



Department
of Health

Requirements for registration with the Care Quality Commission

Response to consultations on fundamental standards, the Duty of Candour and the fit and proper persons requirement for directors

Title: Requirements for registration with the Care Quality Commission
Author: Quality Regulation Branch, Department of Health. 17160
Document Purpose: Policy
Publication date: July 2014
Target audience: Health and social care providers and stakeholders
Contact details: Quality Regulation Team 2E11 Quarry House Quarry Hill Leeds LS72UE

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Requirements for registration with the Care Quality Commission

Response to consultations on fundamental standards, the Duty of Candour and the fit and proper persons requirement for directors

Prepared by the Department of Health

Contents

Foreword.....	5
Introduction	7
Part 1: Fundamental standards	9
Part 2: Fit and proper persons requirement.....	23
Part 3: The Statutory Duty of Candour.....	29

Foreword

The publication of the Francis Inquiry report instigated a great many changes to the health and adult social care system. Our aim throughout has been to give people the confidence that they will be given the best and safest care, that those who provide care are up to the job and, where they are not, that improvements will be made and providers held to account for poor standards of care.

We know that throughout the health and care sector people do receive safe, effective and compassionate care delivered by dedicated staff. But we also know that regulatory standards provide an important protection for people, as well as a means for addressing poor care where it does occur. The Care Quality Commission (CQC) is overhauling its approach to inspection, introducing new specialist inspection teams, targeting its regulatory activity at those providers where there is the greatest cause for concern and looking at the performance of providers over and above compliance with legal requirements. The changes to the regulatory framework that the Department of Health is making will support CQC to be a more effective regulator, that is better able to protect patients and service users from the risks associated with poor health and adult social care.

The Francis Inquiry made a number of recommendations about the standards that should be met by organisations that provide health and social care services. It recommended the introduction of new fundamental standards below which care should never fall, covering those basic things that everyone agrees are important. It also recommended that a culture of candour needs to be encouraged, and a Duty of Candour established. The Department of Health's review of events at Winterbourne View recommended steps to increase the corporate accountability of organisations that deliver care. We outlined our plans to take forward all of these measures in our full response to the Francis Inquiry, *Hard Truths*.

I am pleased to see that many of you have taken an active role in helping us develop and finalise our proposals through the consultations and events that have been held over the last year. I thank everyone who has taken the time to contribute their views, and hope you share my belief that these changes will lead to real improvements in the quality and safety of care.

A handwritten signature in black ink, appearing to read 'Norman Lamb', with a horizontal line underneath.

Norman Lamb
Minister for Care and Support

Introduction

This document sets out our approach to introducing new fundamental standards, the Duty of Candour and the fit and proper persons requirement. It provides a combined response to three separate consultations recently carried out by the Department of Health:

- [Introducing fundamental standards: consultation on proposals to change CQC registration regulations](#)
- [Consultation on the fit and proper persons regulations](#)
- [Introducing the statutory Duty of Candour](#)

Following these consultations, we have decided to introduce these measures in the following sequence:

- The Duty of Candour will be introduced for NHS bodies only in October 2014
- The fit and proper persons requirement will be introduced for NHS bodies only in October 2014
- The fundamental standards will be introduced for all providers in April 2015
- The Duty of Candour and fit and proper persons requirements will be extended to all CQC-registered providers from April 2015

Our plans to introduce fundamental standards, the Duty of Candour and the fit and proper person requirement as Care Quality Commission (CQC) registration requirements were set out in *Patients First and Foremost - The Initial Government Response to the Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry*, published in March 2013¹.

They are part of a wide-ranging set of changes designed to improve the regulation of health and adult social care providers, and provide assurance that service users receive safe, quality care and treatment.

These plans stem from a number of recommendations arising from several inquiries, reviews, consultations and policy initiatives. These include:

- The Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry);²
- Transforming care: A national response to Winterbourne View Hospital³;

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

² <http://www.midstaffspublicinquiry.com/>

³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213215/final-report.pdf

- A promise to learn – a commitment to act: Improving the safety of patients in England⁴; and
- Healthy Living and Social Care theme of the Red Tape Challenge⁵.

Each proposal has been subject to further review and consultation, and *Hard Truths*⁶, the full Government response to the Francis Inquiry, set out in more detail the rationale and intentions behind the proposals.

Approach to commencement and implementation of the regulations

Our decision to implement these measures in stages has been made in order to give both providers and the regulator time to prepare for the introduction of the new measures.

The regulations in Annex A include the fundamental standards, the Duty of Candour for NHS organisations, and the Fit and Proper Persons requirement for NHS organisations. We are laying these regulations before Parliament, where they will be considered by both the House of Commons and the House of Lord. A subsequent set of regulations will be laid later in the year that will introduce the Duty of Candour and the Fit and Proper Persons requirement for all other registered providers.

The fit and proper person requirement and the Duty of Candour will commence for NHS bodies on 1st October 2014, or as soon as is possible following this, subject to Parliamentary timetables.

The fundamental standards will commence for all providers in April 2015, and at the same time, we will extend the fit and proper person requirement and the Duty of Candour so they also cover all providers from that point.

This document is in three parts. Part one covers the fundamental standards. Part two covers the fit and proper person requirement and part three the Duty of Candour. Annex A contains the regulations that we are laying before Parliament to implement these changes. Annexes B, C and D contain more information about the consultation responses.

⁴ <https://www.gov.uk/government/publications/berwick-review-into-patient-safety>

⁵ <http://www.redtapechallenge.cabinetoffice.gov.uk/themehome/healthy-living-and-social-care-2/>

⁶ <https://www.gov.uk/government/publications/mid-staffordshire-nhs-ft-public-inquiry-government-response>

Part 1: Fundamental standards

In the summer of 2013 CQC published a consultation on its new approach to the regulation of health and adult social care providers in England - *A New Start - consultation on changes to the way CQC regulates, inspects and monitors care*. This set out a proposal for a set of fundamental standards of care to be included as requirements for registration with CQC.

In January 2014, the Department of Health published a further consultation, *Introducing Fundamental Standards*⁷. This built on CQC's consultation and set out planned amendments to CQC's registration requirements, in order to introduce fundamental standards of care. In this consultation we invited comments about draft regulations which would apply to all providers registered with CQC.

This part of the document summarises the issues raised in that consultation and sets out the changes we have made in response.

Purpose of these changes

Our aim in the new set of regulations is to set out those requirements that all health and adult social care providers must always meet. Our consultation document set out four broad aims. They were:

a) To introduce fundamental standards

The Francis Inquiry recommended the introduction of new fundamental standards of safety and quality below which care should never fall. The Department committed to incorporate these into the requirements for registering with CQC.

The fundamental standards are intended to be common sense statements that describe the basic requirements that providers should always meet, and set out the outcomes that patients or care service users should always expect to receive. All providers registered with CQC will have to meet the fundamental standards.

b) To make regulations more effective and improve enforcement against them

Introducing fundamental standards provides us with an opportunity to improve the existing registration requirements by making them clearer for providers.

The existing registration requirements were brought in to force in 2010 and set out 16 essential standards of quality and safety that all providers registered with CQC have to meet. The Francis Inquiry noted that:

⁷ <https://www.gov.uk/government/consultations/fundamental-standards-for-health-and-social-care-providers>

“the structure under which CQC is required to work is over-bureaucratic and does not separate clearly what is absolutely essential from that which is merely desirable.”⁸

It also criticised the existing requirements for a “*lack of clarity*”⁹, and recommended that fundamental standards should be introduced as registration requirements, and that compliance with these should be monitored by CQC.

We have addressed this lack of clarity by redrafting the registration requirements as clear outcomes that providers need to meet, and that form the core of a good service.

This means it should be easier for people to judge what must be done to meet the standards, and will also allow CQC to take effective and timely enforcement action where it identifies poor care.

Under the existing regulations CQC is required to issue a warning notice explaining what the provider has done wrong and giving them time to rectify the issue before it can bring a prosecution against a provider for failing to meet the registration requirements. This has made it difficult for CQC to prosecute providers even where the seriousness of the breach would warrant such action. As a result, CQC can be prevented from taking the most appropriate course of enforcement action, and providers may not always be fully held to account.

Revising the requirements to make them clearer will mean that in those cases serious enough to warrant prosecution, CQC will not need to issue a warning notice before bringing a prosecution. This addresses another recommendation from the Francis Inquiry - that the regulations should be clearer and that stronger enforcement action should be available where necessary.

c) To be outcome focused

If the intended outcomes are clearer, it will be simpler for providers to understand how to meet them, leading to safer care for patients and service users.

In the regulations, the main requirement is that the outcomes are met, and providers will need to be able to demonstrate that they are meeting these outcomes. Each outcome is supported by a number of other requirements – these provide CQC with a means of taking appropriate enforcement action where providers are found to be delivering poor care, but are not yet breaching the fundamental standard itself.

d) To reduce the burden on business

The new regulations should be easier for providers to understand, and we believe that this will help reduce the burden associated with the regulations. We have made the regulations easier to understand in two ways – firstly by clearly stating the outcome we expect to see, and secondly by removing some of the detailed references to specific actions that providers are currently required to take to meet the requirements.

⁸ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 2: Analysis of evidence and lessons learned (part 2), paragraph 11.258

⁹ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 2: Analysis of evidence and lessons learned (part 2), paragraph 11.254

Our impact assessment for the changes, which is available alongside this document, goes into more detail on the reduction of burdens.

Following the suggestions received through consultation, we have made changes to the drafting of the regulations. These changes are explained in the rest of this document.

Issues raised and our response

The consultation asked the following questions:

- i. Do the fundamental standards make clear the kinds of outcomes we expect providers to meet or avoid?
- ii. Do you think the fundamental standards reflect the policy aims we have set out for the fundamental standards?
- iii. Are the fundamental standards clear enough that they could be used as a basis for enforcement action?
- iv. Regulation 17 sets out which of the regulations are offences for which CQC will still need to issue a pre-prosecution notice, alongside those that could be prosecuted immediately. Do you think this split reflects our intention that only breaches related to a harmful outcome can be prosecuted without a pre-prosecution notice being issued in advance?
- v. Do you agree that CQC's guidance about complying with these regulations should set out criteria for cases in which it would consider bringing a prosecution?
- vi. Do you think any changes are needed to the draft regulations to ensure they reflect the policy aims we have set out?
- vii. Do you have any other comments about the draft regulations?
- viii. Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?
- ix. Do you have any comments about the estimated costs and benefits of these regulations, as set out in the draft impact assessment?

We received 168 responses online and around 100 more via email correspondence. A list of the organisations that responded is at Annex E. The responses contained a wide range of views and many useful suggestions to improve the draft regulations. We have worked closely with CQC colleagues throughout the consultation to analyse the responses and have made many changes to the regulations as a consequence.

The vast majority of these changes have been made in order to improve clarity, or better reflect our original intentions. The following sections set out the main issues raised, and the changes we have made in response. Further sections then set out the main changes we have made to each regulation. Finally, Annex B sets out the responses we received to each question.

Offences and warning notices

In the consultation, we proposed that breaching any of the fundamental standards should be an offence. For those fundamental standards that were directly related to harm to patients and service users we proposed that CQC would not need to issue a warning notice before bringing a prosecution. For the other fundamental standards, which were not directly related to harm to patients and service users, we proposed that while a breach of the requirement would still be an offence, CQC would have to issue a warning notice before it could bring a prosecution.

In consultation, respondents commented that by making a breach of each of the regulations an offence, we were potentially introducing offences that were either not serious enough or not clear enough (or both) to constitute criminal offences. Similarly, the approach we previously proposed meant all parts of the offences would be subject to the same maximum penalty if breached, regardless of the seriousness of the issue that the regulation covered.

In the light of these comments, we have decided to change our approach on offences, and are proceeding on the following basis:

- a) all of the regulations in Part 3, section 2 (see Annex A) are fundamental standards that all providers must meet.
- b) CQC can use its civil enforcement powers in response to any breach of these regulations;
- c) Only some parts of these regulations have offences attached (see table below) – generally those related directly to harm or the risk of harm to service users.
- d) There is a threshold at which a breach of these regulations becomes an offence (generally, where that breach results in avoidable harm or a risk of such harm to the service user – see regulation 22(2)).
- e) It is no longer necessary for CQC to issue pre-prosecution warning notices (although they can issue a warning notice as part of their civil enforcement).
- f) If a provider breaches one of the regulations that has an offence attached, and that breach meets the threshold set out in regulation 22(2), CQC can bring a prosecution straight away.
- g) We have also created some offences that do not relate to harm, but instead relate to a failure to provide information to service users (Duty of Candour) and CQC where required to do so. These offences carry a lower penalty (see table below).

The benefits of this model are that the offences will now relate clearly to the provision of care that results in avoidable harm or a risk of such harm to patients and service users. This will allow providers who are responsible for unacceptable levels of care to be held to account against a set of clear requirements. In particular those providers that are responsible for corporate neglect, or that allow abuse or harm of patients to occur, could face prosecution.

The table below sets out which parts of the requirements have offences attached

Offence	Coverage and threshold	Penalty
Care and treatment must only be provided with the consent of the relevant person.	Breach of the entirety of this regulation is an offence. No threshold applies to this offence.	Carries a maximum penalty of a £50,000 fine

Care and treatment must be provided in a safe way for service users	Breach of the entirety of this regulation is an offence, although a breach only becomes an offence where it meets the threshold set out in regulation 22(2)	Carries a maximum penalty of a £50,000 fine
Service users must be protected from abuse	Breach of clauses 1-4 of this regulation is an offence, although a breach only becomes an offence where it meets the threshold set out in regulation 22(2)	Carries a maximum penalty of a £50,000 fine
The nutritional and hydration needs of service users must be met	Breach of the entirety of this regulation is an offence, although a breach only becomes an offence where it meets the threshold set out in regulation 22(2)	Carries a maximum penalty of a £50,000 fine
Complaints	It will be an offence not to provide CQC with any information it requests relating to complaints.	Carries a maximum penalty of a level 4 fine on the standard scale (£2,500).
Good governance	It will be an offence not to provide CQC with any information it requests relating to governance processes	Carries a maximum penalty of a level 4 fine on the standard scale (£2,500).
Duty of Candour	It will be an offence to fail to notify a service user (or their representatives) that they have been involved in a notifiable safety incident The regulation also sets out certain actions that a provider must take as part of the process of notifying the relevant person, and failure to carry out these steps is also an offence.	Carries a maximum penalty of a level 4 fine on the standard scale (£2,500).

It is important to note that a serious failure to meet some of those requirements which are not offences, for example person-centred care and dignity and respect, would be likely to result in a breach of those requirements which are offences, such as abuse or safe care and treatment, and could therefore result in a prosecution.

In the case of the requirements that do not have offences attached, CQC will be able to make use of its civil enforcement powers, such as issuing a warning notice, imposing a condition on a provider's registration and cancelling registration in order to hold providers to account.

CQC already has a power to place a condition on a provider's registration, which would provide details about how the provider is failing to meet a registration requirement, as well as setting out the steps that a provider has to take in order to achieve compliance. A failure to comply with such a condition is in itself an offence that can lead to prosecution. The following example

explains how this can operate in respect of those registration requirements which will not be offences in themselves.

During an inspection, CQC discovers that care on a ward is being provided by staff who lack the relevant qualifications. This would be a breach of the staffing regulation, and CQC could place a condition on the provider requiring that staff must not provide that care unsupervised until they have obtained the relevant qualification. If the provider were to continue to allow such staff to perform the role unsupervised, they would be breaching the condition, and could face prosecution.

Penalties

The table above sets out the penalties that will apply for breaches of offences. Offences that relate to harm of individuals carry the maximum fine of £50,000. Offences that relate to failing to provide information to either CQC, or service users (the final three lines in the above table) have a fine limited to level 4 on the standard scale.

It should be noted that section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 removes the maximum limit on fines that can be imposed on summary conviction, and also changes the maximum fines for the other levels on the standard scale. However, this legislation has not yet been commenced. Therefore the maximum penalty for failing to meet the registration requirements will be £50,000, unless the commencement of section 85 increases this to an unlimited fine before these regulations are made. Similarly, the level 4 fines will be £2,500, unless the commencement of section 85 increases this to £10,000 before these regulations are made. If section 85 is not commenced by the time these regulations are made, the fines will be set at the current levels. In that case, we will amend these regulations once section 85 does commence in future, to change the level of fines so they are consistent with section 85.

In addition to bringing a prosecution, CQC has the option of issuing penalty notice for the offences set out in the regulations. The penalty notice in lieu of prosecution for failing to comply with those fundamental standards with a maximum penalty of a £50,000 is set at £4,000 in the case of a service provider and £2,000 in the case of a registered manager.

Clarity of certain terms

We asked in consultation whether people thought the draft regulations were clear enough to support enforcement action. Generally, respondents thought that the regulations were clear and their intention was clear too. However some respondents also made suggestions about how to increase the clarity of the regulations.

This was seen as especially important because of our intention for all of the regulations to be offences. We have addressed this in the changes to the drafting of the regulations.

References to professional standards, practices and principles

The consultation version of the regulations included references to acting 'in accordance with generally accepted professional standards, practices and principles'. However, the consultation

identified a number of issues with this kind of reference and we have therefore removed this wording entirely from the final regulations.

The reference was intended to ensure that providers were providing care and treatment based on recognised best practice, published by expert professional bodies. Although this is clearly important, respondents pointed out that a general reference to ‘standards, practices and principles’ is not effective because it does not direct them to any specific standards.

An alternative approach would be to specify in regulations which standards and practices should be followed – and some respondents did request that certain types of further guidance be referenced, for example NHS Patient Safety Alerts. However this would be unwieldy and would also give legal status to standards which were never intended to be regulatory standards. It would also mean the regulations would need updating frequently when new standards were produced.

Guidance

Providers will still have to have regard to relevant standards and guidance where appropriate, and the Health and Social Care Act 2008 (“the 2008 Act”) (under which these regulations are made) sets out the system for how regulations and other guidance should interact.

The 2008 Act requires CQC to produce guidance about compliance with the registration requirements. This guidance can in turn operate by reference to other documents – including standards, guidance and other information produced by others. The Secretary of State for Health has a similar power to issue a Code of Practice in relation to health care associated infections.

The statutory framework set out in the 2008 Act is clear that providers should look first and foremost to the CQC’s guidance about compliance and the Department of Health’s Code of Practice. We are therefore not making any references in the regulations to any guidance beyond that issued by CQC and the Department of Health.

Applicability of standards in certain settings

A consistent theme in response to CQC’s *A New Start* consultation in summer 2013 was that not all regulations apply in all situations – the most frequently cited example being that GPs and dentists generally do not provide nutrition as part of their services.

In our consultation we included a draft clause that attempted to provide for this kind of exception with the phrase “[the registered person must comply with the regulations] *in so far as they are applicable to each regulated activity*”.

We accept that there are occasions where judgements need to be made about the applicability of certain requirements to specific circumstances. However, the original drafting “*in so far as they are applicable to each regulated activity*” did not give sufficient clarity to providers or CQC inspectors about the circumstances in which the regulations might not apply. It could also lead providers to argue that a particular regulation was not applicable, and to use this as a justification for poor care or treatment. Most of the standards apply in most circumstances – and consultation responses supported this view. We think the best way to account for those few occasions where specific regulations are not applicable is to be as clear as possible about this in the individual regulations. Consequently, we have made changes to the nutrition regulation to make it clear when the regulation does and does not apply.

Some domiciliary care providers raised issues about their responsibilities regarding the equipment that they use where they are not responsible for its maintenance. Our view is that

equipment used in care or treatment must be safe, irrespective of who owns it, and we have reflected this in the regulation by placing the emphasis on “equipment used by the registered provider” being safe, appropriate and clean. We do not feel it is justifiable to introduce regulations which could be interpreted as meaning it is acceptable for providers to use unsafe equipment in some situations.

However, CQC will need to make judgements when assessing whether providers meet the standards and this will include consideration of what a provider could reasonably have done differently in the circumstances. CQC will provide clarity for providers on its approach to such situations in its guidance.

In terms of criminal liability, the “reasonable steps” defence in regulation 22(3) gives providers some protection and grounds to argue that they did all that could be expected of them in the circumstances.

Person-centred care

The consultation draft of the regulations brought together several elements of the current regulations into a new requirement about person-centred care. Many respondents were pleased to see this included, and suggested further areas that this regulation should reference explicitly. We have strengthened the emphasis on various issues related to person-centred care in the regulations, to reflect the progress and expectations on person-centred care that are arising in other parts of the health and care system. For example, we have included a reference to providing opportunities for people to manage their own care.

Mental capacity and best interests

These regulations will apply in a wide range of care settings, and to people with very different needs. Many consultation responses pointed out that an increasing proportion of people in receipt of health and adult social care services lack capacity to make decisions in some areas of their life, making mental capacity and acting in people's best interests an important part of care delivery – especially, but not exclusively, in areas relating to consent, care planning and involvement.

The Mental Capacity Act 2005 already applies to all registered care providers, so our guiding principle when considering issues of mental capacity has been to defer to, rather than repeat or extend, the provisions of that Act.

Link to NHS Constitution

Many people pointed out that for the NHS there is a strong connection between the regulations and the NHS Constitution, which sets out in one place the legal rights of patients, the public and NHS staff as well as pledges made by the NHS, its values and principles.

We recognise this link and when the Department next consults on updating the NHS Constitution, we will consider how the Constitution should best reflect these regulations.

Good employment practices

A number of respondents suggested we include reference in these regulations to matters relating to the way staff should be treated - for example, that providers are required to have whistleblowing policies, or references to treating staff with dignity and respecting their human rights. These are important issues, and in some areas providers will have existing legal obligations in these areas. We did not feel it was appropriate to broaden regulations about the

quality and safety of care and treatment delivered to patients and service users to also include requirements about how staff should be treated.

The good governance regulation does however require providers to seek and act on feedback received from service users and others (including staff), in order to continually evaluate and improve services. This would include concerns raised by whistleblowers, as CQC guidance will make clear.

Inspection of commissioners

A number of respondents highlighted the important role commissioners play in determining whether care is provided to acceptable standards, and some pointed out that poor commissioning could prove to be a barrier to meeting the fundamental standards. Many raised the question as to whether these regulations would also apply to commissioners, or whether CQC has any broader powers to hold commissioners to account where poor commissioning practices are hampering a provider's ability to meet CQC requirements.

The registration requirements apply only to providers of regulated activities that require registration with CQC. The commissioning of health or adult social care services is not a regulated activity, and the registration requirements do not, therefore, apply to commissioning. However, CQC has a power to carry out a special review or investigation of commissioning with the specific agreement of the Secretary of State.

Importance of CQC guidance and inspection

A common theme that ran throughout the responses to the consultation was the importance of CQC guidance in helping providers understand what they must do to comply with the regulations, and to help them understand the situations in which CQC may take enforcement action. Respondents also raised the importance of CQC inspectors understanding the regulations and guidance, and applying them consistently.

We agree with these points. CQC will be consulting on its guidance and enforcement policy in due course.

Increasing the scope of regulation

Some respondents urged us to consider changes to the types of providers who should be required to register with CQC. Others suggested some changes (for example, changing the definition of personal care) that would have extended the number of organisations required to register with CQC.

We have not made any changes that would extend the scope of regulation. In line with the recommendations of the Francis Inquiry, our aim has been to change the requirements that providers must meet, not to change the rules about who has to register with CQC.

Main changes by regulation

This section sets out the main changes we have made to each fundamental standard regulation as a result of consultation.

Person-centred care

- Clarified to specify that needs must be met, and preferences must be reflected, and that care must be appropriate.
- Resolved a potential tension between meeting someone's needs and providing care in accordance with their consent, by making it clear that the requirements of this regulation cannot be a justification for acting against a person's consent.
- Made clear that the regulation is not limited to those things that are specified in paragraph 3.
- Placed greater emphasis on the need to work in collaboration with the service user and/or their representatives when assessing needs and preferences.
- Clarified that meeting needs and preferences should be a feature of care planning.
- Changed the emphasis from 'permitting' involvement to 'enabling and supporting' involvement in decision making and care planning.
- Added a requirement that people should be encouraged to self-manage their care and treatment.
- Added a reference to involving service users and/or their representatives in decisions relating to the way the provider carries on the regulated activity.
- Added a reference to considering people's well-being in the provision of food and drink (this has been placed in this regulation rather than in the nutrition regulation as well-being is a broad and subjective concept and we did not feel it was appropriate to criminalise every instance where it is not being met, as would have been the case if it remained in the nutrition regulation).
- Made a specific reference to providing people with information they may need.
- Clarified references to mental capacity.

Dignity and respect

- Made clear that the regulation is not limited to those things that are specified in paragraph 2 of the regulation.
- Strengthened the reference to privacy so the requirement is to 'ensure' a user's privacy, rather than 'promote' it.
- Clarified reference to the Equalities Act 2010, so that the requirement to have due regard to protected characteristics is consistent with the characteristics that should be considered under the public sector equality duty.

Consent

- Removed the reference to 'in accordance with' - this was superfluous and added confusion.
- Clarified references to the Mental Capacity Act 2005, and to other circumstances where a person may not be able to give consent (e.g. children).

Safe care and treatment

- Removed references to appropriateness, and placed this in the person-centred care regulation instead, in recognition of the fact that safety and appropriateness are different concepts.
- Placed the emphasis of the requirement on the need for care and treatment to be carried out in a safe way, to account for the fact that some kinds of treatment are not completely safe.
- Following the above change, emphasised that risks must be assessed, and providers must do all that is reasonably practicable to mitigate any safety risks.
- Made clear that the regulation is not limited to those things that are specified in paragraph 2 of the regulation.
- Strengthened the requirement about proper and safe management of medicines.
- Included the reference to having sufficient quantities of equipment and medicines (previously part of the person-centred care requirement).
- Included a reference to the fact that care should only be provided by suitably qualified and skilled staff.
- Added clauses on ensuring that premises and equipment are safe to use and used in a safe way (these clauses reflect clauses previously in the premises and equipment regulation).
- Removed references to 'taking appropriate steps' to mitigate risks, so as to place the emphasis on the outcome.
- Clarified the reference to infection control so that it is focused on the outcomes, rather than on having a system in place.
- Removed the references to standards and guidance, as inclusion risked giving such standards quasi-legal status.
- Moved the references to discrimination, control and restraint in to the abuse regulation.
- In this regulation, discrimination is linked to all of the protected characteristics outlined in section 4 of the Equality Act 2010.

Safeguarding against abuse

- This regulation now refers to abuse and improper treatment.
- Emphasised that systems and processes must be established and operated to prevent abuse, and to investigate allegations of abuse, in order to protect people from the risks of abuse occurring.

- Removed the reference to preventing abuse 'before it occurs' as it could be interpreted as not applying to ongoing abuse.
- Clarified that action must be taken 'in response to abuse' (not 'to respond to abuse').
- Moved the references to discrimination, control and restraint in to this regulation from the safe care regulation.
- Following the above change, clarified that care or treatment must not involve discrimination.
- Made clear that care or treatment must not be degrading for the service user, or involve significant disregard for their needs for care and treatment.
- Clarified that care or treatment must not involve deprivation of liberty without lawful authority.

Meeting nutritional needs

- Clarified that this regulation is about meeting both nutritional and hydration needs.
- Clarified that this requirement only applies where the meeting of needs is a component of the regulated activity being provided.
- Resolved a potential tension between meeting someone's needs and providing care in accordance with their consent, by making it clear that the requirements of this regulation cannot be a justification for acting against a person's consent (or best interests).
- Clarified that meeting needs involves meeting reasonable preferences (such as vegetarianism) as well as reasonable religious or cultural requirements.

Premises and equipment

- Removed the references to standards and guidance, as inclusion risked giving such standards quasi-legal status.
- Added a reference to premises and equipment being appropriately located.
- Moved the elements relating to safety to the safe care regulation.

Complaints

- Removed the word 'appropriate' and clarified that we mean 'necessary and proportionate' action must be taken.
- Added a reference to complaints systems needing to be accessible.
- Made clear that there a registered person must provide certain information to CQC when requested within 28 days.

Good governance

- Made clear that the regulation is not limited to those things that are specified in paragraph 2 of the regulation.
- Made explicit that the requirement includes assessing, monitoring and improving the safety of services, alongside the quality.

- Added a reference to the fact that part of records management is about maintaining the security of the record itself.
- Clarified that the record should include records of decisions taken.
- Clarified that persons employed means people employed in the carrying on of the regulated activity (some consultation respondents were unclear as to whether this regulation would only apply to new/future recruits).
- Re-inserted the reference from the current regulations that requires providers to send information to CQC when requested, and made clear that there is a 28 day period in which to provide that information.

Staffing

- Added a reference that staff must be 'competent' alongside the other qualities, in acknowledgement of the fact that having received training is not necessarily equivalent to being competent.
- Made clear that the training and supervision of staff should be in relation to the role they perform.
- Removed the reference to 'from time to time' as it was generally agreed to be unclear.
- Clarified that we mean professional regulator, not professional body.
- Made clear that the requirement to enable employees to provide information to the relevant professional regulator only applies where registration with that body is relevant to their role.

Fit and proper persons employed

- Clarified that this requirement applies to people employed for the purposes of carrying on the regulated activity.
- Added a reference to competence alongside the other fitness criteria.
- Clarified the reference to making reasonable adjustments.

Offences

- Updated this section to reflect the fact that not all of the requirements have offences attached.
- Removed the references to pre-prosecution warning notices.
- Clarified which parts of the regulations do have offences attached (in line with the table on pages 12-13 above).
- Added a threshold related to avoidable harm and risk of harm, which means that a breach of certain regulations is only considered an offence if this threshold is also met.

The fundamental standards

The fundamental standards are:

- care and treatment must be appropriate and reflect people's needs and preferences
- people 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
- people must be protected from abuse
- people's nutritional and hydration needs must be met
- all premises and equipment used must be clean, secure, suitable and be 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
- Providers must be open and transparent with people about their care and treatment (the Duty of Candour)

Part 2: Fit and proper persons requirement

This section tells you about the feedback we received on the draft regulations to introduce a new requirement for directors of health and adult social care providers registered with CQC to be fit and proper persons for their role, and how we are responding to that feedback.

Background

On 4 July 2013 the Department published a consultation on *Strengthening corporate accountability in health and social care*, setting out proposals for all directors of providers registered with the Care Quality Commission (CQC) to meet a new “fit and proper person test.”¹⁰ The consultation asked for views on these proposals, which would require registered providers of health and adult social care to undertake checks to ensure that all directors of Boards or equivalents are fit and proper for their role and to enable CQC to insist on the removal of directors that fail this fit and proper person requirement.

There were 54 responses to this initial consultation which closed on 6th September 2013. The majority of responses (74%) were supportive of the overall principle of introducing the fit and proper person requirement but some people voiced concerns about how the proposals would work in practice. The Department published a summary of consultation responses on 27 March 2014, alongside a further consultation on draft fit and proper person regulations¹¹. That consultation closed on 25 April 2014.

Purpose of the regulations

Users of health and adult social care have a right to receive high quality and safe services. In order for a health and social care provider to provide a high quality service it is vital that the organisation has the right values and culture, and the people who work for it are fit to deliver these services.

The purpose of this regulation is to require providers to take proper steps to ensure that their directors are fit and proper for their role, as is already the case for staff. Requirements will be placed on providers to undertake the necessary checks that all directors exhibit the correct types of personal behaviours, competence and business practices required for their role. The regulations will enable CQC to take action against unfit directors including barring them from individual posts.

¹⁰ *Strengthening corporate accountability in health and social care* Department of Health (July 2013)

¹¹ *Strengthening corporate accountability in health and social care: consultation response* Department of Health (March 2014); *Consultation on the fit and proper person regulations* Department of Health (March 2014);

Draft regulations for consultation

The draft fit and proper person requirement regulations which were published for consultation set out proposed criteria which providers should take into account when assessing whether a director is fit for their role, as well as the grounds for CQC to deem a person to be unfit to be a director of a registered provider.

The consultation proposed the following criteria that a director must meet – they must:

- be of good character;
- have the qualifications, skills and experience necessary for the relevant position;
- be capable of undertaking the relevant position, after any reasonable adjustments under the Equality Act 2010;
- not have been responsible for any misconduct or mismanagement in the course of any employment with a CQC registered provider;
- not be prohibited from holding the relevant position under any other law. e.g. under the Companies Act or the Charities Act.

The consultation proposed that a director will be deemed unfit if they meet the following criteria (Schedule 1):

- have been sentenced to imprisonment for three months or more within the last five years, although CQC could remove this bar on application;
- are an undischarged bankrupt;
- are the subject of a bankruptcy order or an interim bankruptcy order;
- have an undischarged arrangement with creditors; or
- are included on any barring list preventing them from working with children or vulnerable adults.

The consultation asked five questions about the fit and proper person regulations:

1. Do you think the fit and proper person regulations reflect the policy aims?
2. Are there any other criteria that should be included in Schedule 1 (which sets out the grounds for unfitness)?
3. Do you have any other comments about the draft regulations?
4. Do you agree that breach of the requirement should constitute an offence?
5. Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?

In addition, there was a call for evidence from providers about the impact of the proposed changes which was used to inform the impact assessment.

Summary of responses

There were 41 responses to the consultation, mostly from professional bodies, providers and their representative bodies. Twenty-one responses were submitted online and a further 20 were email responses. In addition, we also held meetings with a range of providers and with other key stakeholders, including the CQC, Monitor, the NHS Trust Development Authority and the Charity Commission, to discuss the draft regulations.

The majority of respondents broadly agreed with the draft regulations. Over 78% of all responses thought that the regulations reflected the policy aims. There were some concerns that whilst the regulations provide a mechanism for removing unfit directors it was unclear to what extent this will contribute to the delivery of safe services and reduce the risks of poor quality care.

As set out in Part 1, the new fundamental standards set the standard below which care must not fall and will enable CQC to take action against providers where there is poor quality care. The fit and proper person regulations will contribute to this by enabling CQC to remove unfit directors who have overseen poor care.

The responses contained a wide range of views and many useful suggestions to improve the draft regulations. We have made a number of changes to the draft regulations as a consequence. Most of these changes have been made in order to improve clarity, or better reflect our original intentions.

The following sections set out the main issues raised, and the changes we have made to the regulations in response. Detailed responses to the consultation questions are at Annex C.

The key issues raised were about:

- criminal convictions as grounds for unfitness;
- the interface with existing regulations, in particular professional regulation;
- whether breach of the regulation should constitute a new offence;
- how the barring list applies;
- the definition of misconduct/mismanagement.

Criminal convictions as grounds for unfitness

The draft regulations that we consulted on would have made a person automatically unfit to be a director if they had been convicted of an offence for which they had received a sentence of at least three months' imprisonment in the previous five years. This was included to ensure consistency with the fit and proper person requirement that applies to directors of organisations licensed by Monitor. A discretion to allow CQC to lift the prohibition was included in the draft regulations in response to concerns raised during the initial consultation on the fit and proper persons policy - for example that an addiction service provider would be unable to appoint as a director a service user who would provide valuable insight to the Board but who would be unfit because of recent criminal convictions.

However, respondents to the consultation raised a number of conflicting concerns. Some argued that the requirement was too rigid. Others argued that the condition should apply to other criminal convictions. Some respondents were also concerned that the requirement should

be completely consistent with Monitor's test, and that there should be no discretion for CQC to disapply such a conviction as grounds for unfitness.

We have accepted the argument that the proposed disqualification on the grounds of a criminal conviction resulting in three months imprisonment was too narrow. However, it is important that providers consider the criminal record of a person in deciding whether they are fit to be a director. We have decided that providers should consider criminal offences as part of determining whether a director is "of good character". Schedule 4 of the draft regulations now provides that the test of good character should include 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.

Whilst this means there will be some difference between the fit and proper person requirements for CQC registration and Monitor's licensing of Foundation Trusts, it is reasonable that a more rigid test should apply to a director or board member of a provider licensed by Monitor. CQC registration applies to providers of all sizes and across all sectors – providers requiring a Monitor licence form a small sub-set of this group. CQC's fit and proper person requirement for directors is also consistent with the fit and proper person requirements for other staff and with the registration requirements for sole traders and partnerships. CQC and Monitor will continue to work together to ensure that the regulations are applied as consistently as possible in cases where providers are both registered with CQC and licensed by Monitor.

Professional regulation

A number of respondents raised the issue of how the fit and proper person regulations fit with professional regulation. They were concerned that the criteria in Schedule 1 did not explicitly prevent a director who has been removed from a professional register by a health care professional regulator for fitness to practice reasons from taking up a senior role in a healthcare business. They argued that this potentially posed a risk to public protection and could undermine confidence in both the system of professional regulation and the fit and proper person requirement. Some people proposed that where a person had been judged unfit to practice by a professional regulator, they should also be considered unfit to be a director of a provider registered with CQC.

Where the director is a health care professional and that person has been erased, removed or struck-off from a professional register, then this must be considered by providers as part of being "of good character". In addition where a health care professional regulator has made a finding of impairment (but not necessarily imposed a sanction of striking-off, erasure or removal) then this will also be relevant in determining whether the person is "of good character".

Some Director level posts will specifically require a person to be registered with the relevant professional regulator as a requirement of the role they fulfil (for example a Medical Director who is also the Responsible Officer in an NHS Trust). This will also be considered in whether they have the relevant competence, qualifications and skills for the role.

However, we do not feel that it is reasonable that being subject to sanctions from a professional regulatory body should automatically lead to disqualification from ever holding any director post with any organisation that is registered with CQC.

We have decided that the regulations will require providers to consider as part of assessing whether they are "of good character" whether a person has been erased, removed or struck-off from a health care professional register for fitness to practice reasons. CQC's guidance will set out further detail on how fitness to practice issues should be assessed by providers in determining if a person is fit to be a director.

Barring list

The draft regulations that we consulted on would make a person automatically unfit to be a director if they are included on a barring list preventing them from working with children or vulnerable adults. It is only possible to apply for a disclosure and barring (DBS) check with an additional check against the barred lists for people working in a “regulated” activity (defined in the Safeguarding Vulnerable Groups legislation as having regular and unsupervised contact with children or vulnerable adults). Some consultation respondents were concerned that this means that the majority of people in scope of the fit and proper person requirements as directors would not be eligible for a DBS check, because they would not have regular and unsupervised contact with children or vulnerable adults. It would therefore be difficult for employers to check whether directors meet this criterion. Some people queried whether the intention was to extend the DBS checks to include directors.

We are not extending the scope of the DBS checks. In terms of CQC’s fit and proper persons requirement, those directors whose role currently falls within the definition of “regulated activity” as defined by the Safeguarding Vulnerable Groups legislation will be eligible for a DBS check. Providers should also ask individual directors whether they are on a relevant barring list as part of their recruitment and appointment process, but will not always carry out a DBS check on director posts to verify this. CQC guidance will set out how it expects providers to have regard to this requirement.

New offence

While the majority of people who responded were in favour of the fit and proper person requirement constituting an offence, we have amended the regulations so that only a small number of fundamental standards that directly relate to harm will be subject to an offence if breached. This will not include the fit and proper person requirement.

Where a director is appointed or in post whom CQC considers to be unfit, CQC could impose a condition of registration requiring the removal of that director. Breach of such a condition would itself be an offence and could result in cancellation of registration.

The definition of misconduct and mismanagement

Respondents expressed concerns that the draft regulation on misconduct and mismanagement was too broad and open to interpretation. In particular, that someone who was subject to minor disciplinary action by an employer many years ago, but was otherwise a good candidate, might be deterred from even applying to be a director. In addition, respondents were concerned that whilst misconduct was well understood in the context of professional regulation, mismanagement was open to interpretation.

We have amended the regulation to include a “serious” threshold for both misconduct and mismanagement. CQC guidance will set out further details on what may constitute serious misconduct and mismanagement. Respondents have suggested that this could include the NHS code of conduct and how it aligns with the Nolan principles.

The definition of director

Some respondents thought that the fitness test should apply to commissioners as well as providers and to governors as well as directors. In addition people asked whether, where a local authority is the provider, the requirement covers elected members.

We are clear that the regulations should apply to the “controlling mind” of organisations, rather than the people who appoint the Board – this should include all board members, including executive directors and non-executive directors of NHS Trusts and Foundation Trusts but not the governors of foundation trusts. The intention is that, subject to Parliamentary approval, from April 2015, the requirement will also apply to equivalent director posts in other providers, including trustees of charitable bodies and members of the governing bodies of unincorporated associations. Where a local authority is a provider, the regulations will not apply to elected members as they are accountable through a different route.

Summary of main changes to the regulations

We have made the following changes to the fit and proper person requirement in light of the consultation responses:

- to include a “serious” threshold for the provision relating to misconduct and mismanagement, with CQC guidance to set out further detail on what constitutes serious misconduct and mismanagement;
- to remove the provision in Schedule 4 that a period of imprisonment of at least three months in the previous five years is one of the criteria for deeming a director to be unfit. Instead Schedule 4 requires providers to consider any relevant criminal offences as part of the requirement to consider whether the person is “of good character”;
- to require providers to consider whether someone has been erased, removed or struck-off from a health care professional register as part of considering whether they are “of good character”;
- to remove the provision that failure to adequately apply the fit and proper person requirement should constitute an offence of itself. Instead CQC could impose a condition on a registered provider requiring the removal of an unfit director. Failure to comply with such a condition would itself be an offence and could constitute grounds for cancellation of registration;
- to clarify that the registered person must take action where a director is deemed to be unfit;
- to include where a person is subject to a moratorium period under a debt relief order as one of the conditions for deeming a person to be unfit;
- to apply these regulations to NHS bodies only from October 2014 with the intention of extending the fit and proper person requirement to other providers from April 2015, subject to Parliamentary approval.

Part 3: The Statutory Duty of Candour

Candour is the quality of being open and honest. Patients should, as a matter of course, be properly informed about all the elements of their treatment and care organisations should sustain a culture which supports staff to be candid.

The Department of Health recently consulted on introducing a new statutory Duty of Candour on all providers registered with CQC. The consultation sought comments on the new statutory duty, as outlined in draft regulations, that would require all CQC registered providers to inform people when significant harm to them has occurred, and provide an explanation and apology. The consultation, entitled '*Introducing the Statutory Duty of Candour*', was published on 26 March 2014 and closed on 25 April 2014¹².

In the sections below we review the purpose of the Duty of Candour, set out the feedback we received on the draft regulations to introduce a statutory Duty of Candour as a requirement for registration with CQC, and explain the changes we are making in the light of this feedback.

Purpose of the Duty of Candour

The new statutory Duty of Candour responds to issues and concerns identified in a number of reviews and inquiries. These include:

- The Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry)¹³ and;
- The Berwick Review into Patient Safety¹⁴.

It also reflects the findings of the Dalton Williams Review¹⁵ into the threshold for the Duty of Candour, which was commissioned as part of the Government 's response to the Mid-Staffordshire Inquiry 'Hard Truths' to look at where the threshold for the statutory duty should be drawn. All of these reviews endorsed the need for a culture of candour and for a statutory Duty of Candour to support this cultural change.

¹² Introducing the statutory Duty of Candour: a consultation on proposals to introduce a new CQC registration requirement, March 2014 – <https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers>

¹³ The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, February 2013 – <http://www.midstaffspublicinquiry.com/report>

¹⁴ A promise to learn – a commitment to act: improving the safety of patients in England, August 2013 – https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

¹⁵ 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, March 2014 – <http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

In response we are putting in place a new requirement for providers of health and adult social care to be open with patients, and to apologise, when things go wrong. This duty will initially apply to NHS healthcare bodies (NHS Trusts established under the NHS Act 2006, NHS Foundation Trusts and Special Health Authorities) and will later be brought in for all other registered providers.

To implement the Duty of Candour, provider organisations will need systems and procedures that ensure openness and transparency with service users. For some providers this will mean developing new policies and systems and possibly improving their identification and reporting of harm. The duty will act as a catalyst to improve the understanding of harm and the learning which flows from it at provider level. The duty will be overseen and enforced by CQC.

The statutory Duty of Candour does not apply to individuals, but provider organisations will be expected to implement the new duty through staff across their organisation, requiring the education and training of staff. In addition, the professional regulators are working to strengthen references to candour in their guidance to make it clear that regulated health and care professionals have to be candid with patients and service users about all avoidable harm. Obstructing colleagues in being candid will be a breach of the professional codes. Professional regulators will also review their guidance on professional misconduct panels to ensure they take proper account of whether professionals have raised concerns promptly.

There has been a lot of discussion about the harm threshold above which the statutory Duty of Candour requirements should apply. In the consultation on the Duty of Candour in March, we accepted the Dalton Williams Review definition that the duty should apply where there is 'significant harm'. We discuss the harm threshold in more detail below, but where significant harm has arisen, the provider must inform the service user about this harm and apologise. This requirement sends a powerful signal to providers to improve openness and safety. As the Dalton Williams report noted: 'A culture of candour is a culture of safety, and vice-versa'.¹⁶

Issues raised in the consultation and our responses

There were 116 responses to the Duty of Candour consultation – 50 responses online and 66 more via email correspondence. A summary of responses received is at Annex D and a list of organisations who responded is at Annex E.

Harm threshold chosen for healthcare

In the draft regulations, the harm threshold for healthcare includes death, severe and moderate harm, as recommended in the Dalton Williams review. This is collectively referred to as 'significant harm'. This means that all harm classified as moderate or above, or where 'prolonged psychological harm' has arisen, gives rise to a Duty of Candour to the service user, or a person lawfully acting on their behalf. The Duty will also apply in cases of death, if the death relates to the incident of harm rather than to the natural course of the service user's illness or underlying condition.

¹⁶ Reference to the Dalton Williams Review, Chapter 1, paragraph 19

In the consultation responses, the majority of those who expressed an opinion were in favour of the Duty of Candour threshold chosen for healthcare. The main advantages were seen to be that the threshold is consistent with existing National Reporting and Learning System (NRLS) definitions, and with the 'Being Open' guidance and the NHS Standard Contract Duty of Candour threshold. We intend to keep this proposed threshold and the proposed harm definitions, although we have made some changes to ensure the regulations more accurately mirror the wording in the NRLS harm definitions. This approach reduces uncertainty and administrative burden by using existing harm definitions. Although not in the NRLS definitions, the regulations will include 'prolonged psychological harm' as it is significant harm, which is already notifiable to CQC. This approach follows that outlined in the Consultation Document.

A significant number of respondents suggested that there should be more guidance on the harm definitions. As we are using existing definitions, we are not defining harm further in the regulations and we would expect people to refer to existing NRLS¹⁷ and CQC notification¹⁸ definitions. However, we accept that CQC's guidance will be needed to assist providers in improving their understanding of these definitions. We also accept that CQC guidance will be needed on when and how breaches of the Duty of Candour should be disclosed to others, such as safeguarding boards or family members.

Harm threshold for adult social care

The majority of respondents who expressed an opinion were in favour of the Duty of Candour threshold chosen for adult social care. This threshold is based on the existing CQC notification requirement for serious injuries. The notification requirements are broadly similar in scope to the healthcare harm notification requirements noted above.

Respondents indicated that the main advantage of our approach is the use of existing and known threshold criteria that should be familiar to care providers and should keep reporting simple. As we are using definitions based on CQC's notification requirements, we do not intend to define them further in regulations, but again we accept that CQC's guidance will need to assist providers in improving their understanding of these definitions.

Respondents were also interested in how the thresholds for healthcare and adult social care will work together in practice. In the consultation, we distinguished between healthcare services and adult social care services. The distinction in the final regulations will be between NHS bodies and all other providers. The healthcare harm definitions will now apply to *NHS bodies only*. All other providers will use the CQC notifiable safety incident harm definitions to identify when a disclosure under the Duty of Candour is required. This change takes account of consultation concerns that providers of both healthcare and social care would have to operate under two different sets of harm definitions. The changes make it clear which set of harm definitions apply to which provider, follows the approach taken in CQC's existing notification system and will minimise administrative burden.

In terms of timing, we intend to apply the Duty of Candour to NHS bodies registered with CQC only from October 2014, with the intention of extending the Duty of Candour requirement to all other providers from April 2015, subject to Parliamentary approval.

¹⁷ The NRLS harm definitions can be found in, for example, the Being Open guidance - <http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=83726>

¹⁸ See regulations 16 and 18 of the Care Quality Commission (Registration) Regulations 2009.

Requirements placed on service providers

A significant majority of those who responded to this question were in favour of the requirements to be placed on service providers when there has been a breach of the harm thresholds. It was seen as fitting with current best practice and consistent with Being Open guidance and the requirements of the Duty of Candour outlined in the NHS Standard Contract, as well as mirroring good practice already in place in some organisations.

There were a number of common themes in the comments. Primary amongst them was the importance of ensuring appropriate advocacy and support for service users, possibly through the use of third party advocacy. We accept that advocacy and support for service users is important, but believe that it is adequately addressed in the regulations through the requirement on providers to provide reasonable support to the relevant person in relation to the incident. CQC's guidance will assist providers in understanding what is appropriate for their sector and circumstances.

A number of respondents also thought that the regulations should include provision to ensure that lessons are learnt by providers. It is clearly very important that lessons are learnt from errors. The registration requirement on good governance (see part 1) will require providers to assess, monitor and improve the quality and safety of the services provided – this will also apply to learning from those incidents to which the Duty of Candour applies.

In addition, there was some discussion of apologies, with the idea being raised that apologies may not be appropriate in all instances, including where there had been an honest error. It is important to note that the requirement for an apology in the regulations does not require any admission of liability. The apology is for the harm that has arisen. Section two of the Compensation Act 2006 states that: 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. The NHS Litigation Authority has also made it clear that an apology is not the same as an admission of legal liability¹⁹. We have re-drafted the regulations to make it clearer that that the written notification must contain an apology.

Other issues

In addition to comments directly addressing the questions asked, respondents made a number of other comments. Key themes are considered below.

A few respondents suggested that we need to be clearer about who the 'relevant person' is in different circumstances. We have therefore expanded the definition of 'relevant person' in the regulations. The individual who has suffered harm will, in most instances, be the recipient of information about the incident and the apology. However, the regulations now specify the relevant person when the service user has died, or lacks mental capacity or is under 16 and is not competent to make a decision in relation to their care and treatment.

We have also strengthened the definition of a notifiable safety incident to make it clearer that the judgement of whether significant harm appears to have occurred is in the reasonable opinion of a healthcare professional. This is consistent with the criteria for incidents that have to be notified to CQC.

¹⁹ See, for example, the NHS Litigation Authority leaflet 'Saying Sorry' – <http://www.nhsla.com/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf>

There was a clear understanding in the responses that staff would need training and guidance to implement the Duty of Candour. We accept that training and support for staff will be important, but the requirement to support staff is covered in the staffing registration requirement. We also accept that candour information should always be presented in a way that is comprehensible to the service user.

There was a suggestion that the regulations should require provider organisations to take appropriate action over individuals who prevent the organisation complying with the Duty of Candour. The new duty will apply to organisations. If individuals do not act in accordance with the requirements placed on providers under the statutory Duty of Candour, this will be an internal matter to be resolved by the provider themselves, and is not relevant for inclusion in the regulations. However, individual staff will be subject to the requirements of professional regulation where this applies to them.

The Section on 'Offences and Warning Notices' sets out which of the registration requirements will constitute a criminal offence if breached and the associated penalties. We have decided that in the case of the Duty of Candour, a failure to notify the relevant person of an incident will constitute a criminal offence, with a maximum penalty of a level 4 fine.

Summary of changes to the regulations

This section outlines the main changes we have made to the regulations in response to the consultation.

- We have made some changes to ensure the regulations more accurately mirror the wording in the NRLS harm definitions.
- We have clarified that the healthcare harm definitions, that are used to identify significant harm, will apply to NHS bodies only. All other providers will use the existing CQC notifiable patient safety incident harm definitions to identify when a disclosure under the Duty of Candour is required.
- We have redrafted the regulations to make it clearer that the written notification must contain an apology.
- We have strengthened the definition of a relevant person to be clearer about what happens if the service user dies or lacks mental capacity.
- We have developed the definition of an incident that needs to be notified to the service user or patient. Following the CQC notification regulations, harm that has arisen is now based on the reasonable opinion of a healthcare professional
- We intend to apply these regulations to NHS bodies only from October 2014, with the intention of extending the Duty of Candour requirement to other providers from April 2015, subject to Parliamentary approval.