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SCOTTISH STATUTORY INSTRUMENTS

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**2018 No. 57**

**NATIONAL HEALTH SERVICE  
SOCIAL CARE  
SOCIAL WORK**

**The Duty of Candour Procedure (Scotland) Regulations 2018**

*Made* - - - - 8th February 2018  
*Laid before the Scottish  
Parliament* - - - - 12th February 2018  
*Coming into force* - - 1st April 2018

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 22(1) and (2) of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016<sup>(1)</sup> and all other powers enabling them to do so.

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Duty of Candour Procedure (Scotland) Regulations 2018 and come into force on 1st April 2018.

(2) (a) In these Regulations—

“the Act” means the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016;

“incident” means the unintended or unexpected incident by virtue of which section 21(2) of the Act applies to a person; and

“procedure start date” is the date on which an opinion referred to in section 21(2)(b) of the Act is provided to the responsible person.

(b) A document required by virtue of these Regulations to be “written” includes an electronic communication, as defined in section 15(1) of the Electronic Communications Act 2000<sup>(2)</sup>.

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(1) 2016 asp 14.  
(2) 2000 c.7.

### **Communication with relevant person**

2.—(1) If, in respect of an incident, the responsible person<sup>(3)</sup> is unable to contact the relevant person<sup>(4)</sup> or the relevant person declines to communicate with the responsible person—

- (a) the record kept under regulation 9 must include information about the attempts made to contact or to communicate with the relevant person; and
- (b) any requirement in these Regulations to provide information to, or communicate with, the relevant person does not apply in respect of that incident.

(2) The responsible person must take reasonable steps to ascertain the relevant person’s preferred method of communication and, where reasonably practicable, communicate with the relevant person by this method.

(3) The responsible person must take reasonable steps to ensure any communication with the relevant person is in a manner that the relevant person can understand.

### **Limitations on provision of information**

3. These Regulations do not permit or require a responsible person to disclose any information which—

- (a) would prejudice any criminal investigation or prosecution;
- (b) would contravene any restriction on disclosure arising by virtue of an enactment or rule of law.

### **Notification**

4.—(1) In respect of an incident, the responsible person must notify the relevant person in accordance with this regulation.

(2) The notification must include—

- (a) an account of the incident insofar as the responsible person is aware of the facts at the date the notification is provided;
- (b) an explanation of the actions that the responsible person will take as part of the duty of candour procedure; and
- (c) where the procedure start date is later than one month after the date on which the incident occurred, an explanation of the reason for this.

### **Apology**

5. In addition to any apology provided at the time of an incident, the responsible person must offer the relevant person a written apology in respect of the incident and must provide one if the relevant person wishes it.

### **Meeting**

6.—(1) In respect of an incident, the responsible person must invite the relevant person to attend a meeting as described in paragraph (2), and must give the relevant person the opportunity to ask questions of the responsible person in advance of that meeting.

(2) The meeting must include—

- (a) the provision of an account of the incident by the responsible person;

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(3) “Responsible person” is defined in section 25 of the Act.

(4) “Relevant person” is defined in section 22(3) of the Act.

- (b) the provision of an explanation of any further steps that will be taken by the responsible person to investigate the circumstances which it considers led or contributed to the incident;
  - (c) an opportunity for the relevant person to ask the responsible person questions about the incident;
  - (d) an opportunity for the relevant person to express their views about the incident; and
  - (e) the provision of information to the relevant person about any legal or review procedures that are being followed in respect of the incident in addition to the duty of candour procedure.
- (3) Following the meeting the responsible person must provide the relevant person with—
- (a) a note of the meeting; and
  - (b) contact details for an individual member of staff acting on behalf of the responsible person.
- (4) If the relevant person does not wish to or is unable to attend the meeting, the responsible person must provide the relevant person with the information mentioned in paragraphs (2)(a), (b) and (e) and (3)(b) if the relevant person wishes it.

## **Review**

7.—(1) The responsible person must carry out a review of the circumstances which it considers led or contributed to the incident.

(2) Where the review is not completed within a period of 3 months beginning with the procedure start date, the responsible person must provide the relevant person with an explanation for this.

(3) In carrying out the review, the responsible person must seek the views of the relevant person and take account of any views expressed.

(4) The responsible person must prepare a written report of the review, which must include—

- (a) a description of the manner in which the review was carried out;
- (b) a statement of any actions to be taken by the responsible person for the purpose of—
  - (i) improving the quality of service provided by the responsible person;
  - (ii) sharing learning with other persons or organisations in order to support continuous improvement in the quality of health, care or social work services; and
- (c) a list of the actions taken in accordance with the duty of candour procedure in respect of the incident and the date or dates each action was taken.

(5) The responsible person must offer to send the relevant person—

- (a) a copy of the written report of the review;
- (b) any further information about the actions mentioned in paragraph (4)(b) for the purpose of improving the quality of service provided by the responsible person or other health, care or social work services; and
- (c) details of any services or support which the responsible person considers may provide assistance to the relevant person, taking into account the relevant person's needs.

(6) If the relevant person wishes to receive any of the information mentioned in paragraph (5), this should be provided by—

- (a) the responsible person; or
- (b) where in the opinion of the responsible person it is appropriate to do so, by another responsible person where that other responsible person is—
  - (i) undertaking a duty of candour procedure in respect of the incident; and

(ii) agrees to do so.

### **Training and support**

**8.—**(1) The responsible person must ensure that all employees who carry out the duty of candour procedure on its behalf—

- (a) are aware of the duty of candour procedure;
- (b) can provide relevant persons with the information mentioned in regulation 7(5)(c); and
- (c) receive relevant training and guidance on the duty of candour procedure and any services and support which may be available to relevant persons.

(2) The responsible person must provide an employee who is involved in an incident with details of any services or support of which the responsible person is aware which may provide assistance or support to any such employee, taking into account—

- (a) the circumstances relating to the incident; and
- (b) the employee's needs.

### **Records**

**9.—**(1) The responsible person must keep a written record for each incident in respect of which the duty of candour procedure is followed.

(2) The written record must include a copy of every document and piece of correspondence relating to the application of the duty of candour procedure to the incident.

St Andrew's House, Edinburgh  
8th February 2018

*SHONA ROBISON*  
A member of the Scottish Government

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision about the duty of candour procedure to be undertaken in terms of section 22 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (“the 2016 Act”) in health and social care settings.

Regulation 2 sets out the form and manner of communications for any communication required by virtue of these Regulations.

Regulation 3 sets out limitations on the provision of information.

Regulation 4 provides for the relevant person to be notified by the responsible person and the information to be included in such notification.

Regulation 5 provides that the responsible person must offer a written apology to the relevant person and must provide such apology where the relevant person wishes it.

Regulation 6 provides that the responsible person must invite the relevant person to attend a meeting, and sets out the information to be provided to the relevant person during and after such a meeting as well as the information to be offered to the relevant person if the relevant person does not wish to or is unable to attend the meeting.

Regulation 7 provides that the responsible person must carry out a review of the circumstances which it considers led, or contributed, to the incident and sets out how this is to be done.

Regulation 8 requires the responsible person to provide training and support to relevant employees.

Regulation 9 provides that the responsible person must keep a written record for each incident in respect of which the duty of candour procedure is followed.

A Business Regulatory Impact Assessment has been prepared and can be obtained from the Scottish Government website.