MILLS & REEVE

briefing

June 2015

Statutory Duty of Candour – five key points to bear in mind

The Statutory Duty of Candour has now been in force for approximately six months for health service bodies and one month for all other service providers. But how are you getting on?

Regulation 20 of the snappily entitled Health and Social Care 2008 (Regulated Activities) Regulations 2014 sets out what is required of all providers. David Behan, Chief Executive of the Care Quality Commission, has said that:

> "The introduction of a statutory duty of candour is an important step towards ensuring the open, honest and transparent culture that was lacking at Mid Staffordshire Hospitals NHS Foundation Trust. The failures at Winterbourne View Hospital reveal that there were no levers in the system to hold the "controlling mind" of organisations to account. It is essential that CQC uses this new power to encourage a culture of openness and to hold providers and directors to account."

1. The general duty

The intention of the Regulation is to ensure that providers are open and transparent with people who use services and other "relevant persons" (people acting lawfully on behalf of patients) in general in relation to care and treatment.

Openness: enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency: allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators

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 about it.

This general duty applies **at all times.** In addition, as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, a registered person must **notify** the relevant person that the incident has occurred.

2. Different thresholds for notification

Just to complicate matters, when notification is triggered depends on what type of provider you are.

Health Service Bodies

A notifiable safety incident is defined by referent to the 'Being Open' guidance and means:

"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"

Other providers

A notifiable safety incident is defined by reference to the existing CQC reporting requirements and 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 **appears** to have resulted in:

- Death
- 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,
- changes to the structure of the service user's body
- Prolonged pain or prolonged psychological harm, or
- the shortening of the **life expectancy** of the service user; or
- **treatment** by a health care professional in order to **prevent the death** of the service user, or any **injury** to the service user which, if left untreated, would lead to one or more of the outcomes mentioned above"

You are **not** required by the Regulation to inform a person using a service when a near miss has occurred that has resulted in no harm to that person.

3. What you need to do?

- When a notifiable safety incident has occurred the relevant person must be informed **as soon as reasonably practicable** after the incident has been identified.
- The notification must be **given in person**, by one or more representatives of the registered person.
- You must provide an account which, to the best of your knowledge is true, of **all the facts** you know about the incident.
- You need to tell explain what further **enquiries** you will undertake.
- You must **apologise**.
- You must follow up the conversation in **writing.** In addition, the outcomes of further enquiries must also be provided in writing in due course.

- All reasonable support must be provided to help overcome the physical, psychological and emotional impact of the incident.

4. Consequences of breach

It is a **criminal offence** not to notify a service user of a notifiable safety incident or fail to meet the requirements for such a notification. The CQC can prosecute without serving a warning notice first.

However, if you can prove that you took all appropriate steps and exercised all due diligence to ensure that you complied with the duty this will be a defence. Hence it is very important to ensure that you:

- Are promoting a culture which encourages candour, openness and honesty at all levels.
- Have policies and procedures in place to support that culture and ensure that staff follow them, regardless of seniority or permanency.
- Take action to tackle bullying and harassment in relation to the duty of candour.
- Ensure staff receive appropriate training.

5. Professional duties too

Regulation 20 applies to organisations as opposed to individual members of staff.

Individual members of staff who are professionally registered are separately subject to a professional duty of candour. As a provider you need to be able to identify and deal with possible breaches of the professional duty. This will include investigation / escalation processes which may lead to referral to the relevant professional regulator.

Joint guidance from the GMC and NMC is awaited at the time of writing. It had been expected in March following a joint consultation which closed in January 2015.

Further information

You can obtain further information on the CQC's website. Firstly, there is statutory guidance (which at the time of writing was last updated on 14 April 2015) but do keep an eye on it for changes. You have a legal duty to "have regard" to this guidance which means that if you do not follow it you will need a very good reason as to why!

Secondly, there is a supplementary document entitled Regulation 20: Duty of Candour Information for all providers: NHS bodies, adult social care, primary medical and dental care and independent healthcare.

This is a much longer document. You do not have the same legal duty to "have regard to it" but it still contains helpful information and the CQC inspectors will keep it close at hand. It looks at the relevant Key Lines of Enquiry for the duty of candour, contains a list of definitions and sets out illustrative examples of when the duty would be triggered in surgery, medicine, general practice, mental health, maternity, dentistry and adult social care. Beware, some of these examples are pretty common "recognised complication" type incidents where it may not be possible to say that anything has actually "gone wrong".

Conclusion

Those of you who read Dr Bill Kirkup's report on Morecambe Bay will have noted that he commends the statutory duty but has asked CQC and NHS England to consider his recommendation about involving patients and their families in the actual investigation of serious incidents. This is an ever changing landscape!

We would be delighted to deliver training to your Boards or to your teams or to assist in the review of policies and procedures so please do not hesitate to contact us.

Jill Mason
Partner, patient care and mental health
0121 456 8367
Jill.Mason@mills-reeve.com

Duncan Astill
Partner, patient care and regulatory
01223 222477
Duncan.Astill@mills-reeve.com