

Report for:	Adult Social Services Quality Assurance Board 16 June 2015	Item Number:	3.1
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Title:	Fundamental Standards
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Lead Officer:	Helen Constantine - Head of Business Management, Adult Social Services
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Report Author:	Rebecca Waggott, Business Improvement Officer, Adult Social Services
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1. Introduction

- 1.1 In November 2014, the Government published the Fundamental Standards regulations. The regulations are a key part of the changes the Care Quality Commission (CQC) has made to the way it inspects health and care services.
- 1.2 The Fundamental Standards replace the 16 'essential standards' of quality and safety which were previously used to assess whether care had fallen below acceptable standards.
- 1.3 All registered providers must show that they are meeting these regulatory requirements in order to register with CQC and then continue to deliver regulated services.
- 1.4 The Fundamental Standards include two new regulations – the duty of candour and the fit and proper person requirement for directors – as a direct response to the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. These regulations are designed to ensure that providers have robust systems in place to be open and honest when things go wrong and to hold directors to account when care fails people.
- 1.5 This briefing outlines the new Fundamental Standards and the associated enforcement policy, as well as key aspects of the new regulations relating to the duty of candour and the fit and proper persons requirement for directors.

2. The fundamental standards

- 2.1 The [Fundamental Standards](#) are the standards below which a person's care must never fall. The Fundamental Standards are:
 - care and treatment must be appropriate and reflect service users' needs and preferences.
 - service users must be treated with dignity and respect.
 - care and treatment must only be provided with consent.
 - care and treatment must be provided in a safe way.
 - service users must be protected from abuse and improper treatment.
 - service users' nutritional and hydration needs must be met.



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- all premises and equipment used must be clean, secure, suitable and used properly.
- complaints must be appropriately investigated and appropriate action taken in response.
- systems and processes must be established to ensure compliance with the fundamental standards.
- sufficient numbers of suitably qualified, competent, skilled and experienced staff must be deployed.
- persons employed must be of good character, have the necessary qualifications, skills and experience, and be able to perform the work for which they are employed (fit and proper persons requirement).
- registered persons must be open and transparent with service users about their care and treatment (the duty of candour).

- 2.2 The new CQC inspection model for adult social care looks at five key questions: whether the service is safe; effective; caring; responsive to people's needs; and well-led. This enables inspection teams to identify good care.
- 2.3 When CQC inspectors identify poor care, the newly-established [regulations guidance](#) helps to determine whether there is a breach in the new regulations and if so, what action to take. In some cases, this will result in CQC using their powers to prosecute.
- 2.4 A new [enforcement policy](#) explains CQC's approach to taking action where poor care is identified, or where registered providers and managers do not meet the standards required in the regulations. The enforcement policy will be used to protect people who use services and to hold providers and, in some cases, individuals to account.
- 2.5 Enforcement action will often be used at the same time as placing a service in [special measures](#). If a service is rated inadequate overall, it will be placed straight in special measures and inspected again within six months. If a service is rated inadequate for one of the five key questions it will usually have six months to improve. If insufficient improvements are made, CQC will take enforcement action to either cancel the provider's registration or vary the terms of registration.
- 2.6 The new fundamental standards require that systems and processes are in place to ensure compliance with the fundamental standards. This is set out in Regulation 17: Good governance, which aims to make sure that providers have systems and processes that ensure that they are able to meet the requirements in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Regulations 4 to 20A).
- 2.7 To meet this regulation, providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating to the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.

3. Regulation 20: duty of candour



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- 3.1 From 1 April 2015, all registered providers must meet the new [Regulation 20: Duty of candour](#). Meeting the duty of candour regulation will be central to both registration and inspection.
- 3.2 The aim of this regulation is to make sure that providers are open and transparent with people who use services and other 'relevant persons' in relation to care and treatment.
- 3.3 It sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, giving reasonable support, providing truthful information and an apology.
- 3.4 The regulation requires that providers promote a culture that encourages candour, openness and honesty at all levels. This should be an integral part of a culture of safety that supports organisational and personal learning. There should also be a commitment to being open and transparent at board level, or its equivalent such as a governing body.
- 3.5 In interpreting the duty of candour regulation, CQC use the following definitions used in the Francis Inquiry:
 - **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.
- 3.6 Paragraph 9 of Regulation 20 defines what constitutes a notifiable safety incident, including the thresholds that trigger the duty of candour. The harm thresholds for adult social care are consistent with thresholds for the existing CQC notification system for reporting deaths and serious injuries.
- 3.7 To meet the requirements of Regulation 20, a registered provider 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.
 - 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 provider'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 provider believes are appropriate.
 - Offer an apology.
 - Follow up the apology 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.



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- 3.8 During the registration process, CQC will test with a provider that they understand the requirements of Regulation 20 and ask what systems they have in place to ensure they meet the requirements. This would include, but is not limited to, training for all staff on communicating with people who use services about notifiable safety incidents; incident reporting forms which support the recording of a duty of candour notification; support for staff when they notify people who use services when something has gone wrong; oversight and assurance.
- 3.9 During the inspection process, CQC will look at the following KLOEs under the safe and well-led questions which are relevant to the duty of candour in the inspection of all providers:
- Prompt: Are there plans for responding to any emergencies or untoward events, and are these understood by all staff?
 - Prompt: Is there an emphasis on support, fairness, transparency and an open culture?
- 3.10 Regulation 20 applies to organisations rather than individual members of staff. It requires the provider to make sure that all their staff, regardless of seniority or permanency, understand the organisation's responsibility to be open and transparent in their communication with relevant persons in relation to a notifiable safety incident. It requires the provider to understand their own role, and to put policy and processes in place to ensure they are supported to deliver it.
- 3.11 Providers should also take action to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in exercising their duty of candour.
- 3.12 When CQC identify a breach of Regulation 20, they will assess the impact on people and decide whether or not to take regulatory action, and what action to take, in accordance with the [enforcement policy](#).
- 3.13 Illustrative examples of incidents that trigger the thresholds for duty of candour are set out in Appendix 1.
- 4. Regulation 5: Fit and proper persons: directors**
- 4.1 From 1 April 2015, all registered providers must meet the new [Regulation 5: Fit and proper persons: directors](#). Meeting the fit and proper person requirement for directors (FPPR) regulation will be central to both registration and inspection.
- 4.2 CQC is currently exploring mechanisms for how they can inspect and report on this regulation for organisations other than NHS bodies.
- 4.3 The aim of this regulation is to make sure that all directors of registered providers are responsible for the overall quality and safety of 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. This regulation is about ensuring that those individuals are fit and proper to carry out this important role.
- 4.4 The provider will have to ensure that it complies with the regulations by not having an unfit director in place. CQC will not expect local authority providers to apply the requirement to elected members as they are accountable through a different route. It will apply to the



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relevant management level local authority officers who are responsible for controlling and supervising the service.

- 4.5 It will be the ultimate responsibility of the chair of the provider 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.
- 4.6 In addition to the usual requirements of good character, health, qualifications, skills and experience, the regulation extends to 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".
- 4.7 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, Part 2 of the regulations.
This means that 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 directors available to CQC.
 - Be aware of the various guidelines available and to have implemented procedures in line with this best practice.
 - Where a Director no longer meets the fit and proper persons requirement and that individual is registered with a health or social care professional regulator, inform the regulator in question and take action to ensure the position is held by a person meeting the requirements.
- 4.8 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 the FPPR is met. CQC will not undertake a FPPR test of a director or determine what is serious mismanagement or misconduct, but they will examine how the provider has discharged its responsibility under the new regulation.
- 4.9 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.



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- 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.

- 4.10 From April 2015, CQC has been able to take enforcement action for breaches of the FPPR, in accordance with their [enforcement policy](#).
- 4.11 CQC will check and monitor the extent to which the provider meets the regulation at the point of registration, if concerns are identified during an inspection, on receipt of concerning information and where there is a serious failure of a provider.
- 4.12 During the registration process, CQC will test with the provider that they understand the requirements of the regulation and ask them what systems they have in place to ensure they will be able to meet these requirements.
- 4.13 CQC are currently exploring mechanisms for inspecting and reporting on FFPR for organisations other than NHS bodies. Arrangements are expected to be in place later in 2015.
- 4.14 In the interim, where concerns are raised during a CQC inspection, which may raise issues about the provider's application of the FPPR, the inspector will establish if the concerns relate to a director and their delivery in the quality and safety of care.
- 4.15 Where there is a serious failure of quality and safety of care of a provider, CQC will carry out a focused inspection including assessment of the FFPR aspects concerning recruitment and management of directors. This evidence will inform CQC's judgements about Regulation 5 and any breaches that may have taken place. Action taken will be proportionate to the concerns identified and the impact on people who use services.
- 4.16 There are some core public information sources about providers that CQC believe are relevant for providers to use as part of their FFPR due diligence, e.g. information from public inquiry reports, serious case reviews and Ombudsmen reports in our guidance.
- 4.17 As this is a new regulation, CQC expects to learn from what they find and will publish learning from the early stages of implementation once a sufficient body of information is available.

5. Key implications of the changes

- 5.1 It is important that CQC registered providers and registered managers are aware of the introduction of the Fundamental Standards as a replacement for the 16 'essential standards' of quality and safety. Local governance arrangements will now need to be framed in terms of the new Fundamental Standards and ensure compliance with these standards.
- 5.2 It is crucial that governance arrangements are in place to monitor compliance with the Fundamental Standards as this is a legal requirement. Registered services need to continue to use assurance and auditing systems to monitor and drive improvement in quality and safety. Registered services have also completed PIR assessments against the CQC Key Lines of Enquiry and must now progress the identified areas for improvement.



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- 5.3 The new regulations and enforcement policy mean that providers may be prosecuted and could face an unlimited fine for breaching the Fundamental Standards. This will make it even more important to monitor both internal and external service providers' compliance with the Fundamental Standards in order to prevent service failings, so that service continuity can be maintained and financial risk managed.
- 5.4 It is important that registered providers and managers understand the new requirements of Regulation 20: Duty of candour, and staff training is in place around communicating with people who use services about notifiable safety incidents.
- 5.5 Registered providers must also be aware of the requirements associated with Regulation 5: fit and proper persons: directors.



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Appendix 1: CQC adult social care illustrative examples of incidents that trigger duty of candour thresholds

Examples	Interpretation
<p>An OT completed an assessment with a care home resident whose mobility was deteriorating. The OT advised that grab rails were needed in a person's bathroom before it was safe for them to use the bath and that in the meantime staff should assist the person to have a strip wash each morning. The manager failed to update the person's care plan or inform the care staff of this change, so staff supported the person to take a bath the following morning as usual. The person slipped when getting out of the bath and sustained a broken arm. The arm was put in a plaster cast and the person needed full assistance for all aspects of their care for 6 weeks until the cast was removed. The person made a full recovery.</p>	<p>This would be an example of an incident leading to a service user requiring further treatment to prevent the service user experiencing prolonged pain (regulation 20 (9)(b)(ii))</p>
<p>A new member of staff on induction was shadowing another care worker delivering care to a person who needed to be hoisted. Two trained members of staff were required to operate the hoist safely and the new member of staff had not yet been trained in moving and handling. The new care worker was asked to assist with the manoeuvre and did not attach one of the loops of the sling to the hoist properly. As a result, during the manoeuvre, the person slid out of the sling and onto the floor. The person sustained a broken hip requiring emergency surgery.</p>	<p>This would be an example of an incident leading to a service user experiencing changes to the structure to the body (regulation 20 (9) (b) (iii))</p>
<p>A person with a learning disability was prescribed antipsychotic medicines. They were assessed as needing full staff support in the management of their medicines. Over a period of two weeks they became increasingly anxious and distressed. When the person's medicines were checked it was discovered that their antipsychotic medicines had not been ordered the previous month and did not show on the MAR chart. This was because the correct procedure for ordering and the checking in of medicines had not been followed and the error had gone unnoticed for 18 days. This resulted in a prolonged deterioration in the person's mental health for more than 28 days.</p>	<p>This would be an example of an incident leading to prolonged psychological harm (regulation 20(9)(a)(iv))</p>