

## **Information Note on Open Disclosure Provisions**

### **Department of Health to Joint Committee on Health**

**28<sup>th</sup> July, 2016.**

#### **1. Open disclosure**

Open Disclosure is 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. Open Disclosure is important for building patient and public trust in the health system. An open disclosure that represents a timely explanation when something goes wrong may also reduce litigation that might have been initiated by the patient out of frustration or the need for information.

The purposes of Open Disclosure overall are to:

- ensure that patients are informed when adverse events happen as soon as is practicable,
- assist in supporting appropriate patient care,
- increase trust between patients and their clinicians,
- support staff in managing adverse events, and
- improve patient safety and quality of care through organisational learning.

Open Disclosure can be viewed as an integral element of patient safety incident management and it is government policy that a system of open disclosure is in place and supported across the health system

#### **2. Background to Current Legislative Proposals**

Currently, Ireland has no express protective legislation to assist the open disclosure process where patient safety incidents (adverse events) occur. The Report of the Commission on Patient Safety and Quality Assurance (Madden Report) recommended that legislation be enacted to provide legal protection/privilege for open disclosure of adverse events to patients within a voluntary rather than mandatory framework. It envisaged that such legislation should ensure that open disclosure, which is undertaken in compliance with national standards, cannot be used in litigation against the person making the disclosure.

The recommendations in the Commission's Report form the basis of the legislative provisions on open disclosure approved by the last Government in November 2015. The provisions were also informed by national and international developments in open disclosure since the publication of the report.

### **3. The legislative provisions**

Accordingly, the Open Disclosure legislative provisions in the General Scheme (see also below for information on each Head) are designed to afford legal protection/privilege for the apology/statement of regret made to a patient and/or connected person when made in line with best practice. This means that the apology and expression of regret cannot be interpreted as an admission of liability and therefore cannot be used in litigation against the person making the disclosure. It is considered proper that the protections provided for open disclosure should apply in both the public and private sides of the health service so as to support a uniform system of open disclosure across the health system.

### **4. The legislative provisions and HSE National Policy**

The legislative provisions also support the National Policy on Open Disclosure which was developed jointly by the HSE and the State Claims Agency and launched by the then Minister for Health in November 2013. The Policy is designed to ensure an open, consistent approach to communicating with patients and their families when things go wrong in the provision of their healthcare. HSE policy is that the service user must be informed in a timely manner of the facts relating to the incident. The service user should also be informed if an adverse event is suspected but not yet confirmed. No harm events should generally also be disclosed.

In the case of near misses, HSE policy is that near miss incidents should be assessed on a case by case basis, depending on the potential impact it could have had on the service user. If, after consideration of the near miss incident, it is determined that there is a risk of/potential for future harm from the incident then this should be discussed with the service user.

The HSE has now begun implementing the Policy across all health and social services.

### **5. The General Scheme**

The General Scheme, which is currently with Parliamentary Counsel for drafting, contained the following Heads.

Head 1 was the definitions section and included the key definitions such as “disclosure”, “patient safety incident”, “health services provider” and “apology”.

Head 2 dealt with commencement enabling the Minister for Health to bring the open disclosure provisions (in the Civil Liability (Amendment) Act) into effect.

Head 3 provided for a general regulation making power.

Head 4 provided for standards to be set jointly by the Health Information and Quality Authority (HIQA) and the Mental Health Commission for public and private health service providers on disclosing patient safety incidents to service users and connected persons.

Head 5 covered consultations by HIQA and the Mental Health Commission on draft standards and publication of standards after Ministerial approval.

Head 6 provided for certain protections where a disclosure of a patient safety incident was made in accordance with the standards on open disclosure set under Head 4. The Head also addressed a situation where a practitioner's or provider's indemnity or insurance prohibited them from claiming from their insurer or indemnifier where the practitioner or provider had made an apology to the patient or the patient's connected person in relation to an incident. This was intended to ensure that the insurance or indemnity was not affected by an apology made as part of an Open Disclosure where the statement is made in accordance with the standards.

With Head 7 the intention was to provide that records created solely for the purpose of the disclosure to patients in line with HIQA and Mental Health Commission standards were not admissible as evidence in civil proceedings relating to liability for injury or death. They would be admissible in evidence in other civil proceedings and in criminal proceedings.

Relevant medical records of the patient would of course continue to be admissible in civil proceedings relating to personal injury or death.

Head 8 dealt with consequential amendments to the Health Act 2007 and the Mental Health Act 2001.

## **6. Changes emerging in the Drafting Process**

In the course of the now ongoing drafting process, Parliamentary Counsel advised that, from the perspective of legal certainty, reliance on standards did not represent the best approach. After considering the matter further, and in discussion with Parliamentary Counsel, it was decided that Regulations to be made by the Minister and laid before each House of the Oireachtas was the most appropriate way to proceed. While this change is significant it is procedural more than substantive as the Minister will consult with HIQA and the Mental Health Commission before making any regulations.

The need for procedures to be followed to ensure consistency and clarity both for those making disclosures and for the individuals receiving them was always an important objective and the drafting process is focussing on how this can be best achieved including the role to be played by Regulations and the related use of standard forms and disclosure protocols.

The purpose of the Regulations, therefore, is to ensure that health service providers follow a uniform process in the making of a disclosure in terms of the information communicated in relation to a patient safety incident, how the information is to be communicated, when it is communicated and by whom it is to be communicated.

We are also seeking to ensure that the legislation makes clear that the protections provided will only be available where a disclosure (as defined) is for the purposes set out in the legislation and in accordance with the legislation.

## **7. Open disclosure as part of a better patient safety environment**

Patient safety is fundamental to the delivery of quality healthcare. Each health service has systems and processes for patient safety requirements. The appropriate management and external reporting of patient safety incidents are also key aspects of overall system requirements. Increased external incident reporting should lead to earlier identification of patterns and trends in clinical incidents in order to maximise learning and minimise risk as swiftly as possible in the health system. A strong patient safety culture is linked therefore to external incident reporting as well as disclosure to the patient.

In that context, the National Incident Management System (NIMS) established by the State Claims Agency is important. The NIMS has the capacity to manage no harm incidents, near misses and dangerous occurrences as collectively defined by the World Health Organisation. All incidents in the healthcare sector including Serious Reportable Events (SREs) which are the most serious forms of error that cause harm to patients in the public health system must be reported directly on to NIMS since June 2015.

## **8. Programme for Government**

The Programme for a Partnership Government makes clear that Open Disclosure is an essential component of patient safety and, in line with the recommendations of the Madden Commission on Patient Safety and Quality Assurance (2008), a number of measures to support it will be progressed including legislation to ensure that all open disclosures will be protected when made, in line with national standards and that offering an apology or giving full information up front cannot be seen as an admission of liability.

The Programme also states it will be made mandatory to report specified patient safety incidents or serious reportable events to the authorities and to the patient harmed. Provisions in the General Scheme of the Health Information and Patient Safety Bill, which was approved by the last Government (and now intended for further Pre-Legislative Scrutiny), contain requirements for mandatory external reporting of serious patient safety incidents to HIQA, the Mental Health Commission and the State Claims Agency. The General Scheme of the Health Information and Patient Safety Bill also has provisions on voluntary external reporting of non-serious incidents to the State Claims Agency. That will meet the first element of the Government statement in terms of reporting to authorities. It will also support and complement the reporting to NIMS already in place as described above.

However, at this particular point in time, while the matter will be subject to ongoing consideration it is not proposed to include a mandatory requirement concerning open disclosure to patients. The reason for that is related to creating the positive voluntary climate for open disclosure envisaged by the Madden Report which will be reviewed in line with experience to see whether it needs to be strengthened and how, if necessary, that can best be done. Open disclosure is about a just culture in which providers and health professionals recognise that disclosure and reporting are opportunities to learn, to improve, to address any errors that have happened and to apply the lessons to make the service safer for the next patient and the patient after that. “Apology” laws which protect disclosures- as distinct from requiring them in law- are more common internationally and international experience

indicates that open disclosure will happen best by fostering the development of an open and honest culture.

It is also important to bear in mind when considering open disclosure that the Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2016) already refers to patients being entitled to honest, open and prompt communication about adverse events that may have caused them harm.