

Regulation 5: Fit and proper persons: directors

and

Regulation 20: Duty of candour

Guidance for NHS bodies

November 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.

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Foreword

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 adult 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 and the public across 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. We have published handbooks for providers in each sector, which provide detailed guidance on our new approach to regulating and inspecting 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 persons requirement for directors and the duty of candour – will come into force for ‘NHS bodies’ on 27 November 2014. The term 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 transparent culture that was lacking at Mid Staffordshire NHS Foundation Trust. The failures at Winterbourne View Hospital revealed that there were no levers in the system to hold the ‘controlling mind’ of organisations to account. The fit and proper persons requirement for directors plays a major part in ensuring the accountability of directors of NHS bodies.

It is essential that CQC uses these new powers well to encourage a culture of openness and to hold providers and directors to account.

This guidance on the two new regulations is interim guidance. CQC's new guidance on implementing all the fundamental standards, which will be implemented in April 2015, will replace, in its entirety, the *Guidance about compliance: Essential standards of quality and safety*. It will include guidance for all sectors on the fit and proper persons requirement for directors and the duty of candour for all providers. Our current enforcement policy will also be replaced.

A handwritten signature in black ink, appearing to read 'David Behan', with a large loop at the end of the name.

David Behan
Chief Executive
Care Quality Commission

Introduction

CQC's operating model

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. Our approach in each sector reflects common principles that are intended to ensure that health and adult social care services provide people with safe, effective, compassionate, high-quality care, and to encourage care services to improve.

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. The law states that our guidance on meeting the regulations must be taken into account in relation to all regulatory decisions that CQC makes.

From 27 November 2014, in addition to the existing regulations, NHS bodies, defined as NHS trusts, NHS foundation trusts and any special health authorities carrying on a regulated activity, must meet the new Regulation 5: fit and proper persons: directors and the new Regulation 20: duty of candour.

Throughout the text of this guidance, for ease of language, we refer to Regulation 5 as the fit and proper persons requirement for directors (FPPR). Where we use the term 'provider' in this document it refers to NHS bodies.

Our guidance on meeting the fit and proper person requirement for directors regulation and the duty of candour regulation will be central to both registration and inspection.

1. Registration

As set out in our strategy, we will continue to strengthen our approach to assessing applications for registration with CQC.

From 27 November 2014, when considering new NHS applications for registration, and variation applications made by existing NHS bodies, we will take into account the FPPR and duty of candour. We will use this guidance to do this.

We do not require NHS bodies to notify us when there is a change to the board membership or where there is a merger or acquisition. However, if the newly formed trust is a new legal entity, then the processes described will apply. We will keep this under review.

2. Inspection

In comprehensive inspections (leading 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.

In focused inspections, we either follow up specific concerns from earlier inspections or respond to new, specific, concerning information that has come to our attention. In these circumstances, we assess whether the provider has improved so that it is 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.

We will use our enforcement powers as outlined in our [Judgement Framework](#) and [Enforcement Policy](#) both to protect patients and to hold providers and, in some cases, individuals to account.

Overview of the new regulations

Regulation 5: Fit and proper persons: directors

The aim of this regulation is to ensure that all board level appointments of NHS foundation trusts, NHS trusts and special health authorities¹ carrying on a regulated activity are responsible for the overall quality and safety of that care, and for making sure that care meets the existing regulations and effective requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.² This regulation is about ensuring that those individuals are fit and proper to carry out this important role.

It will apply to directors – by which, we mean executive and non-executive, permanent, interim and associate positions, irrespective of their voting rights. This regulation will not apply to the board of governors of a foundation trust, but will apply to a governor if they are a member of the trust board.

Regulation 5 has been introduced as a direct response to the failings at Winterbourne View Hospital and the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust³, which recommended that a statutory fit and proper persons requirement be imposed on health service bodies.

Health service providers currently have a general obligation to ensure that they only employ individuals who are fit for their role. CQC assesses the fitness of 'corporate' service providers (that is, all providers other than individuals and partnerships) by focusing on the fitness of their 'nominated individuals'. 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 introduction of the fit and proper persons requirement for directors (FPPR) imposes an additional requirement on directors. It will be the ultimate responsibility of the chair of the NHS body to discharge the requirement placed on the provider, to ensure that all directors meet the fitness test and do not meet any of the 'unfit' criteria.

1. NHS foundation trusts, NHS trusts and special health authorities are defined as health service bodies in the regulations.

2. The Health and Social Care Act 2008 (Regulated Activities (Regulations 2014) will come fully into force on 1 April 2015.

3. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC, <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>

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 director's disqualification order) and significantly, excluding 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 providing a service elsewhere which, if provided in England, would be a regulated activity".

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. This will enable valuable information to be shared and will help to avoid imposing additional burden on providers.

To meet the requirements of Regulation 5, a provider has to:

- Provide evidence that appropriate systems and processes are in place to ensure that all new directors and existing directors are, and continue to be, fit, and that no appointments meet any of the unfitness criteria set out in Schedule 4 of the regulation.
 - This means that board directors should be of good character, have the required skills, experience and knowledge and that their health enables them to fulfil the management function. None of the criteria of unfitness should apply, which include bankruptcy, sequestration and insolvency, appearing on barred lists and being prohibited from holding directorships under other laws. Directors should not have been involved or complicit in any serious misconduct, mismanagement or failure of care in carrying on a regulated activity.
- Make every reasonable effort to assure itself about an individual by all means available.
- Make specified information about board directors available to CQC.
- Be aware of the various guidelines available and to have implemented procedures in line with this best practice.
- Where a board member no longer meets the fit and proper persons requirement, inform the regulator in question where the individual is registered with a health care or social care regulator, and take action to ensure the position is held by a person meeting the requirements.

Directors may personally be accused and found guilty by a court of serious misconduct in respect of a range of already prescribed behaviours set out in legislation. Professional regulators may remove an individual from a register for breaches of codes of conduct.

CQC recognises that individuals may be fit for their roles while, collectively, the board demonstrates a lack of fitness. We will address this in the most appropriate, relevant and proportionate approach on a case by case basis.

The provider is responsible for the appointment, management and dismissal of its directors. The provider is responsible, as part of the recruitment and performance management processes, to ensure that FPPR is met. CQC will not undertake a fit and proper persons test of a director or determine what is serious mismanagement or misconduct, but we will examine how the provider has discharged its responsibility under the new regulation.

It is a breach of the regulation to have in place someone who does not satisfy the FPPR. Evidence of this could be if:

- A director is unfit on a 'mandatory' ground, such as a relevant conviction or bankruptcy. The provider will determine this.
- A provider does not have a proper process in place to enable it to make the assessments required by the FPPR.
- On receipt of information about a director's fitness, a decision is reached on the fitness of the director that is not in the range of decisions that a reasonable person would make.

CQC will now be able to take enforcement action for breaches of the fit and proper person requirement, in accordance with our Judgement Framework and Enforcement Policy.

Where a breach is identified, we will use our existing regulatory powers. Breaches of other regulations may give CQC cause to question whether they have resulted from a breach of this regulation.

In response to our consultation on this guidance, people asked for a clearer description of the key terms that are used, and these are given in [appendix A](#).

Our approach to the fit and proper persons requirement for directors

Our approach to FPPR is part of our new inspection approach. CQC will check and monitor the extent to which the provider meets the regulation at the point of registration, during the inspection, on receipt of concerning information and where there is serious a systemic failure of a provider.

During our registration process, we will test out with the provider that they understand the requirements of the regulation and ask them what systems they have in place to ensure that they will be able to meet these requirements.

We will require the chair of the NHS provider to declare that appropriate checks have been undertaken in reaching a judgement that all directors are deemed to be fit and none meet any of the unfit criteria. This will be a self-declaration and we will only follow this up if we have concerns about the recruitment process.

This new requirement will not delay providers' processes for appointing directors, or increase their administrative workload significantly. If we receive concerns about an individual director, we may also ask the provider to check their fitness and provide the same assurance to us.

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 its application.

During the inspection process, we will assess whether the provider is delivering good quality care. The specific key line of enquiry (KLOE) and prompts that are relevant for the FPPR are under the 'well-led' key question, as follows:

- **W3: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?**
 - Prompt: Do leaders have the skills, knowledge, experience and integrity that they need – both when they are appointed and on an ongoing basis?
 - Prompt: Do leaders have the capacity, capability and experience to lead effectively?

Using the 'well-led' key question, CQC will confirm that the provider has undertaken appropriate checks and is satisfied that, on appointment and subsequently, all new and existing directors are of good character and are not unfit. This may involve checking personnel files and records about appraisal rates for directors. The inspection team will want to check providers' awareness of the various guidelines and that they have implemented approaches in line with best practice.

We will report on the FPPR under 'well-led' in our inspection reports at provider level. If we find that providers do not reflect the characteristics of good as described in our handbooks, we will assess whether they require improvement or are inadequate. We will also consider whether a regulation has been breached, including Regulation 5.

Where there is a serious systemic failure of a provider we will carry out a focused inspection, including the FPPR aspects of corporate failure, and will use the evidence of such an inspection to inform our judgements about Regulation 5 and any breaches that may have taken place.

We will not use the fact that a provider is in special measures as evidence or an indication that a director is unfit. However we would, if necessary because of special measures, assess the effectiveness and robustness of the processes for the appointment of directors.

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.

Information received from a member of the public or the provider's staff about an existing board member will be dealt with in line with CQC's [safeguarding](#) and [whistleblowing](#) protocols where relevant. When a concern arises about the fitness of a director, we will follow a clear process explaining to both the individual and the provider what we intend to do. We will manage this in line with information governance requirements.

CQC will convene a panel, led by the Chief Inspector of Hospitals or a person designated by them, to determine whether the information is significant and should be considered by the provider. We will request consent from the director concerned to pass this information to the provider. If we do not gain this consent from the director concerned, CQC will consider whether to share the information, acting in accordance with the Data Protection Act.

The response received will either satisfy the Chief Inspector of Hospitals that due process has been followed or lead to a request for further dialogue with the provider, a follow-up inspection, or regulatory action using CQC's current enforcement policy. CQC will take all circumstances into account when making a decision and would not take action against a provider if we consider it is reasonable for a provider to wait for the decision of a tribunal (such as an employment tribunal) before determining whether a director is unfit. Following this, CQC would then assess whether the provider's judgement is reasonable, taking account of the tribunal's decision.

There are some core public information sources about providers that we believe are relevant for providers to use as part of their FPPR due diligence. We intend to provide some of these on our website, or indicate where they can be found. For example, this includes, but is not limited to, information from public inquiry reports, serious case reviews and Ombudsmen reports as outlined in our guidance.

In all situations, CQC will determine the most appropriate, relevant and proportionate approach to take to meeting this regulation on a case by case basis. These new arrangements will be used to protect people from harm and the risk of

harm. Action taken will be proportionate to the concerns identified and the impact on people who use services.

Where a provider is unable to demonstrate that it has undertaken the appropriate checks in the appointment of its board members, CQC will decide whether or not to take regulatory action, and what action to take. CQC will work alongside the NHS Trust Development Authority and Monitor to ensure that the correct processes are adhered to, that information is shared where appropriate and that enforcement activity is used proportionately.

Providers may appeal to the First-tier Tribunal against a decision by CQC to take enforcement action. The tribunal hears appeals against decisions of the Secretary of State to restrict or bar an individual from working with children or vulnerable adults and decisions to cancel, vary or refuse registration of certain health care, child care and social care provision. Providers may also challenge by way of judicial review if they consider that a decision breaches public law principles such as being unreasonable, irrational and unfair. Judicial review is a procedure in English administrative law by which the courts in England and Wales may be asked to set aside (quash) allegedly unlawful decisions made by a public body, such as government minister, the local council or a statutory tribunal.

As the statutory fit and proper persons requirement for directors is a new regulation, we expect to learn from what we find. We will share our learning from the early stages of implementation and aim to publish this when there is a sufficient body of information available.

This learning will also inform the development of our guidance on meeting the new fundamental standards in all sectors. This guidance on Regulation 5 will be updated and incorporated into our guidance, to be issued before 1 April 2015, on meeting all the fundamental standards.

Regulation 20: Duty of candour

The aim of this regulation is to ensure that health service bodies⁴ are open and transparent with the “relevant person” (as defined in the regulation) when certain incidents occur in relation to the care and treatment provided to people who use services in the carrying on of a regulated activity.

The regulation defines the relevant person as the person using the service and, in certain situations, extend to people acting lawfully on their behalf, for example a person under 16 who is not competent to make decisions about their care and

⁴ Health services bodies are defined in the regulations as NHS trusts, NHS foundation trusts and special health authorities.

treatment, or a person aged 16 or over who lacks the capacity to make decisions about their care and treatment.

If the relevant person cannot be contacted or declines to speak to the representative of the health service body, then the health service body must keep a written record of its attempts to contact or speak to the relevant person.

The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust⁵, which recommended that a statutory duty of candour be imposed on healthcare providers. In interpreting the regulation on the duty of candour, we use the definitions of openness, transparency and candour used by Robert Francis in his report:

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review⁶, including defining a notifiable safety incident to include moderate harm, severe harm, death, and prolonged psychological harm. These definitions are contained within Regulation 20 itself. NHS bodies have been encouraged for some time to voluntarily report moderate incidents.

Most NHS bodies are already subject to a contractual duty of candour under the [NHS Standard Contract](#). Contractual requirements are clearly set out in Standard Condition 35 of the contract. CQC already expects registered providers to meet these requirements, and we include this in our inspection approach as part of the key question “Are services safe?”

Regulation 20 applies to NHS bodies when they are providing care and treatment to people who use services in the carrying on of a regulated activity only.

To meet the requirements of Regulation 20, an NHS body has to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.

5. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC, <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>

6. Sir David Dalton and Prof. Norman Williams, Building a culture of candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid, <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the health service body believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing, and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person.

In response to our consultation on this guidance, people asked for a clearer description of key terms that are used. Where these are not already defined in Regulation 20, these are given in [appendix B](#).

Our approach to the duty of candour

Our approach to the duty of candour is part of our new inspection approach.

During our registration process we will test out with a provider that they understand the requirements of the regulation and ask them what systems they have in place to ensure that they will be able to meet these requirements.

During the inspection process, we will assess whether the provider is delivering good quality care. Two specific key lines of enquiry (KLOEs) under the safe and well-led questions are relevant to the duty of candour:

- **S2: Are lessons learned and improvements made when things go wrong?**
 - Prompt: Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
- **W3: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?**
 - Prompt: Does the culture encourage candour, openness and honesty?

Our handbooks describe what good care looks like in relation to each of the five key questions. Services that are safe ensure that when something goes wrong, people receive a sincere apology and are told about any actions taken to improve

processes to prevent the same thing happening again. In services that are well-led, candour, openness, honesty and transparency and challenges to poor practice are the norm. Leadership at all levels in the organisation is central to ensuring a culture that supports this.

We will report on the duty of candour under the safety key question in our inspection reports at provider level. If we find care that does not reflect the characteristics of good as they are described in our provider handbook, we will assess whether the service 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 a provider is meeting Regulation 20. An internal CQC advisory panel will be set up to support consistency in decision-making and to capture and share learning.

Information received from a member of the public or the provider's staff relating to the statutory duty of candour will be dealt with in line with CQC's [safeguarding](#) and [whistleblowing](#) protocols where relevant.

When we identify a breach of Regulation 20, we will assess the impact on people and decide whether or not to take regulatory action, and what action to take, in accordance with our Judgement Framework and Enforcement Policy.

As the statutory duty of candour is a new regulation, we expect to learn from what we find. This learning will also inform the development of our guidance on meeting the new fundamental standards in all sectors. This guidance on Regulation 20 will be updated and incorporated into our guidance, to be issued before 1 April 2015, on meeting all the fundamental standards.

Our approach to guidance on regulations

We developed this guidance with the help of 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 our guidance that providers must have regard to. For each regulation, we provide links to key legislation and guidance that we will consider when making judgements.

The listed legislation and guidance is not exhaustive. We expect providers to take account of other relevant guidance that is specific to the services they deliver. 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 to decide how to do this.

Guidance for providers

How to meet Regulation 5: Fit and proper persons: directors and Regulation 20: 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>

Regulations 5 and 20 come into force for NHS bodies on 27 November 2014.

Regulation 5: Fit and proper persons: 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.

SCHEDULE 4 Good character and unfit person tests

PART 1 Unfit person test

1. The person is an undischarged bankrupt or a person whose estate has had sequestration awarded in respect of it and who has not been discharged.
2. The person is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order or an order to like effect made in Scotland or Northern Ireland.
3. The person is a person to whom a moratorium period under a debt relief order applies under Part VIIA (debt relief orders) of the Insolvency Act 1986.
4. The person has made a composition or arrangement with, or granted a trust deed for, creditors and not been discharged in respect of it.
5. The person is included in the children's barred list or the adults' barred list maintained under section 2 of the Safeguarding Vulnerable Groups Act 2006, or in any corresponding list maintained under an equivalent enactment in force in Scotland or Northern Ireland.
6. The person is prohibited from holding the relevant office or position, or in the case of an individual from carrying on the regulated activity, by or under any enactment.

PART 2 Good character

7. Whether the person has been convicted in the United Kingdom of any offence or been convicted elsewhere of any offence which, if committed in any part of the United Kingdom, would constitute an offence.
8. Whether the person has been erased, removed or struck-off a register of professionals maintained by a regulator of health care or social work professionals.

SCHEDULE 3: Information Required in Respect of Persons Employed or Appointed for the Purposes of a Regulated Activity

1. Proof of identity including a recent photograph.
2. Where required for the purposes of an exempted question in accordance with section 113A(2)(b) of the Police Act 1997, a copy of a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, the information mentioned in section 30A(3) of the Safeguarding Vulnerable Groups Act 2006 (provision of barring information on request).
3. Where required for the purposes of an exempted question asked for a prescribed purpose under section 113B(2)(b) of the Police Act 1997, a copy of an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.
4. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—
 - (a) health or social care, or
 - (b) children or vulnerable adults.

5. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P's employment in that position ended.
6. In so far as it is reasonably practicable to obtain, satisfactory documentary evidence of any qualification relevant to the duties for which the person is employed or appointed to perform.
7. A full employment history, together with a satisfactory written explanation of any gaps in employment.
8. Satisfactory information about any physical or mental health conditions which are relevant to the person's capability, after reasonable adjustments are made, to properly perform tasks which are intrinsic to their employment or appointment for the purposes of the regulated activity.
9. For the purposes of this Schedule—
 - (a) "the appointed day" means the day on which section 30A of the Safeguarding Vulnerable Groups Act 2006 comes into force;
 - (b) "satisfactory" means satisfactory in the opinion of the Commission;
 - (c) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997.

Summary of the regulation

This regulation applies to health service bodies only, from 27 November 2014. It will be extended to all other providers from 1 April 2015, subject to Parliamentary process and approval. This guidance will be updated and incorporated into our guidance, to be issued before 1 April 2015, on all the new fundamental standards. The intention of this regulation is to ensure that all board level appointments of NHS foundation trusts, NHS trusts and special health authorities carrying on a regulated activity are responsible for the overall quality and safety of that care, and for making sure that care meets the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This regulation is about ensuring that those individuals are fit and proper to carry out this important role.

It will apply to executive and non-executive, permanent, interim and associate positions, irrespective of their voting rights. The regulation applies to the governor(s) of a foundation trust who sit on the trust board as representatives of the board of governors. Any further use of the word 'director' will encompass the above description only. 'Provider' will be used throughout this document to refer to NHS trusts, NHS foundation trusts and special health authorities providing regulated activities.

There is further guidance below about each component of the regulation to which NHS bodies must have regard.

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
5(3)(a) the individual is of good character	<ul style="list-style-type: none"> • Providers must make every effort to ensure that all available information is sought to confirm that the individual is of good character, and have regard to the matters outlined in Schedule 4, Part 2 of the regulations when assessing whether an individual is of good character. Robust systems must be in place to ensure continuous assessment of the temperament, character and empathy of staff. It is not possible to outline every character trait an individual should have but among them we would expect to see that the diligence processes take account of honesty, trust and respect. • 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. • Where, following the application of a robust process, a provider deems the individual suitable despite the individual being convicted of an offence and/or removed from the register of a professional health or social care regulator, the reasons should be recorded and information about the decision should be made available to those that need to be aware. • It is for providers and not CQC to identify that particular directors are fit and proper persons. <p>Note:</p> <ul style="list-style-type: none"> • By “timely” we mean as soon as can be achieved in order to minimise harm or potential harm to people receiving services. We would assess action taken on a case by case basis, but would expect providers to take immediate action to protect people from harm and introduce and complete investigations quickly, evidencing reasons for any delay that any reasonable trust would avoid.
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	<ul style="list-style-type: none"> • 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 who meet the required specification, including any requirements to be registered with a professional regulator. • The provider must 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 must be followed in all cases and relevant records kept.

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
	<ul style="list-style-type: none"> • 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. • There is already a range of good guidance documents for providers that cover value-based recruitment, appraisal and development, and disciplinary actions including dismissal for chief executives, chairs and directors. CQC, the NHS TDA and Monitor will publish a joint document for CEOs and chairs to direct providers to these sources on or after 27 November 2014. • We expect all providers to be aware of the various guidelines and to have implemented procedures in line with this best practice, as well as the seven principles of public life (the Nolan Principles)⁷ and joint guidance from CQC, Monitor and NHS TDA on recruitment, performance management and disciplinary arrangements for CEOs and directors (due to be published on 27 November).
<p>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</p>	<ul style="list-style-type: none"> • People in position of control within health service bodies must be physically and mentally fit. This does not mean that people who have a long-term condition, a disability or mental illness cannot be in such a position. This aspect of the regulation relates to the ability to sustain the management function. • When appointing relevant individuals the provider must have processes for considering a person's physical and mental health in line with the requirements of the role. • Wherever possible, the provider must make reasonable adjustments to enable an individual to carry out the role.

⁷ The 7 principles of Public Life. (The basis of the ethical standards expected of public office holders). Committee on Standards in Public Life, Lord Nolan, 31 May 1995

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
<p>5(3)(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</p>	<ul style="list-style-type: none"> • The provider must have processes in place to assure itself that the individual has not been 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 and making independent enquiries. • 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. • In the case of a director being convicted of breaching a health and safety requirement on the basis of the way the entire management team organised and managed the activities of their organisation, providers are expected to ascertain the role of the individual so that they can make a judgement about whether or not it means they are unfit. Where the evidence demonstrates that the breach is attributable to the individual’s conduct, CQC would expect a provider to find that the individual is unfit. • While CQC will have regard to information on when convictions, bankruptcies or similar matters are to be considered ‘spent’, there is no time limit for considering serious misconduct or responsibility for failure in a previous role. <p>Note:</p> <ul style="list-style-type: none"> • “Serious misconduct or mismanagement” means behaviour that would constitute a breach of any legislation/enactment that CQC deems relevant to meeting these regulations or their component parts. “Serious misconduct” might be expected to include assault, fraud and theft. “Mismanagement” might be expected to include mismanaging funds and/or not adhering to recognised practice, guidance or processes regarding care quality within which the individual is meant to work. These are not exhaustive lists. • “Responsible for, contributed to or facilitated” means that there is evidence that a person has intentionally, or through neglect, behaved in a manner that would be considered to be, or would have led to, serious misconduct or mismanagement.

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
	<ul style="list-style-type: none"> • “Privy to” means that there is evidence that could lead the provider to reasonably conclude that a person was aware of serious misconduct or mismanagement but did not take the appropriate action to ensure it was addressed.
<p>5(3)(e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.</p>	<ul style="list-style-type: none"> • 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). • Providers must seek all available information to assure themselves that directors are not unfit, as defined in Schedule 4 Part 1. Robust systems should be in place to assess directors in relation to bankruptcy, sequestration, insolvency and arrangements with creditors. In addition, providers should establish whether the individual is on the children’s and/or adults’ safeguarding barred list and whether they are prohibited from holding the office in question under other laws such as the Companies Act or Charities Act. • If a provider discovers information that suggests an individual is unfit after they have been appointed to a role, the provider must take appropriate and timely action to investigate and rectify the matter. • Where a provider deems the individual is suitable despite not meeting the characteristics outlined in Schedule 4, Part 1 of these regulations, the reasons must be recorded and information about the decision should be made available to those that need to be aware. <p>Note:</p> <ul style="list-style-type: none"> • Each person will define “appropriate” according to their own particular circumstances. In essence it means suitable or proper for the circumstances. CQC would take into consideration all aspects surrounding decision-making to determine appropriateness. We would expect to see processes in place that include disciplining and dismissing directors where relevant. • By “timely” we mean as soon as can be achieved in order to minimise harm or potential harm to people receiving the service. We would assess action taken on a case by case basis, but would expect providers to take immediate action to protect people from harm and introduce and complete investigations quickly, giving evidence of reasons for any delay which any reasonable person would avoid.

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
<p>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—</p> <p>(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</p> <p>(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</p>	<ul style="list-style-type: none"> • The provider must regularly review the fitness of directors to ensure that they remain fit for the role they are in. The provider must determine how often to review fitness based on the assessed risk to business delivery and/or to the people using the service posed by the individual and/or role. • The provider must have 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 the provider must adhere to these. • The provider must investigate, in a timely manner, any concerns about a person’s fitness or ability to carry out their duties, and where concerns are substantiated, then it must take proportionate, timely action. The provider must demonstrate due diligence in all actions. • Where a person’s fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to people who use the service. • There are some core public information sources about providers that we believe are relevant for providers to use as part of their FPPR due diligence. We intend to provide some of these on our website, or indicate where they can be found. These include the following (this list is not exhaustive): <ul style="list-style-type: none"> ○ Any provider whose registration had been suspended or cancelled due to failings in care in the last five years or longer if the information is available because of previous registration with CQC predecessor bodies. ○ Public inquiry reports about the provider. ○ Information where we are notified about any relevant individuals who have been disqualified from a professional regulatory body. This information would be shared with the individual and the provider in accordance with the Data Protection Act. ○ Serious case reviews relevant to the provider. ○ Homicide investigations for mental health trusts. ○ Criminal prosecutions against providers. ○ Ombudsmen reports relating to providers.

Component of the regulation	Providers must have regard to the following guidance in relation to this component:
	<ul style="list-style-type: none"> We will act in accordance with the Data Protection Act 1998 concerning any information that is classed as “personal data” about an individual within the meaning of the Data Protection Act.

Relevant legislation	Relevant guidance
<p>NHS Provider Licence May 2014 http://www.monitor-nhsft.gov.uk/sites/default/files/publications/Licence%20application%20guidance%20final.pdf</p> <p>Companies Act 2006 http://www.legislation.gov.uk/ukpga/2006/46/part/8/chapter/2</p> <p>The Protection of Freedoms Act 2012 http://www.legislation.gov.uk/uksi/2012/3006/contents/made</p> <p>Safeguarding Vulnerable Adults Group 2006 http://www.legislation.gov.uk/ukpga/2006/47/contents</p> <p>Protection of Freedoms Act 2013 http://www.legislation.gov.uk/ukpga/2012/9/contents/enacted</p>	<p>Professional Standards Authority – standards Nov 2013 http://www.professionalstandards.org.uk/library/document-detail?id=89114436-21e2-47df-b5a0-7d5308b66b8e</p> <p>Charities Commission guidance 2013/2014 http://www.charitycommission.gov.uk/detailed-guidance/</p> <p>Disclosure and Barring identity checking guidance July 2014 https://www.gov.uk/government/publications/dbs-identity-checking-guidelines</p> <p>Disclosure and Barring Service https://www.gov.uk/government/organisations/disclosure-and-barring-service</p> <p>Equality and Human Rights Commission: employment statutory code of practice http://www.equalityhumanrights.com/sites/default/files/documents/EqualityAct/employercode.pdf</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 27 November 2014. It will be extended to all other providers from 1 April 2015, subject to Parliamentary process and approval. This guidance will be updated and incorporated into our guidance, to be issued before 1 April 2015, on all the new fundamental standards.

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other ‘relevant persons’ (people acting lawfully on behalf of them) in general in relation to care and treatment, and specifically when things go wrong with care and treatment, and that they provide them with reasonable support, truthful information and an apology when things go wrong. The regulation applies to NHS bodies when they are carrying on a regulated activity. There is further guidance below about each component of the regulation to which NHS bodies must have regard.

Component of the regulation	Providers must have regard to the following guidance in relation to this component
<p>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.</p>	<p>The Being Open Framework referenced below provides guidance on the action that organisations can take to create a culture that supports staff to act in an open and transparent way. In meeting this component of the regulation, providers must consider the following:</p> <ul style="list-style-type: none"> • There should be a board level commitment to being open and transparent in relation to care and treatment. • The culture of the organisation should encourage candour, openness and honesty at all levels, as an integral part of a culture of safety that supports organisational and personal learning. • The provider should have policies and procedures in place to support a culture of openness and transparency, and ensure these are followed by all staff. • The provider should take action to tackle bullying, harassment and undermining in relation to duty of candour, and must investigate any instances where a member of staff may have obstructed another in exercising their duty of candour. • The provider should have a system in place to identify and deal with possible breaches of the professional duty of candour by staff who are professionally registered, including the obstruction of another in their professional duty of candour. This is likely to include an investigation and escalation process that may lead to referral to their professional regulator or other relevant body. • The provider should make all reasonable efforts to ensure that staff operating at all levels within the organisation operate within a culture of openness and transparency, understand their individual responsibilities in relation to the duty of candour, and are supported to be open and honest with patients and apologise when things go wrong. • Staff should receive appropriate training, and there should be arrangements in place to support staff who are involved in a notifiable safety incident. • In cases where a relevant person informs the provider that something untoward has happened, the provider should treat the allegation seriously, immediately consider whether this is a notifiable safety incident and take appropriate action.

Component of the regulation	Providers must have regard to the following guidance in relation to this component
<p>20(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</p> <p>20(3) The notification to be given under paragraph (2)(a) must—</p> <p>(a) be given in person by one or more representatives of the health service body,</p> <p>(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,</p> <p>(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,</p> <p>(d) include an apology, and</p> <p>(e) be recorded in a written record which is kept securely by the health service body.</p>	<ul style="list-style-type: none"> • When a notifiable safety incident has occurred, the relevant person must be informed as soon as reasonably practicable after the incident has been identified. The NHS Standard Contract requires that the notification must be within at most 10 working days of the incident being reported to local systems, and sooner where possible. • All staff working within a provider must have responsibility to adhere to that organisation’s policies and procedures around duty of candour, regardless of seniority or permanency. • The Being Open Framework referenced below provides guidance on how to ensure good communication with the patient, their families and carers. • Regulation 20 defines what constitutes a notifiable safety incident. It includes incidents that could result in, or appear to have resulted in, the death of the person using the service or severe harm, moderate harm, or prolonged psychological harm. These terms are defined in the regulation (see above). • Where the degree of harm is not yet clear but may fall into the above categories, the relevant person must be informed of the notifiable safety incident in line with the requirements of the regulation. • The NHS body is not required by the regulation to inform a person using the service when a ‘near miss’ has occurred, and the incident has resulted in no harm to that person. • There must be appropriate arrangements place to notify the person using the service who is affected by an incident if they are 16 years and over and lack capacity to make a decision regarding their care or treatment (as determined in accordance with sections 2 and 3 of the 2005 Mental Capacity Act), including ensuring that a person acting lawfully on their behalf is notified as the relevant person. • A person acting lawfully on behalf of the person using the service must be notified as the relevant person where the person using the service is under 16 and not competent to make a decision regarding their care or treatment. • A person acting lawfully on behalf of the person using the service must be notified as the relevant person, upon the death of the person using the service.

Component of the regulation	Providers must have regard to the following guidance in relation to this component
	<ul style="list-style-type: none"> • Other than the situations outlined above, information should only be disclosed to family members or carers where the person using the service has given their express or implied consent. • A step-by-step account of all relevant facts known about the incident at the time must be given, in person, by one or more appropriate representatives of the provider. This should include as much or as little information as the relevant person wants to hear, be jargon free and explain any complicated terms. • The account of the facts must be given in a manner that the relevant person can understand. For example, the provider should consider whether interpreters, advocates, communication aids etc. should be used, while being conscious of any potential breaches of confidentiality in doing so. • The provider must also explain to the relevant person what further enquires they will make. • The provider must ensure that a meaningful apology is given, in person, by one or more appropriate representatives of the provider to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret. The NHS Litigation Authority has produced guidance on making an apology (see below), which states that saying sorry is not an admission of legal liability. • In making a decision about who is most appropriate to provide the notification and/or apology, the provider should consider seniority, relationship to the person using the service, and experience and expertise in the type of notifiable incident that has occurred. The Being Open Framework referenced below provides guidance on this. <p>Note:</p> <ul style="list-style-type: none"> • On occasion, a provider may discover a notifiable safety incident that happened some time ago, or one that relates to care that was delivered by another provider. The provider that discovers the incident should work with others who are responsible for notifying the relevant person of the incident. <p>Please see below for guidance regarding “reasonable attempts”.</p>

Component of the regulation	Providers must have regard to the following guidance in relation to this component
<p>20(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—</p> <p>(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.</p>	<ul style="list-style-type: none"> • The provider must give the relevant person all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident. This could include all or some of the following: <ul style="list-style-type: none"> ○ Treating them with respect, consideration and empathy. ○ Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate. ○ Offering access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille etc. ○ Providing access to any necessary treatment and care to recover from or minimise the harm caused where appropriate. ○ Providing the relevant person with details of specialist independent sources of practical advice and support or emotional support/counselling. ○ Providing the relevant person with information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups, for example Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them deal with the outcome of the incident. ○ Arranging for care and treatment to be delivered by another professional, team or provider if this is possible, should the relevant person wish. ○ Providing support to access its complaints procedure. ○ The Being Open Framework referenced below provides guidance on how to support patients, their families and carers when a patient safety incident has occurred.
<p>20(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—</p>	<ul style="list-style-type: none"> • The provider must ensure that written notification is given to the relevant person following the notification that was given in person, even though enquiries may not yet be complete. • The written notification must contain all the information that was provided in person including an apology, as well as the results of any enquiries that have been made since the notification in person.

Component of the regulation	Providers must have regard to the following guidance in relation to this component
<p>(a) the information provided under paragraph (3)(b),</p> <p>(b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),</p> <p>(c) the results of any further enquiries into the incident, and</p> <p>(d) an apology.</p>	<ul style="list-style-type: none"> • The outcomes or results of any further enquiries and investigations must also be provided in writing to the relevant person through further written notifications, should they wish to receive them.
<p>20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body–</p> <p>(a) paragraphs (2) to (4) are not to apply, and</p> <p>(b) a written record is to be kept of attempts to contact or to speak to the relevant person.</p>	<ul style="list-style-type: none"> • The provider must make every reasonable attempt to contact the relevant person through all available communication means. All attempts to contact the relevant person must be documented. • If the relevant person does not wish to communicate with the provider, their wishes must be respected and a record of this must be kept. • If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.
<p>(6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).</p>	<ul style="list-style-type: none"> • A record of the written notification must be kept by the provider, along with any enquiries and investigations and the outcome or results of the enquiries or investigations. • Any correspondence from the relevant person relating to the incident must be responded to in an appropriate manner and a record of communications should be kept.

Relevant legislation	Relevant guidance
<p>Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf</p> <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</p> <p>Care Quality Commission (Registration Requirements) Regulations 2009 http://www.legislation.gov.uk/uksi/2009/3112/made</p>	<p>The following guidance is relevant to Regulation 20, and should be taken into account by providers:</p> <p>NHS Standard Contract 2014/15: Updated Technical Guidance (Appendix 5: Contractual requirements relating to Duty of Candour) http://www.england.nhs.uk/wp-content/uploads/2014/02/tech-guide-240214.pdf</p> <p>NHS National Patient Safety Agency, Being Open Framework provides guidance on communicating about patient safety incidents with patients, families and carers http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726</p> <p>Definitions of levels of harm included in: National Patient Safety Agency, Seven Steps to Patient Safety http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787</p> <p>Care Quality Commission (Registration Requirement) Regulations 2009: Regulations 16 – 18 outline the notifications required by CQC http://www.legislation.gov.uk/uksi/2009/3112/made</p> <p>NHS Litigation Authority, Saying Sorry http://www.nhs.uk/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf</p> <p>General medical Council, Good Medical Practice 2001, Guidance on ‘duty of candour’ http://www.gmc-uk.org/publications/24152.asp</p>

Appendix A: Description of terms used in our guidance about the fit and proper requirement for directors

Fit and proper person

The purpose of the fit and proper person requirement for directors aims to ensure that NHS trusts are not managed or controlled by individuals who present an unacceptable risk either to the organisation or to people receiving a service. The regulation is about ensuring that directors are fit and proper to assume responsibility for the overall quality and safety of care delivered.

CQC does not offer a clearance service for NHS trusts to confirm that particular individuals are fit and proper persons. CQC will look at the extent to which the provider meets the regulation by checking that the provider has made every reasonable effort to assure themselves of the suitability of their directors and that consequently those directors are fit and proper persons.

A fit and proper person 'test' has been in use across other bodies and sectors for some years, such as HMRC in the management of charities and the aviation sector. It has the same purpose which is to prevent people from being appointed or remaining in a position of authority or control when they are not fit to do so.

Good character

Character determines the response to any given situation and good character will ensure that the response is the correct one, regardless of the circumstances and within agreed processes and systems. It is not possible to outline every character trait that an individual should have. However, among them we would expect to see that the diligence processes take account of honesty, trust and respect.

Individuals should not have been complicit with significant care failures and none of the definitions of unfitness should apply to that individual. These include the appearance of the individual on barred lists of the Safeguarding Vulnerable Groups Act 2006, and/or any decisions made by any professional regulatory bodies that have resulted in removal from their registers. CQC will have regard to information on when convictions, bankruptcies or similar matters are to be considered 'spent'.

A caring and compassionate nature

Caring is one of CQC's key questions against which we rate and we expect this attribute to be at the core of those delivering health care. During inspections we explore whether staff are caring towards people receiving services and whether they are treated with compassion. One way of doing this is by asking people receiving services how they feel when they are being treated or spoken with by staff in that service, and asking staff how senior leaders set the tone and culture of the organisation in this respect.

Serious misconduct and mismanagement

This is determined by the provider through checks at the appointment stage or afterwards and CQC is not involved in this process. In response to comments received, we have fleshed out what serious misconduct might include. We would suggest this could include assault, fraud, theft, breaches of health and safety regulations, intoxication while on duty, any breach of confidentiality, disobedience of lawful and reasonable instruction, and disrespect in the workplace. This is not an exhaustive list.

Mismanagement would indicate, for example, that a director has dealt with responsibilities badly or carelessly, by mismanaging funds and/or not adhering to recognised practice, or following guidance, internal or external processes within which he or she is meant to work.

As stated in the guidance, a director must not have been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement in carrying on a regulated activity. Individuals should not have been complicit with significant care failures.

Physically and mentally fit

People in a position of control within NHS trusts must be physically and mentally fit. This does not mean that people who have a long term condition, a disability or mental illness cannot be in such a position.

This aspect of the regulation relates to the ability to sustain the management function.

Reasonable and what one deems reasonable

Each person will define reasonable according to their own particular circumstances. In essence it means 'fair' and with 'sound judgement', and CQC would take into consideration all aspects surrounding decision-making to determine reasonableness.

Director

This includes executive directors, non-executive directors and associate directors who are members of the board, irrespective of their voting rights. Directors may be existing, interim or permanent. Generally an executive director of an NHS trust holds a position on the board of the NHS organisation, so as well as being in control of a department or directorate, they may also have decision-making responsibility within the organisation.

Non-executive directors sit on an NHS organisation's board but do not directly manage either a financial function or a department or directorate.

How values-based recruitment can help meet the requirement

An organisation must determine its values and recruit against them. Values embedded within all aspects of recruitment could, for example, make it more difficult for people to be untruthful on their application form as the systems in place would carry out all necessary checks. This could help an organisation to recruit 'honest' staff who share the values of the organisation.

Appendix B: Description of terms used in our guidance about duty of candour

Cancelling treatment

Where planned treatment is not carried out as a direct result of the notifiable safety incident.

Reasonable amount of time

A reasonable amount of time is not defined in the regulation. However, the NHS Standard Contract requires that the notification must be within at most 10 working days of the incident being reported to local systems, and sooner where possible.

Appropriate written records

Records are complete, legible, accurate and up to date. Every effort must be made to ensure records are updated without any delays.

Act in an open and transparent way

Clear, honest and effective communication with patients, their families and carers throughout their care and treatment, including when things go wrong, in line with the definitions below.

We will use the following definitions of openness, transparency and candour used by Robert Francis in his report:

- **Openness**

Enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

- **Transparency**

Allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

- **Candour**

Any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

How to contact us

Call us on: **03000 616161**

Email us at: enquiries@cqc.org.uk

Look at our website: www.cqc.org.uk

Write to us at: **Care Quality Commission
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