

Opening Statement to the Oireachtas Joint Committee on Health

Pre-Legislative Scrutiny of the Patient Safety (Licensing) Bill

Good morning Chair,

I would like to begin by thanking the Members for the invitation to appear before the Committee this morning in relation to the Patient Safety (Licensing) Bill.

This legislation has been developed to facilitate the creation of a comprehensive, far reaching system of regulation to oversee all hospitals in the State, public and private, as well as providing the Minister for Health with the authority to designate certain activities as carrying a sufficiently high risk as to warrant their providers to also come within the ambit of the new regime. The Committee's agreeing to undertake pre-legislative scrutiny will contribute significantly to the progression of this important development.

As the Committee will be aware, the health service has been striving in recent years to place the safety of patients at the forefront of its work. There have been a number of initiatives in this sphere over the past decade, including the creation of the Health Information and Quality Authority (HIQA), which is also represented here this morning, and the updating of much of the legislation in relation to the professional regulation of healthcare workers.

There is however something of a lacuna at present, whereby there is no specific legislation in place in relation to the operation of hospitals to minimum standards of clinical governance. The proposed Patient Safety (Licensing) Bill seeks to rectify that situation.

This Bill has been developed over the past number of years by officials in the Department and a working group made up of key stakeholders from the HSE, HIQA, the Private Hospitals Association and the Forum of Professional Regulatory Bodies. The introduction of a licensing system along the lines of that envisaged in the Bill currently before the Committee was a key recommendation of the 2008 Report of the Commission on Patient Safety and Quality ("The Madden Report").

While acute public hospitals are currently subject to thematic monitoring by HIQA, the powers of HIQA are limited. The introduction of a system of licensing will ensure that all hospitals, public and private, are operating to appropriate standards and have the requisite governance arrangements in place to enable the delivery of the safest possible service. We will therefore be able to have assurances that there is a patient safety operating framework in place in all hospitals. Such a framework requires management support and buy-in, patient engagements and accountability. Clinical Audit must be regarded as an integral part of this overall approach.

It should, however, be acknowledged that the delivery of healthcare is an inherently risky activity and it is inevitable that things will go wrong. For example, studies of adverse events worldwide have

demonstrated that between 4% and 16% of patients admitted to hospital experience one or more adverse events, of which up to half are preventable.

Last year, the OECD estimated that more than 15% of hospital expenditure goes towards correcting preventable medical mistakes or infections that people catch in hospitals across its member countries. Expenditure in excess of €350 million is attributed by the State Claims Agency to healthcare patient safety claims for the years 2012-2016.

The ability of the Irish health service to learn from mistakes and system errors also requires improvement. We have, as the Committee will be only too well aware, seen similar issues emerge across many hospitals after an incident has occurred, often related to weak governance and leadership, and this legislation is part of the effort being made to respond to this situation.

The Licensing Bill will not, in and of itself, provide an immediate solution to these issues. In considering it, it is important to recognise that this Bill is just one element in a wider programme of reform, being driven primarily by the National Patient Safety Office of the Department of Health. There are a variety of other initiatives that are also being brought forward, including the publication of monthly patient safety statements by all hospitals within the State, the establishment of a national patient advocacy service, the introduction of a patient safety surveillance system, the measurement of patient experience, the extension of the clinical effectiveness agenda, the roll-out of a Code of Conduct for health service staff, the publication of Annual Reports of the National Healthcare Quality Reporting System, and the planned creation of a National Advisory Council for Patient Safety.

In addition, as the Committee will be aware, Government approval has recently been secured to prepare a new Patient Safety Bill that will provide for mandatory open disclosure of serious reportable events. The Bill will also legislate for mandatory external notifications of incidents to the appropriate regulatory body, for clinical audit as well as the extension of HIQA's remit to private hospitals. This legislation will build on the Civil Liability (Amendment) Act 2017, which provided a framework for the operational delivery of open disclosure.

The Licensing Bill will apply to both public and private hospitals, and it will be an offence to operate a hospital without a licence. We have seen concerns expressed in the recent past about some private providers of, for example, cosmetic surgery, who may not be operating to the standard that would be expected. This legislation will also respond to such situations.

The Bill will also apply to high risk activities, which will be designated, and which are conducted in other settings, such as private clinics. Such activities may, for example, include the use of general anaesthetic. It will likely also include the screening services, the activities of which do not in and of themselves carry a significant risk, but for which, as we have seen all too clearly in recent weeks with the revelations in relation to the CervicalCheck Programme, it is clear that the highest standards must prevail. The activities to be designated will be determined once a full consultation process has been completed, later this year.

HIQA will be the licensing authority, processing applications for licences, and monitoring the performance of licence holders.

Ministerial regulations will be used to establish the standards which licence holders will be required to meet. These regulations will be enforced by HIQA and ensure a level playing field for public and private services. They will be closely aligned with the existing National Standards for Safer Better Healthcare.

Where necessary, in the interests of public safety, HIQA will have at its disposal a series of measures, up to and including the cancellation of a licence, which can be utilised. HIQA will also have the power to attach conditions to a licence or require improvement plans to be submitted.

The Heads also provide for a number of other offences, and for the imposition of a fine and/or a term of imprisonment.

In line with the recommendations of the Report by the Chief Medical Officer, “HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)” (24 February 2014), a licensed provider must prepare a patient safety statement with information on clinical activity, outcomes and patient safety incidents. Patient safety statements must be updated monthly and be available to the public.

Fees will be set by the Minister and will be payable with licence applications and applications to remove or vary a condition of the licence. An annual levy is also proposed, with the intention that the system will be self-funding to the greatest extent possible.

In summary, the aim of the Licensing legislation is to ensure that health providers in Ireland are operating to minimum core standards so that we can all have confidence in the clinical governance, safety, quality and effectiveness of the services that are being provided, whether in the public or the private sector.

It is a key element of the wider patient safety systems approach which we are bringing forward, where we will look to have a greater degree of awareness of the issues that arise within the system, assurances that patients are being informed of errors as they arise and that these are also being reported to Regulators. Meanwhile, improved complaints and advocacy processes are also being developed to assist patients when they are unsatisfied with their experience. Ultimately, all of the data generated through these activities should also be used to provide insights for managers and clinicians within the health service as to how to improve their own services, before the cycle, if you will, begins again.

I hope that the Committee will welcome this new initiative, and I look forward to our discussion.