Are you clear about Duty of Candour guidance?

(This was updated in June 2022 and a review was commissioned by the Secretary of State for Health and Social Care in December 2023. This will be published in Spring 2024).

The statutory duty of candour is about people's right to openness and transparency from their health or social care provider.

It means that when something goes wrong during the provision of health and care services, patients and families have a right to receive explanations for what happened, as soon as possible, and a meaningful apology.

Until 2014 there was no legal duty on care providers to share information with the people who had been harmed, or their families.

As a result of the serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust in 2013, the Francis Inquiry recommended that a statutory duty of candour be introduced for all health and care providers, in addition to the existing professional duty of candour and the requirement for candour in the NHS standard contract.

> *"The way in which the Trust handled the matter can be viewed as an object lesson in how the tragedy of an avoidable death can be exacerbated by inappropriate handling of the case. It demonstrates the sad fact that, for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism." (Francis Inquiry into the failings at Mid-Staffordshire NHS Foundation Trust, 2013)*

There are 2 types of Duty of Candour:

Statutory duty - regulated by CQC under Regluation 20, which puts a legal duty on health and social care providers to be open and transparent with people using services and their families. It sets out actions that providers must take when a 'notifiable safety incident' happens.

Professional duty - regulated by specific healthcare professions, such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).

They both have a similar aim, which is to ensure care providers are open and transparent with the people who use their services, even when something has gone wrong.

CQC Notifiable safety incidents:

'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.

Statutory duty sets out specific requirements for notifiable safety incidents and it is important to know that 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 duty.

A notifiable safety incident must meet all 3 of the following criteria:

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity CQC regulate.
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!)***

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

Paragraph 9 of Regulation 20 defines the notifiable safety incident harm thresholds for all other services (other than NHS Trusts or NHS Foundation Trusts) that CQC regulate:

In the reasonable opinion of a healthcare professional, the incident 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
- 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.

Definitions of harm

These definitions are common to all types of service.

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 a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Prolonged psychological harm - Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Identifying a Notifiable Safety Incident

The presence or absence of fault on the part of a provider has no impact on whether or not something is defined as a notifiable safety incident.

As soon as a notifiable safety incident has been identified, organisations must act promptly and are expected to:

- tell the relevant person, face-to-face, that a notifiable safety incident has taken place
- say sorry
- provide a true account of what happened, explaining what is known at that point
- explain what further enquiries or investigations will take place
- follow up by providing this information and the apology in writing, and giving an update on any enquiries
- keep a secure written record of all meetings and communications with the relevant person

The CQC regulates compliance with the duty. Failure to comply with the duty can result in enforcement activity ranging from warning or requirement notices to criminal prosecution.

Remember!

Saying sorry is not admitting fault.

Even if something does not qualify as a notifiable safety incident, there is always an overarching duty of candour to be open and transparent with people using services.