

# Guidance for NHS bodies on the fit and proper person requirement for directors and the duty of candour

**Consultation**

July 2014

## **The Care Quality Commission is the independent regulator of health and adult social care in England**

### **Our purpose**

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

### **Our role**

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

### **Our principles**

- We put people who use services at the centre of our work.
- We are independent, rigorous, fair and consistent.
- We have an open and accessible culture.
- We work in partnership across the health and social care system.
- We are committed to being a high performing organisation and apply the same standards of continuous improvement to ourselves that we expect of others.
- We promote equality, diversity and human rights.

## Foreword from the Chief Executive

We set out a new vision and direction for the Care Quality Commission (CQC) in our strategy for 2013-2016, *Raising standards, putting people first* and in our consultation, *A new start*, which proposed radical changes to the way we regulate health and social care services. We developed these changes with extensive engagement with the public, our staff, providers and key organisations.

*A new start* set out the new overarching framework, principles and operating model that we will use. This includes the five key questions that we will ask of all services:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive?
- Are they well-led?

Stakeholders in the care sectors welcomed our proposals, which include a more robust approach to registration; the introduction of chief inspectors; expert inspection teams; ratings to help people choose care; a focus on highlighting good practice; and a commitment to listen better to the views and experiences of people who use services.

Within this new approach, we must continue to ensure that providers meet Government regulations about the quality and safety of care. As part of this, we are required to publish guidance for providers to help them meet the requirements of the regulations.

New regulations setting out fundamental standards of care will come into force for all care providers on 1 April 2015. However, two of the new requirements – the fit and proper person requirements for directors and the duty of candour – will come into force for ‘NHS bodies’ sooner. They will apply from 1 October 2014 (or very closely after this date subject to Parliamentary approval). NHS bodies means NHS trusts, NHS foundation trusts and special health authorities.

The introduction of a statutory duty of candour is an important step towards ensuring the open, honest and positive culture that Sir Robert Francis found was lacking at Mid Staffordshire NHS Foundation Trust.

He also said that there should be stronger ways to hold people to account for failures of care. The fit and proper person requirement plays a major part in ensuring the accountability of directors of NHS bodies (and from April 2015, directors or their equivalents in all registered providers). It is essential that CQC uses these new powers well, to encourage a culture of openness and to hold providers and directors to account.

To address the different timescales involved, we are running two public consultations on our guidance for providers:

- This one (“for regulations implemented in October 2014”), which is focused exclusively on guidance for NHS bodies on the fit and proper person requirements for directors and the duty of candour.
- A consultation on the full suite of guidance (“for regulations implemented in April 2015”) for all providers on what they could do to meet the new fundamental standards regulations (including the fit and proper person requirements for directors and the duty of candour).

The new regulations and the Care Act 2014 also introduce changes to our regulatory powers. We have developed a new approach to enforcement to reflect that. This is described in detail in the April 2015 consultation document which contains the full suite of guidance.

This document sets out our proposals for consultation. I hope you will take the time to respond to it. Your views are important in helping us to refine our new approach and get it right.

**David Behan**

A handwritten signature in black ink, appearing to read 'David Behan', written in a cursive style.

Chief Executive  
Care Quality Commission

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# Introduction

## CQC's operating model

In April 2013, CQC published its new strategy: *Raising standards, putting people first*, setting out CQC's clear purpose and role.

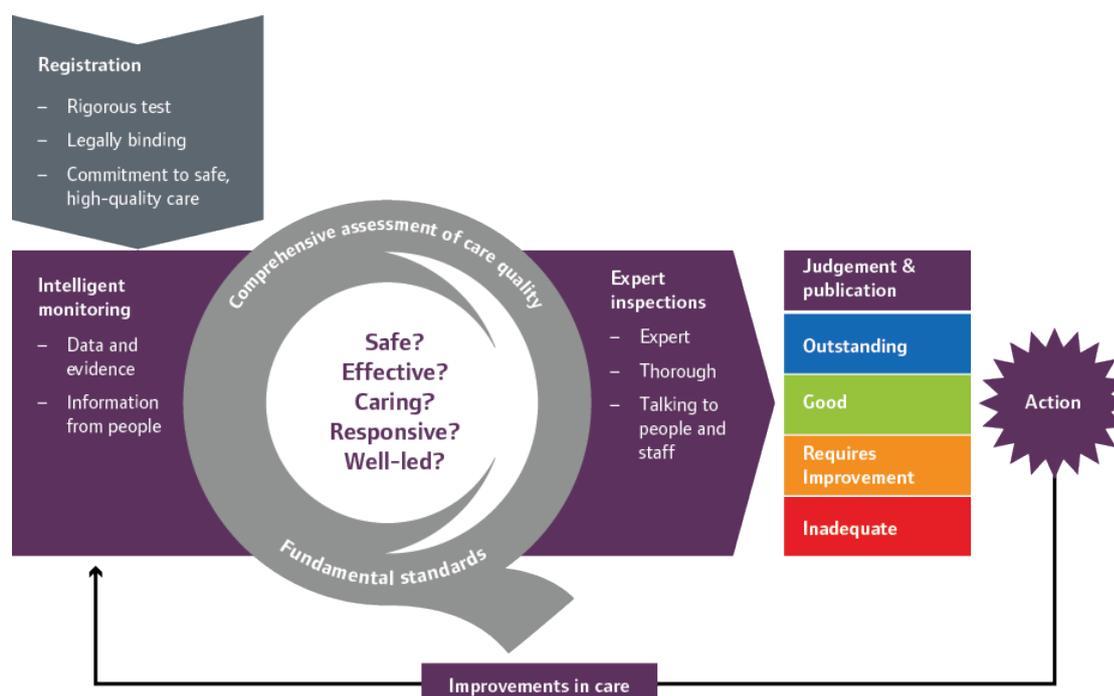
To deliver our purpose, we are introducing significant changes to how we work. We have previously set out the changes to our approach to monitoring, inspecting and regulating providers in our signposting documents and statements for each sector. While our new approach will be tailored to different sectors, types of providers and types of service, they share common principles that are intended to ensure that health and social care services provide people with safe, effective, compassionate, high-quality care, and to encourage care services to improve.

Our provider handbooks set out the details of our new approach for each sector. They describe how we will carry out inspections, make judgements and award ratings to providers. We recently consulted on the handbooks for acute services, specialist mental health services and community health services. This consultation closed on 4 June 2014 and we will publish updated handbooks in September 2014.

We will also in due course publish handbook information for providers of ambulance and independent healthcare services. We may develop separate handbooks for these services, or add supplements to the existing handbooks.

Our new operating model describes how we will register, monitor, inspect and award ratings to providers. It is illustrated by the following diagram:

**Figure 1: CQC's overall operating model**



Within this new approach, we must continue to ensure that providers meet Government regulations about the quality and safety of care.

## **How our guidance on meeting regulations fits into our operating model**

All registered providers must demonstrate that they are meeting regulatory requirements in order to register with CQC and then continue to deliver regulated services.

From 1 October 2014, in addition to the existing regulations, NHS bodies must meet the fit and proper person requirement for directors and the duty of candour.

The law states that our guidance on meeting the regulations must be taken into account in:

- Our regulatory decisions about a provider's registration (that is, granting a registration, refusing an application, cancelling or suspending a registration, or varying the conditions on a registration).
- Proceedings for the urgent cancellation of a registration, or for appeals relating to an urgent cancellation.
- Proceedings for a failure to comply with conditions of registration or for breaches of regulations.

Our guidance on meeting the fit and proper person requirement for directors regulation and the duty of candour regulation will therefore be central to:

### **1. Registration**

As set out in our strategy, we will continue to strengthen our approach to assessing applications for registration with CQC and the registration process. From October, when considering new NHS applications for registration and variation or cancellation of existing NHS registrations, we will take account of the duty and candour and fit and proper person requirement for directors. We will use our guidance to do this.

### **2. Inspection**

In focused inspections, we either follow up specific concerns from earlier inspections or respond to new, specific information that has come to our attention. In these circumstances, we assess whether the provider has improved so that they are no longer in breach of regulations or whether the new concern amounts to a breach of regulations. We will take this guidance into account in making these judgements.

In comprehensive inspections (which lead to ratings of individual services and the provider overall), we primarily look for good care, rather than checking compliance with regulations. We have developed characteristics of what good care looks like in partnership with patients, people who use services and subject matter experts, and therefore what would constitute a 'good' rating. We will use key lines of enquiry (KLOEs) to assess this, checking whether a provider is delivering services that are safe, effective, caring, responsive and well-led. The

characteristics of good care and the KLOEs are set out in our provider handbooks. If we find good care, we will also assess whether it meets the characteristics of an outstanding rating.

However, if we find care that does not reflect the characteristics of good, we will assess whether it requires improvement or is inadequate.

We will also consider whether a regulation has been breached. We will take this guidance into account to determine whether or not a provider has complied with the two new regulations.

We have ensured that all the areas covered by the regulations are also covered in our KLOEs. This means that where we do not see good care, we will be in a position to consider whether a regulation is being breached.

The new duty of candour will carry an offence that means CQC can move directly to prosecution without first serving a warning notice. This is a change from current regulations where we have to serve a warning notice before prosecuting.

It means that, from 1 October 2014, where we identify that patients and people who use services have been harmed or exposed to significant risk of harm and NHS bodies have not been open and honest, we will be able to move directly to prosecution.

We may also use other regulatory powers in parallel to protect patients and hold providers and, in some cases, individuals to account.

Once this consultation on those regulations that will be implemented in October 2014 is complete, we will add the relevant guidance on the fit and proper person requirement for directors and the duty of candour for NHS bodies as an addendum to the *Guidance about compliance: Essential standards of quality and safety*. The rest of *Guidance about compliance: Essential standards of quality and safety* will remain in force, and must be taken into account in regulatory decisions and enforcement until April 2015. Our current enforcement policy will also remain in force until April 2015.

The outcome of the consultation on those regulations that will be implemented in April 2015 will replace, in its entirety, the *Guidance about compliance: Essential standards of quality and safety* and the 28 'outcomes' that it contains. It will also replace our current enforcement policy.

# Overview of the new regulations

## Regulation 5: Fit and proper person requirement for directors

Currently, providers have a general obligation to ensure that they only employ individuals who are fit for their role.

CQC assesses the fitness of 'corporate' providers (that is, all providers other than individuals and partnerships) by focusing on the fitness of their 'nominated individuals'. Providers are able to nominate, for themselves, who will be their nominated individuals. These are usually (although not necessarily) directors of the organisation. When assessing the fitness of the nominated individual, we consider whether the provider has taken appropriate steps to ensure that they are of good character, are physically and mentally fit, have the necessary qualifications, skills and experience for the role, and can supply certain information (including a Disclosure and Barring Service (DBS) check and a full employment history).

The new fit and proper person requirement for directors will have a wider impact, in both the scope of its application and the nature of the test. It makes it clear that individuals who have authority in organisations that deliver care are responsible for the overall quality and safety of that care and, as such, can be held accountable if standards of care do not meet legal requirements.

It will apply to all directors and "equivalents". This will include executive and non-executive directors of NHS trusts and foundation trusts. It will be the responsibility of the provider and, in the case of NHS bodies, the chair, to ensure that all directors meet the fitness test and do not meet any of the 'unfit' criteria.

In addition to the usual requirements of good character, health, qualifications, skills and experience, the regulation goes further by barring individuals who are prevented from holding the office (for example, under a directors' disqualification order) and significantly, excluding from office people who:

"have been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity, or discharging any functions relating to any office or employment with a service provider".

This is a significant restriction. It will enable CQC to decide that a person is not fit to be a director on the basis of any previous misconduct or incompetence in a previous role for a service provider. This would be the case even if the individual was working in a more junior capacity at that time, or working outside England.

We will work collaboratively with the NHS Trust Development Authority, Monitor and councils of governors on how these proposals fit with the appointments of trust chairs.

## **Our approach to the fit and proper person requirement for directors**

We will require the chair of the provider's board of directors to:

- Confirm to us that the fitness of all new directors has been assessed in line with the regulations.
- Declare to us in writing that they are satisfied that they are fit and proper individuals for that role.

A notification is already required following a new director level appointment. This new requirement will not delay the appointment process, or increase the administrative workload significantly. We may also ask the provider to check the fitness of existing directors and provide the same assurance to us, where concerns about them come to our attention. This consultation is therefore a key way in which providers can tell us if the guidance we have prepared will help them to carry out this responsibility.

We will cross-check notifications about new directors against other information that we hold or have access to, to decide whether we want to look further into the individual's fitness. We will have regard to any other information that we hold or obtain about directors in line with current legislation on when convictions, bankruptcies or similar matters are to be considered 'spent'. Where a director is associated with serious misconduct or responsibility for failure in a previous role, we will have regard to the seriousness of the failure, how it was managed, and the individual's role within that. However, there is no time limit for considering such misconduct or responsibility.

If we need to use our enforcement powers to ensure that all directors are fit and proper for that role, we will normally do this by imposing conditions on the provider's registration to ensure that the provider takes the appropriate action to remove the director.

If a provider that aspires to register with CQC cannot demonstrate that it will meet the requirements of the regulation from its first day of business, we may refuse their application.

We will work with providers, other regulators and government departments to define the processes that our inspectors will use to make these assessments and judgments.

## **Regulation 20: Duty of candour**

The aim of the regulation is to ensure that providers are open and honest with patients when things go wrong with their care and treatment.

To meet the requirements of the regulation, a provider has to:

- Make sure it has an open and honest culture across and at all levels within its organisation.
- Tell patients in a timely manner when particular incidents have occurred.

- Provide in writing a truthful account of the incident and an explanation about the enquiries and investigations that they will carry out.
- Offer an apology in writing.
- Provide reasonable support to the person after the incident.

The regulations apply to the patient themselves and, in certain situations, to people acting on the patient's behalf, for example when something happens to a child or to a person over the age of 16 who lacks the capacity to make decisions about their care.

If the provider fails to do any of the things above, CQC can move directly to prosecution without first serving a warning notice.

Although some aspects of the original duty of candour recommendation in the Mid-Staffordshire inquiry have not been adopted (for example, that the statutory duty should also apply to healthcare professionals), overall the original recommendation has been accepted and developed further. This is particularly the case around the threshold at which the duty to notify patients is triggered.

For NHS bodies the regulations adopt the approach suggested by the Dalton/Williams review. Incidents include not only cases of death and severe harm, but also "moderate harm" in line with providers' existing contractual duty under the NHS Standard Contract. This includes unplanned returns to surgery or 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). Incidents also include cases of "prolonged psychological harm" – that is, continuing, or likely to continue, for at least 28 days.

The duty goes on to require the provider to supply the patient or representative with the results of any further enquiries into the incident and to keep records of all correspondence and notifications in person.

It should be noted that, as well as this specific duty of candour around a particular safety incident, the regulations also include a more general obligation on CQC registered persons to "act in an open and transparent way in relation to service user care and treatment".

This means that the default position should be to be open, honest and candid, unless there are justifiable reasons for not being so – for example because the service user actively says that they do not want further information about the incident. However, these circumstances should be the exception rather than the norm.

## **Our approach to the duty of candour**

We have incorporated candour in the key lines of enquiry and descriptors of rating levels that we set out in our provider handbooks for consultation earlier this year.

We expect to mainly use the new regulations on candour to confirm or encourage good practice through the ratings we give, rather than to enforce them directly. We expect to be able to do this by building on the way our inspections already consider safety incidents, training and guidance for staff, and the culture and values that the provider's leadership promotes.

Criminal sanctions have a role to play – and this guidance will be key to deciding when prosecution is appropriate – but by themselves they are unlikely to be the strongest driver for promoting a culture of openness in providers.

We will work with providers, people who use services, and other partners in the system to develop the processes that our inspectors will use to inspect and enforce the duty of candour. This will cover the requirements of the regulations and ensure that our approach is proportionate, for example taking account of the degree of harm and the extent to which a breach was an act of omission as opposed to commission.

We will not shy away from using the full weight of our powers, but we anticipate that this will be in cases where we have evidence of deliberate withholding or manipulation of information. We also know that there is significant, as yet unquantified, scope for improvement in under-reporting of incidents and failing to learn from things that go wrong. In our operational guidance for inspectors, we will seek to encourage (and where appropriate require) good practice in these areas.

## **Our approach to guidance on regulations**

We developed this guidance with the help of many patients and people who use services, organisations that represent them, providers, other regulators and professional bodies. We are grateful for their many suggestions.

In the guidance, we explain the intention of each regulation. We then consider each element of the regulation in turn, setting out the implications for providers in terms of how they could demonstrate compliance. For each regulation, we then signpost key legislation and guidance that providers may want to consider in deciding how they will ensure that they meet the regulation.

The hyperlinks to legislation and guidance relate specifically to either the duty of candour or the fit and proper person requirement for directors. They are not meant to be exhaustive. We expect providers to meet the requirements of all relevant legislation, even if not hyperlinked in the guidance.

We also expect providers to take account of other relevant guidance that might be specific to the services they deliver. We would generally expect NHS secondary care providers to be aware of and take into account nationally recognised guidance – such as that produced by the former National Patient Safety Agency, NHS England, the National Institute for Health and Care Excellence, Skills for Health, clinical and professional bodies, and those organisations that either have a national remit for producing guidelines or are recognised as producers of high-quality guidance recognised by the professions and services.

We intend our guidance to be as helpful as possible to providers. However, it is not CQC's role to tell providers what they must do to deliver their services. It is the provider's responsibility to meet the regulations and they must be empowered to make decisions about how to ensure they meet the regulations.

Our guidance is not enforceable in and of itself. Providers are not legally bound to use it. This is because providers may demonstrate other ways of meeting the regulations than what is described in the guidance. However, the Health and Social Care Act 2008 is clear that this guidance is to be taken into account in our regulatory decisions and where we bring proceedings for breaches of regulations or conditions.

In general, therefore, while we do not require providers to follow this guidance, we will ask providers if they are following the guidance. If they are not, we would ask them to provide an explanation of why not and assurance that their approach is no less effective in enabling them to meet the requirements of the regulations.

# This consultation

This consultation will run for six weeks from 25 July to 5 September 2014. We will then make any amendments required and publish the guidance before we start to use the new regulations in respect of NHS bodies.

We are publishing in parallel a [consultation on the full suite of guidance](#) (incorporating all of the fundamental standards, the fit and proper person requirement for directors and duty of candour for all providers, and our guidance on enforcement) for a 12-week consultation. This longer consultation will enable us to take account of the wide range of considerations and comments we expect across all sectors, and allow time to incorporate all the required amendments into the guidance and provide thorough training for our staff. We will publish the guidance in time to give providers the opportunity to fully consider its implications before it is implemented on 1 April 2015.

## Consultation questions

Our questions in this consultation are:

1. Is it clear what NHS providers should do to meet the fit and proper person requirement for directors? If not, how could it be made clearer?
2. Is it clear what NHS providers should do to fulfil their duty of candour? If not, how could it be made clearer?
3. Is the format and layout of the guidance easy to follow and understand?
4. Are the links to key legislation and guidance helpful? How could we promote these links better?
5. Is there anything missing from the guidance?
6. Is there anything that should be taken out of the guidance?

# How to respond to this consultation

You can respond to our consultation in the following ways. Please send us your views and comments by Friday 5 September 2014.

## Online

Use our online form at:

<http://webdataforms.cqc.org.uk/Checkbox/DutyCandourFitProperPersonTest.aspx>

## By email

Email your response to:

[cqc.consultation@cqc.org.uk](mailto:cqc.consultation@cqc.org.uk)

## By post

Write to us at:

CQC Guidance consultation July 2014  
CQC National Customer Service Centre  
Citygate  
Gallowgate  
Newcastle upon Tyne  
NE1 4PA

## What we will do with responses to the consultation

We will consider all comments received during the consultation and will update and amend the guidance accordingly. We will produce a document that summarises all the responses and all the changes that we have made. We will provide general comments about suggested changes and amendments that we have not made.

## Guidance for providers

### How to meet the regulations for fit and proper person: directors and duty of candour

You can see the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 on this link:  
<http://www.legislation.gov.uk/ukdsi/2014/978011117613/contents>

Please note: this is a draft item of legislation and has not yet been made as a UK Statutory Instrument.

## Regulation 5: Fit and proper person: directors

- 5—(1) This regulation applies where a service provider is a health service body.**
- (2) Unless the individual satisfies all the requirements set out in paragraph (3), the service provider must not appoint or have in place an individual—**
- (a) as a director of the service provider, or**
  - (b) performing the functions of, or functions equivalent or similar to the functions of, such a director.**
- (3) The requirements referred to in paragraph (2) are that—**
- (a) the individual is of good character,**
  - (b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed,**
  - (c) the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed,**
  - (d) the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and**
  - (e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.**
- (4) In assessing an individual's character for the purposes of paragraph (3)(a), the matters considered must include those listed in Part 2 of Schedule 4.**
- (5) The following information must be available to be supplied to the Commission in relation to each individual who holds an office or position referred to in paragraph (2)(a) or (b)—**
- (a) the information specified in Schedule 3, and**
  - (b) such other information as is required to be kept by the service provider under any enactment which is relevant to that individual.**
- (6) Where an individual who holds an office or position referred to in paragraph (2)(a) or (b) no longer meets the requirements in paragraph (3), the service provider must—**

- (a) take such action as is necessary and proportionate to ensure that the office or position in question is held by an individual who meets such requirements, and
- (b) if the individual is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

## Summary of the regulation

**This regulation applies to health service bodies only from 1 October 2014. It will be extended to all other providers from 1 April 2015, subject to Parliamentary process and approval.**

The purpose of this regulation is to require providers to take proper steps to ensure that their directors (both executive and non-executive) are fit and proper for the role (as is the case for staff in Regulation 19, Fit and proper workers employed). It makes clear that individuals who have authority in organisations that deliver care are responsible for the overall quality and safety of that care. As such, they can be held accountable if standards of care do not meet the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

To meet this regulation, the provider must carry out all necessary checks to confirm that persons who are appointed to the role of director (or similar senior level role, whatever it might be called) in an NHS trust or NHS foundation trust are of good character (as defined in Schedule 4, Part 2 of the regulations), have the appropriate qualifications, are competent and skilled (including that they show a caring and compassionate nature and appropriate aptitude), have the relevant experience and ability (including an appropriate level of physical and mental health, taking account of any reasonable adjustments), and exhibit appropriate personal behaviour and business practices. In addition, people appointed to these roles must not have been responsible for or known, contributed to or facilitated any serious misconduct or mismanagement in carrying on a regulated activity.

CQC recognises that a provider may not have access to all relevant information about a person, or that false or misleading information may be supplied to them. However, we expect the provider to demonstrate due diligence in carrying out checks, that is, they have made every reasonable effort to assure themselves about an individual by all means available to them.

Where a provider allows an ‘unfit’ person to be a director, or allows an unfit person to stay in that role, CQC may question the provider’s overall fitness to operate. Additionally, individuals may be fit for their roles while collectively a board (or similar group made up of the individuals to whom this regulation applies) demonstrates a lack of fitness. In this case, we would address the matter under Regulation 17, Good governance or through, in the most serious cases, the single failure regime for NHS trusts.

If a provider that aspires to be registered with CQC cannot demonstrate that it will meet the requirements of this regulation from its first day of business, CQC may refuse its application for registration.

Breaches of this regulation or its component parts do not constitute a prosecutable offence in themselves. However, CQC can take other regulatory action against breaches of the regulation or any of its components. Additionally, breaches of other regulations, including the fundamental standards detailed in Regulations 10 to 21, may give CQC cause to question whether they have resulted from a breach of this regulation.

Component of the regulation	What the provider could do to meet the requirements of the component
<p><b>5(3)(a) the individual is of good character</b></p>	<ul style="list-style-type: none"> <li>• Providers should make every effort to ensure that all available information is sought to confirm that the individual is of good character as defined in Schedule 4, Part 2 of the regulations.</li> <li>• If a provider discovers information that suggests an individual is not of good character after they have been appointed to a role, the provider must take appropriate and timely action to investigate and rectify the matter.</li> <li>• Where a provider deems the individual suitable despite not meeting the characteristics outlined in Schedule 4, Part 2 of these regulations, the reasons should be recorded and information about the decision should be made available to those that need to be aware.</li> </ul>

Component of the regulation	What the provider could do to meet the requirements of the component
<p><b>5(3)(b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed</b></p>	<ul style="list-style-type: none"> <li>• Where specific qualifications are deemed by the provider as necessary for a role, the provider must make this clear and should only employ those individuals that meet the required specification, including any requirements to be registered with a professional regulator.</li> <li>• The provider should have appropriate processes for assessing and checking that the individual holds the required qualifications and has the competence, skills and experience required, (which may include appropriate communication and leadership skills and a caring and compassionate nature), to undertake the role; these should be followed in all cases and relevant records kept.</li> <li>• The provider may consider that an individual can be appointed to a role based on their qualifications, skills and experience with the expectation that they will develop specific competence to undertake the role within a specified timeframe.</li> </ul>
<p><b>5(3)(c) the individual is able by reason of their health, after such reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed</b></p>	<ul style="list-style-type: none"> <li>• When appointing relevant individuals the provider has processes for considering a person's physical and mental health in line with the requirements of the role.</li> <li>• Wherever possible, reasonable adjustments are made in order that an individual can carry out the role.</li> </ul>
<p><b>5(3)(d) the individual has not been responsible for, been privy to, contributed to or facilitated, any serious</b></p>	<ul style="list-style-type: none"> <li>• The provider has processes in place to assure itself that the individual has not been at any time responsible for, privy to, contributed to, or facilitated, any serious misconduct or mismanagement in the carrying on of a regulated activity; this includes investigating any allegation of such.</li> </ul>

Component of the regulation	What the provider could do to meet the requirements of the component
<p><b>misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and</b></p>	<ul style="list-style-type: none"> <li>The provider must not appoint any individual who has been responsible for, privy to, contributed to, or facilitated, any serious misconduct or mismanagement (whether lawful or not) in the carrying on of a regulated activity; this includes investigating any allegation of such.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>Responsible for, contributed to or facilitated means that there is evidence that a person has intentionally or through neglect behaved in a manner which would be considered to be or would have led to serious misconduct or mismanagement.</li> <li>Privy to means that there is evidence that a person was aware of serious misconduct or mismanagement but did not take the appropriate action to ensure it was addressed.</li> <li>Serious misconduct or mismanagement means behaviour that would constitute a breach of any legislation/enactment CQC deems relevant to meeting these regulations or their component parts.</li> </ul>
<p><b>5(3)(e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.</b></p>	<ul style="list-style-type: none"> <li>Only individuals who will be acting in a role that falls within the definition of a “regulated activity” as defined by the Safeguarding Vulnerable Groups Act 2006 will be eligible for a check by the Disclosure and Barring Service (DBS).</li> <li>As part of the recruitment/appointment process, providers should establish whether the individual is on a relevant barring list.</li> </ul> <p><b>Note:</b></p> <p>CQC recognises that it may not always be possible for providers to access a DBS check as an individual may not be eligible.</p>

Component of the regulation	What the provider could do to meet the requirements of the component
<p><b>5(6) Where an individual who holds an office or position referred to in paragraph (2)(a) or (b) no longer meets the requirements in paragraph (3), the service provider must—</b></p> <p><b>(a)take such action as is necessary and proportionate to ensure that the office or position in question is held by an individual who meets such requirements, and</b></p> <p><b>(b)if the individual is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question</b></p>	<ul style="list-style-type: none"> <li>• The fitness of directors is regularly reviewed by the provider to ensure that they remain fit for the role they are in; the provider should determine how often fitness must be reviewed based on the assessed risk to business delivery and/or the service users posed by the individual and/or role.</li> <li>• The provider has arrangements in place to respond to concerns about a person’s fitness after they are appointed to a role, identified by itself or others, and these are adhered to.</li> <li>• The provider investigates, in a timely manner, any concerns about a person’s fitness or ability to carry out their duties, and where concerns are substantiated, proportionate, timely action is taken; the provider must demonstrate due diligence in all actions.</li> <li>• Where a person’s fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to service users.</li> <li>• The provider informs others as appropriate about concerns/findings relating to a person’s fitness; for example, professional regulators, CQC and other relevant bodies, and supports any related enquiries/investigations carried out by others.</li> </ul>

Relevant legislation	Relevant guidance
<p>NHS Provider Licence  <a href="http://www.monitor-nhsft.gov.uk/sites/default/files/publications/Licence%20application%20guidance%20final.pdf">http://www.monitor-nhsft.gov.uk/sites/default/files/publications/Licence%20application%20guidance%20final.pdf</a></p> <p>Companies Act 2006  <a href="http://www.legislation.gov.uk/ukpga/2006/46/part/8/chapter/2">http://www.legislation.gov.uk/ukpga/2006/46/part/8/chapter/2</a></p> <p>The Protection of Freedoms Act 2012  <a href="http://www.legislation.gov.uk/uksi/2012/3006/contents/made">http://www.legislation.gov.uk/uksi/2012/3006/contents/made</a></p> <p>Safeguarding Vulnerable Adults Group 2006  <a href="http://www.legislation.gov.uk/ukpga/2006/47/contents">http://www.legislation.gov.uk/ukpga/2006/47/contents</a></p> <p>Protection of Freedoms Act 2013  <a href="http://www.legislation.gov.uk/ukpga/2012/9/contents/enacted">http://www.legislation.gov.uk/ukpga/2012/9/contents/enacted</a></p>	<p>Professional Standards Authority  <a href="http://www.professionalstandards.org.uk/library/document-detail?id=89114436-21e2-47df-b5a0-7d5308b66b8e">http://www.professionalstandards.org.uk/library/document-detail?id=89114436-21e2-47df-b5a0-7d5308b66b8e</a></p> <p>Charities Commission guidance  <a href="http://www.charitycommission.gov.uk/detailed-guidance/">http://www.charitycommission.gov.uk/detailed-guidance/</a></p> <p>Disclosure and Barring identity checking guidance  <a href="https://www.gov.uk/government/publications/dbs-identity-checking-guidelines">https://www.gov.uk/government/publications/dbs-identity-checking-guidelines</a></p> <p>Disclosure and Barring  <a href="https://www.gov.uk/government/organisations/disclosure-and-barring-service">https://www.gov.uk/government/organisations/disclosure-and-barring-service</a></p> <p>Equality and Human Rights Commission: employment statutory code of practice  <a href="http://www.equalityhumanrights.com/sites/default/files/documents/EqualityAct/employercode.pdf">http://www.equalityhumanrights.com/sites/default/files/documents/EqualityAct/employercode.pdf</a></p>

## Regulation 20: Duty of candour

**20. (1) A health service body 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 health service body 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 health service body,**
- (b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,**
- (c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,**
- (d) include an apology, and**
- (e) be recorded in a written record which is kept securely by the health service body.**

**(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 health service body—**

- (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 health service body 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” 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;**

**“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 (as determined in accordance with sections 2 and 3 of the 2005 Act) 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.**

## Summary of the regulation

**This regulation applies to health service bodies only from 1 October 2014. It will be extended to all other providers from 1 April 2015, subject to Parliamentary process and approval.**

The intention of this regulation is to ensure that providers are open and honest with service users and other 'relevant persons' (people acting lawfully on the behalf of service users) when things go wrong with care and treatment, and that they provide them with reasonable support, truthful information and a written apology.

To meet the requirements of this regulation, providers must ensure an open and honest culture exists across, and at all levels, within their organisation. The provider must ensure it has systems in place for knowing about notifiable safety incidents\* and must tell the relevant person(s), in a timely manner, when such an incident has occurred. This includes providing a truthful account of the incident, providing an explanation in writing about the enquiries and investigations that will be undertaken and offering an apology in writing. In addition, the provider must maintain appropriate written records and offer reasonable support in relation to the incident.

\*The regulation, detailed above, provides an explanation of what is meant by 'notifiable safety incident', 'harm', and an 'apology'.

If a provider that aspires to be registered with CQC cannot demonstrate that it will meet the requirements of this regulation from its first day of business, CQC may refuse its application for registration.

Where a provider fails to inform the relevant person(s) within a reasonable amount of time of a notifiable incident, fails to provide a truthful account to relevant persons, fails to advise the relevant person of the enquiries and investigation process it will undertake, fails to offer reasonable support and/or fails to offer an apology, then CQC can move directly to prosecution without first serving a warning notice.

Component of the regulation	What providers could do to meet the requirements of the component
<p><b>20(1) A health service body 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.</b></p>	<ul style="list-style-type: none"> <li>• There is a health service Board level (or other senior level – whatever it may be called) commitment to being open and transparent.</li> <li>• The provider has policies and procedures in place to support a culture of openness and transparency, and these are followed by all staff. Where the individual is professionally qualified, it may include fitness to practise proceedings and professional disciplinary cases.</li> <li>• The provider makes all reasonable efforts to ensure that staff operating at all levels within the organisation understand and operate within a culture of openness and transparency, this includes providing relevant training and support for staff.</li> <li>• Staff understand their responsibilities in identifying and reporting notifiable incidents. The provider ensures that it has systems in place to support the identification and reporting of notifiable safety incidents.</li> <li>• In cases where a relevant person informs the provider that something untoward has happened, the provider must treat the allegation seriously, immediately considers whether this is a notifiable safety incident and take appropriate action.</li> <li>• Where a provider becomes aware that staff have not acted in accordance with the requirements placed on them under the Duty of Candour they must refer the individual(s) concerned to their relevant professional regulator/body, police, other relevant body etc.</li> </ul>
<p><b>20(2) As soon as practicable after becoming aware that a notifiable safety incident has occurred a health service body must–</b></p>	<ul style="list-style-type: none"> <li>• When a notifiable safety incident has occurred relevant person(s) are informed as soon as practicable (this means as soon as possible after the discovery or occurrence of a notifiable safety incident).</li> <li>• Regulation 20 provides guidance on what constitutes a ‘notifiable safety incident. Further information on definitions of harm and what must be reported to CQC under the Care Quality Commission (Registration Requirement) Regulations 2009 can be found in the relevant guidance below.</li> </ul>

Component of the regulation	What providers could do to meet the requirements of the component
<p><b>(a) notify the relevant person that the incident has occurred in accordance with paragraph (3)</b></p> <p><b>and</b></p> <p><b>20(3) The notification to be given under paragraph (2)(a) must–</b></p> <p><b>(a) be given in person by one or more representatives of the health service body,</b></p> <p><b>(b) provide an account, which to the best of the health service body’s knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,</b></p> <p><b>(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,</b></p> <p><b>(d) include an apology, and</b></p>	<ul style="list-style-type: none"> <li>• Where the service user affected by an incident lacks capacity, or it is felt that it would be counterproductive to disclose information, appropriate arrangements should be in place to support best interest decisions and relevant persons are notified.</li> <li>• Information should only be disclosed to relevant persons other than the person directly suffering if that person has died, lacks mental capacity or has given their explicit consent.</li> <li>• A step by step account of all relevant facts known about the incident at the time should be given, in person, by one or more appropriate representatives of the provider. This should include as much or as little relevant information as the relevant person(s) want to hear, should be jargon free and explain any complicated terms, and should include an explanation of any further planned enquiries and investigations. This account should be given in a manner that relevant person/s can understand (for example, the provider should consider if appropriate interpreters, advocates, communication aids etc. should be present, but should be conscious of any potential breaches of confidentiality in doing so).</li> <li>• Providers must ensure that an apology is given, in person, by one or more appropriate representatives of the provider to relevant persons.</li> <li>• The decision on who is most appropriate to provide the notification and/or apology should consider seniority, relationship to the service user, and experience and expertise in the type of notifiable incident that has occurred.</li> <li>• The relevant person should be advised on what further enquires are appropriate and they should be given all reasonable opportunities to be involved as much as they wish to be in the progress of any enquiries.</li> <li>• The provider should explain that new information may emerge during the course of any inquiries into the incident, and must keep the relevant person(s) informed of new information as it arises.</li> <li>• Providers should keep the relevant person(s) informed (as much or as little as they wish) about the conclusions of its enquiries. The relevant person(s) should also be provided with a single</li> </ul>

Component of the regulation	What providers could do to meet the requirements of the component
<p><b>(e) be recorded in a written record which is kept securely by the health service body.</b></p>	<p>point of contact for any questions or queries and be offered further opportunities to discuss the case:</p> <ul style="list-style-type: none"> <li>○ on an ongoing basis throughout the course of their ongoing recovery and/or treatment and during any investigation or inquiry</li> <li>○ at times and amounts of their choosing</li> </ul> <p>until they are satisfied that all relevant information has been disclosed.</p> <p><b>Note:</b> On occasion, a provider may discover a notifiable safety incident that happened some time ago, including in relation to care that was delivered by another provider. The provider which discovers the incident should work with any others who might be best placed to notify relevant persons of the incident, and should take responsibility for ensuring this happens.</p> <p>Please see below for guidance regarding ‘reasonable attempts’.</p>
<p><b>20(2) As soon as practicable after becoming aware that a notifiable safety incident has occurred a health service body must–</b></p> <p><b>(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.</b></p>	<ul style="list-style-type: none"> <li>● Relevant person(s) should be provided with all reasonable practical and emotional support necessary to help overcome the physical, psychological and emotional impact of the incident, including: <ul style="list-style-type: none"> <li>○ being treated with respect, consideration and empathy</li> <li>○ offered the option of immediate emotional support during the notifications, for example from a family member, a care professional or a trained advocate</li> <li>○ offered access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille, etc.</li> </ul> </li> </ul>

Component of the regulation	What providers could do to meet the requirements of the component
	<ul style="list-style-type: none"> <li>○ providing access to any necessary remedial treatment to minimise or ameliorate the harm caused</li> <li>○ providing the relevant person(s) with information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups, such as Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them deal with the outcome of incident</li> <li>○ arranging for care and treatment be delivered by another professional/team or provider as far as reasonably practicable should relevant persons wish.</li> </ul>
<p><b>20(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person</b></p> <p><b>(6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).</b></p>	<ul style="list-style-type: none"> <li>● The provider must ensure written notification is given to relevant persons in a timely manner following the notification that was given in person. The written notification should contain all the information provided in person including an apology.</li> <li>● A record of this written notification must be kept by the provider, along with any enquiries and investigations and the outcome or results of the enquiries or investigations.</li> <li>● The outcomes or results of any enquiries and investigations should also be provided in writing to the relevant persons, should they wish to receive them.</li> <li>● Any correspondence from relevant person(s) relating to the incident should be responded to in an appropriate and timely manner and a record of communications kept.</li> </ul>
<p><b>20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—</b></p> <p><b>(a) paragraphs (2) to (4) are</b></p>	<ul style="list-style-type: none"> <li>● The provider should make every reasonable effort to contact the relevant person(s) through various communication means. All attempts to contact the relevant person(s) should be documented. If the relevant person declines to contact the provider, their wishes should be respected and a record of this kept.</li> </ul>

Component of the regulation	What providers could do to meet the requirements of the component
<p>not to apply, and</p> <p><b>(b) a written record is to be kept of attempts to contact or to speak to the relevant person.</b></p>	

Relevant legislation	Relevant guidance
<p>Mental Capacity Act 2005  <a href="http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf">http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf</a></p> <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</a></p> <p>Care Quality Commission (Registration Requirements) Regulations 2009  <a href="http://www.legislation.gov.uk/uksi/2009/3112/made">http://www.legislation.gov.uk/uksi/2009/3112/made</a></p>	<p>NHS National Patient Safety Agency, Being Open Framework  <a href="http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726">http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726</a></p> <p>NHS England, Serious Incident Framework (note – due to be updated)  <a href="http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf">http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf</a></p> <p>NHS England Never Events Framework (note – soon to be updated)  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213046/never-events-policy-framework-update-to-policy.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213046/never-events-policy-framework-update-to-policy.pdf</a></p> <p>NHS England Never Events List 2013/14 update  <a href="http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf">http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf</a></p> <p>National Patient Safety Agency, Seven Steps to Patient Safety: Step 4 Promote reporting</p>

Relevant legislation	Relevant guidance
	<p><a href="http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787">http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787</a></p> <p>Care Quality Commission (Registration Requirement) Regulations 2009: Regulations 16 - 18  <a href="http://www.legislation.gov.uk/uksi/2009/3112/made">http://www.legislation.gov.uk/uksi/2009/3112/made</a></p> <p>CQC notifications guidance:</p> <p>NHS providers: <a href="http://www.cqc.org.uk/content/notifications-nhs-trusts">http://www.cqc.org.uk/content/notifications-nhs-trusts</a></p> <p>GP providers: <a href="http://www.cqc.org.uk/content/notifications-gp-providers">http://www.cqc.org.uk/content/notifications-gp-providers</a></p> <p>Other providers: <a href="http://www.cqc.org.uk/content/notifications-non-nhs-trust-providers">http://www.cqc.org.uk/content/notifications-non-nhs-trust-providers</a></p> <p>General medical Council, Good Medical Practice 2001, Guidance on 'duty of candour'  <a href="http://www.gmc-uk.org/publications/24152.asp">http://www.gmc-uk.org/publications/24152.asp</a></p> <p>Gillick competence or Fraser guidelines  <a href="http://www.nspcc.org.uk/Inform/research/briefings/gillick_wda101615.html">http://www.nspcc.org.uk/Inform/research/briefings/gillick_wda101615.html</a></p>

## Consultation questions

1. Is it clear what NHS providers should do to meet the fit and proper person requirement for directors? If not, how could it be made clearer?
2. Is it clear what NHS providers should do to fulfil their duty of candour? If not, how could it be made clearer?
3. Is the format and layout of the guidance easy to follow and understand?
4. Are the links to key legislation and guidance helpful? How could we promote these links better?
5. Is there anything missing from the guidance?
6. Is there anything that should be taken out of the guidance?