

Duty of candour and patient safety incidents: Proposed amendments to CQC Regulations

21 November 2024  Katie Viggers

NHS England and the Care Quality Commission (CQC) have recently published a joint statement on the need for clarity regarding the definition of harm levels associated with patient safety incidents. Their aim is to align, as far as possible, the definitions of harm between CQC Regulations and the Learn From Patient Safety Events (LFPSE) service. To achieve greater consistency, CQC is looking to modify two specific regulations to ensure that their definitions of “harm” are in closer agreement with the updated definitions used by NHS England.

Background

Regulation 18 of the Care Quality Commission (Registration) Regulations 2009 requires providers to notify CQC of certain incidents that affect the health, safety and welfare of people who use services. Within Regulation 18, there is a provision for health service bodies to fulfil their notification obligations by recording incidents on LFPSE, the national learning system hosted by NHS England.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out the organisational duty of candour that requires registered providers and registered managers to act in an open and transparent way with people receiving care or treatment from them. The requirement to meet the duty of candour is triggered by a “notifiable safety incident”. A notifiable safety incident is one which is unintended or unexpected, that occurred during the provision of a regulated activity, and that has or might result in death or severe or moderate harm. The definition of “moderate harm” used in Regulation 20 is intended to be equivalent to the definition of “moderate harm” used in NHS England’s national learning systems.

“Moderate harm” – different wording but the same meaning

The new LFPSE service has replaced the previous National Reporting and Learning System (NRLS), which was decommissioned in June 2024. In developing the LFPSE service, NHS England has refined and expanded the definitions for moderate harm from the previous NRLS guidance. This has caused some concern that the definitions used by CQC and NHS England have diverged. However, CQC and NHS England have jointly confirmed that, although they do not use (and have not ever used) the same wording for “moderate harm”, **there is no intent for the definitions to be different.**

Proposed amendment to regulations

CQC is now seeking amendments to Regulations 18 and 20, to ensure the wording aligns more closely with NHS England’s revised harm definitions. However, they acknowledge that some differences will remain due to the broad applications of these regulations across various providers.

The potential changes relate to definitions of notifiable incidents, including in respect of the duty of candour. Efforts to aid consistency and simplify the day-to-day application of these principles will no doubt be welcomed. A public consultation will be necessary before these changes can be implemented.

Immediate action for NHS Trusts

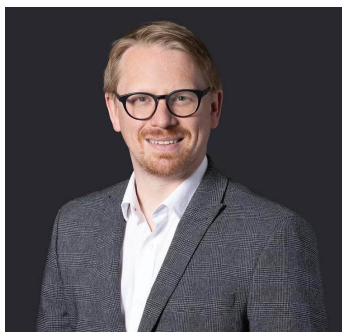
In the meantime, CQC and NHS England have said that, although the wording of the CQC and LFPSE definitions varies, LFPSE's "moderate physical" and "moderate psychological" harms should be considered equivalent to the CQC thresholds.

What should NHS providers do in the interim when applying the duty of candour? Many will wish to take an inclusive approach, which will mean:

1. Continuing to apply the duty wherever they currently do.
2. Considering amendments to internal duty of candour triggers, to include some incidents that meet the LFPSE definitions, even if they do not result in a moderate increase in treatment.
3. Keeping an eye out for further guidance.

If you have any questions or would like to discuss this further, please don't hesitate to get in touch.

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