Department of Health

Introducing Fundamental Standards

Consultation on proposals to change CQC registration regulations

January 2014

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Introducing Fundamental Standards

Consultation on proposals to change CQC registration regulations

Prepared by the Department of Health

Foreword

When we published our full response to the Francis Inquiry Report, we wanted people to have confidence that they will be given the best and safest 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 need the confidence that wherever we experience care, standards will not be allowed to fall below what we expect.

The Francis Report made a number of recommendations about the standards that should be met by organisations that provide our 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. We agreed with this recommendation and set about developing these Fundamental Standards as legal requirements that all providers should meet. The Care Quality Commission began a conversation over the summer on what these standards should cover in its consultation *A New Start.*

We have taken forward the responses to that consultation to draft new regulations that will introduce the Fundamental Standards. These standards will be at the foundation of a system that promotes care that is safe, high quality, and puts patients first. They should be easy for all to understand, and give the Care Quality Commission the power to take swift action where they are not being met.

This document describes the key issues that have emerged from the feedback we have received, explains our aims for the Fundamental Standards in more detail, and gives you an opportunity to comment on our draft regulations.

I would like to thank you all for participating in the development of these important standards.

Norman Lamb
Minister for Care and Support

Contents

1 Introduction

This consultation sets out proposed amendments to CQC's registration requirements[1], in order to introduce Fundamental Standards of care.

Our proposals to amend the CQC registration requirements are part of a wide-ranging set of changes designed to improve the regulation of health and social care providers, and provide assurance that service users receive safe, quality care and treatment.

Our proposed changes are designed to meet 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);
- The Winterbourne View Review;
- The Berwick Review in to Patient Safety;
- The government's Red Tape Challenge.

Our plans to introduce Fundamental Standards were originally 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 2013.

Over the summer, CQC's consultation *A New Start - consultation on changes to the way CQC regulates, inspects and monitors care* included a number of specific questions about Fundamental Standards.

Hard Truths, the full Government response to the Francis Inquiry report, set out in more detail the role that Fundamental Standards will play alongside the other changes being made to the health and social care system in response to the Francis Inquiry.

This document provides our response to the questions asked in *A New Start,* and asks further consultation questions about the draft regulations in Annex A, and about the impact of our proposals.

Duty of Candour and Fit and Proper Persons Test.

This consultation does not cover the proposed new Duty of Candour or the Fit and Proper Persons requirement for Directors of providers registered with CQC.

We will consult separately on each of these proposals, although the intention is to introduce these measures alongside the Fundamental Standards as part of the same set of regulations.

[1] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

2 Purpose of these changes

a) To introduce Fundamental Standards

The Francis Inquiry report 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. All care providers registered with CQC will have to meet them.

They are set out in the draft regulations at Annex A, and CQC will produce guidance that explains how they will judge whether providers are complying with them.

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, and also by reducing the burden of regulation.

The existing registration requirements were brought in to force in 2010 and set out 16 essential standards of quality and safety that all providers have to meet when they register with CQC, and on an on-going basis after that. The Francis Inquiry report noted that:

"The current outcomes are over-bureaucratic and fail to separate clearly what is absolutely essential from that which is merely desirable."[2]

It also criticised them for a "*lack of clarity*"[3]**,** and recommended that fundamental standards should be introduced as registration requirements, and that compliance with these should be monitored by CQC.

The current requirements contain a lot of detail, and as a consequence, it is not always clear what the overall intended effect is. It is also not obvious what a breach of the overall requirement would entail.

We have tried to rectify this lack of clarity by redrafting the current registration requirements so that they become the new Fundamental Standards – clear outcomes that providers need to meet, and that are widely accepted to be the core of a good service.

We want the new requirements to be more precise than the present versions, with the outcomes we expect providers to achieve or avoid clearly stated. This means it should be easier for

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

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

people to judge what must be done to meet them, and will allow CQC to take effective and timely enforcement action where they identify poor care.

The complexity of the existing regulations means that CQC is currently required to issue a warning notice explaining what the provider has done wrong and giving them time to rectify the issue before they can bring a prosecution against a provider. This makes it hard for CQC to prosecute providers in cases where the seriousness of the breach might warrant such action. As a result, CQC is sometimes 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 for those cases that CQC considers serious enough to warrant prosecution, it will not need to issue a warning notice before bringing a prosecution.

This will help us meet 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 is more likely that providers will be able to meet them, leading to safer care for patients and service users.

In our new draft, the main requirement is that the outcomes are met, and providers will need to be able to demonstrate that they are meeting the outcomes. Each outcome is supported by a small number of other conditions –these provide CQC with a means of taking appropriate enforcement action where providers are found to be slipping, but have not yet breached the requirement.

This supports CQC's new emerging approach to inspection and enforcement which is based less around checking compliance with detailed regulations, and is instead focuses on five questions about care:

- Is it safe?
- Is it effective?
- Is it responsive?
- Is it caring?
- Is it well-led?

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 intend to do this 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.

Our impact assessment for the changes goes in to more detail on the reduction of burden, and we are interested in gathering views that will help us make a more accurate judgement about the impacts and benefits of these changes. See the *call for evidence* section in Annex C.

3 Previous consultation and our response

CQC's summer 2013 consultation *A New Start - consultation on changes to the way CQC regulates, inspects and monitors care* set out the principles that CQC and the Department have in mind in developing the Fundamental Standards, and asked questions about a proposed list of "fundamental of care". It also explained how the Fundamental Standards would sit alongside another set of proposed 'expected' standards.

CQC's response[4] to that consultation explains how it intend to use the responses they received to develop their new inspection model, including issuing ratings over the coming months.

The Department has responsibility for drafting the regulations, and CQC has responsibility for drafting the guidance that sits alongside them. We have worked closely with CQC over the last six months to develop the regulations, and will continue to do so in future.

In this section we set out what we asked in the last consultation, what we heard, and our response to what we heard.

We asked: Do you think any of the areas in the draft fundamentals of care below should not be included?

- I will be cared for in a clean environment.
- I will be protected from abuse and discrimination.
- I will be protected from harm during my care and treatment.
- I will be given pain relief or other prescribed medication when I need it.
- When I am discharged, my on-going care will have been organised properly first.
- I will be helped to use the toilet and to wash when I need it.
- I will be given enough food and drink and helped to eat and drink if I need it.
- If I complain about my care, I will be listened to and not victimised as a result.
- I will not be held against my will, coerced or denied care and treatment without my consent or the proper legal authority.

We heard:

Consultation respondents agreed almost unanimously that the areas covered in the draft list were worthy of being Fundamental Standards. It is clear from the responses to the other questions we asked that many did not feel this list was comprehensive, that the draft fundamentals of care were not always expressed perfectly, or that they were entirely relevant for every sector. But nevertheless, the overwhelming sentiment was that the things in the list were fit to be considered as Fundamental Standards.

[4] http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

Our response:

We agree that all of the areas are important, and also note that they are all covered in some way under the current registration requirements. The Francis Inquiry report stressed the need for the fundamental standards to be based on consensus between the public and professional representatives, so it is pleasing to see such consensus around the standards proposed.

The idea of having some basic universal outcomes for care and treatment is not in itself novel, and many attempts have been made previously to outline the kinds of things that might be considered funamental to care. Sources like the Royal College of Nursing Principles of Nursing Practice, the NHS Patient Experience Framework, the National Voices Principles of Integrated Care, and the Patients Association Care campaign, amongst many others, all attempt to encapsulate the things that are fundamental to good care. These sources demonstrate that there is already a large degree of consensus as to what is important, and they also demonstrate that there is more than one way to categorise and express those things that are deemed fundamental.

We can use those sources to test whether the things identified as important by others are covered by the Fundamental Standards.

We asked: Do you think there are additional areas that should be fundamentals of care?

We heard:

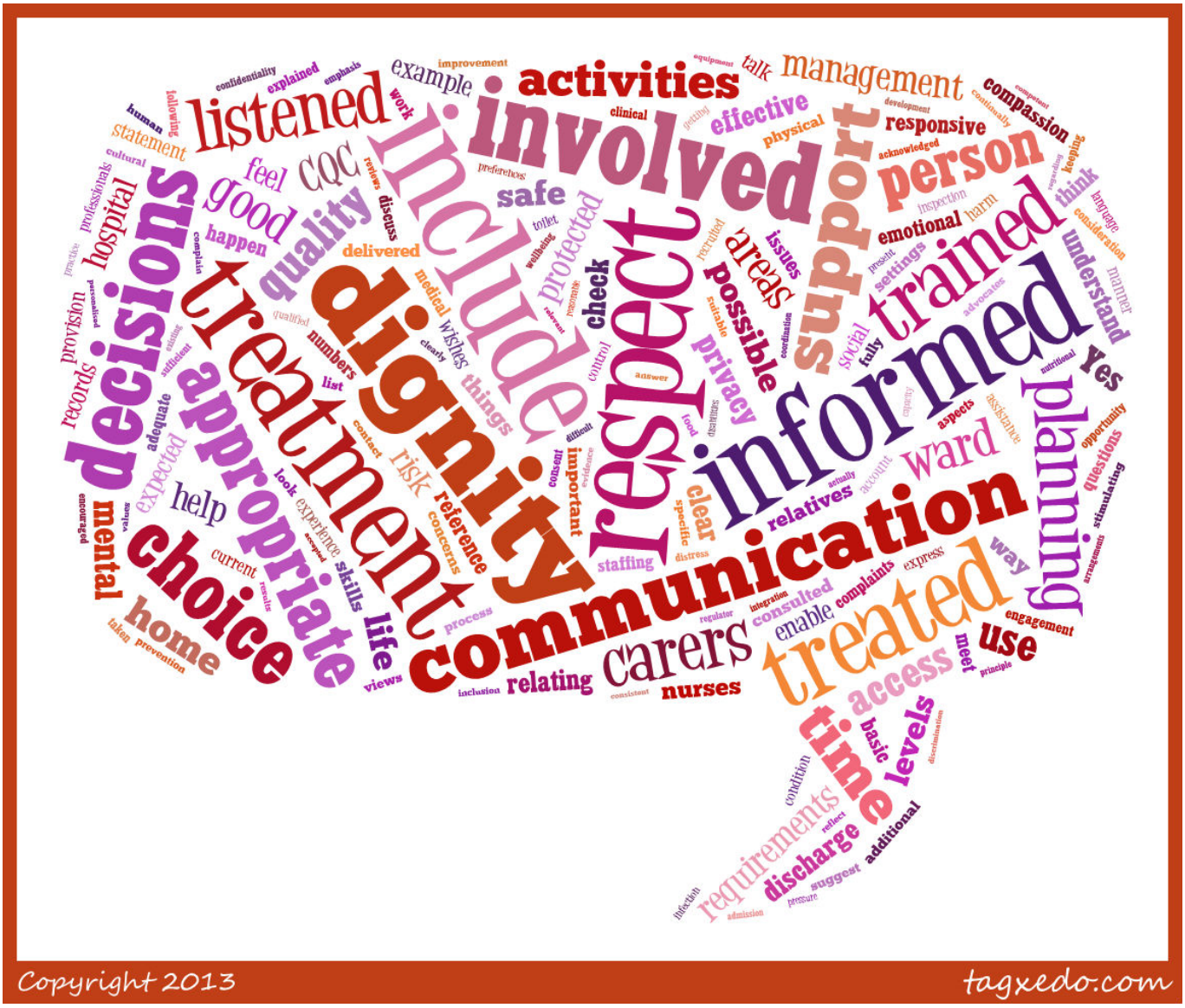
A number of respondents thought no further areas were required, but most respondents suggested additional areas that should also be considered fundamental. These suggestions ranged from general areas such as dignity and respect, to detailed comments about the need to cover particular services or outcomes related to specific conditions. A proportion of responses also made the point that although the list could be expanded, it is important not to make it too long.

The types of additional areas being suggested were often linked to a particular care setting, indicating that what is considered fundamental may depend on the care setting.

This was the question that elicited the biggest response and an analysis of all the responses show there were a number of prominent areas which could be considered fundamental. These were:

- Being treated with dignity and respect, including an emphasis on equality, diversity and human rights;
- Involvement in care planning;
- Involvement of friends, family and carers in decisions/planning of care;
- Being listened to;
- Communication in a way people understand;
- Appropriate levels of qualified staff.

The word-cloud below gives an indication of how often certain areas were mentioned (the bigger the word, the more times it appeared in a response)



Many responses to this question also asked whether it was necessary or helpful to have a distinction between 'fundamental' standards and 'expected' standards.

There were various issues raised with this idea. People were not clear about the difference between something being fundamental and something being expected, and some challenged the concept of separating the standards into groups when they would ultimately all be equal in law. The general view, expressed quite regularly, was that it would be simpler to just have one set of standards.

Many of the new 'fundamentals' that were suggested by respondents were ones that we had originally considered to be 'expected' – perhaps showing that our original distinction between 'fundamental' and 'expected' was unclear.

Our response:

Our initial intention was to have distinct ‘fundamental’ and ‘expected’ standards written in to the regulations.

However, this idea has proved confusing, and we accept that many of the areas we had imagined to be expected standards, such as dignity and respect, cleanliness, and involvement are considered by most people to be fundamental.

We agree that many of the additional areas highlighted by respondents are essential to the delivery of safe, quality care. The Fundamental Standards as set in regulations will apply to a large number of care settings and situations, so they will have to be quite broadly drawn, and are unlikely to align exactly with other attempts to express what is fundamental, or be a long list of outcomes. Our aim is to ensure that the Fundamental Standards are capable of encompassing all of the areas that have been identified as important. We have decided not to include a separate set of expected standards.

We asked: Are the fundamentals of care expressed in a way that makes it clear whether they have been broken?

We heard:

Responses to this question were varied – many respondents felt they weren’t clear enough and should be more specific, but many other respondents felt they were clear enough already. A lot of responses also picked up on the fact that many of the proposed standards use subjective terms like ‘clean’ and ‘enough’, and these make it difficult to reach an objective conclusion about whether the standards have been broken.

One of the most common responses to this question was that however the standards are written, they will need to be accompanied by guidance that adds clarity about how and when CQC would judge them to be broken, especially given the potential significance of a breach.

Generally, respondents thought the phrases were easy to understand, and thought that it was important to retain this simplicity, even if some of the words or concepts were open to subjective interpretation.

Many felt that despite this subjectivity, the intention behind each statement was clear.

A number of respondents commented that when considered as a group, the statements were paternalistic and gave the overall impression that care would be ‘done to’ patients. Answers to this question also included detailed comments on the wording of individual statements, often pointing out nuances or caveats that should be considered, or unintended consequences that might result.

Our response:

The responses overall made it clear that there is a tension between the need to use simple and easily understood language, and the need to write standards that are clear enough to give providers clarity about what a breach means. We think it will be impossible to retain the simplicity of the standards without also using some words that could be interpreted subjectively. But we agree with many responses that the solution to that tension is to make sure the guidance associated with the standards makes clear how CQC will judge breaches.

Related to this, we think that the legal requirements that will underpin these standards need to strike the right balance between being simply and clearly expressed, and being comprehensive and detailed enough to reflect the range of situations and uses to which they will apply. When he initially suggested the development of Fundamental Standards, Robert Francis stressed the need for them to be easily understood.

The issue about the statements being paternalistic shows the importance of considering the statements as a group as well as individually, and we need to be aware of the overall impression they give. We think our decision, in response to the previous question, to reflect the importance of dignity, respect and person-centred care in the standards addresses the issue of the standards being paternalistic.

We are grateful to respondents for highlighting the nuances and possible unintended consequences with the proposed wording and we will take these in to account as we develop the standards further.

4 We asked: Do the draft fundamentals of care feel relevant to all groups of people and settings?

We heard:

Views on this question were mixed. While many people felt quite strongly that the standards were not relevant to all, many others thought their coverage was good and they could apply universally. The main criticism levelled at the standards was that as a group, they fit a residential model of care (especially hospital-based models) much better than other models of care. However, plenty of respondents replying on behalf of non-residential providers/service users still thought the standards were broadly applicable.

Specific issues were raised about how well the standards applied in mental health and domiciliary settings, and to children and those with poor mental capacity. These issues highlighted the fact that different standards will apply in different settings - for example where care is being delivered in people's homes, providers may not be in charge of the cleanliness of the environment.

Our response:

We accept that while there was a lot of support for the draft standards, they could be improved in a number of ways to make them more relevant to all groups of people and settings. There are several elements to this, including:

- making sure the overall framework in which the standards work makes clear that they won't always apply in the same way everywhere;
- making sure that as a group, the standards are broad enough to cover all of the issues relevant in all settings or for particular groups; and
- making sure that the wording of the individual standards does not cause problems for their application in particular settings or for particular groups.

Other things we learned about the fundamentals standards

Many respondents made comments that were not directly related to the questions we asked, but nevertheless are important and have informed our thinking.

Many people pointed out that for the NHS there is a strong link and overlap with 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 updates to the NHS Constitution, we will consider how to reflect the Fundamental Standards.

Many respondents also pointed out that commissioners play an important role in determining the quality of care, or the level of service to be provided. Subject to the passage of the Care Bill, CQC will no longer have a role in routinely assessing the quality of commissioning, but they will retain the power to conduct special reviews where appropriate. However, the results of CQC's inspections and intelligence monitoring of providers will highlight commissioning issues at national, regional and local level which will help to promote improvement amongst clinical commissioning groups and local authorities.

4 What are we proposing?

This section sets out what we aim to deliver with the new draft regulations, and how we think the drafts address what we have heard through consultation.

These regulations will be a key part of CQCs new inspection regime, and will be used to support the assessment of existing providers, and the registration of new providers. CQC will consult on guidance that will explain how it will inspect providers, its enforcement policy, and its plans for rating providers.

Fundamental Standards that describe clear outcomes

The new draft regulations construct the registration requirements as clear outcomes that providers must meet both at the point of registration with CQC, and on an on-going basis once they are registered.

Where necessary, we have included additional clauses that place a responsibility on providers to act in particular ways that help to achieve the required outcome. We have done this for three reasons – firstly so that meeting the outcome is not left to chance, secondly so that new providers understand what is expected of them, and thirdly, to enable CQC to take action in cases where although the outcome is technically being met, the provider is taking a risky approach that is likely to compromise safety or quality in the future.

We have also included some definitions of particular terms within the requirements where appropriate.

Annex A contains a draft of the regulations that will introduce the Fundamental Standards. In summary, these are:

(a) care and treatment must reflect service users' needs and preferences;
(b) service users must be treated with dignity and respect;
(c) care and treatment must only be provided with consent;
(d) all care and treatment provided must be appropriate and safe;
(e) service users must not be subject to abuse;
(f) service users' nutritional needs must be met;
(g) all premises and equipment used must be safe, clean, secure, suitable for the purpose for which they are being used, and properly used and maintained;
(h) complaints must be appropriately investigated and appropriate action taken in response;
(i) systems and processes must be established to ensure compliance with these Fundamental Standards;
(j) sufficient numbers of suitably qualified, skilled and experienced staff must be deployed to meet these standards;
(k) persons employed must be of good character, have the necessary qualifications, skills and experience, and be capable of performing the work for which they are employed.

Clearer offences - removing the need for a notice for prosecution for some offences

Our draft requirements include clear outcomes that providers must meet (for example, “service users must not be subject to abuse”). If a provider is not meeting that outcome, they are committing an offence.

In all cases it is important that providers can be held to account for the quality of care that they have provided, including by the courts where this is appropriate.

Our intention is that where a breach of a requirement has an outcome which could directly result in a person or group of people being harmed, CQC has the power to bring a prosecution straight away, but where a breach has not or would not directly result in harm, CQC would use its other enforcement powers.

A proportionate response

While a breach of the fundamental standards will be an offence, it is our intention that CQC’s prosecution activity should focus on the most serious failings in care. Our draft regulations will make it possible for CQC to bring prosecutions without having to issue a warning notice in cases where these failings have happened.

By serious, we mean, for example, individual failings in care which fall far below any acceptable standard, those where there are multiple breaches of regulations across a provider at a given point in time, or those where there are persistent breaches over time.

CQC will be responsible for setting out the criteria that it will apply in deciding the appropriate level of enforcement action, including prosecution. CQC will consult on these criteria. In addition to this, CQC will follow the Code for Crown Prosecutors[5] which makes it clear that prosecutions should only be brought where there is enough evidence to support the charge, and it is in the public interest to bring the case to court.

Issuing warnings and addressing risks

Not all of the requirements are serious enough to warrant immediate prosecution if breached, and in some cases it will be appropriate for CQC to take other action, including issuing notices to providers requiring improvement before they prosecute. We are retaining a pre-prosecution notice system for these standards. A subsequent prosecution would be possible if the provider did not address the risk highlighted in the notice.

Regulation 17(2) of the draft regulations lists those requirements for which CQC could not prosecute without issuing a pre-prosecution notice in advance (standards i, j and k in the above list). Question iv of this consultation asks if you think we have drawn this distinction correctly.

[5] https://www.cps.gov.uk/publications/code_for_crown_prosecutors/

In some cases, a requirement contains an overall outcome (for example that care must be appropriate and safe), and a small number of additional supporting conditions (for example that steps be taken to mitigate the risks of care being inappropriate or unsafe). A breach of one of the supporting conditions would be a less serious breach of the requirement and CQC's enforcement activity would be proportionate to this.

These supporting conditions are included in the regulations to provide CQC with a means of taking appropriate enforcement where providers are found to be slipping, or not taking reasonable steps to manage risks, but these have not resulted in harm. They also show potential new providers what they need to do to be able to register with CQC.

High-level standards that encompass all of the things people have said are important

The consultation has helped us identify a wide range of things that are important. We think the draft regulations provide broad coverage and encapsulate all of the issues people identified as important via the consultation. The standards matrix at Annex D shows how the areas identified as important in CQC's consultation fit within the draft requirements.

One list of standards – no hierarchy

We accept that the split between fundamental and expected standards included in the original consultation was confusing. The registration requirements in our draft are all Fundamental Standards.

Standards that are generally applicable, yet realistic

Many consultation respondents were concerned that earlier drafts of the standards were too focused on residential care settings, and less relevant for other settings like GP practices or domiciliary care. However, CQC registration requirements apply to all registered health and social care providers. To address this, our draft standards are less specific than those in CQCs consultation and therefore more broadly applicable. We have also included standards covering dignity, respect and involvement to ensure that care and treatment is always person-centred rather than dictated by the setting. We have also included a general caveat in regulation 3 ('in so far as they are applicable to each regulated activity') to account for those situations where a standard may not apply to a service or setting.

Clear distinction between regulations and guidance

The relationship between regulations and guidance is of great importance, and to understand either in isolation of the other is difficult.

The existing requirements contain a lot of detail and in many cases also start to outline how the requirement should be met. The fact that the current requirements often contain sub-requirements, each of which can be broken, yet contains no clarity of where the offence threshold is, makes it hard for providers to identify what they must to do avoid breach. It also constrains CQC's ability to take appropriate enforcement action.

The draft regulations seek to improve this by focusing the regulations more closely on outcomes, rather than on the steps that must be taken to achieve that outcome, and by clearly specifying the offences. CQC's guidance will clarify what is required of providers in order to meet the fundamental standards.

Reduces the burden on providers

Our draft makes clear outcomes that providers must meet, and reduces the complexity and the length of the requirements. We believe the scope of the new requirements has not significantly changed, but that the intentions are clearer. Or initial work with providers indicates that this added clarity will make the requirements easier to work with, increasing understanding of the requirements, and saving time for providers when referring to them and working with them.

We have assessed the costs and benefits of our proposals in an Impact Assessment, available alongside this consultation, and have included a call for evidence in Annex C to help us further understand the likely impact of the changes.

Other changes to note

The new draft regulations (regulation 17(6)) take account of section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012. This removes the maximum limit on fines that can be imposed on summary conviction. In line with this legislation, which has not yet been commenced, the penalty for failing to meet the registration requirements will change from a maximum fine of £50,000 to an unlimited fine. If section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act is not commenced by the time these regulations come in to force, the maximum penalty will continue to be £50,000, until the commencement of section 85 permits this to be increased to an unlimited fine.

Next Steps

The new draft regulations that will introduce the Fundamental Standards as registration requirements are included in Annex A. The draft of the new regulations sets out how we are changing the registration requirements. In time, the new registration requirements will form part of a consolidated set of regulations that will replace the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 in their entirety.

We would like your opinion on these draft regulations. The specific questions we would like you to consider are included in Annex B.

5 Responding to the consultation

This section outlines the scope of the response we are seeking to this consultation.

CQCs consultation *A New Start - consultation on changes to the way CQC regulates, inspects and monitors care* gave people an opportunity to feed in to the early development of the Fundamental Standards. The measures were well supported and we have used the responses to that consultation to develop the Fundamental Standards as regulations that meet our aims.

In this document we have set out our aims and intentions, shared our reasoning for the proposals we have made, and in **Annex A** have set out draft regulations to meet these aims.

The scope of this consultation is to establish whether the regulations we have drafted will meet the aims we have set out. **The consultation questions are listed at Annex B.**

We would also like your help to establish an evidence base for the likely impact of these changes on your organisations. A call for evidence asking for more evidence is included in **Annex C.** This is mainly of interest to provider organisations.

In order to accommodate the Parliamentary process associated with laying and making regulations, and because we have, through CQC, already consulted on the background policy that these regulations relate to, this consultation will run for 10 weeks, closing on **4 April 2014.**

To respond to this consultation, you can:

Answer the questions online, at http://consultations.dh.gov.uk/standards/fundamental-standards

Email your responses to cqc.regulations@dh.gsi.gov.uk

Post your responses to:

Fundamental Standards Consultation
c/o John Culkin
Room 2E11
Quarry House
Quarry Hill
Leeds,
West Yorkshire
LS2 7UE

An **Easy Read** version of the document is available online at:

http://consultations.dh.gov.uk/standards/fundamental-standards

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please:

contact Consultations Coordinator
Department of Health
2e08, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send *consultation responses* to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.** (http://transparency.dh.gov.uk/dataprotection/information-charter/)

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Annex A – Draft Regulations

N.B. This draft is an abridged version of the new regulations which set out how we are changing the registration requirements. In time, the new registration requirements will form part of a consolidated set of regulations that will replace the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 in their entirety.

Draft Regulations laid before Parliament under section 162(3)(b) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

S T A T U T O R Y I N S T R U M E N T S

2014 No. 000

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

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

Made - - - - ***

Coming into force - - *1st October 2014*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 20 and 161(3) and (4) of the Health and Social Care Act 2008([6]).

In accordance with section 20(8) of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008, and was approved by a resolution of each House of Parliament.

([6]) 2008 c. 14.

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and come into force on 1st October 2014.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Health and Social Care Act 2008;

"the 2005 Act" means the Mental Capacity Act 2005([7]);

"the 2006 Act" means the National Health Service Act 2006([8]);

"the 2010 Regulations" means Health and Social Care Act 2008 (Regulated Activities) Regulations 2010([9]);

"adult placement carer" means an individual who, under the terms of a carer agreement, provides, or intends to provide, personal care for service users together with, where necessary, accommodation in the individual's home;

"adult placement scheme" means a scheme carried on (whether or not for profit) by a local authority or other person for the purposes of—

(a) recruiting and training adult placement carers,

(b) making arrangements for the placing of service users with adult placement carers, and

(c) supporting and monitoring placements;

"agency worker" and "temporary work agency" have the same meaning as in the Agency Workers Regulations 2010([10]);

"carer agreement" means an agreement entered into between a person carrying on an adult placement scheme and an individual for the provision, by that individual, of personal care to a service user together with, where necessary, accommodation in the individual's home;

"chiropodist or podiatrist" means a person registered as such with the Health and Care Professions Council([11]) pursuant to article 5 of the Health Professions Order 2001([12]);

"employment" means—

(d) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, and

(e) the grant of practising privileges,

and "employed" is to be construed accordingly;

"equipment" includes a medical device and materials used in, or used by persons employed in, the carrying on of a regulated activity;

([7]) 2005 c. 9.

([8]) 2006 c. 41.

([9]) S.I. 2010/781, as amended by S.I. 2011/2711, 2012/921, 2012/979, 2012/1479, 2012/1513, 2013/235 and 2013/472.

([10]) S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.

([11]) The Health and Care Professions Council is the body corporate, formally known as the Health Professions Council, continued under section 214(1) of the Health and Social Care Act 2012 (c. 7).

([12]) S.I. 2002/254. *See* the definition of "relevant professions" in Schedule 3, paragraph 1 of the Order as amended by S.I. 2004/2033, article 10(5)(b)(i).

"healthcare professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999([13]) (regulation of health professions, social workers, other care workers, etc) applies;

"hospital" has the same meaning as in section 275 of the 2006 Act;

"medical device" has the same meaning as in regulation 2 (interpretation) of the Medical Devices Regulations 2002([14]);

"medical practitioner" means a registered medical practitioner;

"personal care" means—

(a) physical assistance given to a person in connection with—

(i) eating or drinking (including the maintenance of established parenteral nutrition),

(ii) toileting (including in relation to the process of menstruation),

(iii) washing or bathing,

(iv) dressing,

(v) oral care, or

(vi) the skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist); or

(b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

"practising privileges" means the grant by a service provider to a registered medical practitioner of permission to practice as a medical practitioner in a hospital managed by the service provider;

"premises" means—

(c) any building or other structure, including any machinery, engineering systems or other objects which are physically affixed and integral to such building or structure, and any surrounding grounds; or

(d) a vehicle;

"registered manager" means, in respect of a regulated activity, a person registered with the Commission([15]) under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

"registered person" means, in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity;

"relevant person" means the service user or, where the service user is not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

"service provider" means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

"service user" means a person who receives services provided in the carrying on of a regulated activity;

"treatment" includes—

(e) a diagnostic or screening procedure carried out for medical purposes;

(f) the ongoing assessment of a service user's mental or physical state;

(g) nursing, personal and palliative care; and

(h) the giving of vaccinations and immunisations; and

"vulnerable adult" has the same meaning as in section 60(1) of the Safeguarding Vulnerable Groups Act 2006([16]).

(2) In the definition of "employment" in paragraph (1), the reference to otherwise than under a contract includes—

(a) under a carer agreement;

([13]) 1999 c. 21.

([14]) S.I. 2002/618. Relevant amendments were made by S.I. 2008/2986.

([15]) By section 1(1) of the Health and Social Care Act 2008, "the Commission" means the Care Quality Commission.

([16]) 2006 c. 47.

(b) under an agreement between the service provider and a temporary work agency for the supply of an agency worker to the service provider; and

(c) under arrangements for persons to provide their services voluntarily.

PART 2

Quality and Safety of Service Provision in Relation to Regulated Activity

SECTION 1

General

General

3. A registered person must, in so far as they are applicable to each regulated activity, comply with regulations 4 to 14 in carrying on the regulated activities in respect of which they are registered.

SECTION 2

Fundamental standards

Person-centred care

4.—(1) The care and treatment of service users must reflect their needs and preferences.

(2) Paragraph (1) applies—

(a) subject to paragraph (4), and

(b) in so far as it is in accordance with generally accepted professional standards, practices and principles for the care and treatment to reflect such needs and preferences.

(3) The things which a registered person is required to do to comply with paragraph (1) include—

(a) carrying out an assessment of the needs and preferences for care and treatment of the service user;

(b) designing care or treatment with a view to ensuring service users' welfare;

(c) so far as is reasonably practicable, permitting and encouraging service users to make, or participate in making, decisions relating to their care or treatment to the maximum extent possible;

(d) where the service user is unable to express their preferences because they lack capacity, determining and acting in accordance with the best interests of the service user;

(e) where applicable, providing for the making of reasonable adjustments to meet the service user's individual needs; and

(f) have sufficient quantities of suitably accessible equipment and medicines to ensure the safety of service users and to meet their assessed needs.

(4) Where Part 4 or 4A of the Mental Health Act 1983([17]) applies to a service user, care and treatment must be provided in accordance with the provisions of that Act.

(5) For the purposes of paragraph (3)(d)—

(a) section 2 of the 2005 Act (people who lack capacity) applies for the purposes of determining whether a service user lacks capacity, and

(b) section 4 of the 2005 Act (best interests) applies as it applies for the purposes of that Act.

Dignity and respect

5.—(1) Service users must be treated with dignity and respect.

(2) The things which a registered person is required to do to comply with paragraph (1) include—

(a) promoting the privacy, autonomy, independence and involvement in the community of the service user; and

([17]) 1983 c. 20.

(b) having due regard to any protected characteristics (as laid down in section 4 of the Equality Act 2010([18])) of the service user.

Need for consent

6.—(1) Care and treatment must only be provided with, and in accordance with, the consent of the relevant person.

(2) Where the relevant person is unable to give such consent because they lack capacity, the registered person must determine and act in accordance with the best interests of the service user.

(3) Where Part 4 or 4A of the Mental Health Act 1983 applies to a service user, paragraph (1) is subject to the provisions of that Act.

(4) For the purposes of paragraph (2)—

(a) section 2 of the 2005 Act applies for the purposes of determining whether a service user lacks capacity, and

(b) section 4 of the 2005 Act (best interests) applies as it applies for the purposes of that Act.

Safe and appropriate care and treatment

7.—(1) All care and treatment provided to service users must be appropriate and safe.

(2) The things which a registered person is required to do to comply with paragraph (1) include—

(a) taking appropriate steps to mitigate the risks to service users of receiving care or treatment that is inappropriate or unsafe;

(b) taking appropriate steps for the proper and safe management of medicines;

(c) establishing and operating effectively systems designed to assess the risk of, and to prevent, detect and control the spread of, infections, including those that are health care associated; and

(d) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working in cooperation with such other persons to ensure that appropriate care planning takes place to ensure the health, safety and welfare of the service users.

(3) For the purposes of paragraph (1), care or treatment will not be appropriate if it is not provided in accordance with generally accepted professional standards, practices and principles or if it includes—

(a) unlawful discrimination against service users, or

(b) control or restraint which is—

(i) unlawful, or

(ii) not necessary to prevent, or not proportionate to, the risk posed if the service user was not subject to control or restraint.

Safeguarding service users from abuse

8.—(1) Service users must not be subject to abuse.

(2) Appropriate steps must be taken—

(i) to prevent abuse before it occurs, and

(ii) to respond to any allegation of abuse.

(3) For the purposes of this regulation, "abuse", in relation to a service user, includes—

(a) sexual abuse,

(b) physical or psychological ill-treatment,

(c) theft, misuse or misappropriation of money or property, or

(d) neglect and acts of omission which cause harm to a service user or place the service user at risk of harm.

([18]) 2010 c. 15.

Meeting nutritional needs

9.—(1) The nutritional needs of service users must be met.

(2) In this regulation, "nutritional needs" means adequate nutrition to sustain life and good health and includes—

(a) those needs which can be met wholly or in part by the provision of food or drink,

(b) parenteral nutrition and dietary supplements when prescribed by a healthcare professional,

(c) any reasonable requirements arising from a service user's religious or cultural background, and

(d) where necessary, support to eat and drink.

Cleanliness, safety and suitability of premises and equipment

10.—(1) All premises and equipment used by the registered provider must, in accordance with generally accepted professional standards, practices and principles, be—

(a) safe, clean and secure,

(b) suitable for the purpose for which they are being used, and

(c) properly used and maintained.

(2) The registered provider must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purpose for which they are being used.

(3) For the purposes of this regulation "premises" does not include a service user's own home

Receiving and acting on complaints

11.—(1) Any complaint received must be appropriately investigated and appropriate action must be taken in response to the complaint.

(2) The registered person must establish and operate effectively a system for identifying, receiving, recording, handling and responding appropriately to complaints, and requests for action to be taken, by service users and other persons in relation to the carrying on of the regulated activity.

(3) The registered person must send to the Commission, when requested to do so, a summary of—

(a) complaints made under such complaints system,

(b) responses made by the registered person to such complaints and any further correspondence with the complainants in relation to such complaints, and

(c) any other relevant information in relation to such complaints as the Commission may request.

Good governance

12.—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.

(2) Such systems or processes must enable the registered person, in particular, to—

(a) assess, monitor and improve the quality of the services provided (including the quality of the experience of service users in receiving those services);

(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

(c) maintain an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user;

(d) maintain such other records as are appropriate in relation to—

(i) persons employed, and

(ii) the management of the regulated activity;

(e) seek and act on feedback from service users and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services; and

(f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

Staffing

13.—(1) The registered person must deploy sufficient numbers of suitably qualified, skilled and experienced persons in order to meet the requirements of this Part.

(2) The registered person must ensure that persons employed by the registered provider in the provision of a regulated activity—

(a) receive appropriate support, training, professional development, supervision and appraisal;

(b) are enabled where appropriate, from time to time, to obtain further qualifications appropriate to the work they perform; and

(c) where such persons are healthcare professionals, or social workers or other professionals registered with the Health and Care Professions Council, are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practice.

Fit and proper persons employed

14.—(1) Persons employed by the registered person must—

(a) be of good character,

(b) have the qualifications, skills and experience which are necessary for the work to be performed, and

(c) be physically and mentally capable, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.

(2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in paragraph (1).

(3) The information specified in the Schedule and such other information as is appropriate must be available in relation to each such person employed.

(4) Persons employed must be registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—

(a) the work that the person is to perform, or

(b) the title that the person takes or uses.

(5) Appropriate steps must be taken in relation to a person employed by the registered person who no longer meets the criteria in paragraph (1), including—

(a) where the person is a healthcare professional, informing the body responsible for regulation of the health care profession in question, or

(b) where the person is a social worker or other professional registered with the Health and Care Professions Council, informing the Council.

PART 3

Compliance and Offences

Compliance with regulations

15. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on at or from particular premises, anything which is required under these Regulations to be done by the registered person is not, if done by one of the registered persons, to be required to be done by any of the other registered persons.

Guidance and Code

16. For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to—

(a) guidance issued by the Commission under section 23 of the Act in relation to the requirements set out in Part 2 (with the exception of regulation 7 in so far as it applies to health care associated infections); and

(b) in relation to regulation 7, any code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of health care associated infections.

Offences

17.—(1) A breach of any of regulations 4 to 14 is an offence.

(2) The Commission may not bring proceedings in respect of a failure to comply with any of those regulations where such breach is a result only of a failure to comply with any of regulations 4(3)(c) or (f), 7(2), 11(2), 11(3) or 12 to 14 unless the conditions in paragraph (3) or (4) (as the case may be) have been met.

(3) In the case of an NHS trust established under section 25 of the National Health Service Act 2006 or an NHS foundation trust—

(a) the Commission has given the registered person a notice in respect of the alleged failure, setting out what the alleged failure is, and

(b) the registered person did not secure compliance with the relevant requirement within the period specified in the notice.

(4) In the case of any other registered person—

(a) the alleged failure is one in respect of which the Commission has given a warning notice to the registered person under section 29 of the Act;

(b) that warning notice specified a time within which the registered person must take action to secure compliance pursuant to section 29(2)(c)(ii) of the Act; and

(c) the registered person did not secure compliance within the specified time.

(5) No proceedings may be brought against an NHS trust or an NHS foundation trust for an offence that arises out of a failure to which a notice under paragraph (3)(a) relates, so far as occurring before the time specified in that notice for securing compliance with the relevant requirement.

(6) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine.

(7) In any proceedings for an offence under this regulation, it is a defence for the registered person to prove that they took all appropriate steps and exercised all due diligence to ensure that the provision in question was complied with.

Onus of proving limits of what is practicable etc

18. In any proceedings for an offence under regulation 4 or 14 consisting of a failure to comply with a requirement to do something so far as is reasonably practicable, it is for the accused to prove that it was not reasonably practicable to do more than was in fact done to satisfy the requirement, or that there was no better practicable means than was in fact used to satisfy the requirement.

PART 4

Revocations, Amendments and Review

Revocations

19. Regulations 8 to 24, 27 and 30 of the 2010 Regulations are revoked.

Amendments

20.—(1) The 2010 Regulations are amended in accordance with this regulation.

(2) In regulation 1, omit the entries for “employment” and “practising privileges”.

(3) In regulation 26—

(a) in paragraph (1)(a), for the words “set out in Part 3 and 4” to the end substitute “Part 3”; and

(b) omit paragraphs (1)(b) and (2)(b).

(4) For the entry relating to regulation 27 of the 2010 Regulations in Schedule 4 (fixed penalty offences) substitute—

“Regulation 17 of the Health and Social Care Act 2008	Contravention of, or failure to comply with, requirements	£4,000 in the case of an offence committed by a

(Regulation of Regulated Activities) Regulations 2014	relating to quality and safety of service provision in relation to a regulated activity	service provider; £2,000 in the case of an offence committed by a registered manager”

Review

21.—(1) Before 1st October 2017, the Secretary of State must—

(a) carry out a review of these Regulations and the 2010 Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations and the 2010 Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

Signed by the authority of the Secretary of State for Health

Name
Minister of State
Department of Health

00th ***** 2014

SCHEDULE

Regulation 14

Information Required in Respect of Persons Employed for the Purposes of a Regulated Activity

22. Proof of identity including a recent photograph.

23. Where required for a purpose referred to in section 113A(2)(b) of the Police Act 1997([19]), a copy of a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, the information mentioned in section 30A(3) of the Safeguarding Vulnerable Groups Act 2006 (provision of barring information on request)([20]).

24. Where required for a purpose referred to in section 113B(2)(b) of the Police Act 1997, a copy of an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.

25. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—

(a) health or social care, or

(b) children or vulnerable adults.

26. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P’s employment in that position ended.

27. Satisfactory documentary evidence of any relevant qualification.

28. A full employment history, together with a satisfactory written explanation of any gaps in employment.

([19]) 1997 c. 50.

([20]) 2006 c. 47.

29. Satisfactory information about any physical or mental health conditions which are relevant to the person's capability to properly perform tasks which are intrinsic to their employment for the purposes of the regulated activity.

30. For the purposes of this Schedule—

(a) "the appointed day" means the day on which section 30A of the Safeguarding Vulnerable Groups Act 2006 comes into force;

(b) "satisfactory" means satisfactory in the opinion of the Commission; and

(c) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the requirements that will apply in relation to the way in which regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 ("the Act") are carried on. Regulations 4 to 14 lay down fundamental standards to be met by registered persons.

The fundamental standards provide that, in so far as they are applicable to the carrying on of a regulated activity:

(d) care and treatment must reflect service users needs and preferences (regulation 4);

(e) service users must be treated with dignity and respect (regulation 5);

(f) care and treatment must only be provided with consent (regulation 6)

(g) all care and treatment provided must be appropriate and safe (regulation 7);

(h) service users must not be subject to abuse (regulation 8);

(i) service users' nutritional needs must be met (regulation 9);

(j) all premises and equipment used must be safe, clean, secure, suitable for the purpose for which they are being used, and properly used and maintained (regulation 10);

(k) complaints must be appropriately investigated and appropriate action taken in response (regulation 11);

(l) systems and processes must be established to ensure compliance with the fundamental standards (regulation 12);

(m) sufficient numbers of suitably qualified, skilled and experienced staff must be deployed (regulation 13); and

(n) persons employed must be of good character, have the necessary qualifications, skills and experience, and be capable of performing the work for which they are employed (regulation 14).

Regulation 15 deals with who is responsible for complying with the Regulations in circumstances where there is more than one registered person in respect of a regulated activity. Regulation 16 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Care Quality Commission under section 23 of the Act and the code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of healthcare associated infections.

Regulation 17 provides that a breach of regulations 4 to 14 is to be an offence, and also includes a due diligence defence relating to any proceedings under the Regulations. In addition, it provides that no prosecution may be brought for a breach of any of the requirements listed in paragraph (2) of regulation 17 unless the breach is one which the registered person has failed to remedy in response to a notice from the Care Quality Commission.

Regulation 19 revokes regulations 8 to 24, 27 and 30 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 ("the 2010 Regulations"), which are replaced by regulations 3 to 14, 17 and 21 of these Regulations. Regulation 20 makes amendments to the 2010 Regulations which are needed as a consequence of these Regulations.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health) and is published alongside this instrument and its Explanatory Memorandum at www.legislation.gov.uk.

Annex B - Consultation questions

i. Do the Fundamental Standards (regulations 4-14) make clear the kinds of outcomes we expect providers to meet/avoid?

ii. Do you think the Fundamental Standards (regulations 4-14) reflect the policy aims we have set out for the Fundamental Standards in Chapter 4?

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 (see chapter 4) 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 agree that the health and adult social care system should always seek to meet the standards outlined in chapter 4?

vii. Do you think any changes are needed to the draft regulations to ensure they reflect the policy aims we have set out in chapter 4?

viii. Do you have any other comments about the draft regulations?

ix. Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?

(The protected characteristics are age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation.)

x. Do you have any comments about the estimated costs and benefits of these regulations, as set out in the draft impact assessment (published alongside this consultation)? See Annex C for more detailed questions on impact.

Annex C - Assessing the impact of these changes

Calls for evidence

The impact assessment relating to these changes is available alongside this document. To help us calculate the likely impact of these changes, we would be interested in any relevant evidence you have, in answer to the questions below.

The following questions are primarily aimed at provider organisations:

Fundamental Standards and registration requirements

When and why would you need to read or refer to the CQC regulations or guidance?

- When designing services ☐
- When evaluating services ☐
- When inducting staff ☐
- General day-to day work ☐
- Other Click here to enter text.

How much time do you think you spend reading or thinking about them at the moment?

- 0-2 hours a month ☐
- 2-4 hours a month ☐
- 4-8 hours a month ☐
- Over 8 hours a month ☐

Do you think the current regulations are easy to understand?

Yes ☐ No ☐

If the regulations were easier to understand, would this be beneficial to your business?

Yes ☐ No change ☐ No, it would make it worse ☐

If yes, what kinds of benefits would you expect to see?

- Saved time ☐

Reduced costs ☐

Better compliance ☐

Better service ☐

Other ☐

(If you don't think there would be benefits, can you explain why?)

Click here to enter text.

Do you think the new draft versions are easier to understand?

Yes ☐ No ☐

What other impacts might the proposed changes have for you, either positive or negative? Please give as much detail as possible - including estimates of the size of the benefits/impact where possible.

Click here to enter text.

Do you think our Impact Assessment on Fundamental Standards accurately highlights the nature and size of the costs and benefits of this proposal?

Yes ☐ No ☐

If no, why not?

Click here to enter text.

Annex D - Standards matrix

The response we received to *A New Start - consultation on changes to the way CQC regulates, inspects and monitors care* helped us identify a range of potential standards that are important. The Francis Inquiry Report and the Department of Health's initial response also suggested a number of potential standards. We think the new drafts provide broad coverage and encapsulate all of the issues people identified as important. This annex shows how the areas others have identified as important fit within the new draft requirements. It demonstrates that all of the things people have identified as important are covered in one way or another under the new draft requirements. In some cases, there is more than one potential fit – this is this is not intended to show strict correlations.

Key:

Purple Text = suggestions arising from CQC consultation

Red Text = Suggestions form the Francis Inquiry Report

Green Text = suggestions from Patients First and Foremost – the Government's initial response to the Francis Inquiry

Fundamental standard	Area of importance suggested by others
All care and treatment provided to service users must be appropriate and safe	I will be protected from abuse and discrimination. I will be protected from harm during my care and treatment. I will be given pain relief or other prescribed medication when I need it. When I am discharged my on-going care will have been organised properly first. It is unacceptable for a patient to be injured in the course of treatment by a failure without reasonable excuse to provide prescribed medications. It is unacceptable for a patient to be injured by contracting certain types of infection as a result of the failure to apply methods of hygiene and infection control accepted by a specified standard-setting body, preferably NICE. It is unacceptable for a patient to be discharged from hospital without adequate notice for arrangements to be made for the provision of any continuous care or support required. People are getting the medicines they have been prescribed at the right time and the right

	dose, including appropriate pain relief.
All care and treatment must reflect a service user's needs and preferences	I will be helped to use the toilet and to wash when I need it. Being treated with dignity and respect, including an emphasis on equality, diversity and human rights. Being listened to. Involvement in care planning. Communication in a way people understand. Involvement of friends/family/others. People are being helped when they need it to go to the lavatory and not left in wet or soiled clothing or beds. People are being asked to consent to treatment and all staff communicate with patients effectively about their care and treatment.
Service users must not be subject to abuse	I will be protected from abuse and discrimination. I will not be held against my will, coerced or denied care and treatment without my consent or the proper legal authority.
The nutritional needs of service users must be met	I will be given enough food and drink and helped to eat and drink if I need it. It is unacceptable for a patient to be left without the nutrition and hydration reasonably required by a patient in his or her condition, or any necessary assistance to consume such nutrition and hydration. People are getting food and water, and help to eat and drink if they need it.
Any complaint received must be appropriately investigated and appropriate action must be taken in response	If I complain about my care, I will be listened to and not victimised as a result.
All premises and equipment used by the registered provider must be clean, safe, secure, suitable, properly used and maintained	I will be cared for in a clean environment. People are being helped when they need it to go to the lavatory and not left in wet or soiled clothing or beds. The environment is clean and hygienic.
All care and treatment must only be provided with, and in accordance with	I will not be held against my will, coerced or denied care and treatment without my consent or the proper legal authority.

the consent of the relevant person	It is unacceptable for treatment to be given to a patient without his or her informed consent or other lawful authority. People are being asked to consent to treatment and all staff communicate with patients effectively about their care and treatment.
The registered person must deploy sufficient numbers of suitably qualified, skilled and experienced persons…	Appropriate levels of qualified staff.
Employees must be of good character, have the qualifications, skills and experience…	Appropriate levels of qualified staff.
Service users must be treated with dignity and respect	People are being helped when they need it to go to the lavatory and not left in wet or soiled clothing or beds. I will be helped to use the toilet and to wash when I need it. Being treated with dignity and respect, including an emphasis on equality, diversity and human rights.
Good governance	