

# **REVISED GENERAL SCHEME OF THE HEALTH INFORMATION AND PATIENT SAFETY BILL**

## **REGULATORY IMPACT ANALYSIS**

### **1. POLICY CONTEXT**

#### **1.1 Background**

The Health Information Bill has been renamed the Health Information and Patient Safety Bill to take account of the patient safety elements contained in it. This Regulatory Impact Analysis (RIA) replaces the RIA carried out on the original General Scheme of the Health Information Bill and reflects changes to the original scheme. In particular, this RIA deals with the further development of provisions for research ethics approval processes, the further development of provisions on data matching, the further development of provisions on health information resources (i.e. population registries, databases and indexes), and the inclusion of new provisions on extending the remit of the Health Information and Quality Authority (HIQA) to the private health service.

1.2 At European level, work is ongoing on a new EU Regulation on Data Protection to replace the current EU Data Protection Directive. Progress on that Regulation is being monitored to ensure that the Bill is consistent with the draft Regulation.

#### **1.3 Health Information**

1.3.1 Good information is an essential component in achieving health service objectives and the effective planning, management and delivery of safer better healthcare. The eHealth Strategy (launched in 2013), the establishment of the Office of the CIO (2015) and the launch of the work plan set out in the HSE Knowledge and Information Plan (2015) are some of the key elements already initiated. The enactment of the Health Identifiers Act 2014 was also a very important initiative. The Health Information and Patient Safety Bill is intended to add to these initiatives through providing for the setting of standards by the Minister for Health on the efficient electronic exchange (inter-operability) of health information and the setting of voluntary best practice standards by HIQA for health service providers on the processing of health information

1.3.2 The revised General Scheme also sets out a regulatory framework for data matching in the health service and a similar framework for health information resources. Data matching (sometimes called data linking) is where personal information collected for one purpose by one organisation is subsequently matched with data collected for another purpose by the same or another organisation. Data matching is therefore about building up a bigger picture, for health related purposes, of an individual from various unrelated strands of information collected for various unrelated purposes. This can assist patient care and help health service management, allowing the information necessary to make a decision to be put together from various available sources without the need to collect the same information again. It is potentially an efficient and cost-effective information management tool.

1.3.3 Health information resources are defined in the revised General Scheme to cover health information registries, databases, indexes, etc. that contain personal data. These data collections have considerable benefits in areas like disease monitoring and health service management and have a major role to play in supporting and driving improvements in health service planning and outcomes. Their effectiveness is related to their population coverage and they need to be (relevant) population based, of high quality, with robust information governance structures. The National Cancer Registry would be an example of a national health information resource.

1.3.4 While data matching and health information resources can bring undoubted benefits to the health services, they also bring privacy considerations. It is essential therefore that the enabling legislation has the appropriate checks and balances for proper regulation and control and helping to ensure public confidence. In that regard, the Bill sets out a detailed governance framework that will be further underpinned by Regulations and with roles for both HIQA and the Data Protection Commissioner.

## **1.4 Health Research**

1.4.1 Health research makes a valuable contribution to the health service and to the achievement of wider social and economic goals. Knowledge derived from research is paramount in providing the evidence-base for better health policies, practices and systems. This evidence is essential to the creation of a fairer, more efficient health system and for the delivery of better health outcomes. Health research provides us with the evidence to address key challenges in our society - radical demographic change, an ageing population, increases in the number of people living with chronic diseases, the spiralling cost of providing healthcare services and medication, greater demand from citizens for higher quality and more personalised care and greater need to shift investment from acute to primary, community and self-managed care. The highest performing health care systems have research embedded in service delivery and produce innovation and outcomes which are of benefit to patients, enterprise, the nation's health and the tax payer as funder.

Consideration of ethical issues has long been a feature of this research and ethical scrutiny both builds and maintains public confidence in research and assists researchers in identifying and addressing ethics issues. Research ethics approval in regard to clinical trials of medicinal products for human use and medical devices is provided for under EU law, currently transposed by Statutory Instruments. However, structures for research ethics in relation to other types of human research are more fragmented involving local or institutional based research ethics committees. This fragmentation, and its accompanying potential for lack of uniformity, can result in variable outcomes. It also means that researchers carrying out national or regional human health research projects, not coming under an ethics structure provided for in EU law, may in some instances have to go a number of local/institutional research ethics committees before their project may commence. A streamlined process would therefore benefit this research.

1.4.2 In addition, in some instances, health research projects that might yield significant benefit may not perhaps be carried out because the obtaining of individual consent in regard to personal data by a researcher would, for example, be overly onerous or costly. Accordingly, a transparent, limited and controlled consent exemption would have merit.

## **1.5 Patient Safety**

### **1.5.1 Supporting appropriate sharing of personal data by health regulatory bodies - Part 1**

The Bill facilitates a health regulatory body in disclosing personal data information to another regulatory body where the regulatory body believes the information is relevant to the functions of that other body. The intention is to support earlier action on patient safety matters.

### **1.5.2 Supporting clinical audit and improving patient safety through learning from patient safety incidents**

#### **1.5.3 Clinical audit**

Patient safety and quality improvement is a critical aspect of healthcare provision. As part of a range of patient safety initiatives, the Report of the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety*, included recommendations designed to support quality improvement learning systems. The Commission identified clinical audit as an essential mechanism to monitor quality, assure the safety and quality of services and ensure ongoing quality improvement through identifying opportunities for improvement.

1.5.4 The Commission said: *"It is recognised that clinical audit needs to be at the heart of clinical practice, and is something that all health practitioners should be engaged in. Clinical audit is about continuing evaluation and improvement by health professionals working towards delivery of safe, high quality care for patients. Clinical audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides. It is one of the principal methods used to monitor clinical quality and the results provided by clinical audit are a source of indispensable information to patients, the public, clinicians and health managers. It also provides a powerful mechanism for ongoing quality improvement, highlighting incidents where standards are not met and identifying opportunities for improvement."*

Challenges to clinical audit were identified including that: *"If clinicians are to learn and improve from clinical audit, conclusions reached during these processes need to be documented. However, to encourage participation in clinical audit, clinicians need to feel safe with the process and to be assured that it will not be used against them in a punitive manner."*

In view of this, the Commission went on to recommend that legislation should be enacted to give exemption from Freedom of Information legislation and to grant legal protections from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for the purposes of improving safety and quality. The Commission also said that if clinical audit is to be granted any such exemption or legal privilege, organisations or clinicians who participate in clinical audit must publish aggregated information about clinical audit.

### **1.5.5 External notification of patient safety incidents**

As well as clinical audit, the Commission looked at adverse event reporting. In describing the objectives of adverse event reporting, the Commission said that *"The primary purpose of event reporting is to learn from the experience of adverse events and near-misses in order to reduce or prevent patient injury or harm."* The Commission recommended that there should be mandatory national reporting of adverse events which result in death or serious harm and provision for (voluntary) reporting of other less serious adverse events and 'near-misses'.

It is important to acknowledge that many adverse events and poor outcomes in healthcare arise from system wide factors acting together and rarely arise solely because of shortcomings or failures on the part of individuals. However, the Commission recognised that fear of litigation and damage to professional reputation can present a significant challenge for professionals in engaging with incident reporting processes. This is supported by international experience. Recommendations were therefore made on FOI exemptions and on legal protections.

### **1.5.6 Open disclosure of adverse events to patients**

Recommendations were also made by the Commission on open disclosure to patients of adverse incidents. Provisions in relation to this are to be included in other legislation.

## **1.6 Extending HIQA's remit to the private health service**

1.6.1 Establishing a licensing system for public and private health service providers is an integral part of the Government's Health Service Reform Programme, arising from commitments in the Programme or Government and the Strategic Framework for Reform of the Health Service 2012 – 2015 *Future Health*. Previously, the Commission on Patient Safety and Quality Assurance also made recommendations on the development of a licensing system to be operated by HIQA, initially focusing on hospitals and other high risk clinical activities provided in other settings.

1.6.2 The Government is adopting a phased approach to the regulation of healthcare. Currently private healthcare providers of clinical health services are not within HIQA's remit. However, the Health Act 2007 inter alia provides for HIQA to set standards for the HSE and service providers funded by the HSE on the safety and quality of clinical services they provide. While these standards are not mandatory, HIQA has extensive powers to monitor compliance with the standards. HIQA can also, on its own initiative or when required by the Minister for Health, undertake investigations as to the safety and quality and standards of services. As part of the move towards licensing, the Government proposes to bring the private/independent healthcare service within HIQA's remit in the same way as the HSE clinical services and HSE funded clinical services are under the Health Act 2007.

1.6.3 In recent years concerns have been expressed about the safety and quality of some services being provided privately or independently particularly in the area of cosmetic surgery. Extending HIQA's remit to private health services would mean that private providers of services designated as "high risk" would be subject to the same conditions that apply at present to public providers. HIQA could monitor compliance in the private health

service with the National Standards for Safer Better Healthcare. The National Standards would enable HIQA to identify where quality and safety improvements might be made in the delivery of services. Furthermore, under section 9 of the Health Act 2007 HIQA would be provided with the power to undertake an investigation in the private health service as to the safety, quality and standards of the services if HIQA or the Minister believes that there is a serious risk to the health or welfare of a person receiving those services.

1.6.4 The changing face of delivery models in healthcare has the potential for higher risk clinical activities to be provided outside of the traditional hospital setting. There is inadequate information overall on the number of private providers of healthcare services, the range of services provided and the quality of such services. HIQA is undertaking a scoping exercise to assess the extent and diversity of “high risk” activity in private healthcare in Ireland. High risk activities include medical treatment under anaesthesia or sedation, dental treatment under general anaesthesia, cosmetic surgery and techniques or technologies such as laser eye surgery. HIQA has reported that this exercise has become more complex as it progresses in view of the diversity of private healthcare and the services being provided. However, a report on the scoping exercise is due shortly and the results of this work will inform decisions on prioritisation of particular activities for regulation.

## **2. OBJECTIVES**

The objectives of the draft Bill are to:

- (1) strengthen arrangements for patients in regard to their health information in specific areas;
- (2) facilitate the structured development of information technology and the eHealth agenda and also improve the standard of data management in the health service;
- (3) provide for a streamlined research ethics approval framework;
- (4) facilitate a population based approach to the use of health information in important areas of the health service - data matching programmes and health information resources;
- (5) support a culture of patient safety and also facilitate appropriate sharing of information;
- (6) extend HIQA's remit to the private health service.

## **3. IDENTIFICATION OF POLICY OPTIONS**

### ***3.1 Arrangements for patients in regard to their health information - Part 2 of the revised General Scheme***

3.1.1 The draft Bill is intended to strengthen arrangements for patients in regard to their health information including by (1) requiring health services providers to forward health records to another health services provider on request from the patient, (2) providing for patients to be notified of arrangements for their health records where the health service provider will no longer be providing services or is moving to another location and (3) requiring data controllers to keep a record in relation to any disclosure of personal health data. The Bill also makes it an offence to buy or sell personal health information (which covers information relating to identifiable living and deceased individuals) obtained in a professional capacity.

**Option 1:** No change. This would be a missed opportunity to strengthen arrangements for patients in regard to their information and is therefore not recommended.

**Option 2:** Include the provisions. This is the recommended option. It reflects current good practice in regard to forwarding health records when needed and keeping patient informed of changes in regard to providers. Data controllers keeping a record of disclosures of personal health data will ensure that individuals know who their medical information has been disclosed to. Provisions on offences in regard to buying and selling of personal health information have the objective of promoting public confidence in the handling of patient information and were recommended by HIQA.

### ***3.2 Structured development of information technology and the eHealth agenda and also improve the standard of data management in the health service - Part 2 of the revised General Scheme***

3.2.1 The draft Bill provides for a standards based approach to support computer ‘interoperability’ (the ability of computer systems to link to each other) which will allow for the evolution of linkable ICT systems throughout the health service by enabling the Minister to set standards for the efficient and effective electronic exchange of health information to promote interoperability in health service computer systems. HIQA and the HSE will also have a role in this area.

3.2.2 In regard to standards for the management of health data, the draft Bill provides that, at the request of the Minister, HIQA may set non-binding standards for public and private health services providers on the processing of personal information relating to the provision and management of health services. These will be best practice standards that data controllers will aspire to meet because they represent a quality approach to data management. Standards will be approved by the Minister after consulting with the Data Protection Commissioner. This power is in addition to HIQA’s power under the Health Act 2007 to set standards for the HSE and public health service providers respecting data and information in their possession in relation to services and the health and welfare of the population.

**Option 1:** No change. This option is not recommended as the proposals have the scope for facilitating the coherent development of information and communications technologies in the health services and for facilitating best practice standards for information management.

**Option 2:** Include the provisions. Information technology can play an important role in helping to maximize the usefulness of health information both for individual patient care (for example, electronic patient records and communication linkages between primary and secondary care) and for the management of the health services. Successful implementation of electronic patient systems is greatly facilitated by a standards based approach. As the level of information technology in the Irish health services is very variable, the future development of information technology needs to be driven in a structured and consistent way. Given the objective of a structured, incremental approach to progressing healthcare IT systems coupled with the mix of public and private health service providers, the best approach is a standards

based one where standards can be set that are regarded (a) as being in line with national and international best practice and (b) as setting out the direction that healthcare ICT in Ireland is likely to take in terms of evolving interoperability. A useful example would be the introduction of common coding standards and terminologies across the health systems.

### ***3.3. Provide for a streamlined Research Ethics Approval Framework -Part 3 of the revised General Scheme***

3.3.1 The draft Bill supports a new voluntary streamlined and uniform research ethics approval structure for human health research that is not already governed by a legislative national ethical approval structure. This will benefit individual researchers and will complement other Government measures to provide a supportive environment for health research and innovation, thus improving Ireland's attractiveness for conducting health research. HIQA will be the supervisory body for approved research ethics committees in the new structure and will issue guidelines designed to facilitate a consistent and quality based approach to procedures (including timelines) and decision-making. The draft Bill also provides for a data protection consent exemption for research in certain limited situations, facilitating valuable research, subject to rules designed to protect privacy and confidentiality of any information provided under this exemption.

**Option 1:** No change. There would continue to be less than optimal timelines for receiving decisions on ethical approval for national and regional health research projects with accompanying costs and delays. Ireland would be at a disadvantage internationally compared to other jurisdictions that have more structured national and regional ethical approval structures.

**Option 2:** One option would be the creation of a new national ethical approval structure located in a new or existing statutory body that would consider and determine all applications for ethical approval from researchers. While this approach was considered, it was considered preferable to build on what is already there in terms of local and institutional research ethics committees and to embed a consistent quality through the health research ethics approval system by the provision of guidance and training etc.

**Option 3:** Build on what is already there and allow organisations (usually hospitals and universities) to apply to HIQA for approval of their Research Ethics Committees and in turn be able to give national or regional ethical approval. Quality would be achieved and maintained by HIQA having a supervisory role that included issuing guidelines that would ensure consistency and good practice across the approved Research Ethics Committees.

### ***3.4 Population based approach to the use of health information - data matching programmes and health information resources - Parts 4 and 5 of the revised General Scheme***

3.4.1 Data matching provisions are in Part 4 of the revised General Scheme and provisions for health information resources are in Part 5. While health information resources are different to data matching programmes, there is considerable similarity in terms of objectives, principles and provisions between Parts 4 and 5. The provisions on health information

resources and data matching programmes in the Bill are not similar to or based on the NHS care.data scheme in England and Wales.

3.4.2 The draft Bill allows the Minister to prescribe (after consulting with the Data Protection Commissioner and HIQA and subject to specified privacy safeguards) identified health information resources and data matching programmes where he or she is satisfied that the objective of the health information resource or data matching programme relates to a matter of significant health importance. Where a health information resource or data matching programme is prescribed the person operating it will be able to require the provision of relevant personal information to it. A civil sanction is provided where the information is not forwarded. Such resources/programmes will operate under HIQA standards approved by the Minister and will, as they involve personal data, come under the remit of the Data Protection Commissioner. HIQA and the Data Protection Commissioner have monitoring and policing functions, as appropriate, in regard to the operation of prescribed resources/programmes and the Bill expressly provides that they will co-operate with each other and provide assistance to each other in the performance of their respective functions in relation to the programmes and information resources. The Minister may amend or revoke regulations when the objective of the programme or information resource has been achieved or if the operator breaches some of the requirements under the Bill.

**Option 1:** No change. This would mean that the potential contribution of population based registers and data matching programmes would continue to be inhibited, resulting in unnecessary and undesirable information deficits.

**Option 2:** Address the issues. Addressing the issue in a structured manner will allow information to be collected, used and shared for identified and important health services purposes while at the same time creating an appropriate governance structure for the handling of personal health information. Accordingly, the recommended option is to provide in the Bill a clear regulatory framework and governance structure for the processing of personal health data in a way that seeks to balance the needs of a modern integrated health service (which benefits everyone) with the need to have regard to the privacy considerations of individual data subjects.

### **3.5 Patient safety**

**3.5.1 *Facilitating appropriate sharing of personal data by health regulatory bodies - Part 1*** Head 10 of the revised General Scheme (Part 2) deals with the disclosure of personal data by a regulatory body to another regulatory body where the information is relevant to that other body.

**Option 1:** No change. Head 10 is intended to facilitate the sharing of information. If not included it may be that relevant information may not be shared.

**Option 2:** The recommended option is to have a legislative provision which sets out the framework within which such sharing may take place.



### **3.5.2 Supporting a culture of patient safety - Parts 6 and 7**

3.5.3 Parts 6 and 7 of the revised General Scheme are designed to further support a culture of patient safety through patient safety incident notification and through clinical audit.

3.5.4 Part 6 of the Bill is concerned with the notification of patient safety incidents (adverse events) following on from recommendations by the Commission on Patient Safety and Quality Assurance. The critical issue is that incidents are notified so that the health service can learn from these incidents and the lessons learned are communicated nationally. Also important is the quality of the information reported.

3.5.5 Under Part 6, publicly funded bodies must notify serious patient safety incidents to the State Claims Agency, HIQA and the Mental Health Commission as appropriate. Serious patient safety incidents in private nursing homes must be notified to the Chief Inspector of Social Services. Serious patient safety incidents in private mental health services must be notified to the Mental Health Commission. Less serious patient safety incidents and "near misses" may also be reported by public providers to the State Claims Agency.

3.5.6 The State Claims Agency is given functions on compiling, analysing, disseminating and publishing information derived from patient safety incidents notified to it and disseminating information and analysis of specific or general issues of patient safety. Standards for all notifications will be set jointly by HIQA and the Mental Health Commission. To help foster this improved culture of patient safety, notifications of patient safety incidents, if made in accordance with these standards, will have the legal protection and third party FOI exemption recommended by the Commission on Patient Safety and Quality Assurance.

3.5.7 Part 7 of the Bill sets out provisions to support clinical audit throughout the public and private health service, to improve patient care and outcomes. Guidance on clinical audit will be issued by the Minister including guidance on governance, methodology and identifying clinical standards to be used in carrying out the clinical audit. The Minister will also specify matters relating to publishing aggregate clinical audit results. Again in line with recommendations by the Commission on Patient Safety and Quality Assurance, the legal protection and third party FOI exemption recommended by the Commission on Patient Safety and Quality Assurance will be available for clinical audit only if done in accordance with the guidance issued by the Minister and if aggregate results are published.

**Option 1:** No change. Clinical audit, adverse event reporting and the dissemination of learning are crucial elements to improving the safety of quality of health services but, as evidenced in the recommendations by the Commission on Patient Safety and Quality Assurance, challenges arise which hinder these essential issues.

**Option 2:** Await licensing legislation for clinical services with potential sanctions for noncompliance.

**Option 3:** Introduce the requirements and the supports now to promote a culture of patient safety and support management and staff in addressing deficits where they exist. This is the option that can best help further the development of a culture of patient safety which in turn

will be a useful stepping stone towards licensing and sanctions for noncompliance under the licensing system.

### **3.6 Extending HIQA's remit to the private health service - Part 9**

3.6.1 The objective is that private providers of health services designated as “high risk” would be subject to the same conditions that apply currently to public providers. HIQA could monitor compliance in the private health service with the National Standards for Safer Better Healthcare. Furthermore, under section 9 of the Health Act 2007, as amended, HIQA would be able to undertake an investigation in the private health service as to the safety, quality and standards of services if HIQA or the Minister believes that there is a serious risk to the health or welfare of persons receiving those services.

**Option 1:** No change at present and await the introduction of a licensing system. Private healthcare in Ireland has expanded and diversified in recent years. Pending the enactment of licensing legislation and then the introduction of the licensing system, it would not be in the best interests of public health to continue the status quo when there is an alternative approach available. The overall policy objective is to introduce a licensing system for public and private health services. Bringing the private health service within HIQA’s remit is a logical progression towards this policy objective and addresses matters in the interim.

**Option 2:** Ask the private healthcare service to voluntarily adopt HIQA standards and report on self-compliance. This would result in an uneven situation as while many providers would participate, some may not. Also, HIQA would not be in a position to undertake an investigation as to the safety, quality and standards of services where it or the Minister believes that there is a serious risk to the health or welfare of a person receiving those services.

**Option 3:** Bring the private health services within HIQA’s remit as soon as possible. Options 1 and 2 above set out the justification for not allowing the status quo to continue. Bringing the private healthcare service within HIQA’s remit now is a logical step on the pathway to a licensing system. The same standards and monitoring regime would apply equally to public and private health services and would help both the regulator and the regulated in preparing for licensing. Moreover, more information will be available to patients on the safety and quality of services.

## **4. ANALYSIS OF COSTS, BENEFITS AND IMPACTS OF OPTIONS**

### **4.1 Costs and benefits of no change options in all areas of the draft Bill**

4.4.1 The costs of the no change options are qualitative (for example in relation to patient care and patient safety), reputational (failure to address information deficits) and quantitative (for example, administrative and clinical costs associated with poor records management). There are no direct benefits associated with the no change options.

### **4.2 Costs and benefits of recommended options for arrangements for patients in regard to their health information (option 2) and structured development of information technology and the eHealth agenda (option 2)**

4.2.1 It is not anticipated that these provisions will result in significant additional costs for providers. The provisions will assist in the development of interoperability and also better management of patient information. They will meet policy objectives in regard to patients' information, improved standards on the processing of this information and on integrated information technology development.

#### **4.3. Costs and benefits of recommended option on health research ethics committees (option 2)**

4.3.1 The proposed system for research ethics committees is voluntary and is not expected to result in additional costs for research ethics committees while there are gains to be made in relation to improved processes for national and regional health research.

#### **4.4 Costs and benefits of recommended options for facilitating a population based approach to the use of health information in important areas of the health service - data matching programmes (option 2) and health information resources (option 2)**

4.4.1 Care will be taken to minimise the burden on those required to provide information to prescribed data matching programmes and prescribed health information resources and a proportionate approach will be taken. Benefits will accrue from better information management for patient care and for health service delivery.

#### **4.5 Supporting a culture of patient safety - clinical audit (option 2) and notifications of patient safety incidents (option 2)**

4.5.1 The proposals will not result in additional cost for providers while the learning to be gained will see better outcomes for patients. The new National Incident Management System (NIMS) was introduced by the State Claims Agency (SCA) in 2014 and represents a national recording management system to be utilised by the health service, facilitating more detailed and consistent reporting of incidents. The SCA and the HSE are continuing to work towards more comprehensive and consistent reporting.

#### **4.6 Costs and benefits of options 2 and 3 on extending HIQA's remit to the private health service**

4.6.1 Option 2: Ask the private healthcare service to voluntarily adopt HIQA standards and report on self-compliance. This has the potential for benefits in that some private healthcare providers would adopt HIQA standards. However, some might not. HIQA would not be in a position to carry out an investigation of the service if warranted.

Option 3: Extend HIQA's remit under the Health Act 2007. This has the benefits associated with the application of standards to all relevant service providers, public and private, and the monitoring of compliance with those standards. It also has the benefit of enabling HIQA to carry out investigations.

In regard to costs for providers, HIQA standards are intended to be proportionate, reflecting the level of safety and quality that providers should currently be meeting. In the case of some private providers, for example private hospitals, many providers have undergone international accreditation programmes to improve the quality and safety of services.

## **4.7 Impacts**

### **4.7.1 National Competitiveness**

A more streamlined approach in regard to research ethics approval will bring a number of advantages including making Ireland a more attractive location for international research.

### **4.7.2 Compliance Burden**

4.7.3 There are limited compliance impacts in relation to research ethics provisions as the new research ethics structure is voluntary.

4.7.4 As indicated earlier, a proportionate approach will be taken in regard to prescribed data matching and health information resources.

4.7.5 Turning to the extension of HIQA's remit to the private health service, as indicated earlier, HIQA standards in relation to publicly funded clinical health services are not currently mandatory. The same conditions will apply to private providers. In regard to compliance burden, it should also be noted that the Independent Hospitals Association of Ireland has indeed welcomed HIQA's National Standards for Safer Better Healthcare.

## **5. CONSULTATION**

A major public consultation exercise was carried out in relation to the original Health Information Bill some years ago. Since then, there has been ongoing engagement with stakeholders.

In regard to the new provisions on extending HIQA's remit to the private health service, consultations have taken place with HIQA and discussions are continuing on the timing of the introduction of this additional responsibility.

## **6. ENFORCEMENT AND COMPLIANCE**

6.1 The Data Protection Commissioner is the national supervisory and enforcement authority for matters relating to the processing of personal data.

6.2 In terms of the research ethics framework provided for in the Bill, HIQA will be the supervisory authority of approved research ethics committees and the Data Protection Commissioner will determine applications for a consent exemption.

6.3 HIQA has a monitoring role in regard to compliance with standards for prescribed data matching programmes and health information resources and the Data Protection Commissioner also has a policing role with regard to these resources/programmes.

6.4 Extending HIQA's remit to the private health service is part of a phased approach to regulation. Enforcement and compliance with standards set will be addressed and strengthened when the hospital licensing system is being put in place.

## **7. REVIEW**

7.1 The operation of the Bill will be kept under review in consultation with stakeholders.

7.2 The proposed research ethics structures are new and may take time to become embedded. HIQA will keep matters under review as part of its supervisory remit.

7.3 The extension of HIQA's remit to private healthcare services will be continuously monitored as the licensing system for public and private health services is being developed.