The Civil Liability Amendment Act 2017 and Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018

Overview and Frequently Asked Questions

Current Legislation	Key messages
Part 4 of the Civil Liability Amendment Act 2017	○ Part 4 of the Civil Liability Amendment Act 2017 (the "Act") was commenced in September 2018 ○ It contains protective provisions for health care providers as follows: 1. Open disclosure: (a) shall not constitute an express or implied admission of fault or liability in relation to the incident or any clinical negligence arising from the incident (b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability in Court in relation to the incident or clinical negligence action arising out of the incident and (c) shall not invalidate insurance or otherwise affect the cover provided by such policy 2. Information provided, and an apology where it is made, shall not a) constitute an express or implied admission, by a health practitioner, of fault, professional misconduct, poor professional performance, unfitness to practice a health service of other failure or omission in relation to any complaint made by a patient to a regulatory body subsequently and are not admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise a health service, or other failure or omission, in such proceedings. (b) be admissible as evidence of fault or liability in a court in relation to that patient safety incident or a clinical negligence action which arises (whether in whole or in part) from the consequences of that patient Safety. ○ The Act relates to **voluntary** open disclosure ○ The protections relate to the information **and** apology provided at an open disclosure meeting. ○ To obtain the protections of the Act open disclosure must be managed **strictly in accordance** with the procedure set out within Part 4 of the Act. This procedure is available via the link below: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/open-disclosure-legislation/civil-liability-amendment-act-2017.pdf

	○ There are 8 regulations which accompany Part 4 of the Act (see below). These regulations provide the form of the various written statement(s) to be provided and/or maintained on record in relation to the open disclosure process. These must be adhered to, as appropriate, as outlined within the open disclosure process. ○ The protections of the Act will be automatic when open disclosure is managed strictly in accordance with the procedure outlined within Part 4 of the Act.
Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018	○ There are 8 Regulations ○ These take the form of prescribed statements (forms) that relate to various stages of the open disclosure process ○ Staff are obliged to ○ Complete ○ Sign (signed by principal health care practitioner or another person deemed appropriate by the health services provider) ○ Provide (relevant forms) to patients as set out in the procedure, where appropriate ○ Maintain a copy on record in a file separate to the healthcare record e.g. Open Disclosure file or incident management file The forms are available via the link below: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/open-disclosure-legislation/civil-liability-forms.html
FAQs	***Question 1. Are the provisions of the Act automatic for health service providers who manage open disclosure in compliance with the provisions of the Act?*** a. Yes, the protections are automatic when open disclosure is managed as per the procedure set out in the Act. The protections under the Act apply once the requirements of the Act are followed. There is no need to specifically say that the protections are being claimed. b. In particular, the protections only apply to disclosures/discussions which take place as part of an Open Disclosure meeting (which normally is in person, but can be by telephone/other similar method if the patient is not in a position to attend a meeting). c. Not every discussion/ encounter with a patient constitutes an Open Disclosure meeting. d. To constitute such a meeting, there has to be compliance with the requirements of the Act and in particular the requirement that it is the

health service provider making this disclosure. Section 16 of the Act further sets out what information should be provided to the patient at the disclosure meeting such as a statement, details of people present at the meeting, description of the patient safety incident, dates when it occurred and day on which they first became aware, manner in which they became aware, information regarding the consequences and whether it is likely or not likely to have physical/psychological consequences and an apology, if appropriate.

Question 2. Are staff obliged to indicate that they are seeking the protections set out in the Act and if so how should they indicate this?

a. Provided there is compliance with the Act, it is not necessary for staff to specifically indicate that they are seeking the protections of the Act.

b. Any invitation to an Open Disclosure Meeting should refer to the meeting being an Open Disclosure Meeting and any pre-printed forms should recite the fact that it is taking place within the meaning of the legislation.

Question 3. Is the initial open disclosure meeting, sometimes referred to as clinician disclosure, protected under the Act if the CLA process is not followed?

The meaning of open disclosure as outlined in Part 4 of the Act is as follows:

*"Open disclosure is where a health services provider discloses, **at an open disclosure meeting**, to—*

a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her

b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or

c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient.

To avail of the protections of the Act open disclosure must be managed strictly as per the procedure set out within the Act and using the relevant prescribed statements.

Question 4. Can the prescribed statement "Form A: Statement of Information provided at an open disclosure meeting" be sent to the patient after the Open Disclosure meeting?

The Act requires that the information statement is prepared before the Open Disclosure meeting and provided to the patient at the meeting.
Where it is not practicable for a patient or a relevant person (or both of them) to attend a meeting with the health services provider, the patient or relevant person (or both of them) can be contacted by telephone (or other similar method of communication). In this situation the prescribed statement must be sent to the patient and/or relevant person as soon as is practicable after the meeting.

Question 5. Am I now required to seek the protections of Part 4 of the Act for all open disclosures?

No. Availing of the protections of the Act is optional.

Question 6. Will the indemnity provided by the State Claims Agency (SCA) be affected if I opt not to avail of the protections of Part 4 of the Act and opt to manage open disclosure under the provisions of the HSE Open Disclosure policy?

Choosing not to use the CLA open disclosure process, which is voluntary, will not invalidate the indemnity cover provided by the SCA.

Question 7. Will the indemnity provided by the SCA be affected if I opt to avail of the protections of the Act and the process outlined within the Act.?

If you choose to use the CLA open disclosure process, it has no bearing on the SCA indemnity. Section 10 (c) of the Act states that information and/or apology given as part of the CLA open disclosure process shall not " invalidate or otherwise affect the cover provided by{a] policy or contract of insurance that is, or but for such information and such apology would be, available in respect of the patient safety incident concerned or any matter alleged which arises (whether in whole or in part) from that patient safety incident".

Question 8: Should a copy of these prescribed forms (regulations) be kept by the health service provider within the health care record?

- **A.** The Act 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.
- **B.** 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. Until such time a guidance is provided by the Minister on the keeping and maintenance of the prescribed forms, these should be stored separately but identified using the service user's unique identifier and an inventory of such records should 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. **Question 9: Are the protections of the Act available to the health service organisation or individuals involved?** It is intended to protect both. Disclosure is made by the health services provider and any information provided, apology or statement is deemed not to be an admission of fault on the part of a health practitioner and is not admissible as evidence of fault/professional misconduct/poor professional performance/unfitness to practice in any proceedings. The important point is that the Open Disclosure must be made by the health services provider. So, it is the HSE that is making the disclosure. It can designate a particular health practitioner to be the person doing so but they are doing so on behalf of HSE. **Question 10: Does the Act protect private practitioners who manage open disclosure as per the provisions of the Act? Is a Consultant covered for open disclosure relating to public and private work?** Yes. The Act does not distinguish between public/private work. It applies to all healthcare providers and specifically refers to those who have privileges (which covers private work in public hospitals). **Question 11: Must the staff member involved in an error be involved in the open disclosure meeting to be protected in relation to the information provided in the open disclosure meeting?** No, it is not necessary for a staff member involved in the error to partake in the meeting to be protected. The Act specifically states at section 10 that any information or apology given during the course of an open disclosure shall not constitute an express or implied admission of fault or liability by:- 1 The Health Service Provider 2 An employee of that Provider (whether the employee is a Health Practitioner or otherwise), 3 A Health Practitioner who provides, or provided a health service for and on behalf of that Provider. 4 An Agency Health Practitioner who provides, or provided a Health Service for or on behalf of Provider. 5 A Health Practitioner including in the case of Health Service Providers which is a partnership, a partner of the Health Practitioner, providing a Health Service for the Provider. 6 An Agency worker.

	Similar provisions are set out that information and/or an apology given by a Health Service Provider in an open disclosure meeting in respect of a patient safety incident shall not constitute an expressed or implied admission, by a Health Practitioner, of fault, professional misconduct, poor professional performance, unfitness to practice or other failure. ***Question 12:*** **Do the protections of the Act apply to medical indemnity insurance availed of by practitioners in private practice i.e. Can private practitioners avail of the protections in relation to patient safety incidents that occur in private practice?** Yes, no distinction is made. Section 10 (1)(c) specifically states that any information or apology given as part of open disclosure will not invalidate or otherwise effect the cover provided by a policy or contract of insurance.