Opening Statement by Dr Tony Holohan, Chief Medical Officer at the Department of Health to the Joint Committee on Health (13 October 2016)

Legislative Provisions to Support Open Disclosure

Chairman and Members of the Committee

I thank the Chairman and the committee for the opportunity to come before you today on the legislative provisions to support open disclosure. I will keep my introductory statement as brief as possible and I will be happy to reply to any questions and comments. I am joined by Dr Kathleen MacLellan who is Director of Patient Safety, Susan Reilly from the Patient Safety Unit, and Bernie Ryan and Peter Lennon from Corporate Legislation Unit.

Patient safety and quality are at the heart of our health services and it is important to keep our patients and service users at the centre of everything we do. Delivery of healthcare is, however, inherently risky and while it is inevitable that things go wrong, there is much that can be done to prevent harm or error, identify and act on when it occurs and to learn from this to improve services.

The Department is fully committed to progressing the programme of major patient safety reforms agreed by Government last November. These measures are focused on legislation, establishment of a national patient advocacy service, introduction of a patient safety surveillance system, extending the clinical effectiveness agenda, a national patient experience survey, a National Patient Safety Office in the Department and the setting up a National Advisory Council for Patient Safety. Within the programme of legislation we intend to progress the licensing of our public and private hospitals, the Health Information and Patent Safety Bill and provisions for Open Disclosure.

The Committee will already have a copy of the General Scheme for Open Disclosure approved last November and an Information Note forwarded by the Department's Secretary General on 28 July together with certain HSE documents on open disclosure.

Creating a culture of open disclosure and learning from the things that go wrong is the bedrock of making services safer. Recent reports highlight that service users have felt unsupported by the system, are not afforded adequate explanations following adverse events and find the health service complex to navigate.

Open disclosure is an open and consistent approach to communicating with patients and their families when things go wrong in healthcare. It is a human experience for all involved and one that should not be hindered by other concerns and fears. That view has shaped our approach which recognises the importance of the quality of the open disclosure engagement by the health professional with the patient over a period of time.

The background to the proposed legislation lies in the Commission on Patient Safety and Quality Assurance which recommended that legislation be enacted to provide legal protection/privilege for open disclosure of adverse events to patients. The provisions are therefore designed to give legal protection/privilege for the information and apology made to

a patient when made in line with the legislation. The apology cannot be interpreted as an admission of liability and cannot be used in litigation against the provider. This approach is intended to create a positive voluntary climate for open disclosure and will support the *National Policy on Open Disclosure* which was developed jointly by the HSE and the State Claims Agency in November 2013.

Our goal from the outset has been to create a safe space where there can and should be full disclosure of the facts surrounding a patient safety incident and of the implications, if any, for the patient's care and treatment. It is important that where an apology is warranted it is made when the facts of the incident are known and not years later on the steps of the High Court.

The Ombudsman is clear that many people who complain to his Office say that what they are looking for is for the service provider to acknowledge that something went wrong and to receive a meaningful apology. People say they want to be listened to and to be reassured that lessons have been learned and that the same mistake will not happen again.

The *Evaluation of the 2013 HSE's National Open Disclosure Policy* published in July this year provides valuable lessons for building a culture of open disclosure in Ireland. It identified that one of those persistent barriers was perceived fears of the medico-legal consequences of open disclosure. These barriers have also been identified in other jurisdictions.

The legislative provisions are, therefore, being drafted to ensure that there is clarity for everyone involved in the open disclosure process and that there is appropriate consistency across the various parts of the health system in how open disclosure is understood and delivered. It will only be where there is compliance with the primary legislation and the Ministerial Regulations that protections will be available. The 28 July Information Note explained why we are now using Regulations rather than Standards.

The provisions are intended to support an environment where the patient's information needs can be addressed as soon as possible. In a hospital setting, the open disclosure should usually be made by the lead clinician in charge of the patient's care. The current draft provisions say that the disclosure should be made as soon as practicable and that the information given should cover a description of the patient safety incident, the date it happened, the date the provider became aware of the incident and how the provider became aware of the incident. Information must be given on any known physical, psychological or emotional effects arising from the incident and how these are being managed. The patient is also told about any actions being taken to ensure learning from the incident to avoid a recurrence. This is clearly a lot of information to take in and the intention is that the Minister will prescribe a form to be given to the patient so that we have uniformity in the provision so information across the health service. While the oral information and the information in writing in the form cannot be used in litigation, the patient could of course use their medical records if taking legal action.

Open disclosure is about building patient and public trust in the health system. For that reason, it is important to make it very clear today that there is no question that the provisions provide protections for incompetent, negligent or other unprofessional patient care. Such a

scenario would completely undermine what we are trying to achieve. Organisations and health professionals continue to have accountability mechanisms.

An open and just culture for patient safety balances the need for an open and honest reporting environment that facilitates a learning environment and quality healthcare with accountability for both individuals and organisations. Disclosure and reporting are opportunities to learn, to improve, to address errors that have happened and to apply the lessons to make the service safer for the next patient and the patient after that.

The open disclosure provisions form part of a number of initiatives to improve the management of patient safety incidents. HIQA and the Mental Health Commission are at an advanced stage of development of *Standards on the Conduct of Reviews of Patient Safety Incidents* which expand on the *National Standards for Safer Better Healthcare.* This set of standards along with the mandatory reporting of serious reportable events provided for in the Health Information and Patient Safety Bill and the provisions intended for open disclosure will provide a comprehensive patient-centred approach to preventing, managing and learning from incidents.

In terms of timelines, the intention is to include the provisions to support open disclosure in the Civil Liability (Amendment) Bill which is being progressed by the Department of Justice and Equality and which is expected to be published this session.

Finally, as I have outlined earlier the provisions for open disclosure form part of the broad and ambitious programme of patient safety reforms being progressed by the Department This programme of reform is aimed at a whole systems approach to improving patient safety.

End.