leadership arrangements at all levels to support all staff to exercise personal and professional responsibility for the quality and safety of the care being provided
- arrangements by service providers to set clear objectives and develop plans to deliver high quality, safe and reliable healthcare.

Subsection (2)(f) provides for regulations to require providers to have systems for the planning and organisation of staff, as well as the recruitment, management and training. Staff employed should have appropriate supports, training, professional development, supervision and appraisal to enable them to carry out their duties.

Regulations made under subsection (2)(g) would require arrangements for the effective use of resources. Resources would encompass personnel, funding and physical resources to maintain the quality of care. A licensed provider of a hospital or designated activity would be expected to have arrangements in place to plan and manage the use of resources to deliver high quality, safe and reliable healthcare efficiently. The provider would also be obliged to put in place arrangements for appropriate planning and management of physical assets, hazardous materials and waste.

Subsection (2)(h) allows regulations requiring arrangements for the appropriate use of information. Service providers should use information as a resource in planning, delivering, managing, and improving the quality, safety and reliability of healthcare with effective information governance arrangements in place. The hospital or designated activity would also be expected to have arrangements in place to ensure that information is used appropriately during individual episodes of care, so that health professionals have access to a patient's medical history and necessary information is shared appropriately. All arrangements must take into account patient confidentiality and data protection requirements.

Subsection (2)(i) provides for regulations to cover arrangements for dealing with service users' complaints.

Subsection (2)(j) provides for regulations for providers to have arrangements to properly manage patient safety incidents. A provider is required to effectively identify, manage, respond to and report on patient-safety incidents; and engage in open disclosure as soon as possible after an adverse event occurs or becomes known.

Subsection (3) provides that the Minister must publish a draft of the regulations on the internet and to invite representation from interested parties within a given period of time which will be specified in the notice. The time period can be no less than 28 days.

PART 3

REPEALS AND REVOCATIONS OF OTHER ENACTMENTS

HEAD 21: REPEALS AND REVOCATIONS OF OTHER ENACTMENTS.

21 (1) The Registration of Maternity Homes Act, 1934 is repealed.

EXPLANATORY NOTE:

The Registration of Maternity Homes Act, 1934 provided for a limited inspection and registration system for maternity homes. It will be repealed in light of the new licensing system.

