



BACKGROUND

The statutory Duty of Candour was implemented by Regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust which recommended that a statutory duty of candour be introduced for health and care providers.

The intention of this regulation is to ensure that providers are open and transparent with people who use their services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.

However, there is also a general duty of candour that applies at all times. Albeit there is no official sanction that can be imposed for a breach of the general duty.

It is important to note that whilst there is a statutory Duty of Candour and the general duty to be open and transparent, the two are inextricably linked. Therefore, providers should not seek to focus their intention on the legal and statutory side of things and forget their general duty. Instead, they should look to implement a “culture that encourages candour” within their organisation, which staff at levels throughout the organisation should be well versed on. This culture involves honesty, openness and transparency and candour.

THE STATUTORY DUTY AND WHEN IT APPLIES

Under Regulation 20, the statutory duty of candour is triggered when there has been a “**notifiable safety incident**”.

A notifiable safety incident is defined at paragraph 8 of Regulation 20 in respect of health care bodies and paragraph 9 of Regulation 20 for all other providers who are not health service bodies.

Following there being a “**notifiable safety incident**” the provider must provide notification of the same and provide reasonable support to the relevant person in relation to such incident, including when giving them the notification. It is the failure to comply with the notification, which constitutes a breach of the duty, for which the CQC can subsequently prosecute, without prior warning.



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THE FIRST SUCCESSFUL PROSECUTION FOR THE BREACH OF THE DUTY OF CANDOUR

The method of notification as expected under the regulation, is contained at paragraphs 2-4 of Regulation 20, which in summary must include the following and be followed up in writing:

- Be given in person;
- Provide a true account of the facts known about the incident at that time;
- Explain what further investigation would be appropriate to follow;
- Be recorded in writing; and
- Include an apology i.e. an expression of sorrow or regret. (It should be noted that an apology does not automatically equal an admission of liability.)

The results of any investigation must be provided to the service user or relevant person in a timely way. A copy of all correspondence must be kept.

CONSEQUENCES

The Duty of Candour is overseen by the Care Quality Commission (CQC). This monitoring is undertaken by inspection (and therefore compliance with Duty of Candour could have an effect on a hospital's inspection rating).

Regulation 20 applies to the providers directly as opposed to individual members of staff. However, it is important to remember that Individual members of staff who are professionally registered are usually separately subject to a professional duty of candour, for example Doctors. Providers therefore need to be able to identify and deal with any potential individual breaches of the professional duty and this could include investigation and escalation processes which may as a result, lead to referral to the relevant professional regulator.

The CQC does have the power to bring a criminal prosecution against the organisation if it identifies that the Duty of Candour is breached. The fine imposed may be up to £2,500. However, not only are there financial consequences attached to a breach but a prosecution can cause significant reputational damage and attract further scrutiny from the CQC.

Below are two early examples of breaches of the duty of candour and the outcome:

- In January 2019 Bradford Teaching Hospital NHS Foundation Trust was fined £1,250 for failing to apologise to a bereaved family following the death of a baby within a 'reasonable' time.
- In October 2019 a further similar fine was issued to Royal Cornwall Hospitals for 13 breaches of the duty of candour – in this case, the hospital was fined a total of £16,250 for failing to notify patients or their family of the facts available as soon as reasonably possible.

THE FIRST SUCCESSFUL PROSECUTION – THE FACTS

- The first successful prosecution of a provider for the breach of the statutory duty of candour, took place over a year ago, on 23rd September 2020.
- The prosecution related to the handling of the death of 91 year old, Elsie Woodfield, at Derriford Hospital, which is part of University Hospitals Plymouth NHS Trust.
- Ms Woodfield's oesophagus was perforated during an endoscopy which later resulted in Ms Woodfield's death.
- The court heard that the Trust's incident report did not conclude that her death was a Serious Incident and so her family were not properly informed about the death and the facts at that time and no timely apology was offered.
- The family made a complaint that the Trust had not been open with them about the incident.
- The Trust admitted to breaching the statutory duty and issued a "wholehearted apology" to the family after the hearing.

"This offence is a very good example of why these regulatory offences are very important. Not only have the family had to come to terms with their tragic death, but their loss has been compounded by the trust's lack of candour."

THE JUDGEMENT

- The Trust were fined £1,600 and ordered to pay legal costs of £10,845.43 together with a victim surcharge of £120.
- The Trust was therefore ordered to pay a total of £12,565.
- Although the prosecution related to the breach of the statutory Duty of Candour, the Judge was reported to have referred throughout the case to the Trust's general duty to be open and transparent.

"The fine is not sufficient to cover the distress caused to Ms Woodfield's family"

POINTS TO NOTE

It may be nearly seven years since the regulations were officially implemented but it seems clear from this case, that the CQC will take action in cases where they feel there has been a serious failing in a provider's statutory duty to be open and honest.

This case re-emphasises the point that whilst there is a statutory duty that must be adhered to, there is also a general duty for providers to be open and honest.

"Candour is integral to a 'just culture' and it is vital that we help providers get this right. Candour cannot be an 'add on' or a simple matter of compliance - it will only be effective as part of a wider commitment to safety, learning and improvement."

The Duty of Candour, understandably so, remains an ongoing priority for those working in the area and it should be noted that CQC have, this year, updated their guidance on Regulation 20, for providers. The updated guidance, as described by CQC *"gives a more specific explanation of what is defined as a notifiable safety incident and examples covering a range of scenarios. And, it makes clear that the apology required to fulfil the duty of candour does not mean accepting liability and will not affect a provider's indemnity cover."* The link to the updated guidance can be found here [Regulation 20: Duty of candour | Care Quality Commission \(cqc.org.uk\)](https://www.cqc.org.uk/publications/regulation-20-duty-of-candour)

Speaking about the same, **Ted Baker, CQC's Chief Inspector of Hospitals, said:** *"Good progress has been made by many providers, but more needs to be done to ensure that the culture of openness is fully embedded. CQC will keep its focus on this essential element of a safe culture going forward and we have updated the guidance for providers to help them drive further improvements."*

Moving forward, it is essential to understand that there are not only financial consequences for providers, but of course, significant reputational consequences. Therefore, the outcome and conclusion of this case, combined with the updated guidance from CQC, provides the opportune moment for providers to consider their policies in this area and analyse whether there are being utilised effectively and correctly. For example, a provider should look into ensuring that their staff are fully briefed on the relevant policies and that appropriate support and training is given to them. It would also be sensible for proper written records to be kept of any issues that arise in relation to the Duty of Candour and in relation to the provider being open and honest, as this may form evidence, should matters escalate in the future.

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Our experienced team of 10 fee earners can provide advice on the following:-

- NHS Trust or local authority disputes

THE FIRST SUCCESSFUL PROSECUTION FOR THE BREACH OF THE DUTY OF CANDOUR

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- Cases relating to end of life
- Closure of healthcare facilities – such as hospitals, clinics, care homes and day care services
- Court of Protection Health and welfare disputes
- Deprivation of Liberty challenges
- Mental Health Act Matters
- Coroners Investigations
- Health and Social Care Integration
- Healthcare funding disputes

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