Procedure for Managing Open Disclosure within the Provisions of

Part 4 of the Civil Liability (Amendment) Act 2017
and
Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018

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INTRODUCTION

- Open disclosure has been the policy of the HSE since November 2013 and all staff are expected to comply with this policy. A copy of the current HSE Open Disclosure Policy is available here: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/open-disclosure-information-for-hse-employees/open-disclosure-information-for-hse-employees.html

- There is now also a new statutory process of voluntary open disclosure of patient safety incidents (for convenience, referred to here as "Civil Liability Act (CLA) Open Disclosure"). CLA Open Disclosure is a process set out in legislation called the Civil Liability (Amendment) Act, 2017. It commenced on 22nd September 2018 and provides important protections regarding information and apologies given during the CLA Open Disclosure process.

- The fundamental difference between Open Disclosure managed outside of the 2017 Act and CLA Open Disclosure as set out in the 2017 Act is that CLA Open Disclosure provides certain protections in respect of how the information and/or apology given to the patient can be used subsequently.

- While the provisions of the Act have been informed by the HSE open disclosure policy 2013 and accompanying guidelines there are certain additional requirements that staff must comply with under the Act when seeking the protections provided within the Act.

- The statutory protections do not apply to any disclosures made to patients, unless they are made completely and entirely in line with the steps set out under CLA Open Disclosure.

- CLA Open Disclosure is not mandatory - it is a voluntary process.

- This document has been developed to set out the procedure in which open disclosure must be managed when staff are seeking the protections provided within the provisions of the 2017 Act.

- Open disclosure must always be managed in a manner which is compassionate, caring and empathetic for all those involved in and/or affected by patient safety incidents.

- This document must be read in conjunction with the HSE National Open Disclosure Policy 2019 "Communicating with Patients following Patient Safety Incidents" (Reference Number NATOD-POL-001) which provides detailed information and guidance for staff in relation to the open disclosure process.

VOLUNTARY OPEN DISCLOSURE OF A PATIENT SAFETY INCIDENT

- Where a Patient Safety Incident occurs, the health services provider may make an open disclosure of the incident to the patient and/or a relevant person (where the patient lacks capacity, has died or has requested the health services provider make open disclosure to the relevant person).

- A Patient Safety Incident is defined as an incident which occurred in the course of the provision of health service to a patient:

    1. Which caused unintended or unanticipated injury, or harm;

    2. Which did not result in actual injury or harm but was one which caused the health services provider to have reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm or

    3. Where, in the absence of prevention by intervention, could have resulted in unanticipated or unintended injury or harm.

- A Patient Safety Incident therefore includes incidents causing actual harm as well as *"near miss"* and *"no harm"* events.

MAKING AN OPEN DISCLOSURE UNDER THE CIVIL LIABILITY (AMENDMENT) ACT 2017

- In order to make CLA Open Disclosure, it is a strict requirement that a detailed process is followed. Otherwise, the statutory protections will not apply.

- The disclosure must be made at a specific open disclosure meeting by the patient's principal healthcare practitioner, or a health practitioner deemed appropriate by the health service provider, to the patient on behalf of the health services provider.

- It must be done ideally by a face-to-face meeting but if it is not practicable for the patient to attend a meeting, the patient can be contacted by phone or similar method of communication.

- The open disclosure meeting must be held as soon as practicable after the patient safety incident.

PREPARING FOR THE OPEN DISCLOSURE MEETING

- Before the meeting, consider: -

    - When the disclosure should be made and who should make it, taking into account all the circumstances of the patient and the nature of the incident.

- Whether an apology is appropriate.

- Designation of a person to liaise with the patient i.e. key contact person. This designation must be recorded in the records.

- Whether other parties who may have an interest in the disclosure should attend.

- The preparation of the written statement to be provided to the patient at the open disclosure meeting. **See Form A**

AT THE MEETING

- The patient must be provided with the following information known to the health services provider at the time of the open disclosure meeting: -

  - Who is present at the open disclosure meeting?
  - A description of the patient safety incident
  - The date on which the incident occurred.
  - When and how it came to the notice of the healthcare provider.
  - A description of the incident, its physical and psychological consequences and any further consequences that are likely or less likely to occur.
  - Where there are reasonable grounds for believing that no physical or psychological consequences are likely to present or develop a statement to that effect must be provided.
  - What the treatment and care plan for the patient is to deal with any of the consequences arising out of the incident.
  - Actions, policies and procedures proposed or that have been taken to address the incident.
  - An apology, where appropriate.
  - Statement in writing which includes the above information, the wording of the apology and the date of the meeting. The statement must be signed by the health services provider. **(See Form A)**

AFTER THE MEETING

- Provision is made for *"additional information"* and *"clarification" requests* where relevant additional information becomes available. These meetings have similar procedural requirements and legal protections.

ADDITIONAL INFORMATION

- The health services provider may at any time after the holding of the open disclosure meeting, provide additional information to the patient which becomes available after the original open disclosure meeting in respect of the patient safety incident.

- In order to avail of the protections provided by the CLA open disclosure procedure, when disclosing additional information, there is a strict requirement that a detailed process be followed. Otherwise, the statutory protections will not apply.

- The disclosure of additional information must be made preferably at a specific open disclosure meeting by the patient's principal healthcare practitioner to the patient on behalf of the health services provider.

- Where it is not practicable for a patient to attend a meeting with the provider, the provision of the additional information can be made by phone or a similar method of communication.

- The patient must be provided with the following information at the meeting disclosing the additional information: -

    - Who was present at the additional information meeting?
    - A description of the additional information being provided.
    - An apology, if appropriate.
    - Further information in respect of any physical or psychological consequences which are likely or unlikely to present or develop as a result of the additional information available.
    - The treatment and care plan for the patient to deal with any of the consequences arising out of the incident.
    - Actions, policies and procedures proposed or that have been taken to address the incident.
    - Statement in writing which includes the above information, the wording of the apology and the date of the meeting. The statement must be signed by the healthcare provider. (**See Form E**).

CLARIFICATION REQUESTS

- A patient, may at any time after the open disclosure or additional information meeting, make a request to the designated person for clarification of the information provided to them.

- The designated person must keep a record of this request. **(See Form F).**

- Where this request is made, the designated person will notify the health practitioner of the request and also liaise with the patient and the healthcare practitioner to arrange a response.

- The healthcare practitioner must provide the clarification to the patient insofar as he or she can, based on the information available to him/her at the time of the request for clarification.

- The healthcare provider may provide the clarification to the patient orally but must also provide the patient with a copy of the statement in writing. This statement must be signed by the health services provider and a copy maintained on record**. (See Form G).**

PROTECTIONS – INFORMATION AND APOLOGY PROVIDED DURING OPEN DISCLOSURE PROCESS

- The legislation (Section 10) says that any information/ statements/apology provided during an open disclosure, additional information or clarification meeting: -

  - Will not constitute an admission of, and shall not be admissible of evidence of, fault or liability in civil proceedings.

  - Will not constitute or be admissible of evidence of fault, professional misconduct, poor professional performance in any disciplinary proceedings.

  - Will not invalidate insurance or indemnity.

CAN A PATIENT DECLINE TO ENGAGE IN OPEN DISCLOSURE?

- A patient or relevant person can decline to take part in an open disclosure meeting. Where a health service provider informs the patient that they propose holding an open disclosure meeting, and the patient does not want to attend this, the patient is obliged to inform the provider that: -

  a) They will not attend the open disclosure meeting;
  b) Do not wish to receive the information which is provided at that meeting;
  c) Do not wish to receive any additional information, or apology that might be made.

  In those circumstances**, Form B** must be completed. A copy of this form must be sent to the patient or relevant person, unless they have refused to receive this. A copy of this form must be maintained by the health services provider.

  If both the patient and the relevant person refuse to attend an open disclosure meeting, **Form C** must be completed. A copy of this form must be sent to the patient and relevant person, unless they have refused to receive this. A copy of this form must be maintained by the health services provider.

- Where a patient and/or relevant person refuse to accept the statement confirming that they have declined to participate in the open disclosure process, **Form D** must be completed, and the record kept by the health services provider.

ESTABLISHING CONTACT WITH A PATIENT/RELEVANT PERSON TO MAKE AN OPEN DISCLOSURE

- Where a health service provider is unable to contact a patient for the purpose of arranging an open disclosure meeting on the basis of the contact information provided to by the patient, the health service provider must take "*all steps reasonably open*" to establish contact.

- In the situation where the health services provider is unable to contact a relevant person for the purpose of arranging an open disclosure meeting (e.g. the relevant person is not contactable via the contact information provided by the patient in their clinical/care record) the health services provider must take all reasonable steps open to them to try to establish contact with the relevant person.

- The legislation does not set out what *"all steps reasonably open"* are, but this would include attempting to contact the patient/relevant person at the telephone number provided, writing to the patient/relevant person at the address provided, or e-mail address if known.

- Any such steps must be in compliance with the health services provider's other statutory obligations such as data protection.

- The health service provider must set out a statement in writing of the steps taken by them to establish contact with the patient/relevant person. **(See Form H)**. This statement must be signed and dated and a copy maintained on record.

Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018

General Information

The prescribed statements (forms) as referred to the in procedure above are available on the HSE website

https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/open-disclosure-legislation/civil-liability-forms.html

There are helpful instructions with each form in relation to how to complete the form.
Note: These are legal forms and must only be amended in the ways specified within the form e.g. when it is indicated *delete as appropriate.
The name of the form must remain on the form.
When the information requested in the form is not known at the time that the form is being completed please state "not known at this time".
The information provided in the form must be factual and not speculative.
The forms must be signed as indicated.
A copy of the form must be maintained on record*

(*In respect of where the form should be stored, the legislation does allow for the Minister to prescribe the form of the records and also any matter relating to the keeping and maintenance of such records (Section 21), however, the Minister has not as yet set out where these records should be kept. The Health Service Executive Standards and Recommended Practices for Healthcare Records Management sets out at Section 23 what documents should be held on the healthcare record. This specifically states that "*the healthcare record should contain only information that is pertinent to the diagnosis and management of the service user*." Among the documents that this policy advises should not be included in the main healthcare record are health & safety forms, incident report forms and risk management incident/complaint reviews. In respect of the prescribed forms, these should be stored separately but identified using the service user's unique identifier and an inventory of such records must be maintained. However, if the form contains information which relates to the diagnosis and management of the patient, a copy of this should also be put on the healthcare record.)

<u>The following is a list of the prescribed statements (forms) as referred to in the above procedure.</u>

Statement of Information provided at open disclosure meeting
(**referred to as Form A**)

Statement of Non-Attendance at Open Disclosure Meeting S 17 (3) (a)
(**referred to as Form B)**

Statement of Non-Attendance at Open Disclosure Meeting S 17 (5) (a**)**
(referred to as Form C)

Refusal to Accept Statement
(referred to as Form D)

Statement of Additional information
(referred to as Form E)

Request for Clarification Meeting
(referred to as Form F)

Statement of Clarification of Information
(referred to as Form G)

Statement of Steps to establish Contact
(referred to as Form H)

Checklist for Staff
Summary of Procedure for Managing Open Disclosure (OD) under the Provisions of Part 4 of the Civil Liability (Amendment) Act 2017

No	Action	Comments
1.	When a patient safety incident occurs and open disclosure (OD) is required the health services provider will consider whether open disclosure will be managed under the provisions of the CLA Act 2017.	
2.	CLA open disclosure is voluntary.	
3.	CLA open disclosure must be managed as per the procedure set out in Part 4 of the 2017 Act.	
4.	CLA OD is undertaken at a face to face meeting preferably but can be undertaken by phone or similar method of communication if a face to face meeting is not practicable.	
5.	The meeting must be held as soon as is practicable – It is not necessary to know all the facts/answers and this should not be used as a reason to defer the meeting.	
6.	OD must always be managed in a manner which is empathic and compassionate.	
	PREPARATION FOR THE OPEN DISCLOSURE MEETING	
7.	• Establish who will make the open disclosure – ie principal health care practitioner or a health practitioner deemed appropriate by the health services provider. • Consider if an apology is appropriate. • Designate a key contact person i.e. designated person to liaise between patient/relevant person and service provider. Record name of designated person in incident management/open disclosure file. • Prepare **Form A (Information to be Provided at an Open Disclosure Meeting).**	
	AT THE MEETING	
8.	• Introductions – those present and roles. • Describe what happened, when it happened and when and how the incident came to the attention of the health services provider. • Description of the incident to include physical and psychological consequences and any further physical and psychological consequences that are likely or less likely to occur. • State if there are reasonable grounds for believing there are no physical or psychological consequences at the time or likely to present or develop. • Discuss care plan and treatment for consequences arising. • Discuss actions taken or planned to address the incident. • Provide an apology, as appropriate. • Provide **Form A** - which must be signed by the health services provider and a copy kept on record.	
	AFTER THE MEETING	
9.	**Management of Additional Information Provided:** • Additional information should be disclosed at a face to face meeting preferably but can be undertaken by phone or similar method of communication if face to face not practicable	

	• Manage as per No 7 above providing additional information, additional apology as appropriate, describe any likely and unlikely physical and psychological consequences as a result of the additional information provided, any changes to care plan and treatment and any additional actions taken to address the incident as a result of the additional information. • Provide **Form E** (**Statement of Additional Information)** signed statement in writing which includes the information above to the patient and/or relevant person. Keep a copy of Form E on record.	
10.	**Clarification requests:** Clarification request should be made to designated person – the clarification must be documented on **Form F (Clarification Request)** and must be kept on record. Clarification must be sought from the principal healthcare practitioner and provided by the principal healthcare practitioner in statement in writing **Form G** (**Statement of Clarification of Information).** The clarification can be provided orally but must also be provided in a signed statement in writing to the patient/relevant person and a copy kept on record by health services provider.	
	PATIENT AND/OR RELEVANT PERSON DECLINES TO ENGAGE IN OPEN DISCLOSURE	
11.	(a) Patient or relevant person declines to attend OD meeting, receive information, receive additional information and/or an apology Complete and sign **Form B (Statement of Non-Attendance at Open Disclosure Meeting Patient or Relevant Person).** Provide Form B to patient or relevant person. Keep a copy on record. (b) Patient and relevant person declines to attend OD meeting, receive information, receive additional information and/or an apology Complete and sign **Form C (Statement of Non-Attendance at Open Disclosure Meeting Patient and Relevant Person)**. Provide Form C to patient and relevant person. Keep a copy on record. (c) Patient and/or relevant person refuses to receive Form B and /or Form C. Complete and sign **Form D (Refusal to Accept Statement)** and keep on record.	
	ESTABLISHING CONTACT WITH A PATIENT AND/OR RELEVANT PERSON	
12.	When unable to contact the patient and/or relevant person for the purpose of engaging in OD the health services provider must demonstrate using a statement in writing **Form H** (**Statement of Steps to Establish Contact)** the reasonable steps taken to establish contact with the patient and relevant. This form must be signed by the health services provider and a copy maintained on record.	
12.	**RECORD KEEPING**	
	The salient points discussed at the open disclosure meeting, names of persons present, details of the apology and actions agreed must be documented in the patients clinical/care record.	

	CLA Forms A, B, C, D, E, F, G and H are stored in a separate file e.g. incident management file/open disclosure file. These forms must be identified using the patient's unique identified number and an inventory of such records maintained.	