Opening Statement by Dr Tony Holohan, Chief Medical Officer at the Department of Health to the Oireachtas Joint Committee on Health (26 September 2018)

Legislative provisions to support mandatory open disclosure of serious reportable patient safety incidents, notification of reportable incidents, clinical audit to improve patient care and outcomes and the extension of the Health Information Quality Authority's remit to private health services.

I thank the Chairman and the Committee for the opportunity to come before you today on the legislative provisions proposed within the general scheme of the Patient Safety Bill. I will keep my introductory statement as brief as possible and I will be happy to reply to any questions and comments.

The Government directed the Department to undertake the development of the Patient Safety Bill in May of this year. The Bill incorporates the patient safety elements of the Health Information and Patient Safety Bill, which introduces a requirement for external notification of patient safety incidents to the appropriate regulator and the State Claims Agency, empowers the Minister to issue guidance with respect to clinical audit and extends the remit of the Health Information Quality Authority (HIQA) to private hospitals. These elements in fact previously underwent pre-legislative scrutiny in January 2016 when consideration was given to the Health Information and Patient Safety Bill. In addition, the Patient Safety Bill also provides for mandatory open disclosure of serious reportable events. As such, this legislation compliments the measures contained within the Civil Liability (Amendment) Act 2017, passed by the Houses of the Oireachtas last year, which provides protections from liability for clinicians engaging with open disclosure.

I would also wish to alert the Committee to an additional aspect that has emerged since the Government approved the Bill. Earlier this month the High Court over-ruled the Minister's decision to require HIQA to undertake an investigation into the circumstances surrounding the death of Mrs Malak Thawley in the National Maternity Hospital in May 2016. This judgment has revealed that there may be a need to enhance the Minister's powers under Section 9 of the Health Act 2007, which could require amending legislation. While the Department is currently considering how best to address this matter, it might be that some modifying provisions will be brought forward within this Bill to address the issue.

I will now turn to the primary elements of the Bill, beginning with open disclosure.

Mandatory open disclosure

Creating a culture of open disclosure and learning from the things that go wrong is the bedrock of making services safer. In line with the longstanding approach of the Department to this issue, open disclosure should be an open and consistent approach to communicating with patients and their families when things go wrong in healthcare. This includes expressing

regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.

I would recall that last year the Houses of the Oireachtas provided protections from liability for clinicians making a disclosure through the Civil (Liability) Amendment Act 2017. During the passage of that Act, a number of Deputies sought to amend the legislation to provide for a mandatory approach. However, as that legislation was extremely broad and applicable to a wide variety of health and social care settings, it was ultimately decided not to be the appropriate vehicle for mandatory open disclosure. The Minister for Health did however undertake to bring forward legislation to provide for a mandatory duty to disclose at an early opportunity, hence the Bill that is before you today.

It should also be noted that, with the commencement of Part 4 of the Civil (Liability) Amendment Act, and the Regulations arising from it which came into effect earlier this week, the framework to support openness, transparency, timely disclosure, and an apology, for any unintended or unanticipated injury has now come into effect.

Mandatory open disclosure is about building patient and public trust in the health system. Dr Gabriel Scally's recent report provides a clear analysis of the system failures that occurred in CervicalCheck, based on patient and family accounts of their experiences. We must now ensure that the learning from this report is used to drive the changes we want to see so as to ensure that patient safety is a primary element driving and shaping policy for the health service. I would like to reassure the Committee that the Department has taken close note of Dr Scally's findings, in particular regarding the "primacy of the right of patients to have full knowledge about their healthcare, as and when they wish". While the current approach to disclosure within the health service has had positive impacts within and across services, the Scally Report has identified significant issues which now need to be remedied. The Patient Safety Bill, while in development prior to receipt of the Scally Report, will be one of the primary means for responding to his findings and will provide the legislative underpinning for mandatory open disclosure.

Fundamentally, the Bill will introduce a requirement for disclosure of serious patient safety incidents. The definition of a serious patient safety incident includes the death of a person, a permanent lessening of bodily, sensory, motor, physical or intellectual functions, harm which is not severe but which results in, for example, an increase in treatment or a requirement for treatment to prevent death or injury. The Minister for Health will prescribe the specific incidents to be disclosed in secondary legislation. Internationally, this definition is in line with the most recent legislative definition incorporated within Scottish Legislation, the Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016 which in turn builds on the Statutory Duty of Candour in operation in England since 2015.

The Bill provides the legislative framework for a number of recommendations of the Scally report in relation to CervicalCheck, including in relation to placing a statutory duty of candour both on individual healthcare professionals and on healthcare organisations.

The Patient Safety Bill provides that it shall be an offence for a health service provider to fail to make a mandatory open disclosure or notify a reportable incident to the external authority. A registered health services provider guilty of an offence will be subject to penalties in the form of a fine or imprisonment. It is similar to the approach of the UK, where the Duty of Candour regulation seeks to hold "providers and directors to account". It is a mechanism to hold the owner, management or board of an organisation to account and ensure that the individuals at the top of the organisation are invested in quality and patient safety. In relation to individual health practitioners, the policy is to distinguish between genuine unintentional acts of omission or commission that can lead to harm and the much rarer acts of wilful neglect or deliberate breach of acceptable practice. In the drafting of the Bill the inclusion of a defence will also be incorporated.

Notification of Reportable Serious Patient Safety Incidents

In relation to notification of reportable patient safety incidents, the Report of the Commission on Patient Safety and Quality Assurance recommended that provision should be made for the mandatory reporting of adverse events which result in death or serious harm to the appropriate regulatory body. The Commission recommended that provision be made for (voluntary) reporting of other less serious adverse events and 'near-misses'. The Commission concluded that a mandatory system will improve patient safety and ensure greater accountability by requiring specific reports of serious injury to be made by healthcare providers, with disseminating lessons to be learned throughout the system.

The Patient Safety Bill provides for mandatory notification of serious patient safety incidents to the appropriate authority, i.e. the State Claims Agency, the Health Information Quality Authority (HIQA) and the Mental Health Commission.

Clinical Audit

Turning to clinical audit, I think it would be helpful in the first instance to give some definition to what we mean. In this context, clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and acting to improve care where these standards are not met. Defining clinical audit in legislation recognises the need to have a standard definition and associated methodology to ensure a consistency of approach. The Commission on Patient Safety and Quality Assurance advocated building a positive culture of participation that would benefit patients and the health services as a whole, and recommended that legislation should be introduced providing for:

- Exemptions from FOI legislation for records arising from these specific activities
- Protections for these records from admissibility as evidence in civil proceedings; it was envisaged that certain legal privileges will be granted if guidance on governance, methodology and clinical standards for clinical audit is followed.

This Bill will enable the Minister to issue such guidance, subject to public consultation. Where clinical audit is carried out in accordance with the Minister's guidance and aggregate results are published, any record created solely for the purpose of the clinical audit will not be admissible as evidence in civil proceedings and the Freedom of Information Act will not apply to the record. This part of the Bill will therefore support those that use clinical audit to improve the quality of care provided. Such protections do not exempt healthcare organisations or health professionals from their responsibilities where a serious patient incident has been discovered during the audit process. In relation to any serious patient safety incident being discovered due to a clinical audit, mandatory open disclosure to the patents affected and external reporting by all health practitioners and health services providers will apply when this Bill comes into effect. The Governance framework, methodology and reporting of clinical audit will all be incorporated into the Minister's guidance on clinical audit that will be developed by the National Clinical Effectiveness Committee.

Extension of powers to Health Information Quality Authority (HIQA)

The Committee will recall that it recently examined the Patient Safety (Licensing) Bill, which will provide HIQA with full regulatory responsibility for all hospitals, public and private. In advance of that, the Patient Safety Bill will provide for the extension of HIQA's existing powers in relation to setting standards, monitoring compliance and undertaking investigations to the private hospital sector.

Extending these powers to HIQA will ensure that all defined private and public health services will be subject to the same standards and be monitored by the same Authority, with the exception of those centres regulated by the Mental Health Commission or designated centres.

Conclusion

In conclusion, I would recall the *Scoping Inquiry into the CervicalCheck Screening Programme,* which identified what those involved in a patient safety incident want:

- To be told what happened and why (the truth);
- For someone who was involved to say they are sorry, and mean it;
- To be assured that this won't happen again to anyone else.

Through this Bill, and the other policy and legislative steps which the Department is taking, that is exactly what we are trying to achieve.

End.