

Regulation 20: Duty of candour

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 sections:

[Notifiable safety incidents](#)

[Examples of notifiable safety incidents](#)

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The duty of candour: guidance for providers

The duty of candour is a general duty to be open and transparent with people receiving care from you.

It applies to every health and social care provider that CQC regulates.

The duty of candour requires registered providers and registered managers (known as 'registered persons') to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines '[notifiable safety incidents](#)' and specifies how registered persons must apply the duty of candour if these incidents occur.

See [Regulation 20 of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#).

Statutory and professional duties of candour

There are two types of duty of candour, statutory and professional.

Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.

This guidance is about the statutory duty of candour. We regulate the statutory duty, while the professional duty is overseen by regulators of specific healthcare professions such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).

The statutory duty also includes specific requirements for certain situations known as '[notifiable safety incidents](#)'. If something qualifies as a notifiable safety incident, carrying out the professional duty alone will not be enough to meet the requirements of the statutory duty.

Saying sorry is not admitting fault

A crucial part of the duty of candour is the apology. Apologising is not an admission of liability. This is the case, regardless of whether you are in the health or social care, or public or private sectors.

In many cases it is [the lack of timely apology](#) that pushes people to take legal action. To fulfil the duty of candour, you must apologise for the harm caused, regardless of fault, as well as being open and transparent about what has happened.

NHS Resolution is the organisation that manages clinical negligence claims against the NHS. Their '[Saying Sorry](#)' leaflet confirms that apologising will not affect indemnity cover:

"Saying sorry is:

- always the right thing to do
- not an admission of liability
- acknowledges that something could have gone better
- the first step to learning from what happened and preventing it recurring."

Background to the duty of candour

Until 2014 there was no legal duty on care providers to share information with the people who had been harmed, or their families.

The tragic case of Robbie Powell and the perseverance of his parents through the UK courts and then the European Court of Human Rights exposed the absence of this legal duty.

In 2013, the Francis Inquiry also found serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust:

“The way in which the Trust handled the matter can be viewed as an object lesson in how the tragedy of an avoidable death can be exacerbated by inappropriate handling of the case. It demonstrates the sad fact that, for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism.” (Francis Inquiry into the failings at Mid-Staffordshire NHS Foundation Trust, 2013)

The Francis Inquiry recommended that a statutory duty of candour be introduced for all health and care providers, in addition to the existing professional duty of candour and the requirement for candour in the NHS standard contract.

This statutory duty of candour was brought into law in 2014 for NHS Trusts and 2015 for all other providers and is now seen as a crucial, underpinning aspect of a safe, open and transparent culture. It is so fundamentally linked to concepts of openness and transparency that often the policies and procedures related to it have come to be known by staff by other names, for example, “Being Open”, “Saying Sorry”, and “Just Culture”.

Duty of candour: notifiable safety incidents

'Notifiable safety incident' is a specific term defined in the [duty of candour regulation](#). It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all 3 of the following criteria:

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an [activity we regulate](#).
3. In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care. This element varies slightly depending on the type of provider.

If any of these three criteria are not met, it is not a notifiable safety incident (but remember that the overarching duty of candour, to be open and transparent, always applies).

You should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" we mean the care or treatment provided. By "outcome" we mean the harm that occurred or could have occurred. So, if the treatment or care provided went as intended, and as expected, an incident **may** not qualify as a Notifiable Safety Incident, even if harm occurred.

This does **not** mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended.

The definitions of harm vary slightly between health service bodies and all other providers. This is because when the regulation was written, harm thresholds were aligned with existing notification systems to reduce the burden on providers.

It is possible for an incident to trigger the harm threshold for NHS trusts, but not for other service types, or vice versa.

It is helpful to remember that the statutory duty relates to the provision of regulated activities, and so you should follow the notifiable safety incident definition relating to the type of organisation or provider you are working within.

Health service body

Section 9 of the [National Health Service Act 2006](#) defines a 'health service body'. For the purposes of the duty of candour, a health service body means either an:

- NHS trust
- NHS Foundation trust.

Paragraph 8 of [Regulation 20](#) defines the harm thresholds for Health Service Bodies:

In the reasonable opinion of a healthcare professional, the incident could result in or appears to have:

- resulted in the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
- led to the person experiencing severe harm, moderate harm or prolonged psychological harm.

These definitions of harm are linked to the National Reporting and Learning System (NRLS) definitions.

All other services we regulate

Paragraph 9 of [Regulation 20](#) defines the notifiable safety incident harm thresholds for all other services we regulate:

In the reasonable opinion of a healthcare professional, the incident appears to have resulted in, or requires treatment to prevent:

- the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
- the person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last, for a continuous period of at least 28 days
- changes to the structure of the person's body
- the person experiencing prolonged pain or prolonged psychological harm, or
- a shorter life expectancy for the person using the service.

These definitions of harm are aligned to CQC's [notification system for reporting deaths and serious injuries](#).

Definitions of harm

These definitions are common to all types of service.

Moderate harm

Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

Severe harm

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.

Moderate increase in treatment

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).

Prolonged pain

Pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Prolonged psychological harm

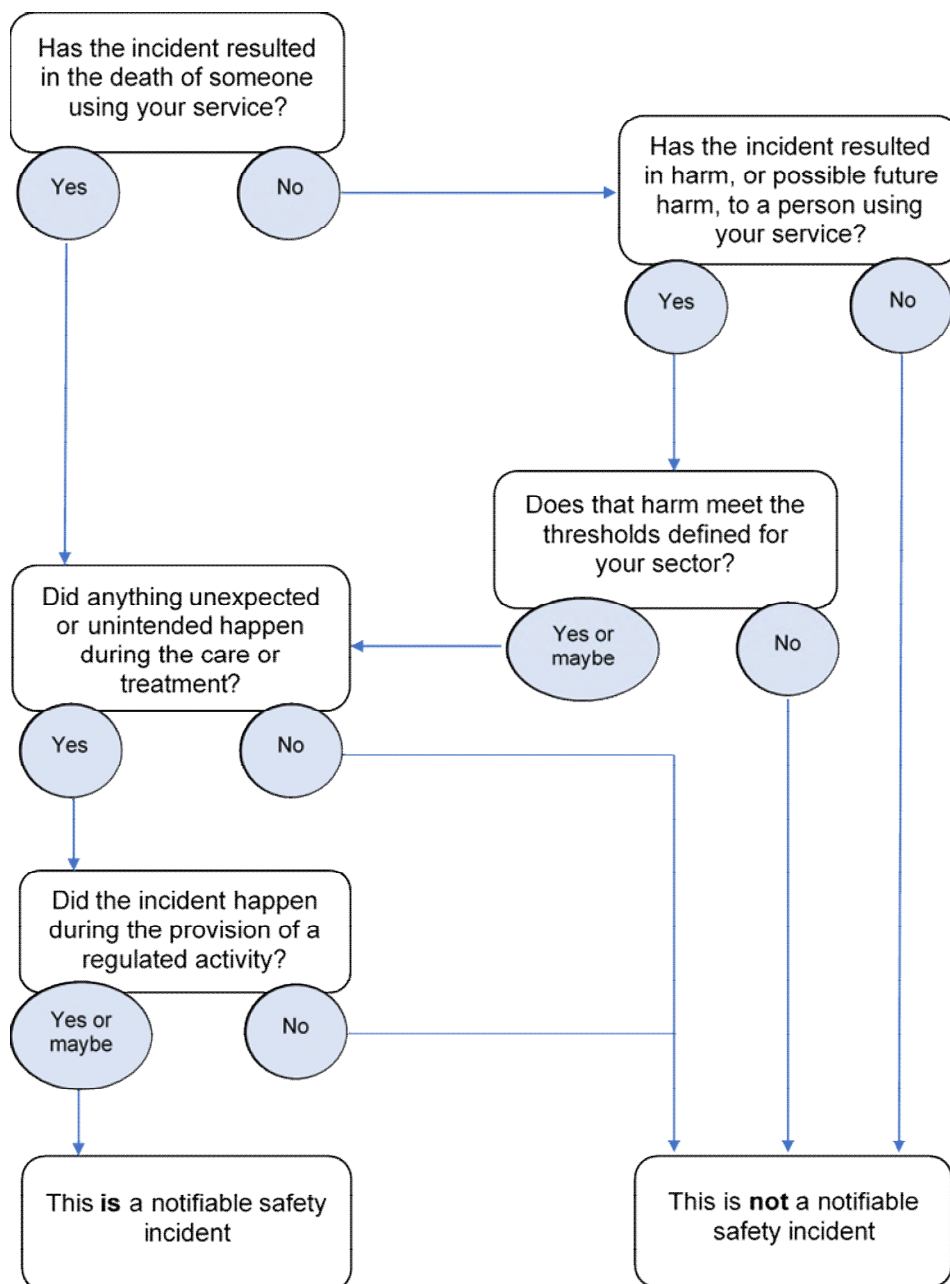
Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Identifying a notifiable safety incident

The presence or absence of fault on the part of a provider has no impact on whether or not something is defined as a notifiable safety incident. **Saying sorry is not admitting fault.**

Even if something does not qualify as a notifiable safety incident, there is always an overarching duty of candour to be open and transparent with people using services.

Flow chart



Patient gave consent

Something can qualify as a notifiable safety incident even if the patient gave consent for a procedure to be carried out. It all depends on the level of harm and whether something unexpected or unintended happened during the care or treatment, regardless of whether consent was given.

Notifiable safety incident occurred in a different provider

If you discover a notifiable safety incident that occurred in a different provider, you should inform the previous provider.

You must also be open and transparent with the person receiving care about whatever you have discovered. But you do not need to carry out the specific procedures relating to notifiable safety incidents.

The provider where the incident happened must carry out the notifiable safety incidents procedures.

Multiple providers contributed to the harm

If multiple providers contributed to the harm, they should liaise and work together in the investigation that follows as they would for any other incident. Each provider still has its own responsibilities under the duty of candour. They must assure themselves that they have met them.

Incidents that occurred before the duty of candour came into force

There is no legal requirement to carry out the specific requirements laid out in Regulation 20 for something that happened before the regulation existed. However, we would still expect you to carry out the general duty of candour – to apologise and to be open and transparent with people about whatever has been discovered.

Retrospective reviews and patient recalls

If the notifiable safety incident was not realised at the time but was discovered through a retrospective case review, or as part of a large scale patient recall, the duty still applies.

Incidents where there are no staff actively caring for the person

For example, this might be where a person has an unwitnessed fall in a care home.

The care being delivered is described by the regulated activity. In this example that is 'accommodation for people who require nursing or personal care'. The person fell during the delivery of the accommodation part of the regulated activity. So provided the harm thresholds are met, this could qualify as a notifiable safety incident.

Return to theatre following surgery or a transfer to another treatment area

The term 'moderate increase in treatment' does include situations such as a transfer or an unplanned return to surgery. But 'moderate increase in treatment' is only one part of the overall definition of 'moderate harm'. And it is the description of 'moderate harm' that helps define if something is a notifiable safety incident. To meet the 'moderate harm' threshold the harm must require a moderate increase in treatment and there must be significant, but not permanent, harm.

So a transfer or unplanned return to theatre does not automatically qualify as a notifiable safety incident.

Near misses

The intention of the term "could result in harm" in the harm definitions is not to bring near misses into scope as notifiable safety incidents. It is designed to reflect harm that is not apparent at the time of the incident but that may appear later.

We provide some worked examples of notifiable safety incidents in the section below.

Examples of notifiable safety incidents (duty of candour)

These case studies provide examples of how to apply the notifiable safety incident criteria.

Example 1: Maternity

What happened

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?

Yes. The woman had not received enough anaesthesia.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.

3. Has it resulted in death or severe or moderate harm?

Yes. The incident has resulted in "prolonged psychological harm" (psychological harm lasting more than 28 days).

The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 2: Care home

What happened

An occupational therapist completed an assessment with a care home resident whose mobility was deteriorating. They advised that grab rails were needed in his bathroom before it was safe for him to use the bath, and that in the meantime staff should assist him with a wash each morning. The manager failed to update the man's care plan or inform the care staff of this change, so staff supported him to take a bath the following morning as usual. He slipped when getting out of the bath and broke his arm. The arm was put in a plaster cast and the man needed full assistance for all aspects of his care for six weeks until the cast was removed. He made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?

Yes. The man slipped getting out of the bath when the occupational therapist's advice was not followed.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred during the provision of the regulated activity 'accommodation for persons who require nursing or personal care'.

Has it resulted in death or severe or moderate harm?

Yes. The injury in this case is a broken arm and would fall under Regulation 20(9)(b)(ii) as if the injury was left untreated the person using the service

could experience one or more of the scenarios referred to in Regulation 20(9)(a)(i) to (v).

The person was receiving care in a care home so the definitions in section 9 rather than 8 apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 3: Surgery

What happened

An elderly woman undergoes a coronary artery bypass operation. The operation is carried out according to plan, with no unexpected or unintended incidences. But the woman suffers a large stroke during the operation and dies soon after.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?

No. In this case, nothing unexpected or unintended occurred during the course of treatment.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

3. Has it resulted in death or severe or moderate harm?

Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply.

Conclusion

In this case, one of the answers to the three questions is “no”. So, this does not qualify as a notifiable safety incident. Of course, the overarching aspect of the duty of candour, to be open and transparent about what happened, always applies, whether or not something is a notifiable safety incident.

Example 4: Mental health

What happened

A prescribing error on a mental health ward resulted in a detained patient being given double her normal dose of lithium for several days. She developed lithium toxicity, which required inpatient admission. She made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
Yes. A patient was given the wrong dose of her medication.
2. Did it occur during provision of a regulated activity?
Yes. It occurred during provision of the regulated activity 'assessment or medical treatment for persons detained under the Mental Health Act 1983'.
3. Has it resulted in death or severe or moderate harm?
Yes. The incident resulted in moderate harm as defined in 20(7) (significant, but not permanent, harm, and a moderate increase in treatment). The patient was receiving care in an NHS trust so the definitions in Regulation 20(8) apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 5: Dental

What happened

A child with an unknown allergy to latex went for a dental check-up. The dentist wore latex gloves. The child had a very severe anaphylactic reaction which required hospitalisation. The child made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
Yes. The child had an allergic reaction.
2. Did it occur during provision of a regulated activity?
Yes. It occurred during provision of the regulated activity 'diagnostic and screening'.
3. Has it resulted in death or severe or moderate harm?
Yes. The incident meant that the person required further treatment to prevent death from anaphylaxis (Regulation 20 (9)(b)(i)). The patient was receiving care in a dentist surgery so the definitions in Regulation 20(9) apply. Note that on the facts provided in this example, there is no suggestion of error or fault on the part of the provider. But neither is required for something to qualify as a notifiable safety incident.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out. Note, there was no fault in this case, but there is no need for someone to have been at fault for an incident to qualify as a notifiable safety incident.

Example 6: General practice

What happened

A young man fell over while playing badminton and goes to his GP the next day with a swollen and painful foot and ankle. His GP decides not to order an x-ray and sends him home with advice to rest, ice, compress and elevate the leg. He tells the man he can weight bear fully. Over the following week, the pain and swelling does not improve, and the man goes back to the GP surgery and sees a different doctor who sends him for an x-ray. He is found to have a fracture of the base of fifth metatarsal that should have been put into a plaster cast and should have been non-weight bearing. Due to this mismanagement, the patient develops a non-union over the following six weeks which causes him ongoing pain and eventually requires surgical intervention in hospital.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
Yes. The GP made a misdiagnosis.
2. Did it occur during provision of a regulated activity?
Yes. It occurred during provision of the regulated activity 'treatment of disease, disorder or injury'.
3. Has it resulted in death or severe or moderate harm?
Yes. The incident resulted in prolonged pain, impairment of motor functions,

and the need for surgical intervention. The patient was receiving care in a GP surgery so the definitions in Regulation 20(9) apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

What you must do when you discover a notifiable safety incident (duty of candour)

You must start the specific procedure laid out in the duty of candour regulation 'as soon as reasonably practicable'.

We will always expect to see providers acting promptly as soon as a notifiable safety incident has been discovered.

The 'registered person' is responsible for carrying out, or delegating the responsibility for carrying out, the duty and must liaise with the 'relevant person'.

The 'registered person' is the registered manager or the registered provider. If you do not need to have a registered manager, such as NHS Trusts, responsibility sits with the leaders of the organisation.

The relevant person is either the person who was harmed or someone acting lawfully on their behalf.

Someone may act on the behalf of the person who was harmed if:

- the person has died
- is under 16 and not competent to make decisions about their care or the consequences of the incident
- is over 16 and lacking mental capacity.

This is in accordance with the Mental Capacity Act 2005.

The regulation states that you must:

1. Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
2. Apologise.

3. Provide a true account of what happened, explaining whatever you know at that point.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
5. Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
6. Keep a secure written record of all meetings and communications with the relevant person.

The purpose of these meetings and communications is to share whatever is known about the incident truthfully, openly and with compassion and support. The person who was harmed has a right to understand what has happened to them. The meeting is not about trying to apportion blame, and in any case, it is likely that investigations will still be underway at this point.

People are sometimes uncertain about how to apologise when an incident is still being investigated. But from the start, simple straightforward expressions of sorrow and regret can and should be made for the harm the person has suffered.

Throughout the process you must give 'reasonable support' to the relevant person, both in relation to the incident itself and when communicating with them about the incident.

'Reasonable support' will vary with every situation, but could include, for example:

- environmental adjustments for someone who has a physical disability
- an interpreter for someone who does not speak English well
- information in accessible formats
- signposting to mental health services
- the support of an advocate

- drawing their attention to other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care.

If the relevant person consents, we would expect to see that you have involved family members and carers in any discussions. It is about taking reasonable steps to make sure you communicate in a way that is as accessible and supportive as possible.

You must keep your own clear records of cases where you have responded to notifiable safety incidents. It may be that the incident also meets the notification thresholds and if so should be reported through the STEIS and NRLS/PSIMS systems or the CQC [notification system](#) dependent on care sector.

If the relevant person cannot be, or refuses to be, contacted, you may not be able to carry out paragraphs 2 to 4 of the regulation (the parts relating to notifiable safety incidents), but must keep a written record of all attempts to make contact. You must still report the incident through the appropriate notifications system and investigate it in order to prevent harm occurring to others.

How we regulate the duty of candour

The duty of candour is one of the fundamental standards – below which care should never fall. As such it is an area of regulation we pay special attention to.

We do not investigate every notifiable safety incident – this responsibility lies with the provider. Our role is to regulate the provider and ensure it is fulfilling its responsibility to carry out all aspects of the duty of candour. But we will investigate specific notifiable safety incidents where we have concerns.

We do not make judgements about the performance of individual healthcare professionals. In the event of a breach, our judgement will be on the registered person. They are the representative of the care provider.

Every provider should be creating an environment that encourages candour, openness and transparency at all levels. Candour underpins a culture of safety; it is only when organisations are open and honest that they can effectively learn from incidents that cause harm and improve the care that people receive.

During our public consultation in 2018, people shared examples of both poor and good practice that they had experienced. They told us that cover ups (whether real or perceived) and a lack of apology compounded the level of harm they had experienced following the initial incident.

However, when the duty of candour had been carried out well, people talked about how they had received a “heartfelt apology”, that the care provider had been “honest from the outset”, that “it was not a tick-box exercise”, and that assurance was given that things were being put in place to prevent the incident happening to others – that the incidents had been acknowledged and learned from.

Registration

The duty of candour applies to every provider registered with us.

We expect to see evidence during the registration process that the registered person understands their obligations under Regulation 20.

They should understand when and how to carry out the Duty of Candour and have training, policies and systems in place to ensure their employees are able to implement it. Providers should also be able to explain how they will support their staff to be open and transparent when something goes wrong and how this sits within a broader culture of safety.

Monitoring, assessment and inspection

We approach the monitoring of the duty of candour through the lens of the service:

- being well-led
- having an open and safe culture
- meeting the regulatory requirements of the duty of candour

When we hold monitoring calls, assess the data and information we receive, or visit the provider on inspection, we will be looking for evidence that all three factors are met.

It is important to realise that it is possible for the provider to be open and transparent (under Regulation 20(1)) but still not meeting some specific aspects of the duty of candour. This is because Regulation 20(2) is very specific about exactly how the duty must be carried out in relation to:

- the definition of notifiable safety incidents
- the various process steps, meetings and records that must take place
- what those meetings and records should cover

- that the process should be carried out in a timely manner
- that appropriate support should be provided to the person harmed or their representative

There's a range of ways that we assess compliance with the duty. We may:

- Follow up incidents reported through STEIS or CQC notifications that have been marked as triggering the duty of candour to ensure the process was followed through appropriately.
- Follow up incidents reported through STEIS or CQC notifications that were not marked as triggering the duty of candour but appear from the descriptions and harm levels to have required it.
- Ask providers to tell us about recent incidents.
- Follow up on reports of incidents from the public or people using services that appear to have met the threshold of a notifiable safety incident to ensure the specific requirements in the duty of candour took place.
- Ask people who have experienced a notifiable safety incident how the provider responded.
- Question frontline staff about their understanding of the duty of candour and notifiable safety incidents.
- Question the registered person about their policies and processes for recording and carrying out the duty, and for training staff.
- Investigate senior staff and board members' level of understanding of the duty and how they ensure staff feel supported to speak up and be open and honest about incidents.

Not all forms of monitoring and assessment undertaken by CQC will result in a published report, but whenever we do write such reports, we will reference our findings in relation to the duty of candour.

Enforcement

The ultimate responsibility for ensuring the duty of candour is carried out rests with the registered person (in the form of the registered manager or provider).

Where we believe this is not happening, we can use our powers of enforcement, and can prosecute breaches of the regulation.

Regulation 20 also allows us to move directly to criminal enforcement action.

Where an inspector considers a breach may have taken place, they will follow [CQC's Enforcement Policy and Decision Tree](#).

All options are open to us, including warning and requirement notices, imposition of conditions and criminal prosecution.

Regulation 20: Duty of candour

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

The regulation in full

20.—

- 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).