The Duty of Candour

Clare Chapman, Solicitor

April 2015 saw significant pieces of legislation come into force which will impact greatly upon healthcare professionals. From 1st April 2015, the duty of candour now applies universally to all CQC registered providers and on 13th April the criminal offences of ill-treatment or wilful neglect came into force.

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Duty of Candour

The Duty of Candour was introduced by regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The duty requires all CQC registered providers to act in an open and transparent way in relation to care and treatment provided to service users. The duty will apply whenever providers become aware of a "notifiable safety incident".

What is a "notifiable safety incident"?

The definitions of a "notifiable safety incident" vary slightly for health service bodies and other registered providers.

For health service bodies it is:
"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" (Regulation 20(8))

For other providers it is:
"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

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lead to one or more of the outcomes mentioned in sub-paragraph (a)." (Regulation 20(9))

"Moderate harm" is defined as a) harm that requires a moderate increase in treatment, and b) significant, but not permanent, harm.

Although the definitions are similar, it appears that a health service body's duty to be candid about near misses is broader than that of other registered providers.

What exactly is required?

The registered provider must:
- Notify the relevant person that a notifiable safety incident has occurred;
- Provide reasonable support;
- Provide an account, which is true to the best of the body's knowledge, of all the facts known about the incident at the time of notification;
- Advise about other relevant enquiries;
- Include an apology (defined as an expression of sorrow or regret); and
- Record the account in writing and keep it securely.

What happens if there is non-compliance?

The CQC can issue fixed penalty notices and prosecute providers for a breach. Non-compliance could also affect a provider's continued registration with the CQC.

What do I need to do to ensure compliance?

Whilst the statutory offence applies only to health care providers and not to individual health care professionals, individuals have a professional duty of candour, which is overseen by the professional regulators.

You should:
- Know what your employing Trust's policy is on duty of candour:
  - Be familiar with any guidance documents on the Trust's definition/interpretation of what constitutes a "notifiable safety incident" and the steps to be taken when such an incident occurs;
  - Identify the staff members to whom any notifiable safety incident should be reported and the mechanism by which the report should take place; and
- Ensure detailed records are kept of all patient care and any investigations when things go wrong.

Ill-treatment or wilful neglect

The criminal offences of ill-treatment or wilful neglect are contained in sections 20 and 21 of the Criminal Justice and Courts Act 2015. They were introduced to address a gap in existing law which meant that a patient who received poor treatment, but had capacity and did not die, had no protection. The section 20 offence applies to individual care workers, whilst the section 21 offence applies to health care organisations.

When is an offence committed?

A care worker commits an offence if they ill-treat or wilfully neglect an individual under their care.

A care provider commits an offence if:
a) An individual providing care as part of the care provider's arrangements ill-treats or wilfully neglects another individual under their care;
b) The management or organisation of the care provider's activities amounts to a gross breach of a relevant duty of care owed by the care provider to the individual who is ill-treated or neglected; and
c) In the absence of the breach, the ill-treatment or neglect would not have occurred, or would have been less likely to occur.

A "gross breach" is one which falls far below what can reasonably be expected of the provider in the circumstances. The focus is on conduct, not the resultant harm, so an offence can be committed without any harm being suffered. However, the level of harm is likely to have an impact at the sentencing stage. There will need to be proof of intent or knowledge that the care or treatment being provided was inadequate or of a "couldn't care less" attitude in order to establish the offence.

To whom does the offence apply?

The offences only apply to those individuals who provide care as paid work, as part of a contractual or employment arrangement. Individuals who provide informal care on a voluntary basis, e.g. family and friends, are not subject to the offence.

The offence applies to:
- Paid managers and supervisors of the provision of care (and directors of organisations performing this function);
- Services where children receive health care, including young offenders institutions;
- Pharmacists; and
- The private sector as well as the NHS.

However, the offence will not apply to:
- Schools;
- Children's homes;
- Residential family centres;
- Child care services; or
- Children's social care.
- It will apply though to situations where adults are receiving formal domiciliary care.

What are the sanctions?

Individual care workers found guilty of the offence could be liable to up to five years' imprisonment and/or an unlimited fine. Care providers

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could face an unlimited fine, a remedial order (requiring the provider to address the failing which led to the offence), and/or a "naming and shaming" publicity order.

What impact will the new offence have?

Whilst the offence is not intended to penalise genuine accidents or errors or to hinder the free exercise of clinical judgment, and it is expected that the offence will only be used in extreme cases, the Department of Health has said that the offence is intended to "send a strong message that poor care will not be tolerated and ensure that wherever ill-treatment or wilful neglect occurs, those responsible will be held to account". The government estimates that there could be in the region of 240 prosecutions per year.

Detailed guidance about when prosecutions should take place is awaited and an element of uncertainty is expected, particularly given the lack of definitions of "ill-treat" and "wilful neglect". There may also be uncertainty following a prosecution as to whether a jury would be satisfied "beyond reasonable doubt".

Despite assurances that genuine human error will not lead to criminal liability, concerns have been raised that the new offence will lead to a climate of fear.

However, it should be possible for an individual to defend themselves on the basis that they were acting in what they thought were the patient's best interests and that they were exercising clinical judgment. In any event, there are practical steps that can be taken which would assist in the unlikely event of criminal proceedings being commenced.

What should I do to avoid criminal liability?

Good note keeping will be very important, as evidence of the care and treatment provided and as a tool to ensure continuity of care. You should ensure that a patient's records contain sufficient detail to explain all clinical decisions made. As set out above, the ability to justify clinical decisions, and to demonstrate that clinical judgment was being exercised, when faced with allegations of wilful neglect can have a significant impact on investigations, assist in defending any criminal proceedings brought and could prevent a prosecution being made at all.

Equally, good communication skills and a caring, compassionate attitude shown towards patients can help to deflect a "couldn't care less" finding, and could in some circumstances avoid a matter being reported to the police in the first instance.

Concerns have been expressed that the new criminal offence could inadvertently undermine the duty of candour if individuals fear criminal sanctions where things have gone wrong. The circumstances in which the criminal offence will arise are rare and it is essential that there is a culture change, with openness and honesty being embraced. It is worth remembering that, in addition to the statutory offence for health care providers, individuals have a professional duty of candour, policed by the healthcare regulators, so any failure to be open and honest could result in regulatory action. Patient safety must be the priority and any fear of prosecution must be overcome. ■

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