BEYOND LIMITS
Beyond the limits of conventional support

Duty of Candour Policy

The duty of candour requires registered providers and registered mangers to act in an open and transparent way with people receiving care and/or treatment from them.

January 2024

Review: January 2025

INTRODUCTION

This policy provides guidance about the Duty of Candour, along with clarification of the relevant mandatory procedures.

A 'notifiable safety incident' is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incident or notifications.

In the simplest of terms, the Duty of Candour is a general duty to be open and transparent with people receiving care and support.

Please note, this policy has been completed in response to updated guidance issued on June 30th 2022. The changes clarify how colleagues should apply the term 'unexpected or unintended' to decide if someone qualifies as a notifiable safety incident or not.

RELEVANT REGULATIONS

REGULATION 20 (DUTY OF CANDOUR)

1. The registered manager must act in an open and transparent way with relevant persons in relation to care and treatment provided to people using services in carrying out a regulated activity.

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, a registered manager must:
a. Notify the relevant person that the incident has occurred in accordance with paragraph (3), and
b. Provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

3. The notification to be given under paragraph (2) (a) must:
   a. Be given in person by one or more representatives of the registered manager.
   b. Provide an account, which to the best of the registered manger's knowledge is true of all the facts about the incident as at the date of the notification.

c. Advise the relevant person what further enquiries into the incident the registered manager believes are appropriate
d. Include an apology,
e. Be recorded in a written record which is kept securely by the registered manager.

4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing:
   a. The information provided under paragraph (3)(b)
   b. Details of any enquiries to be undertaken in accordance with paragraph (3)(c)
   c. The results of any further enquiries into the incident, and
   d. An apology.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered manager –
a. Paragraphs (2) to (4) are not to apply, and
b. A written record is to be kept of attempts to contact or to speak to the relevant person.

6. The registered manager must keep a copy of all correspondence with the relevant person under paragraph (4).

7. In this regulation – 'apology' means an expression of sorrow or regret. In respect of a notifiable safety incident, 'moderate harm' means:

   a. Harm that requires a moderate increase in treatment, and
   b. Significant, but not permanent harm.

'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 outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).
'Notifiable safety incident' has the meaning given in paragraphs (8) and (9).
'Prolonged pain' means pain in which a person who receives support has experienced or is likely to experience for a continuous period of at least 28 days.
'Relevant person' means the person who receives support, or in the following circumstances, a person lawfully acting on their behalf:

   c. On the death of the person who receives support

d. Where the person who receives support is under 16 and not competent to make a decision in relation to their care or treatment, or
e. Where the person who receives support is 16 or over and lacks capacity in relation to the matter.

'Severe Harm' means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the person's illness or underlying condition.

8. In relation to a health service body, a *'notifiable safety incident'* means any unintended or unexpected incident that occurred in respect of a person who uses services during the provision of a regulated activity that, in the reasonable opinion of health care professional, could result in, or appears to have resulted in:
   a. The death of the person, where the death relates directly to the incident rather than to the natural course of the person who uses services illness or underlying condition, or
   b. Severe harm, moderate harm or prolonged psychological harm to the person who uses services.

9. In relation to any other registered person, *'notifiable safety incident'* means any unintended or unexpected incident that occurred in respect of a person who uses services during the provision of a regulated activity that, in the reasonable opinion of a health care professional:
   a. Appears to have resulted in:
      i. The death of the person, where the death relates directly to the incident rather than to the natural course of the person's illness or underlying condition.
      ii. An impairment of the sensory, motor or intellectual functions of the person which has lasted or is likely to last, for a continuous period of at least 28 days.
      iii. Changes to the structure of the person's body.
      iv. The person experiencing prolonged pain prolonged psychological harm, or the shortening of life.

WHAT IS THE DUTY OF CANDOUR

As the name suggests, the Duty of Candour has been created to promote and ensure continued openness and transparency when any notifiable safety incident has occurred. All colleagues must follow a clear procedure in the event of a notifiable incident, part of which involves offering a verbal and written apology. Click here for information on background to the duty of candour.

STATUTORY AND PROFESSIONAL DUTIES OF CANDOUR

As confirmed within the CQC guidance, there are two types of duty of candour, statutory and professional.

Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.

This guidance is about the statutory duty of candour. We regulate the statutory duty, while the professional duty is overseen by regulators of specific healthcare professions such as the General Medical Council (GMC) Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).

The statutory duty also includes specific requirements for certain situations known as 'notifiable safety incidents.' If something qualifies as a notifiable safety incident, carrying out the professional duty alone will not be enough to meet the requirements of the statutory.

SAYING SORRY IS NOT ADMITTING FAULT

Colleagues must be aware that offering an apology (i.e., 'saying sorry') is not an admission of liability. Whilst it is appropriate to express sympathy or regret, it is important to note that the apology should not include any admission of fault (which is particularly important in cases where an investigation is being undertaken for example).

In all cases, colleagues must consider responses carefully and must speak to their line manager before a formal written apology is provided to any relevant individuals. In all cases any such apology must come from the Directors.

The following CQC guidance is important. Colleagues must speak with their line manager if unsure about the below extract or any aspect of this policy:

> A crucial part of the duty of candour is the apology. Apologising is not an admission of liability. This is the case, regardless of whether you are in the health or social care, or public or private sectors.
>
> In many cases it is the lack of timely apology that pushes people to take legal action. To fulfil the duty of candour, you must apologise for the harm caused, regardless of fault, as well as being open and transparent about what has happened.
>
> NHS Resolution is the organisation that manages clinical negligence claims against the NHS. Their 'Saying Sorry' leaflet confirms that apologising will not affect indemnity cover: Saying sorry is:
>
> - Always the right thing to do
> - Not an admission of liability
> - Acknowledges that something could have gone better
> - The first step to learning from what happened and preventing it recurring."

The CQC is clear that a 'notifiable safety incident' is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications. A notifiable safety incident must meet all three of the following criteria:

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity regulated by the CQC. (N.B. Regulated activity means "care or treatment provided.")
3. In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care. This element varies slightly depending on the type of provider.

If any of these three criteria are not met, it is not a notifiable safety incident (but remember that the overarching duty of candour, to be open and transparent, always applies).

Colleagues 'should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" [the CQC] mean the care or treatment provided. By "outcome" [the CQC] refer to the harm that occurred or could have occurred. So, if the treatment or care provided went as intended, and as expected, an incident may not qualify as a Notifiable Safety Incident, even if harm occurred.'

PLEASE NOTE:

This does not mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended.

The definitions of harm vary slightly between health service bodies and all other providers. This is because when the regulation was written, harm thresholds were aligned with existing notification systems to reduce the burden on providers. Therefore, It is possible for an incident to trigger the harm threshold for NHS trusts (for example), but not for other service types, or vice versa.

It is helpful to remember that the statutory duty relates to the provision of regulated activities. Therefore, this policy covers 'all other services the CQC regulates' and colleagues must follow the pertinent the notifiable safety incident definition relating to Beyond Limits. This means that if in the reasonable opinion of a healthcare professional, an incident at Beyond Limits appears to have resulted in, or requires treatment to prevent:

- The death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
- The person experiencing a sensory, motor, or intellectual impairment that has lasted, or is likely to last, for a continuous period of at least 28 days
- Changes to the structure of the person's body
- The person experiencing prolonged pain or prolonged psychological harm, or
- A shorter life expectancy for the person using the service.

These definitions of harm are aligned to CQC's notification system for reporting deaths and serious injuries.

DEFINTIONS OF HARM

The following provides a summary of the definitions of harm applied to the duty of candour:

- MODERATE HARM
  Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

- SEVERE HARM
  A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

- MODERATE INCREASE IN TREATMENT
  An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)

- PROLONGED PAIN
  Pain which an ["individual"] has experienced, or is likely to experience, for a continuous period of at least 28 days.

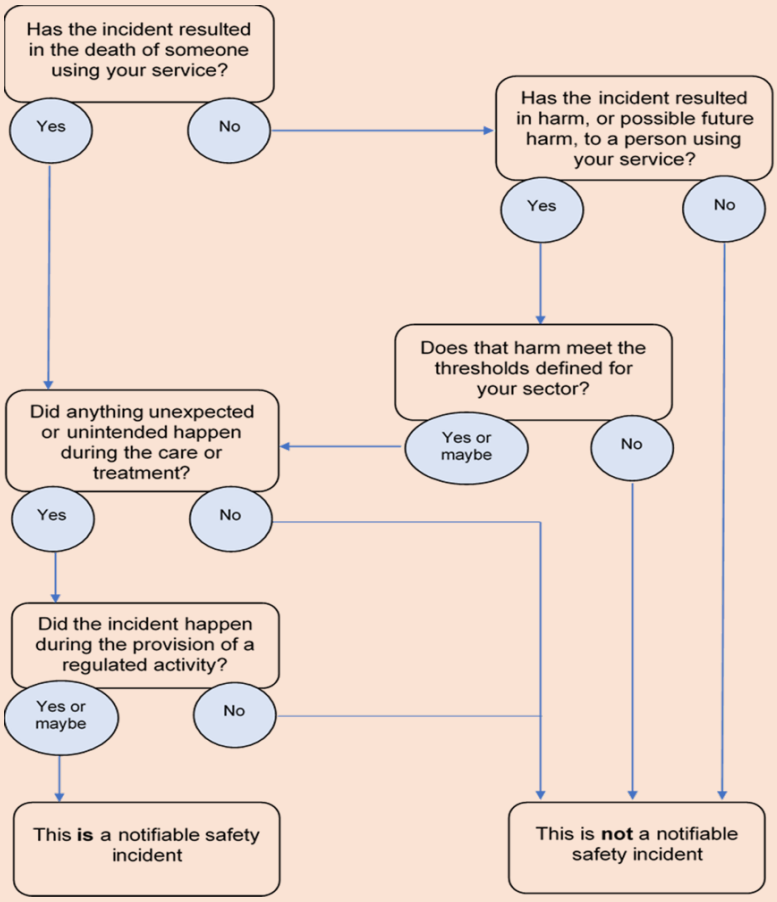
- PROLONGED PSYCHOLOGICAL HARM
  Psychological harm which a person who uses services has experienced, or is likely to experience, for a continuous period of at least 28 days.

IDENTIFYING A NOTIFIABLE SAFETY INCIDENT

CQC guidance states clearly that the presence or absence of fault on the part of a provider has no impact on whether something is defined as a notifiable safety incident.

REMEMBER:
Saying sorry is not admitting fault.

Colleagues must remember that even if something does not qualify as a notifiable safety incident, there remains an overarching duty of candour to be open and transparent with people using services. The next part clarifies some potential areas of ambiguity relating to notifiable safety incidents. (See Below)



PERSON GAVE CONSENT

Something can qualify as a notifiable safety incident even if the person gave consent for a procedure to be carried out. It all depends on the level of harm and whether something unexpected or unintended happened during the care or treatment, regardless of whether consent was given.

NOTIFIABLE INCIDENT OCCURRED IN A DIFFERENT PROVIDER

If you discover a notifiable safety incident that occurred in a different provider, you should inform the previous provider.

You must also be open and transparent with the person receiving care about whatever you have discovered. However, you do not need to carry out the specific procedures relating to notifiable safety incidents. The provider where the incident happened must carry out the notifiable safety incidents procedures

MULTIPLE PROVIDERS CONTRIBUTED TO THE HARM

If multiple providers contributed to the harm, they should liaise and work together in the investigation that follows as they would for any other incident. Each provider still has its own responsibilities under the duty of candour. They must assure themselves that they have met them.

INCIDENTS THAT OCCURRED BEFORE THE DUTY OF CANDOUR CAME INTO FORCE

There is no legal requirement to carry out the specific requirements laid out in Regulation 20 for something that happened before the regulation existed. However, we would still expect you to carry out the general duty of candour – to apologise and to be open and transparent with people about whatever has been discovered.

RETROSPECTIVE REVIEWS

If the notifiable safety incident was not realised at the time but was discovered through a retrospective case review, or as part of a large-scale recall, the duty still applies.

MANDATORY PROCEDURE: DUTY OF CANDOUR

The CQC expect Beyond Limits to act promptly as soon as a notifiable safety incident has been discovered.

CLARIFICATIONS

The 'registered manager' is responsible for carrying out, or delegating the responsibility for carrying out, the duty and must liaise with the 'relevant person'.

The 'relevant person' is either the person who was harmed or someone acting lawfully on their behalf. Please note that a person may act on the behalf of the person who was harmed if:

- The person has died
- Is under 16 and not competent to make decisions about their care or the consequences of the incident
- Is over 16 and lacking mental capacity.

Regulation 20 states, Beyond Limits must ensure the following is completed without compromise:

- STEP ONE: Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
- STEP TWO: Apologise.
- STEP THREE: Provide a true account of what happened, explaining whatever you know at that point.
- STEP FOUR: Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
- STEP FIVE: Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
- STEP SIX: Keep a secure written record of all meetings and communications with the relevant person.

The CQC are clear that:

> "The duty of candour is one of the fundamental standards – below which care should never fall. As such it is an area of regulation [the CQC] pay special attention to."

REGISTERED PROVIDERS

The duty of candour applies to every provider registered with the CQC, and they will expect to see evidence during the registration process that the registered manager understands their obligations under Regulation 20.

Every registered provider should understand when and how to carry out the Duty of Candour and have training, policies, and systems in place to ensure their employees are able to implement it. Providers should also be able to explain how they will support their staff to be open and transparent when something goes wrong and how this sits within a broader culture of psychological safety.

The CQC approach the monitoring of the duty of candour "through the lens of the service".

- Being well-led
- Having an open and safe culture
- Meeting the regulatory requirements of the duty of candour

When the CQC hold monitoring calls, assess the data and information received, or visit the provider on inspection, they will be looking for evidence that all three factors are met. It is the expectation that this policy will be followed in its entirety, any deviations must be discussed with your line manager.

Beyond Limits (Plymouth) Limited
Registered in England and Wales under
Company Number: 07998863

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