

Duty of Candour

Study Guide

Objectives

The aim of this module is to provide an understanding of the Duty of Candour legislation and what is required from individuals.

- We will look at:
- The terms used
- Reporting requirements
- Notification requirements
- The Trust's policy

Duty of Candour and Being Open

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20: Duty of Candour

“20(1) A health service body must act in an open and transparent way with relevant persons in relation to the care and treatment provided to service users in carrying on a regulated activity.”

The purpose of the statute is to create “a new culture”. The principles of being open should be used to inform patients of incidents that have caused low harm.

Definitions

Candour

Any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked.

Openness

Enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency

Allowing information about the trust regarding performance and outcomes to be shared with staff, patients, the public, and regulators.

What is Regulation 20

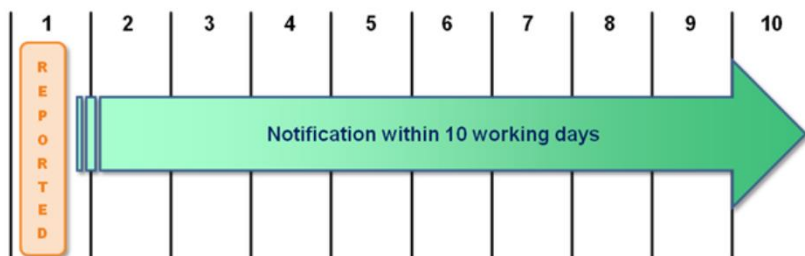
Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust, which recommended that a statutory duty of candour be imposed on healthcare providers.

i The new legislation came into force for NHS bodies on 27 November 2014
Most NHS bodies were already subject to a contractual duty of candour under the NHS Standard Contract (Standard Condition 35) before this legislation.

The Regulation

"20(2) As soon as *reasonably practicable* after becoming aware that a **notifiable safety incident** has occurred a health service body must... notify the relevant person that the incident has occurred..."

In practice, the NHS Standard Contract requires that the notification must be within at most **10 working days of the incident being reported**.



“Notifiable safety incident”

Notifiable safety incident is defined as:

Any unintended or unexpected incident that occurred in respect of a service user during the provision of regulated activity that, in the reasonable opinion of a healthcare professional, *could* result in, or appears to have resulted in:

- **Death**
- **Severe harm**
- **Moderate harm**
- **Prolonged psychological harm over 28 days**
- **Prolonged pain over 28 days**

**⚠ All serious incidents regardless of level of harm are subject to Duty of Candour.
All incidents must be reported on Datix.**

Any “Unintended or unexpected incident”

Any unintended or unexpected incident is a catch all term for instances where harm has occurred even though there may not have been a lapse in the care provided.

This means that the Duty of Candour will apply in instances of recognised complications associated with moderate or severe harm even when the patient has consented in advance and there has been no failure of care.

Regulation 20 – Levels of Harm

Death

This is only where the death relates directly to the incident rather than the natural course of the service user's illness or underlying condition.

Severe Harm

Severe harm means a permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of the wrong limb or organ, or brain damage. This must be directly related to the incident and not related to the natural course of the service user's illness or underlying condition.

Moderate Harm

Moderate harm means:

- a) harm that requires a moderate increase in treatment

AND results in

- b) significant, but not permanent, harm. This is a judgement as it is not further defined.

Moderate increase in treatment means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or, as an out patient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

Prolonged Psychological Harm

The patient must have experienced, or is likely to experience, psychological harm, for a continuous period of at least 28 days.

Notification can be Retrospective

i A provider may discover a notifiable safety incident that happened some time ago, or that relates to care that was delivered by another provider.

The provider that discovers the incident must work with others who are responsible for notifying the relevant person of the incident.

Reporting Requirements – Notification Checklist

The following checklist is based upon regulation 20(3) & (4) which gives guidance as to what notification must include:

- Be given in person.
- ICHT Duty of Candour and Being Open Policy states that the consultant in charge of the patient's care at the time that the incident occurred, is responsible for ensuring the Duty of Candour conversation is held with the patient or relevant person and documenting the conversation in the patient's medical records.
 - They must provide an **account of the facts** as known at the date of notification;
 - Advise the relevant person (usually the patient themselves) what further enquiries into the incident will be undertaken;
 - Include an **apology**;
 - Recorded in writing to be kept securely by the health service body.
- Confirmed in writing to the relevant person.
- **Reasonable support** should be offered to the relevant person throughout this process by providing a named point of contact.
- The outcomes or results of any further enquiries and investigations should also be offered in writing to the **relevant person** along with an offer of a meeting.

Reporting Requirements – Notification Checklist Terms

Account of the facts

An account of the facts should:

- Include as much or as little information as the relevant person wants
- Be jargon free – explain any complicated terms
- Be neutral – stick to the known facts and do not speculate/provide opinion – can say there will be an investigation
- Be given in a manner the relevant person can understand – consider interpreters, advocates and/or communication aids, but be conscious of any breaches of confidentiality

Apology

Providers must ensure that one or more appropriate representatives of the provider gives a meaningful apology, in person, to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret.

Patients should receive a meaningful apology consistent with the known facts – further enquiries will be made.

The NHSLA states that saying sorry is not an admission of liability.

Reasonable support

To provide reasonable support you should:

- Offer the option of emotional support (family member, friend, care professional, advocate)
- Provide access to necessary treatment to recover or minimise harm (by another professional if the relevant person wishes)
- Provide access to impartial advocacy/practical advice (AVMA –Action Against Medical Accidents – a charity for patient safety and advice)
- Provide support to access the Trust’s complaint’s process

Relevant person

The relevant person will be the service user or a person lawfully acting on their behalf:

- On the death of the service user
- Where the patient is unconscious and unable to communicate
- Where the service user is under 16 and not competent to make a decision in relation to their care or treatment
- Where the service user is 16 or over and lacks capacity (as determined by section 2 and 3 of the Mental Capacity Act) in relation to the matter

Contacting the relevant person

If the relevant person cannot be contacted in person, or declines to speak to the Trust Representative, notification is not required.

A written record of the attempts to contact and/or speak to the relevant contact, or the refusal, must be entered in the medical records and on Datix.

The Trust's Policy

Accessing the policy

The Statutory Duty of Candour and Being Open policy is available on the intranet.

Reporting incidents and Duty of Candour

All incidents reported as moderate or above on Datix are subject to the statutory requirements of Duty of Candour. All incidents reported as moderate or above will be reviewed at the weekly Medical Director's Incident Review Meeting.

Where it is agreed there has been moderate, major or extreme harm a letter will be sent to the patient/relevant person advising them that an investigation is underway. The letter must be uploaded to Datix.

Following the investigation, the patient/relevant person must be notified of the findings of the investigation and how to arrange a meeting with the team. The patient may refuse further information and this must be documented in the medical records and recorded on Datix. The letter must be uploaded to Datix.

Responsibilities of the Consultant in charge of the patient's care

Notification should be given to the patient by the consultant in charge within 24 hours of the incident occurring (with possible assistance from the ward manager or other members of the clinical team).

A record of the duty of candour must be entered into the patient's medical records.

This must include:

- Confirmation that an apology has been provided (give specific details)
- Details of the known facts at the time of the incident
- Details of any support provided
- Details of the Trust's point of contact
- Details of any further enquiries being undertaken

This must also be confirmed in writing to the patient by the person who held the Duty of Candour conversation. This will be supported by the divisional governance staff in each division.

Summary

In this study guide we have looked at the Duty of Candour legislation:

- The terms used
- Reporting requirements
- Notification requirements
- The Trust's policy

Further information and the latest version of the policy can be found on the intranet

You can also contact the divisional team, safety and effectiveness team or legal team who can offer advice and/or support.