



**Tithe an  
Oireachtais**  
Houses of the  
Oireachtas

**AN COMHCHOISTE UM SLÁINTE**

**Tuarascáil maidir leis an nGrinnscrúdú Réamhrechtach ar Scéim  
Ghinearálta an Bhille um Shábháilteacht Othar (Ceadúnú)**

**Iúil 2018**

---

**JOINT COMMITTEE ON HEALTH**

**Report on Pre-Legislative Scrutiny of the General Scheme of the  
Patient Safety (Licensing) Bill**

**July 2018**

**[32H022]**

## Contents

<b>Chair’s Foreword</b> .....	<b>1</b>
<b>Executive Summary</b> .....	<b>2</b>
<b>Recommendations</b> .....	<b>3</b>
<b>1. Introduction</b> .....	<b>5</b>
1.1 Pre-Legislative Scrutiny (PLS) of the General Scheme .....	5
1.2 Why legislate.....	5
1.3 Background to Legislation.....	6
<b>2. Summary of the General Scheme</b> .....	<b>8</b>
2.1 Outline of the General Scheme.....	8
2.2 Definitions .....	10
2.3 HIQA .....	11
2.4 Standards and other requirements.....	12
<b>3. Key Issues</b> .....	<b>14</b>
3.1 Designated Person in Charge .....	14
3.2 Principal Officers .....	15
3.3 Financial capacity .....	15
3.4 Resources .....	16
3.5 Costs.....	16
3.6 Enforcement .....	17
3.7 Other Key Issues.....	17
<b>3 Appendices</b> .....	<b>20</b>
Appendix 1: Membership of the Joint Committee on Health.....	20
Appendix 2: Stakeholders and Transcripts .....	21
Appendix 3 – Terms of Reference of Committee .....	22

## Chair's Foreword



**Dr. Michael Harty T.D.**  
**(Rural Independent Technical Group)**

The Patient Safety (Licensing) Bill intends to place Ireland and its health service, both public and private, in line with international standards of regulation and governance. The Bill introduces a licensing system which establishes the Health Information and Quality Authority (HIQA) as the authority from which licences are granted.

The Bill also sets a number of requirements which health service providers must meet. Such requirements include providing financial statements and continuous patient safety reports to HIQA.

The Joint Oireachtas Committee on Health welcomes the opportunity to undertake prelegislative scrutiny of the Patient Safety (Licensing) Bill. The Committee met with officials from the Department of Health and HIQA. I wish to thank all witnesses for addressing the Committee and for their previous work up to this point in assisting with the drafting of this Bill.

This Bill is one step in an ongoing programme to improve quality in our health service. It is essential that high standards of governance and regulation are applied to the service to ensure patient safety. It is also essential that health services continue to react to patients' needs and that quality standards continue to improve.

The Committee has highlighted a number of key issues which require further consideration by the Minister.

A handwritten signature in black ink that reads "Dr. Michael Harty T.D." followed by a stylized flourish.

---

Dr. Michael Harty, T.D.  
Chair  
Joint Committee on Health  
11 July 2018

## Executive Summary

The Patient Safety (Licensing) Bill, hereinafter referred to as the Bill, sets out a licensing framework for hospitals and other services not already included in other licensing type legislation.

The aim of the licensing system is to apply governance measures to a number of high risk health services. Such services include acute hospitals both public and private. The Bill also sets out to regulate 'designated services'; high-risk clinical services provided outside of the hospital settings. Examples of designated services include facilities that provide general anaesthesia and cosmetic surgery clinics.

The Bill establishes the Health Information and Quality Authority (HIQA) as the licensing authority and increases the remit and powers of HIQA. HIQA will process licence applications and monitor the performance of licence holders. The Bill allows for Ministerial regulations with which providers must comply. The Bill will make it an offence to operate a health service without a licence.

The Bill is one part of an initiative which sets out to improve safety legislation. Section 1.3 of this report sets down some of the previous steps implemented.

This report scrutinises the General Scheme of the Patient Safety (Licensing) Bill. The report's recommendations are intended to assist in the Bills introduction to Irish law. A number of topics related to patient safety were discussed at the Committee's meeting, such as mediation during medical litigation cases and the associated costs. However, this report only refers to items specifically related to the General Scheme.

The Joint Committee on Health agreed to undertake pre-legislative scrutiny and met with officials from the Department of Health and the Health Information and Quality Authority (HIQA) on 13 June 2018.

The Committee recommends that further consideration be given to a number of key areas which were highlighted during its meeting.

## Recommendations

1. The Committee recommends that further consideration be given to the specifics on how HIQA will assess the fitness of the person in charge and clarity on the legal entity to be licensed.
2. The Committee recommends that HIQA assess the character and competence of principal officers in all hospitals and designated services. The Committee believes that equal standards of governance should be applied to public, private and voluntary hospitals and to designated activities.
3. The Committee recommends that financial assessments conducted by HIQA should be applied to both private, public and voluntary managed hospitals.
4. The Committee recommends that adequate resources be provided to HIQA to meet the obligations set out in the Bill.
5. The Committee recommends that, following the publication of the Regulatory Impact Assessment, assistance and guidance should be provided to hospitals and designated services. Such information may be crucial in informing health providers of the expected requirements and the resources required to meet them.
6. The Committee notes that HIQA will require further powers to allow it to enforce recommendations and that such enforcement powers may be included in subsequent legislation. The Committee recommends that these enforcement powers are established as quickly as possible.
7. The Committee recommends that the majority of standards set out in the Bill should be mandatory as these are more effective than non-mandatory standards.
8. The Committee recommends that in Head 9, the word “may” be replaced with “should” to ensure that all HIQA requests for information from health service providers are compulsory.
9. The Committee recommends that further consideration be given with regard to hospital groups and licensing. The Committee recommends further clarification in relation to how issues within individual hospitals would be examined, and whether additional legislation would be required to examine such situations.
10. The Committee, in reference to Section 39Q and 39R, recommends that further clarification be given on the definition of a serious risk to the life or a serious risk to the health and welfare of patients. The Committee is cognisant that grading risk presents difficulty and defining “risk” in the Bill may be necessary.

11. The Committee recommends that further consideration be given to hospitals that continue to operate while awaiting assessment. The Committee acknowledges that assessment will take time, particularly when the legislation is first implemented. However, the Committee has concerns that process delays may result in many hospitals operating without licence.

## 1. Introduction

### 1.1 Pre-Legislative Scrutiny (PLS) of the General Scheme

The drafting of the General Scheme of the Patient Safety (Licensing) Bill was approved by Government on 8 December 2017.

In January 2018, the Minister of Health, Mr Simon Harris TD, wrote to the Joint Committee on Health, referring the Bill for pre-legislative scrutiny.

The Joint Oireachtas Committee on Health met on 13 June 2018 to debate the Bill. Officials from the Department of Health and the Health Information and Quality Authority (HIQA) were in attendance to discuss the proposed legislation.

### 1.2 Why legislate

The Bill aims to bring all social and health care services in Ireland in line with international best practice in terms of regulation.

Minister Simon Harris stated that “the aim of this licensing legislation is to ensure that hospital providers in Ireland are operating to minimum core standards so that we can all have confidence in the safety, quality and effectiveness of the services that are being provided, whether in the public or the private sector.”

The Bill is part of a two-step approach in bringing all hospital providers and designated services under standards of governance.

The Health Information and Patient Safety Bill will bring all hospitals, both private and public, under HIQA’s remit<sup>1</sup>.

The Patient Safety (Licensing) Bill will give HIQA adequate powers through a system of licensing which will ensure that all hospitals and high-risk clinical activities are operating to appropriate standards and have the requisite governance arrangements in place. The Bill will grant enforcement powers to HIQA.

---

<sup>1</sup>Part 9, <https://health.gov.ie/wp-content/uploads/2015/11/Revised-General-Scheme-HIPS-Bill.pdf>

Officials from the Department of Health referred to OECD (Organisation for Economic Co-operation and Development) estimates that more than 15% of hospital expenditure goes toward correcting preventable medical mistakes or infections that people catch in hospitals across member countries.

The officials also told the Committee that in excess of €350 million is attributed by the State Claims Agency to healthcare patient safety claims for years 2012 to 2016.

### 1.3 Background to Legislation

The Patient Safety (Licensing) Bill is a part of an overall strategy to establish strong safety standards in all healthcare facilities and to establish governance and regulation in all such facilities. The following key steps illustrate some of the measures taken in this policy area.

- 2007:** The establishment of the Health Information and Quality Authority (HIQA) introduced an independent authority to promote quality and safety standards in the health service. Its remit only covers HSE-funded facilities.
- 2008:** The Report of the Commission of Patient Safety and Quality Assurance was published. The report recommended a mandatory licensing system in Ireland to cover both public and private healthcare providers.<sup>2</sup>
- 2012:** The report on the National Standards for Safer Better Healthcare was published<sup>3</sup>. This report introduced a number of patient safety standards, based on best international evidence. The report also re-iterated the Department's intention that in the future, service providers would require a licence in order to provide healthcare services.
- 2016:** The Department of Health established the National Patient Safety Office to lead patient safety policy.
- 2017:** The Oireachtas Committee on the Future of Healthcare published the Sláintecare Report in May 2017<sup>4</sup>. The report advocated for greater focus on

---

<sup>2</sup> Recommendation 6.1 [https://health.gov.ie/wp-content/uploads/2014/03/en\\_patientsafety.pdf](https://health.gov.ie/wp-content/uploads/2014/03/en_patientsafety.pdf)

<sup>3</sup> <https://www.hiqa.ie/system/files/Safer-Better-Healthcare-Standards.pdf>

<sup>4</sup> <https://webarchive.oireachtas.ie/parliament/media/committees/futureofhealthcare/oireachtas-committee-on-the-future-of-healthcare-slaintecare-report-300517.pdf>



clinical governance and recommended, inter alia “legislate for national standards in clinical governance, national and local accountability structures”.

**2018:** The Health Information and Patient Safety (HIPS) Bill<sup>5</sup> was approved by Government. The HIPS Bill intends to bring private healthcare under HIQA’s remit.

**2018:** Scrutiny of the Patient Safety (Licensing) Bill. This Bill will set up a licensing framework for all acute hospitals and designated services.

---

<sup>5</sup> <https://health.gov.ie/wp-content/uploads/2015/11/Revised-General-Scheme-HIPS-Bill.pdf>

## 2. Summary of the General Scheme

### 2.1 Outline of the General Scheme

The General Scheme of the Patient Safety (Licensing) Bill has three parts.

**Part 1:** Preliminary and General. Heads 1 to 3

**Part 2:** Amendments to the Health Act 2007, hereinafter referred to as the Act 2007

- Head 4 to 9
- Head 10, Sections 39A to 39Z and Sections 39AA to 39AN
- Head 11 to 20

**Part 3:** Repeals and Revocations Head 21

Head	Content
1	This is a standard head and gives the short title of the Bill.
2	Interpretation.
3	This is a standard head and provides for the making of order by the Minister with regard to setting the day in which the Bill will come into operations.
4	This head amends section 2 of the Act 2007 and includes key terms used in the General Scheme (See Section 2.1).
5	This head amends Section 8 of the Act and provides additional functions which HIQA will be required to undertake in order to operate a licensing regime.
6	This head amends Section 9 of the Health Act 2007 to take account of the licensing system, empowering HIQA to investigate licensed hospitals and licensed designated activities.
7	Head 7 amends Section 10 of the Act 2007 and sets out the requirements for publishing and consulting on draft standards which HIQA develops for health and social service providers. It also provides for HIQA to assess costs and benefits of a draft standard.
8	Head 8 amends section 10A and 10B of the Act 2007 and sets out guidance on compliances with standards, so that providers may be clear on what is expected in order to be in compliant.
9	This head amends Section 12 of the Health Act 2007 to also include private hospitals and private providers of designated activities among the entities that HIQA may require to provide it with information or statistics in order to determine the level of compliance by these organisations with standards set by

	HIQA.
10	This head provides that HIQA may require licensed providers or providers of hospitals and designated activities to give HIQA any information HIQA needs to determine compliance with Ministerial regulation on standards.
11	Head 11 inserts a new Part, Part 6A, in the Health Act 2007. Head 11 lists sections 39A to 39Z and Sections 39AA to 39AN.
12	Head 12 allows HIQA to appoint persons known as “authorised persons” to monitor compliance with standards and to carry out investigations into services.
13	This head amends Section 73 of the Act 2007 and sets out powers for authorised persons in relation to inspecting hospitals and premises where designated clinical activities are carried on.
14	Section 74 of the Act 2007 provides that the Chief Inspector of Social Services cannot enter the dwelling other than with the consent of the occupier or with a warrant from the District Court authorising such entry. Head 14 amends this section to include authorised persons in relation to hospitals and designated clinical activities.
15	Head 15 amends Section 75 of the Act 2007 to provide for the circumstances where the District Court may issue a warrant for entry for an authorised person inspecting in regard to compliance to the regulations listed in the Bill.
16	Head 16 amends Section 78 of the Act 2007 to set out the procedures to be followed in regard to reports of HIQA.
17	Head 17 inserts Section 79A to the Act of 2007 and sets out offences and resulting penalties in regard to licensing under the Bill.
18	Head 18 amends Section 80 of the Act 2007, and deals with proceedings for the summary prosecution of offences.
19	Head 19 repeals Section 100 of the Act 2007 because the provisions relating to the publication of proposed standards, consultations and consultation periods along with provision relating to the publication of standards are now provided for under Section 10 (Standards set by the Authority) as amended under Head 7.
20	Head 20 requires that the Minister establishes regulations to ensure proper standards including systems for corporate and clinical governance, for hospitals and designated activities.
21	Under the legislation, all hospitals and designated activities will be required to apply to HIQA for a licence. When considering a licence application, HIQA will assess whether or not the licenced provider and the person in charge are “fit and proper person”.

## 2.2 Definitions

Head 4 of the General Scheme of the Bill amends the Health Act 2007<sup>6</sup> to include key terms used in the Bill.

The Bill is intended to apply to health services not currently under regulation. Therefore, services already regulated under other legislation are excluded from the definitions of hospital and health services.

- Hospitals are defined as institutes at or through which in-patient services – medical and surgery, or palliative or obstetric care are provided under the direction of registered medical practitioners from at least three of the specialists recognised by the Medical Council in accordance with section 89 of the Medical Practitioners Act 2007.
- Health Services are defined as 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.
- A licensed provider means a person whose name is entered on a licence as a person carrying on the business of the hospital or designated activity.

---

<sup>6</sup> Section 2

## 2.3 HIQA

HIQA is an independent authority whose role is to promote quality and safety in the provision of health and social services in Ireland. It was established under the Health Act 2007.

Currently, HIQA's mandate extends to a specific range of public, private and voluntary sector services. HIQA also monitors the safety and quality of HSE-funded hospitals against the National Standards for Safer Better Healthcare.

HIQA does not monitor or regulate the private healthcare sector and as such any organisation or individual is free to establish a private facility without restrictions.

HIQA also conducts statutory investigations if there is a specific concern about the health and safety of people using health or social care services. However, any recommendations that HIQA may issue on completion of an investigation are not legally binding.

Specifically, the new Bill will add the following obligations to HIQA

- Assess all licence applications,
- Monitor hospital patient safety statement reports,
- Assess the financial capabilities of hospitals,
- Consider the competence of designated persons in charge,
- Monitor ongoing standards in private and public hospitals and designated activities.

## 2.4 Standards and other requirements

The Patient Safety (Licensing) Bill sets out a number of requirements that health care providers must meet in order to be permitted to provide high-risk health services.

- [Application for Licence](#)

It will be an offence to operate a hospital or designated activity without the appropriate licence<sup>7</sup>. All health service providers<sup>8</sup> must apply for a licence before commencing services. The Bill provides arrangements for existing hospitals while their licence applications are being processed.<sup>9</sup>

- [Statement of Purpose](#)

Health providers subject to the Bill will also be requested to include a statement of purpose for the hospital or activity<sup>10</sup>. This statement sets out the services to be provided and how regulations on standards will be met. HIQA will monitor the performance of hospitals and designated activities against this statement.

- [Designated Person in Charge](#)

Under the Bill<sup>11</sup> a licensed provider must appoint a specified person who is responsible for the overall management of the hospital or designated activity, to be known as the “person in charge”. However, the licensed provider remains ultimately responsible for the licensed service. HIQA will assess the “fitness of the person” under areas such as the competency of the person in safeguarding people and patients in the hospital, Garda vetting, and the appropriate qualifications. If such a person is deemed unfit, the provider is deemed as not compliant with the regulation.

---

<sup>7</sup>Section 39B

<sup>8</sup> Excluding those already subjected to regulation e.g. retail pharmacies, psychiatric hospitals, residential centres for older people and residential centres for people with disabilities.

<sup>9</sup> Section 39K

<sup>10</sup> Section 39AD

<sup>11</sup> Section 39i

- [Financial Statement](#)

Licensed providers will be required to submit evidence of their financial capability to carry on the business of the hospital<sup>12</sup>. Section 39F (6D) states that the licensed provider must be able to provide:

“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”.

- [Patient Safety Statement](#)

A licensed provider must prepare a patient safety statement with information on clinical activity, outcomes and patient safety incidents<sup>13</sup>. Patient Safety statements must be updated monthly and be available to the public.

Inspections may be carried out by HIQA. The frequency of such inspections is at the discretion of HIQA based on risk assessment.

---

<sup>12</sup> Section 39F (6k)

<sup>13</sup> Section 39F (6E)

### 3. Key Issues

#### 3.1 Designated Person in Charge

Section 39i (1) reads that:

“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”.

When HIQA is considering a licence application it will assess whether the licensed provider and the designated person in charge are fit and proper persons. Persons in charge are nominated by the licensed provider and are responsible for managing the service on a day-to-day basis.

However, the bill does not explicitly outline the specifics for assessment and that judgement is to be made at HIQA’s discretion.

The licensed provider in a statutory hospital will be the HSE or a voluntary organisation funded under the section 38 arrangement. In the case of a private hospital, it is likely that the licensed provider will be the body corporate i.e. the legal entity that owns the hospital. The officials from HIQA stated that clarity on the legal entity to be licensed is essential.

1. The Committee recommends that further consideration be given to the specifics on how HIQA will assess the fitness of the person in charge and clarity on the legal entity to be licensed.



### 3.2 Principal Officers

When determining whether a licensed provider of a private facility is a fit and proper person, HIQA will need to assess the character and competence of the licensed provider as well as all of its principal officers.

Principal officers are defined as directors, secretaries or members of the management committee. The Bill will require that HIQA assess the fitness of either the HSE or voluntary hospital as a whole, but are precluded from assessing the character and competence of its principal officers. Such an approach limits HIQA's ability to assess the fitness of individual managers in public hospitals and obstructs efforts to create a standardised governance mechanism across both public and private hospitals.

2. The Committee recommends that HIQA assess the character and competence of principal officers in all hospitals and designated services. The Committee believes that equal standards of governance should be applied to public, private and voluntary hospitals and to designated activities.

### 3.3 Financial capacity

The Bill requires that licensed providers submit evidence of their financial capability to carry on the business of the hospital. HIQA will assess the ability of the intended licensee to meet the costs of carrying on the business of the hospital or the designated activity.

However, this measure only applies to private providers with the HSE and voluntary organisations being excluded from the measure. HIQA acknowledges the argument to exclude HSE as they are state funded. Nonetheless, officials from HIQA recommended that voluntary hospitals should also be required to demonstrate their financial capability.

3. The Committee recommends that financial assessments conducted by HIQA should be applied to both private, public and voluntary managed hospitals.

### 3.4 Resources

The Bill will significantly increase the remit of HIQA.

HIQA currently provides regulation in social care. This Bill will allow HIQA to monitor and assess a greater number of hospitals and designated activities. As a result it will require an adequate, skilled and knowledgeable workforce not only in the area of front-line inspection but also in terms of managerial, administrative and technical support.

4. The Committee recommends that adequate resources be provided to HIQA so that it may adequately meet its increased obligations as set out in the Bill.

### 3.5 Costs

Officials from HIQA outlined some concerns regarding the readiness of the acute hospital to meet regulations and standards proposed on the Bill. The officials referred to the introduction of independent regulation into the social care sector and noted that significant investment was required in many nursing homes and residential centres for people with disabilities. The officials expect that the hospital sector will also require further investment.

The officials referenced a proposed regulatory impact assessment to be carried out by the Department of Health, which will examine the costs and benefits of introducing a licensing framework.

5. The Committee recommends that, following the publication of the Regulatory Impact Assessment, assistance and guidance should be provided to hospitals and designated services. Such information may be crucial in informing health providers of the expected requirements and the resources required to meet them.

### 3.6 Enforcement

The Bill will bring enforcement powers to HIQA in terms of the authorising of licences. Failure to meet the mandatory requirements could result in HIQA not awarding a licence or removing an already authorised licence.

However, HIQA noted that under Section 8 (referring to monitoring powers) and Section 9 (regarding investigative powers) they can make recommendations on foot of investigations but cannot enforce those recommendations. The officials from the Department of Health stated their intention to bring further enforcement powers in subsequent legislation.

6. The Committee notes that HIQA will require further powers to allow it to enforce recommendations and that such enforcement powers may be included in subsequent legislation. The Committee recommends that these enforcement powers are established as quickly as possible.

### 3.7 Other Key Issues

The Committee queried a number of specific details of the General Scheme.

#### Head 5

Head 5 states that HIQA will continue to set non-mandatory standards for hospitals and designated activities and will monitor compliance with those standards. The officials from the Department of Health stated that regulations made by the Minister will be mandatory and health service providers must meet these requirements to obtain a licence.

HIQA will set further quality standards that are recommended but not mandatory. The Committee is of the opinion that as many standards as possible should be mandatory to drive quality improvements and that there may be no incentive to meet non-mandatory standards.

7. The Committee recommends that the majority of standards set out in the Bill should be mandatory as these are more effective than non-mandatory standards.

## Head 9

Head 9 deals with statistical information to gauge compliance.

“The Authority (HIQA) may require health providers to provide it with any information or statistics the Authority needs.

The Committee stated that the word “may” be replaced with “should” to make this compulsory.

8. The Committee recommends that in Head 9, the word “may” be replaced with “should” to ensure that all HIQA requests for information from health service providers are compulsory.

## Section 39F

Section 39F sets out the detail on applications for a licence. A separate application for a licence must be made in respect of each hospital. However, hospital groups do not need to apply for individual hospital licences within their group.

However, further clarity is required as to how to address problems that may exist within an individual hospital. The Committee queried whether additional legislation would be required to take account of individual hospitals?

9. The Committee recommends that further consideration be given with regard to hospital groups and licensing. The Committee recommends further clarification in relation to how issues within individual hospitals will be examined, and whether additional legislation is required to examine such situations.

### Section 39Q

Section 39Q refers to an appeal being brought to the District Court and Section 39R refers to a belief that there is a risk to the life or a serious risk to the health and welfare of the patients. The Committee noted that there may be some difficulty in grading risk and whether the responsibility of risk is subjective. The Committee stated that a definition of risk may be required in the Bill.

10. The Committee, in reference to Section 39Q and 39R, recommends that further clarification be given on the definition of a serious risk to the life or a serious risk to the health and welfare of patients. The Committee is cognisant that grading risk presents some difficulty and defining “risk” in the Bill may be necessary.

### Section AK

Section AK provides that a hospital that has not applied for a licence can be allowed to operate until the outcome of the licence application is known. Officials from the HSE stated that this is a transitional arrangement. They noted the difficulty when legislation is first implemented and there will be a requirement to assess up to 60 hospitals within a short period of time. The Committee has concerns that unintended delays may result in a large number of hospitals operating without licence for some time.

11. The Committee recommends that further consideration be given to hospitals that continue to operate while awaiting assessment. The Committee acknowledges that assessment will take time, particularly when the legislation is first implemented. However, the Committee has concerns that process delays may result in many hospitals operating without licence.

### 3 Appendices

#### Appendix 1: Membership of the Joint Committee on Health

##### Deputies:

- Stephen Donnelly (Fianna Fáil)
- Bernard Durkan (Fine Gael)
- Dr Michael Harty [Chairman] (Rural Independent Technical Group)
- Alan Kelly (Labour)
- Kate O'Connell (Fine Gael)
- Margaret Murphy O'Mahony (Fianna Fáil)
- Louise O'Reilly (Sinn Féin)

##### Senators:

- Colm Burke (Fine Gael)
- John Dolan (Civil Engagement Technical Group)
- Rónán Mullen (Independent)
- Dr Keith Swanick (Fianna Fáil)

## Appendix 2: Stakeholders and Transcripts

The Joint Committee on Health held a hearing on 13 June 2018 to engage with relevant stakeholders to discuss the General Scheme of the Patients Safety (Licensing) Bill. The table below identifies all stakeholders who made presentations to the Committee.

### 13 June 2018

- Dr Tony Holohan, Department of Health
- Dr Kathleen MacLellan, Director of Patient Safety Office, Department of Health
- David Keating, Principal Officer, Department of Health
- Phelim Quinn, CEO, HIQA
- Mary Dunnion Chief Inspector of Social Services and Director of Regulation, HIQA
- Máirín Ryan Deputy Chief Executive and Director of Health Technology Assessment. HIQA

The transcript of the meeting of 13 [June 2018](#) is available online<sup>14</sup>.

---

<sup>14</sup> [https://data.oireachtas.ie/ie/oireachtas/debateRecord/joint\\_committee\\_on\\_health/2018-06-13/debate/mul@/main.pdf](https://data.oireachtas.ie/ie/oireachtas/debateRecord/joint_committee_on_health/2018-06-13/debate/mul@/main.pdf)

## Appendix 3 – Terms of Reference of Committee

### A) Functions of the Committee [derived from Standing Orders – DSO 84A and SSO 70A]

(1) The Committee shall consider and report to the relevant House(s) on-

- (a) such aspects of the expenditure, administration and policy of a Government Department or Departments and associated public bodies as the Committee may select, and
- (b) European Union matters within the remit of the relevant Department or Departments.

(2) The Select Committee appointed by Dáil Éireann is joined with a Select Committee appointed by Seanad Éireann (to form a Joint Committee) for the purposes of the functions set out in this Standing Order, other than at paragraph (3), and to report thereon to both Houses of the Oireachtas.

(3) Without prejudice to the generality of paragraph (1), the Select Committee shall consider, in respect of the relevant Department or Departments, such—

- (a) Bills,
- (b) proposals contained in any motion, including any motion within the meaning of DSO 187,
- (c) Estimates for Public Services, and
- (d) other matters

as shall be referred to the Select Committee by the Dáil, and

- (e) Annual Output Statements including performance, efficiency and effectiveness in the use of public moneys, and
- (f) such Value for Money and Policy Reviews as the Select Committee may select.

(4) Without prejudice to the generality of paragraph (1), the Joint Committee may consider the following matters in respect of the relevant Department or Departments and associated public bodies:

- (a) matters of policy and governance for which the Minister is officially responsible,
- (b) public affairs administered by the Department,
- (c) policy issues arising from Value for Money and Policy Reviews conducted or commissioned by the Department,



- (d) Government policy and governance in respect of bodies under the aegis of the Department,
- (e) policy and governance issues concerning bodies which are partly or wholly funded by the State or which are established or appointed by a member of the Government or the Oireachtas,
- (f) the general scheme or draft heads of any Bill
- (g) any post-enactment report laid before either House or both Houses by a member of the Government or Minister of State on any Bill enacted by the Houses of the Oireachtas,
- (h) statutory instruments, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009,
- (i) strategy statements laid before either or both Houses of the Oireachtas pursuant to the Public Service Management Act 1997,
- (j) annual reports or annual reports and accounts, required by law, and laid before either or both Houses of the Oireachtas, of the Department or bodies referred to in subparagraphs (d) and (e) and the overall performance and operational results, statements of strategy and corporate plans of such bodies, and
- (k) such other matters as may be referred to it by the Dáil from time to time.

(5) Without prejudice to the generality of paragraph (1), the Joint Committee shall consider, in respect of the relevant Department or Departments—

- (a) EU draft legislative acts standing referred to the Committee under DSO 114 and SSO 107, including the compliance of such acts with the principle of subsidiarity,
- (b) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,
- (c) non-legislative documents published by any EU institution in relation to EU policy matters, and
- (d) matters listed for consideration on the agenda for meetings of the relevant EU Council of Ministers and the outcome of such meetings.

(6) Where the Select Committee appointed by Dáil Éireann has been joined with a Select Committee appointed by Seanad Éireann, the Chairman of the Dáil Select Committee shall also be the Chairman of the Joint Committee.

(7) The following may attend meetings of the Joint Committee, for the purposes of the functions set out in paragraph (5) and may take part in proceedings without having a right to vote or to move motions and amendments:

- (a) members of the European Parliament elected from constituencies in Ireland, including Northern Ireland,
- (b) members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and
- (c) at the invitation of the Committee, other members of the European Parliament.

(8) The Joint Committee may, in respect of any Ombudsman charged with oversight of public services within the policy remit of the relevant Department or Departments, consider—

- (a) such motions relating to the appointment of an Ombudsman as may be referred to the Committee, and
- (b) such Ombudsman reports laid before either or both Houses of the Oireachtas as the Committee may select: Provided that the provisions of DSO 111F apply where the Committee has not considered the Ombudsman report, or a portion or portions thereof, within two months (excluding Christmas, Easter or summer recess periods) of the report being laid before either or both Houses of the Oireachtas.

**B) Powers of the Committee [derived from Standing Orders – DSO 85, 114 and 116 and SSO 71, 107 and 109]**

The Joint Committee has:-

- (1) power to take oral and written evidence and to print and publish from time to time minutes of such evidence taken in public before the Committee together with such related documents as the Committee thinks fit;
- (2) power to invite and accept oral presentations and written submissions from interested persons or bodies;
- (3) power to appoint sub-Committees and to refer to such sub-Committees any matter comprehended by its orders of reference and to delegate any of its powers to such sub-Committees, including power to report directly to the Dáil and to the Seanad;
- (4) power to draft recommendations for legislative change and for new legislation;
- (4A) power to examine any statutory instrument, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009,

and to recommend, where it considers that such action is warranted, whether the instrument should be annulled or amended;

- (4B) for the purposes of paragraph (4A), power to require any Government Department or instrument-making authority concerned to submit a Memorandum to the Committee explaining any statutory instrument under consideration or to attend a meeting of the Committee for the purpose of explaining any such statutory instrument: Provided that such Department or authority may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil;
- (5) power to require that a member of the Government or Minister of State shall attend before the Committee to discuss policy for which he or she is officially responsible: Provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil and Seanad: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Committee to enable him or her to discuss such policy;
- (6) power to require that a member of the Government or Minister of State shall attend before the Committee to discuss proposed primary or secondary legislation (prior to such legislation being published) for which he or she is officially responsible: Provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil and Seanad: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Committee to enable him or her to discuss such proposed legislation;
- (6A) power to require that a member of the Government or Minister of State shall attend before the Committee and provide, in private session if so requested by the member of the Government or Minister of State, oral briefings in advance of meetings of the relevant EU Council of Ministers to enable the Committee to make known its views: Provided that the Committee may also require such attendance following such meetings;
- (6B) power to require that the Chairperson designate of a body or agency under the aegis of a Department shall, prior to his or her appointment, attend before the Committee to discuss his or her strategic priorities for the role;
- (6C) power to require that a member of the Government or Minister of State who is officially responsible for the implementation of an Act shall attend before a Committee in relation to the consideration of a report under DSO 164A and SSO 157A;
- (7) subject to any constraints otherwise prescribed by law, power to require that principal office-holders in bodies in the State which are partly or wholly funded by the State or which are established or appointed by members of the Government or by the Oireachtas shall attend

meetings of the Committee, as appropriate, to discuss issues for which they are officially responsible: Provided that such an office-holder may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the relevant House(s);

- (8) power to engage, subject to the consent of the Houses of the Oireachtas Commission, the services of persons with specialist or technical knowledge, to assist it or any of its sub-Committees in considering particular matters; and
- (9) power to undertake travel, subject to—
  - (a) such recommendations as may be made by the Working Group of Committee Chairmen under DSO 108(4)(a) and SSO 104(2) (a); and
  - (b) the consent of the Houses of the Oireachtas Commission, and normal accounting *procedures*.

*In accordance with Articles 6 and 8 of Protocol No. 2 to the Treaty on European Union and the Treaty on the Functioning of the European Union (Protocol on the Application of the Principles of Subsidiarity and Proportionality) as applied by sections 7(3) and 7(4) of the European Union Act 2009, the Committee has the power-*

- (a) to consider whether any act of an institution of the European Union infringes the principle of subsidiarity [DSO 116; SSO 109]; and
- (b) to form a reasoned opinion that a draft legislative act (within the meaning of Article 3 of the said Protocol) does not comply with the principle of subsidiarity [DSO 114 and SSO 107].

### **C: Scope and context of activities of the Committee**

In addition to the powers and functions that are given to Committees when they are established, all Oireachtas Committees must operate within the scope and context of activities in Dáil Standing Order 84 and Seanad Standing Order 70 as set out below.

- A Committee may only consider such matters, engage in such activities, exercise such powers and discharge such functions as are specifically authorised under its orders of reference and under Standing Orders;
- Such matters, activities, powers and functions shall be relevant to, and shall arise only in the context of, the preparation of a report to the relevant House(s).
- A Committee shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Committee of Public Accounts pursuant to DSO 186 and/or the Comptroller and Auditor General (Amendment) Act 1993;
- A Committee shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Joint Committee on Public Petitions in the exercise of its functions under DSO 111A(1); and
- A Committee shall refrain from inquiring into in public session or publishing confidential information regarding any matter if so requested, for stated reasons given in writing, by—
  - (i) a member of the Government or a Minister of State, or
  - (ii) the principal office-holder of a body under the aegis of a Department or which is partly or wholly funded by the State or established or appointed by a member of the Government or by the Oireachtas:

Provided that the Chairman may appeal any such request made to the Ceann Comhairle, whose decision shall be final.