



STATUTORY INSTRUMENTS.

S.I. No. 237 of 2018



CIVIL LIABILITY (OPEN DISCLOSURE) (PRESCRIBED
STATEMENTS) REGULATIONS 2018

CIVIL LIABILITY (OPEN DISCLOSURE) (PRESCRIBED STATEMENTS) REGULATIONS 2018

I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 22 of the Civil Liability (Amendment) Act 2017 (No. 30 of 2017), hereby make the following regulations:

1. (1) These Regulations may be cited as the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018.

(2) These Regulations shall come into operation on 23 September 2018.

2. In these Regulations, “Act of 2017” means the Civil Liability (Amendment) Act 2017 (No. 30 of 2017).

3. The statement referred to in section 16(5) of the Act of 2017 shall be in the form set out in Schedule 1.

4. For the purposes of section 17 of the Act of 2017—

(a) the statement referred to in—

(i) section 17(3) of that Act shall be in the form set out in Part 1 of Schedule 2, and

(ii) section 17(5) of that Act shall be in the form set out in Part 2 of Schedule 2, and

(b) the note referred to in section 17(6)(i) of that Act, shall be in the form set out in Part 3 of Schedule 2.

5. The statement referred to in section 18(6) of the Act of 2017 shall be in the form set out in Schedule 3.

6. The statement referred to in—

(a) section 19(2)(e)(i) of the Act of 2017 shall be in the form set out in Part 1 of Schedule 4, and

(b) section 19(5) of Act of 2017 shall be in the form set out in Part 2 of Schedule 4.

7. The statement referred to in section 20(4) of the Act of 2017 shall be in the form set out in Schedule 5.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 10th July, 2018.

Schedule 1

Regulation 3

Civil Liability (Amendment) Act 2017

Statement of information referred to in section 16(5) of the Civil Liability (Amendment) Act 2017 provided at an Open Disclosure meeting

Statement for the purpose of section 16 of the Civil Liability (Amendment) Act 2017 setting out the information provided at an open disclosure meeting held on dd/mm/year under section 16 of the Civil Liability (Amendment) Act 2017.

Part 1

Health services provider and patient

Health services provider

Name of health services provider: _____

Address: _____

Contact information: _____

Patient:

Name: _____

Medical Record Number: _____

Address: _____

Date of birth: dd/mm/year

Contact information:

Telephone number of patient: _____

email address: _____

Part 2

Date of, and persons present at, open disclosure meeting

1. Date of open disclosure meeting: dd/mm/year.
2. Open disclosure meeting was held:
 - (a) in person*
 - (b) by telephone or other similar method of communication*.

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3. Persons present at the open disclosure meeting-

Patient*,

Relevant person*,

Patient and relevant person*,

Principal health practitioner*: Name _____,

Health practitioner referred to in section 13(2)* of the Civil Liability (Amendment) Act 2017:

Name _____,

Other persons, if any, present including any person present on behalf of [name of health services provider]*: [name of other persons].

4. Person* persons* to whom the open disclosure was made:

(a) patient*;

(b) relevant person*;

(c) patient and relevant person*.

5. Where the open disclosure was made to a relevant person (whether separately or with the patient)*:

Name of relevant person: _____

Address of relevant person: _____

Contact information of relevant person:

Telephone number: _____

email address: _____

6. The following information was provided to—

the patient*:

the relevant person*:

the patient and the relevant person*:

at the open disclosure meeting.

Part 3

Patient Safety Incident

7. The following information was provided at the open disclosure meeting to the person* or persons* referred to in paragraph 6:

- (a) description of the patient safety incident: [insert description];
- (b) date of occurrence of patient safety incident (if known): [dd/mm/year]* [unknown]*;
- (c) date on which patient safety incident came to the notice of the health services provider: dd/mm/year;
- (d) description of manner in which the patient safety incident came to the notice of the health services provider:[insert description].

Part 4

Information in respect of physical or psychological consequences of patient safety incident

8. The following information was provided at the open disclosure meeting to the person* or persons* referred to in paragraph 6 in respect of any physical or psychological consequences arising from the patient safety incident:

- (a) information on the physical or psychological consequences of the patient safety incident which, in the opinion of the health services provider, are present or have developed at the time of the open disclosure meeting [insert information];
- (b) information on further physical or psychological consequences of the patient safety incident which, the health services provider has reasonable grounds for believing, are likely to present or develop-
 - (i) information on those consequences which have not presented or developed but which the health services provider reasonably believes are likely to present or develop after the open disclosure meeting [insert information, if any, provided];
 - (ii) information on those consequences which have not presented or developed at the time of the open disclosure meeting and which the health services provider believes are less likely or unlikely to present or develop after the open disclosure meeting [insert information, if any, provided].
- (c) there are reasonable grounds for believing that no physical or psychological consequences are likely to present or develop after the open disclosure meeting*;

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- (d) where the patient is under the clinical care of the health services provider at the time of the open disclosure meeting and any of those consequences have presented or developed at that time, information provided at the meeting for the treatment, and relevant clinical care, that the health services provider is providing to the patient to address those consequences [insert the information if any provided].

Part 5*

Actions taken or proposed to be taken to address the patient safety incident

9. The following information was provided at the open disclosure meeting to the person* or persons* referred to in paragraph 6 in relation to the actions the health services provider has taken, or proposes to take to address the knowledge obtained from the patient safety incident including the procedures and processes to be implemented: [insert information provided].

[Part 6 is not to be included in statement if apology not given at open disclosure meeting]

Part 6*

Apology

10. An apology was made at the open disclosure meeting to the person* or persons* referred to in paragraph 6 [Insert statement of apology].

Part 7

Signing of statement

Signing of statement

Signed: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of health services provider].

Health practitioner referred to in section 13(1) of the Civil Liability (Amendment) Act 2017* on behalf of [name of health services provider].

***delete as appropriate**

Schedule 2

Regulation 4

Part 1

Civil Liability (Amendment) Act 2017

Statement of non-attendance at open disclosure meeting by patient or relevant person for purposes of section 17(3)(a) of Civil Liability (Amendment) Act 2017

Health services provider

Name: _____

Address: _____

Contact information: _____

Patient*

Relevant person*

Name: _____

Name: _____

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year

Telephone number: _____

Telephone number: _____

email address: _____

email address: _____

Name of person informed of proposal to hold an open disclosure meeting

1. The following person was informed of the proposal to hold an open disclosure meeting:

(a) Patient*

(b) Relevant person*.

Statement of non-attendance at open disclosure meeting

2. On dd/mm/year [insert name of health services provider] informed—

- (a) the patient*
- (b) the relevant person*

that [insert name of health services provider] proposed to hold an open disclosure meeting in respect of a patient safety incident.

3. On dd/mm/year the patient* (relevant person*) informed the health services provider that he* (she*)—

- (a) will not attend that open disclosure meeting,
- (b) does not wish to receive the information which is to be provided at that open disclosure meeting,
- (c) does not wish to receive, any additional information that may be provided to him or her, and
- (d) does not wish to receive an apology that may be made pursuant to section 18 of the Civil Liability (Amendment) Act 2017.

Signed on dd/mm/year by: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [insert name of the health services provider].

Health practitioner referred to in section 13(2)* on behalf of [insert name of the health services provider:]

* **Delete as appropriate.**

Part 2**Civil Liability (Amendment) Act 2017****Statement of non-attendance at open disclosure meeting by patient and relevant person for purposes of section 17(5)(a) of Civil Liability (Amendment) Act 2017****Health services provider**

Name: _____

Address: _____

Contact information: _____

Patient***Relevant person***

Name: _____

Name: _____

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year

Telephone number: _____

Telephone number: _____

email address: _____

email address: _____

Names of persons informed of proposal to hold an open disclosure meeting

1. The following persons were informed of the proposal to hold an open disclosure meeting:

(a) patient, and

(b) relevant person.

Statement of non-attendance at open disclosure meeting

2. On dd/mm/year [insert name of health services provider] informed the patient and relevant person that [insert name of health services provider] proposed to hold an open disclosure meeting in respect of a patient safety incident.

3. On dd/mm/year the patient and relevant person informed the health services provider that they—

- (a) will not attend that open disclosure meeting,
- (b) do not wish to receive the information which is to be provided at that open disclosure meeting,
- (c) do not wish to receive, any additional information that may be provided to them, and
- (d) do not wish to receive an apology that may be made pursuant to section 18 of the Civil Liability (Amendment) Act 2017.

Signed on dd/mm/year by: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of the health services provider].

Health practitioner referred to in section 13(2)* on behalf of [name of the health services provider].

*** Delete as appropriate.**

Part 3**Civil Liability (Amendment) Act 2017****Note required under section 17(6)(i) of Civil Liability (Amendment) Act 2017****Health services provider**

Name: _____

Address: _____

Contact information: _____

Patient***Relevant person***

Name: _____

Name: _____

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year**Telephone number:** _____**Telephone number:** _____**email address:** _____**email address:** _____**Refusal by patient or relevant person to accept a statement provided for the purposes of section 17(3) of Civil Liability (Amendment) Act 2017***

1.1 The patient* [insert name of patient] refused to accept the statement prepared for the purposes of section 17(3) of the Civil Liability (Amendment) Act 2017 and provided to him or her in accordance with that section.

1.2 The relevant person* [insert name of relevant person] refused to accept the statement prepared for the purposes of section 17(3) of the Civil Liability (Amendment) Act 2017 and provided to him or her in accordance with that section.

Refusal by patient and relevant person to accept a statement provided for the purposes of section 17(5) of Civil Liability (Amendment) Act 2017*

2. The patient [insert name of patient] and relevant person [insert name of relevant person] refused to accept the statement prepared for the purposes of section 17(5) of the Civil Liability (Amendment) Act 2017 and provided to them in accordance with that section.

14 [237]

Signed on dd/mm/year by: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of the health services provider].

Health practitioner referred to in section 13(2)* on behalf of [name of the health services provider].

*** Delete as appropriate.**

Schedule 3

Regulation 5

Civil Liability (Amendment) Act 2017

Statement of additional information referred to in section 18(6) of the Civil Liability (Amendment) Act 2017 provided at an additional information meeting

Statement for the purpose of section 18 of the Civil Liability (Amendment) Act 2017 setting out the additional information provided at an additional information meeting held on dd/mm/year under section 18 of the Civil Liability (Amendment) Act 2017.

Part 1

Health services provider and patient

Health services provider

Name of health services provider: _____

Address: _____

Contact information: _____

Patient: _____

Medical Record Number: _____

Address: _____

Date of birth: dd/mm/year

Contact information:

Telephone number of patient: _____

email address: _____

Part 2

Date of, and persons present at, additional information meeting

1. Date of additional information meeting: dd/mm/year.

2. Additional information meeting was held:

(a) in person*

(b) by telephone or other similar method of communication*.

3. Persons present at the additional information meeting—

Patient*,

Relevant person*,

Patient and relevant person*,

Principal health practitioner*: Name _____,

Health practitioner referred to in section 18(1)(ii)* or 18(1)(iii)* of the Civil Liability (Amendment) Act 2017: Name _____,

Other persons, if any, present including any person present on behalf of [name of health services provider]*: [name of other persons].

4. Person* (persons*) to whom the additional information was provided:

(a) patient*:

(b) relevant person*:

(c) patient and relevant person*.

5. Where the additional information was provided to a relevant person (whether separately or with the patient)*:

Name of relevant person: _____

Address of relevant person: _____

Contact information of relevant person:

Telephone number: _____

email address: _____

6. The following additional information was provided to-
the patient*:
the relevant person*:
the patient and the relevant person*:
at the additional information meeting.

Part 3

Additional information relating to Patient Safety Incident

7. The following additional information was provided at the additional information meeting to the person* or persons* referred to in paragraph 6:

- (a) description of the patient safety incident: [insert description]*;
- (b) date of occurrence of patient safety incident (if known):[dd/mm/year]* [unknown]*;
- (c) date on which patient safety incident came to the notice of the health services provider: dd/mm/year;
- (d) description of manner in which the patient safety incident came to the notice of the health services provider:[insert description]*.

Part 4

Additional information in respect of physical or psychological consequences of the patient safety incident

8. The following additional information was provided at the additional information meeting to the person* or persons* referred to in paragraph 6 in respect of any physical or psychological consequences arising from the patient safety incident:

- (a) additional information provided at the meeting in respect of the matters set out in Parts 3 and 4 of the statement provided in respect of the open disclosure meeting and information given, if any, in relation to Part 5 of that statement [insert information provided];
- (b) additional information on the physical or psychological consequences of the patient safety incident which, in the opinion of the health services provider, are present or have developed at the time of the additional information meeting—
 - (i) none of these consequences are present or developed at that time*;
 - (ii) description of those consequences*: [insert description];

- (c) additional information on further physical or psychological consequences of the patient safety incident, which the health services provider has reasonable grounds for believing, are likely to present or develop after the date of the additional information meeting—
 - (i) information on those consequences which the health services provider reasonably believes are likely to present or develop after the date of the additional information meeting [insert information, if any, provided];
 - (ii) information on those consequences which have not presented or developed and which the health services provider reasonably believes are less likely or unlikely to present or develop after the additional information meeting [insert information, if any, provided].
- (d) where the patient is under the clinical care of the health services provider which provided the additional information at the additional information meeting and any of those consequences have presented or developed at the time of the meeting and the health services provider proposes to make changes to the treatment, and relevant clinical care to address those consequences—
 - (i) the following information was provided: [insert information]*
 - (ii) the health services provider does not propose to change the treatment and clinical care*.

Part 5*

Additional information in respect of actions taken or proposed to be taken to address the patient safety incident

9. The following additional information was provided at the additional information meeting to the person* or persons* referred to in paragraph 6 in relation to the actions the health services provider has taken, or proposes to take to address the knowledge obtained from the patient safety incident including the procedures and processes to be implemented: [information, if any, provided].

[Part 6 is not to be included in statement if apology not given at additional information meeting]

Part 6*

Apology

10. An apology was made at the additional information meeting to the person* or persons* referred to in paragraph 6 [Insert statement of apology].

Part 7

Signing of statement

Signing of statement

Signed: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of health services provider].

Health practitioner referred to in section 18(1)(ii)* or 18(1)(iii)* of the Civil Liability (Amendment) Act 2017* on behalf of [name of health services provider].

***delete as appropriate**

Schedule 4

Regulation 6

Part 1

Civil Liability (Amendment) Act 2017

Request for clarification of information

Statement for purposes of section 19(2)(e)(i) of Civil Liability (Amendment) Act 2017

Health services provider

Name: _____

Address: _____

Contact information: _____

Patient*

Relevant person*

Name: _____

Name: [Full name of relevant person]

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year

Telephone number: _____

Telephone number: _____

email address: _____

email address: _____

1. The following person* (persons*) made a request for clarification under section 19 of the Civil Liability (Amendment) Act 2017:

Patient*

Relevant person*

Patient and relevant person*.

2. The request was for clarification of-

- (a) any information provided to the patient* relevant person* (or the patient and relevant person*) at the open disclosure meeting*
- (b) any additional information provided to the patient* relevant person* (or the patient and relevant person*) at the additional information meeting.

3. The clarification requested was provided on: dd/mm/year.

Designated person: _____

Print name in Block Capitals _____

Part 2

Civil Liability (Amendment) Act 2017

Clarification of information

Statement for purposes of section 19(5) of Civil Liability (Amendment) Act 2017

Health services provider

Name: _____

Address: _____

Contact information: _____

Patient*

Relevant person*

Name: _____

Name: _____

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year

Telephone number: _____

Telephone number: _____

email address: _____

email address: _____

1. The following information was provided to—

- (a) the patient*,
- (b) the relevant person*,
- (c) the patient and relevant person*,

[Insert information provided].

2. The clarification was provided on dd/mm/year by:

- (a) the principal health practitioner*
- (b) the health practitioner referred to in section 19(3) of the Civil Liability (Amendment) Act 2017*.

Signed: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of health services provider].

Health practitioner referred to in section 19(3) of the Civil Liability (Amendment) Act 2017*on behalf of [name of health services provider].

***Delete as appropriate**

Schedule 5

Regulation 7

Civil Liability (Amendment) Act 2017

Statement for purposes of section 20(4) of Civil Liability (Amendment) Act 2017 regarding establishing contact with certain persons for purpose of arranging an open disclosure meeting

Health services provider

Name: _____

Address: _____

Contact information: _____

Patient*

Relevant person*

Name: _____

Name: _____

Medical Record Number: _____

Address: _____

Address: _____

Date of Birth: dd/mm/year

Telephone number: _____

Telephone number: _____

Steps taken by health services provider to establish contact for purpose of arranging an open disclosure meeting

1. [Name of health services provider] was unable to establish contact with-
 - (a) the patient*
 - (b) the relevant person*
 - (c) the patient and relevant person*

for the purpose of arranging the open disclosure meeting on the basis of the contact information provided to it.

2. The following steps were taken by [name of health services provider] to establish contact with

- (a) the patient*
- (b) relevant person*
- (c) the patient and relevant person*

for that purpose:[insert information on steps taken].

Signed on dd/mm/year by:

Signed: _____

Print name in Block Capitals: _____

Principal health practitioner* on behalf of [name of health services provider].

Health practitioner referred to in section 13(1) of the Civil Liability (Amendment) Act 2017* on behalf of [name of health services provider].

*** Delete as appropriate**



GIVEN under my Official Seal,
4 July 2018.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

The Civil Liability (Open disclosure) (Prescribed statements) Regulations 2018 prescribe the statements referred to in sections 16(5), 17(3), 17(5), 18(6), 19(2)(e)(i), 19(5) and 20(4) and the note referred to in section 17(6)(i) of Part 4 of the Civil Liability (Amendment) Act 2017 to come into operation on 23rd day of September 2018.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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