



MANX CARE (DUTY OF CANDOUR PROCEDURE) REGULATIONS 2021

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Manx Care Act 2021

MANX CARE (DUTY OF CANDOUR PROCEDURE) REGULATIONS 2021

Approved by Tynwald:

Coming into Operation:

1 April 2021

The Department of Health and Social Care makes the following Regulations under section 11 of the Manx Care Act 2021.

1 Title

These Regulations are the Manx Care (Duty of Candour Procedure) Regulations 2021.

2 Commencement

If approved by Tynwald, these Regulations come into operation on 1 April 2021¹.

3 Interpretation

(1) In these Regulations —

“**the Act**” means the Manx Care Act 2021;

“**duty of candour procedure**” means the actions to be taken by a service provider in accordance with these Regulations;

“**incident**” means the unintended or unexpected incident by virtue of which regulation 4(2) applies to a service user;

“**procedure start date**” means the date on which an opinion referred to in regulation 4(2)(b) is provided to the service provider;

“**registered health or social care professional**” means —

- (a) a registered health professional;
- (b) a registered social worker; or
- (c) a registered manager of a service provider;

¹ Tynwald approval is required by section 11(2) of the Act.

“registered health professional” means a professional who is regulated in accordance with any of the following –

- (a) Dental Act 1985;
- (b) Health Care Professionals Act 2014;
- (c) Medicines Act 2003; or
- (d) Opticians Act 1996;

“registered manager” has the same meaning as in section 39 of the Regulation of Care Act 2013;

“registered social worker” means a person registered under a UK care Act or regulations under section 161(2)(a) of the Regulation of Care Act 2013 to perform work of any type (however described) that is social work;

“relevant person” means –

- (a) the service user referred to in regulation 4(2); or
- (b) in a case where the service user referred to in paragraph (a) does not wish to act on his or her own behalf, a person with written authority to act on the service user’s behalf; or
- (c) a person lawfully acting on the service user’s behalf –
 - (i) if the service user has died;
 - (ii) if the service user is under the age of 18 and is not competent to make a decision in relation to his or her own care or treatment; or
 - (iii) if the service user is aged 18 or over and lacks capacity in relation to the matter; or
- (d) if no person is identified as the relevant person under paragraphs (a), (b) or (c), a person who the service provider considers, having regard to any information in the service provider’s records with respect to the service user, –
 - (i) has sufficient interest in the service user’s welfare; and
 - (ii) is suitable to act on the service user’s behalf;

“relevant service” means a health service or a social care service;

“service provider” means a relevant service provider; and

“UK care Act” has the same meaning as in the Schedule to the Regulation of Care Act 2013.

- (2) A document required by virtue of these Regulations to be “written” includes an electronic communication, as defined in section 12 of the Electronic Transactions Act 2000.

4 Incident which activates duty of candour procedure

- (1) A service provider must follow the duty of candour procedure set out in these Regulations as soon as reasonably practicable after becoming aware that paragraph (2) applies to a service user who has received a relevant service from the service provider.
- (2) This paragraph applies to a service user if —
 - (a) an unintended or unexpected incident (including where an error of omission has occurred) in the provision of a relevant service to the service user; and
 - (b) in the reasonable opinion of a registered health or social care professional—
 - (i) that incident appears to have resulted in or is likely to result in an outcome mentioned in paragraph (3); and
 - (ii) that outcome relates directly to the incident rather than to the natural course of the service user's illness or underlying condition.
- (3) The outcomes referred to in paragraph (2)(b) are —
 - (a) the death of the service user;
 - (b) a permanent lessening of the service user's bodily, sensory, motor, physiologic or intellectual functions;
 - (c) harm which is not listed in sub-paragraph (b) but which results in —
 - (i) an increase in the service user's treatment;
 - (ii) changes to the structure of the service user's body;
 - (iii) the shortening of the life expectancy of the service user;
 - (iv) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of 28 days or more;
 - (v) the service user experiencing pain or psychological harm which has been, or is likely to be, experienced by the service user for a continuous period of 28 days or more;
 - (d) the service user requiring treatment by a registered health professional in order to prevent —
 - (i) the death of the service user; or
 - (ii) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in subparagraph (b) or (c); and
 - (e) if the service user is a child, in addition to the outcomes specified in subparagraphs (a) to (d), significant harm that results in the impairment of the health or development of the service user.

(4) For the purposes of paragraph (3)(e), where question of whether harm suffered by a child is significant turns on that child's health or development, the child's health or development must be compared with that which could reasonably be expected of a similar child.

(5) In this regulation –

“**child**” means a person under 18 years of age;

“**development**” means physical, intellectual, emotional, social and behavioural development; and

“**health**” means physical or mental health.

5 Communication with relevant person

(1) If, in respect of an incident, a service provider is unable to contact the relevant person or the relevant person declines to communicate with the service provider –

(a) the record kept under regulation 12 must include information about the attempts made to contact or 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) If, in respect of an incident, a service provider is unable to identify a relevant person, despite taking reasonable steps to do so –

(a) the record kept under regulation 12 must include information about the attempts made to identify the relevant person; and

(b) paragraph (1)(b) applies.

(3) The service provider 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.

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

6 Limitations on provision of information

These Regulations do not permit or require a service provider to disclose any information which would –

(a) prejudice any active criminal investigation or prosecution;

(b) contravene any restriction on disclosure arising by virtue of an enactment or rule of law.

7 Notification

- (1) In respect of an incident, the service provider must notify the relevant person as soon as reasonably practicable in accordance with this regulation.
- (2) The notification must include—
 - (a) an account of the incident insofar as the service provider is aware of the facts at the date the notification is provided;
 - (b) an explanation of the actions that the service provider 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.
- (3) If the service provider is a person with whom Manx Care has entered into an agreement in accordance with section 17(1) of the Act, that person must notify Manx Care about the incident no later than the date on which notification is made to the relevant person.

8 Apology

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

9 Meeting

- (1) In respect of an incident, the service provider must invite the relevant person to attend a meeting as described in paragraph (2), and must give the relevant person an opportunity to ask questions of the service provider in advance of that meeting.
- (2) The meeting must include —
 - (a) the provision of an account of the incident by the service provider;
 - (b) the provision of an explanation of any further steps that will be taken by the service provider to investigate the circumstances which it considers led or contributed to the incident;
 - (c) an opportunity for the relevant person to ask the service provider questions about the incident;
 - (d) an opportunity for the relevant person to express his or her 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 service provider must provide the relevant person with —

- (a) a note of the meeting;
 - (b) answers to any questions asked by the relevant person in accordance with paragraph (1) or (2)(c) that remain unanswered; and
 - (c) contact details for an individual member of staff acting on behalf of the service provider.
- (4) If the relevant person does not wish to or is unable to attend the meeting, the service provider must provide the relevant person with the information mentioned in paragraphs (2)(a), (b) and (e) and (3)(c) if the relevant person wishes it.

10 Review

- (1) The service provider 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 6 months beginning with the procedure start date, the service provider must provide the relevant person with an explanation for this.
- (3) If requested by the relevant person, regular updates must be provided on the progress of the review.
- (4) In carrying out the review, the service provider must seek the views of the relevant person and take account of any views expressed.
- (5) The service provider 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 service provider for the purpose of –
 - (i) improving the quality of service provided by the service provider;
 - (ii) sharing learning with other persons or organisations in order to support continuous improvement in the quality of health services or social care 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.
- (6) The service provider must offer to send the relevant person –
- (a) a copy of the written report of the review; and
 - (b) any further information about the actions mentioned in paragraph (5)(b) for the purpose of improving the quality of service provided by the service provider or other relevant services.

- (7) As soon as is reasonably practicable after the incident, the service provider must offer to supply the relevant person with details of any services or support which it considers may provide assistance to the relevant person, taking into account that person's needs.
- (8) If the relevant person wishes to receive any of the information mentioned in paragraphs (6) or (7), this should be provided by —
 - (a) the service provider; or
 - (b) where in the opinion of the service provider it is appropriate to do so, by another service provider where that other service provider is —
 - (i) undertaking a duty of candour procedure in respect of the incident; and
 - (ii) agrees to do so.

11 Training and support

- (1) The service provider must ensure that, in the case of Manx Care all Manx Care staff, and in the case of any other service provider all employees or contracted persons 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 10(7);
 - (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 service provider must debrief a member of staff, employee or contracted person who is involved in an incident and provide that person with details of any services or support of which the service provider is aware which may provide assistance or support to that person, taking into account —
 - (a) the circumstances relating to the incident; and
 - (b) the person's needs.

12 Records

- (1) The service provider 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.

13 Procedures

- (1) A service provider must establish and maintain written operational procedures in relation to the duty under regulation 4(1).
- (2) A service provider must make a copy of its operational procedures available to a service user on request.

14 Reporting

- (1) As soon as reasonably practicable and no later than 3 months after the end of each financial year, the relevant service provider must—
 - (a) prepare an annual report on the duty of candour during that financial year; and
 - (b) submit a copy of the report to Manx Care (if the relevant service provider is not Manx Care).
- (2) The report must set out in relation to that financial year —
 - (a) information about the number and nature of incidents to which the duty under regulation 4(1) has applied in relation to all relevant services;
 - (b) an assessment of the extent to which the duty under regulation 4(1) has been carried out by the relevant service provider for each of the relevant services;
 - (c) information about the relevant service provider’s policies and operational procedures in relation to the duty under regulation 4(1), including information about —
 - (i) procedures for identifying and reporting incidents; and
 - (ii) support available to staff and to persons affected by incidents;
 - (d) information about any changes to the service provider’s policies and procedures as a result of incidents to which the duty under regulation 4(1) has applied; and
 - (e) such other information as the relevant service provider thinks fit.
- (3) A report must not —
 - (a) mention the name of any individual;
 - (b) contain any information which, in the relevant service provider’s opinion, is likely to identify any individual.

15 Publicity of duty of candour procedure

A service provider must ensure that its duty of candour obligations as required under these Regulations are effectively publicised.

MADE 16 MARCH 2021

DAVID ASHFORD
Minister for Health and Social Care

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

These Regulations make provisions about the duty of candour procedure to be followed if things go wrong in health and social care settings on the Island.

Regulation 4 requires a service provider to follow the duty of candour procedure established by these Regulations and describes the incidents to which the duty of candour applies.

Regulation 5 sets out the manner of communications for any communication required with a relevant person (the service user or person acting on their behalf) by virtue of these Regulations.

Regulation 6 sets out limitations on the provision of information.

Regulation 7 provides for the relevant person to be notified by the service provider and the information to be included in such notification. If the service provider is not Manx Care, it provides that Manx Care must also be notified about any duty of candour incidents.

Regulation 8 requires the service provider to offer the relevant person a written apology in respect of the incident and to provide such an apology if the relevant person wishes it.

Regulation 9 provides that the service provider 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 if the relevant person does not wish, or is unable, to attend the meeting.

Regulation 10 provides that the service provider 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 11 requires the service provider to provide training and support to its staff.

Regulation 12 provides that the service provider must keep a written record for each incident in respect of which the duty of candour procedure is followed.

Regulation 13 requires a service provider to establish and maintain written operational procedures and to make a copy of such procedures available to a service user on request.

Regulation 14 requires the relevant service provider to report on the duty of candour and where the service provider is not Manx Care, requires the service provider to submit a copy of the report to Manx Care.

Regulation 15 requires the relevant service provider to ensure its duty of candour obligations, as required by these Regulations, are effectively publicised.