

ISLE OF MAN GOVERNMENT

DEPARTMENT OF HEALTH AND SOCIAL CARE

DUTY OF CANDOUR

Consultation on draft legislation

Issue date: 18 December 2020

Closing date: 22 January 2021

Consultation Paper

The purpose of this Consultation

This consultation paper is issued by the Department for Health and Social Care (“the Department”) in conjunction with the Health and Care Transformation Programme in the Cabinet Office, for the purpose of gathering views about regulations for implementing a statutory duty of candour for health and social care services (a duty to be open and honest with service users)

The Manx Care Bill will establish in statute Manx Care as the new organisation responsible for the delivery of health and care services on the Island. They will be instructed by the Department on what services are to be delivered, to what standard and for what budget. Manx Care will then deliver services in the way it deems best and the Department will hold Manx Care to account for Manx Care’s performance.

It is anticipated that the Manx Care Bill will bring in this new legal duty for health and social care services to be open and transparent with service users from 1 April 2021. The intention in bringing in a duty of candour is to provide patients and service users with greater confidence in the providers of health and social care services as well as encouraging a culture of openness, improvement and learning from mistakes.

The duty of candour in the Manx Care Bill does not provide any detail on how the duty should operate in practice. For that, a new set of Regulations is needed, which will require organisations providing people with health and care services to follow a set procedure where a person’s safety has been, or is likely to be, affected as a result of using a health or social care service. The Regulations set out what information must be provided and when.

The intention is for these Regulations to come into operation at the same time as the establishment of Manx Care, i.e. 1 April 2021 and the purpose of this consultation is to seek your views on the proposed content of these draft regulations.

There are a number of questions throughout this consultation paper on specific aspects of such a duty. They are there as guidance as to what you may wish to consider when responding. They should not be taken to be prescriptive or restrictive; you are free to raise any points or make any comments that you believe to be relevant.

The deadline by which we need your response is 21 January 2021.

Paper copies of this consultation are available from either the Department of Health and Social Care or the Health and Care Transformation Programme. Contact details for each are provided below:

Duty of Candour Consultation, Georgina Jones, Department of Health and Social Care, Crookall House, Demesne Road, Douglas, IM1 3QA. Telephone: +44 1624 642608

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When submitting a response please bear in mind the following:

1. Your response, subject to 2 and 3 below, will be carefully considered; however it does not guarantee that your proposals or preferences will ultimately form a part of the new legal framework for the duty of candour.
2. Any abusive or offensive responses will be discounted.
3. Please let us know the name of the organisation that you are responding on behalf of, if applicable.
4. We would welcome your response at the earliest opportunity ahead of the closing date.

Publishing responses

During the consultation we may publish the responses received and we will publish a summary of the responses after the consultation has closed. Therefore information you provide to us, including personal information may be published or disclosed. Where this is the case, it will be done in accordance with the Island's data protection legislation.

In respect of written responses (e.g. by letter or email) you may want your response and/or personal information included with the response to remain confidential. If this is the case please mark your response clearly. An automatic confidentiality disclaimer generated by your IT system will not, in itself, be regarded as binding.

In respect of responses made via the Isle of Man Government's consultation hub at consult.gov.im, you will be able to indicate your preference regarding the publication, or otherwise, of your response prior to commencing the consultation.

Queries

If you have any query that relates to how this consultation has been carried out please contact Nicola Igoea by e-mail at Nicola.Igoea2@gov.im.

Code of Practice on Consultation

This consultation is being carried out in accordance with the Government's Public Engagement and Consultation Principles, October 2017 ("Code").

The Code sets out eight criteria for consultations, being:

1. Consultations have a purpose and offer genuine opportunities to make a difference.
2. Consultations follow a clear and open process.
3. Consultations are well planned and delivered in a reasonable timescale.
4. We encourage and enable everyone affected to get involved, if they wish to.
5. We provide jargon free and understandable information.
6. Use suitable methods to deliver the consultation.
7. We learn and share lessons to improve future consultations.
8. We tell people the impact of their contribution.

Background

1. In January 2018 Tynwald gave its support to an independent review being undertaken into how the provision of health and social care services, in the Island, would look in the future.
2. Subsequently, Sir Jonathan Michael was appointed to undertake the review and, having done so, the Independent Health and Social Care Review Final Report dated 18 April 2019 ("the Report") was presented to, and approved by, Tynwald in May 2019. A copy of that Report can be found [here](#).
3. Amongst the series of recommendations made by Sir Jonathan Michael for improving the governance of health and care in the Island was to provide, in legislation, a duty of candour.

What is a duty of candour?

4. A duty of candour, in law, will require organisations providing health and care services to be open, honest and transparent with the people that use those services, particularly when things have gone wrong.

Proposal

5. To recap, when the Manx Care Bill 2020 comes into operation on 1 April 2021, the following happens:
 - a) Manx Care becomes responsible for providing all health and care services (or for arranging for those services to be provided by other organisations)
 - b) the Department of Health and Social Care will have a legal duty to act in a way that is open and transparent;
 - c) Manx Care will have the same legal duty to act in an open and transparent manner; and
 - d) Manx Care and anyone that it has entered into an arrangement with to provide health or social care services on its behalf, must act in accordance with these Regulations

which set out a duty of candour procedure to be followed in the event of an unintended incident which has resulted in or is likely to result in harm to the service user.

6. For the purposes of this consultation, references to Manx Care below include those with whom it has entered into arrangements for the provision of health and social care services.

When will the duty of candour procedure apply?

7. We are proposing that Manx Care will have to follow the duty of candour procedure when the following occurs:

a) in the provision of care to a service user there is an unintended or unexpected incident;

b) this incident resulted in, or is likely to result in, any one of the following happening:

- death or severe harm,
- harm, which although not severe, results in:
 - an increase in treatment,
 - changes to the structure of the service user's body,
 - the shortening of life expectancy,
 - an impairment which has lasted, or is likely to last, for 28 days or more,
 - pain or psychological harm which has been, or is likely to be, experienced for 28 days or more,
 - treatment being required to prevent death or any injury which would lead to severe or non-severe harm if left untreated,
- where the service user is a child, the suffering of significant harm that results in an impairment to their health or development.

Question

Do you have any comments on the proposed harm threshold for when the duty of candour procedure would be triggered?

What does Manx Care have to do?

8. When the duty of candour procedure applies, we are proposing that Manx Care will be required to take the steps outlined below:

9. *Tell the service user what has happened.*

One of the steps is they must notify the service user (or a person acting on their behalf) of the incident. This notification must include an account as to what has happened so far and what action Manx Care intends to take, as part of the duty of candour procedure.

Where the duty of candour procedure start date is more than a month after the incident occurred an explanation as to why must be given.

10. *Invite the service user to a meeting.*

As well as notifying the service user (or a person acting on their behalf) Manx Care will also be required to invite them in for a meeting. The purpose of the meeting will be to allow the opportunity for;

- a) an account of the incident to be provided,
- b) an explanation to be given as to the further steps that will be taken to investigate why this happened,
- c) the service user (or a person acting on their behalf) to ask questions and express their views about what has happened,
- d) Manx Care to provide information about any legal or other procedures now being followed that are in addition to the duty of candour procedure.

After the meeting Manx Care must provide a note of what was said at the meeting and also the details of an individual member of staff that the service user (or a person acting on their behalf) can contact, should they so wish.

11. *Apologise*

We are proposing that, in addition to any apology that may have been given at the time the incident occurred, Manx Care must offer the service user (or a person acting on their behalf) a written apology and, if that offer is then accepted, provide them with one.

The Manx Care Bill makes it clear that an apology is a statement of sorrow or regret and does not itself amount to an admission of negligence or breach of statutory duty.

12. *Carry out a review*

As a part of the duty of candour procedure we are proposing that Manx Care has a legal obligation to undertake a review of the circumstances that led or contributed to the incident.

Further, as a part of the review process, Manx Care must seek and take into consideration the service user's (or the person acting on their behalf) views and provide regular updates to them on the progress being made, if requested to do so.

In addition, following completion of the review process, Manx Care will be required to produce a written report of the review. That report must include the following:

- a) how the review was carried out;
- b) what it has done and when in respect to the incident;
- c) what lessons have been learnt and what actions it will be taking as a result to:
 - improve the quality of the service it provides to service users; and
 - share what it has learnt to help continuously improve the quality of health and social care services.

Manx Care must ensure that the service user (or the person acting on their behalf) is offered a copy of the report and also offered such further information as to the lessons that have been learnt and the actions that it will be taking in the future.

13. *Services and support*

We are also proposing that as a part of the duty of candour procedure Manx Care has a duty to offer to supply the service user (or the person acting on their behalf) with the details of services and support that s/he might need.

Question

Do you agree with the steps that Manx Care will be required to take under the Duty of Candour procedure?

14. *Record keeping and reporting*

For the purposes of ensuring good governance, openness and transparency we are proposing to include provisions in these draft Regulations requiring Manx Care to keep accurate records as to what it has done and when, following an incident, as a part of the duty of candour procedure.

Also, for the same purposes, it is proposed that Manx Care will be required to report annually to the Department on its performance in relation to the duty of candour.

Who should be able to act on a service user's behalf if the service user has died or lacks capacity?

15. *A person acting lawfully on their behalf*

The wording in the Regulations (a person acting lawfully on their behalf) is not currently defined, but would mean:

- if the service user is under 18 then a person with parental responsibility (subject to a Gillick competency test¹),
 - if the service user lacks capacity then a person who has been given an appropriate power of attorney (the Department of Health and Social Care is currently working on a draft Capacity Bill which is proposed to modernise this),
- or

¹ Children can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment. This is known as being Gillick competent. For more information see <https://www.nhs.uk/conditions/consent-to-treatment/children/>

- if the service user is deceased then a person who is the personal representative of the deceased (which would include the executor or administrator of the individual's estate).

This definition is fairly narrow in scope. As such, consideration is being given to alternative wording based on that outlined for a person's representative in relation to those able to make complaints on a person's behalf:

"In the case of a person who has died or who lacks capacity, the representative must be a relative or other person who, in the opinion of the registered health or social care professional had or has a sufficient interest in his or her welfare and is a suitable person to act as representative. If in any case the registered health or social care professional is of the opinion that a representative does or did not have a sufficient interest in the person's welfare or is unsuitable to act as a representative, he must notify that person in writing, stating his reasons".

Question

Which approach would you prefer? Please give a reason for your view.

Alternatively, is there a different approach that you feel would work better?

Question

Do you have any other comments regarding the draft Regulations?