



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Opening statement to the Joint Committee on Health

Phelim Quinn, HIQA CEO

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Chairperson, members, on behalf of the Health Information and Quality Authority (HIQA) I would like to thank you for the opportunity to address the Joint Committee on Health today. I am joined by my colleagues Mary Dunnion, Chief Inspector of Social Services and Director of Regulation, and Máirín Ryan, Deputy Chief Executive and Director of Health Technology Assessment.

We are pleased to be here today to discuss the General Scheme of the Patient Safety (Licensing) Bill. With 11 years' experience regulating and monitoring Ireland's health and social care services, and our knowledge of systems and models of international best practice, HIQA is well placed to provide observations and advice on this significant piece of legislation.

HIQA's current remit in the healthcare sector

Before I discuss the main provisions of the General Scheme of the Patient Safety (Licensing) Bill, I feel it is important to explain HIQA's current role in the healthcare sector.

HIQA is known as the State's health and social care regulator, yet we do not have the power to regulate hospitals, public or private. Our remit solely extends to monitoring the safety and quality of HSE-funded hospitals against the National Standards for Safer Better Healthcare. We monitor a number of key areas of risk, for example, medication safety, antibiotic resistance, infection prevention, and nutrition and hydration. We have also conducted full service reviews against the National Standards.

In addition, under Section 9 of the Health Act 2007, we can conduct statutory investigations if there is a concern about the health and welfare of people using health or social care services. However, similar to our monitoring function, the recommendations HIQA issues on completion of an investigation are not legally binding. We do not have the power to oversee or insist on the implementation of these recommendations, which, in the past, have often gone unheeded.

Furthermore, I must stress that HIQA currently has no role in the monitoring or regulation of the private healthcare sector. There is effectively no statutory oversight of private hospitals in Ireland and any organisation or individual is free to establish a private facility without restriction. Last month, the Government approved a different patient safety bill, based on the previous Health Information and Patient Safety Bill, which will extend HIQA's remit to private hospitals, and provide for mandatory notification of serious patient safety incidents to either HIQA or the Mental Health Commission, as appropriate.

It is important to be clear that even under the provisions of this new bill, HIQA will not have any enforcement powers — making Ireland an outlier in terms of healthcare regulation internationally. This new patient safety bill will simply extend our current powers to the private sector, that is, to set standards, monitor compliance and undertake investigations. My concern is that upon enactment of this legislation the public may be of the impression that the private healthcare sector is now regulated and therefore that they, as patients, are protected. Interestingly, a Red C poll conducted for HIQA last year showed that 83% of people believe that private hospitals in Ireland are already subject to regulation.

The Patient Safety (Licensing) Bill

I will now move on to discuss the General Scheme of the Patient Safety (Licensing) Bill as it relates to HIQA.

The bill sets out the legislative framework for the introduction of a mandatory system of licensing for public and private hospitals and other providers of high-risk healthcare activities — so called ‘designated activities’. Under the bill, HIQA will be the licensing authority and will process licence applications, monitor the performance of licence holders against regulations and standards, and take enforcement measures to address non-compliances or where there is a risk to the health or safety of the public.

What is to be licensed?

Under the proposed scheme, HIQA will grant a licence to an applicant when a number of criteria have been satisfied. When considering a licence application, HIQA will assess whether or not the licenced provider and the person in charge are ‘fit and proper persons’.

Persons in charge are nominated by the licensed provider and are described in the general scheme as the person with responsibility for managing the service on a day-to-day basis. While HIQA must be satisfied that the person in charge is a ‘fit and proper person’ for this role, the bill is not explicit in outlining the specifics and it appears that this judgment is to be made at HIQA’s discretion.

In the absence of any statutory underpinning of hospital groups, the licensed provider in a statutory hospital will either be the HSE or a voluntary organisation (funded under a section 38 arrangement). In the case of private hospitals, the licensed provider will likely be the body corporate, that is, the legal entity that owns the hospital.

It is our understanding that, in situations of sustained non-compliance in an individual public hospital, enforcement will centre on the HSE Directorate as the licenced provider. Clarity on the status of the legal entity to be licensed is thus essential.

Licensing private, public and voluntary services

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. This is a reasonable measure and is broadly in line with how HIQA currently assesses fitness in a designated centre.

However, the bill explicitly precludes the regulator from assessing the character and competence of the principal officers of HSE or voluntary hospitals. This means that HIQA will assess the fitness of either the HSE or the voluntary organisation as a whole, and will not be required to assess the character and competence of its principal officers.

This approach effectively treats private providers differently to public or voluntary providers, and will limit the regulator's power to assess the fitness of individual senior managers in public hospitals. It could result in a situation whereby oversight of the governance arrangements and competence of decision-makers in public or voluntary hospitals is less rigorous. Clear lines of accountability are essential to ensure that hospitals, which are large and complex organisations, are well-governed and provide good-quality, safe care to the public. Our experience has shown that many failures in the provision of health and social care can be traced back to poor governance and a lack of accountability.

Applying different approaches to the regulation of private versus public and voluntary providers, specifically in terms of governance and financial capability, could lead to a lower standard of care in public and voluntary hospitals compared to private hospitals, and could be open to legal challenge by private providers and patients.

An additional point to note in this context is the requirement to assess the financial viability of the service provider. According to the bill, licensed providers will be required to submit evidence of their financial capability to carry on the business of a hospital. HIQA will assess the ability of the intended licensee to meet the costs of carrying on the hospital or the designated activity, and also the licensee's insurance, indemnity provisions and other financial assurance instruments to cover liabilities.

HIQA welcomes this measure, and it is something we advocated for in our discussions with the Department of Health. However, this test of financial capability only applies to private providers, not to HSE and voluntary organisations. There may be an argument for excluding the HSE from such a test as it is fully funded by the State; however, it would be prudent to require voluntary providers to also prove their financial capability.

Lastly, in this context, it is crucial that legislators recognise that healthcare is continually evolving and that current service models may not be suitable in the future. We believe that reform of how HIQA registers and regulates services is needed in order to respond to the various existing and emerging models of care in Ireland.

Resources

I am sure many of you here today would question the readiness of the acute hospital sector to meet the regulations and standards that will arise out of the proposed licensing system. When independent regulation was introduced to the social care sector, significant investment in many nursing homes and residential centres for people with disabilities was required to make them compliant with the regulations. It is reasonable to expect that the hospital sector will be no different.

I note that the Department of Health proposes to carry out a regulatory impact assessment (RIA) to examine the costs and benefits of introducing a licensing framework. The results of this RIA must be examined closely as it is likely to give an indication of the level of public investment needed to bring the hospital sector up to the required standards.

There has been a lot of discussion in recent years about reforms to our health service. The Sláintecare Report and the Health Service Capacity Review both looked at our future needs and, if implemented, will require significant levels of funding. This level of investment, coupled with the resources required to meet licensing regulations, would represent a massive commitment of public funds.

Conclusion

Based on our research on healthcare regulation internationally and our experience of social care regulation, HIQA strongly supports the proposal to introduce a system of licensing to the healthcare sector to bring Ireland in line with our OECD peers. HIQA's experience in the social care sector has shown that regulation drives improvement, and we welcome the proposals contained in this bill. Retaining the

status quo is simply not a viable option. Nonetheless a number of issues still need to be ironed out. Clarity on the legal status of the licensed provider is necessary, as is a greater emphasis in the legislation on effective governance and clear accountability at the level of the provider.

The Department of Health must be realistic about the resourcing of HIQA as the regulator of hospitals and other designated activities. Hospitals and clinics providing healthcare services are complex organisation, different from the types of services that HIQA encounters in social care regulation. The proposed model of regulation will require competent and robust assessment by an adequate, skilled and knowledgeable workforce, not only in the area of frontline inspection, but also in terms of managerial, administrative and technical support.

I wish to thank members of the committee for inviting us here this morning. We would be happy to answer any questions you may have.

ENDS

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