

Regulation 20: Duty of candour (regulation in full)

Guidance updated 30 June 2022

The changes clarify how you should apply the term “unexpected or unintended” to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- [Notifiable safety incidents](#)
- [Examples of notifiable safety incidents](#)

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

The regulation in full

1. Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person 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 person,
 - b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
 - c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
 - d. include an apology, and
 - e. be recorded in a written record which is kept securely by the registered person.

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 person —
 - 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 provider 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 which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

- a. on the death of the service user,
- b. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- c. where the service user 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 service user's illness or underlying condition.

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—
- a. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
 - b. severe harm, moderate harm or prolonged psychological harm to the service user.

9. In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user 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 service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
 - ii. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
 - iii. changes to the structure of the service user's body,
 - iv. the service user experiencing prolonged pain or prolonged psychological harm, or
 - v. the shortening of the life expectancy of the service user; or
 - b. requires treatment by a health care professional in order to prevent—
 - i. the death of the service user, or
 - ii. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).