

Guidance for providers on meeting the fundamental standards and on CQC's enforcement powers

Consultation

July 2014

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

Our purpose

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

Our role

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

Our principles

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

Foreword from the Chief Executive

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

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

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

Stakeholders in the care sectors welcomed our new approach.

New regulations setting out fundamental standards of quality and safety now enable us to move to the next stage of development. The regulations are called the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. They are more focused than the previous ones. They will enable us to pinpoint more clearly the standards below which care must not fall, and take appropriate enforcement action, in line with Sir Robert Francis's recommendations arising from his inquiry into care at Mid-Staffordshire NHS Foundation Trust.

The regulations also introduce a new duty of candour, and a fit and proper person requirement for directors, which will enable greater accountability of directors. These are significant changes.

The statutory duty of candour is an important step towards ensuring the open, honest and positive culture that Sir Robert Francis found was lacking at Mid Staffordshire. He also said that there should be stronger ways to hold people to account for failures of care. The fit and proper person requirement plays a major part in ensuring the accountability of directors for failures in care. It is essential that CQC uses these new powers well, to encourage a culture of openness and to hold providers and directors to account.

This consultation sets out our proposed guidance for providers to help them meet the requirements of the regulations, and our proposed guidance on how we use our enforcement powers.

It will lead to the replacement in its entirety, from April 2015, of CQC's current *Guidance about compliance: Essential standards of quality and safety* and the 28 'outcomes' that it contains. It will also replace CQC's current enforcement policy.

The new guidance will be central to our process for considering new applications for registration, and varying existing registrations. Our inspections will focus on rating providers on the five key questions for identifying good care, but where we identify poor care this guidance will help us to also determine whether there is a breach of regulations and, if so, what action to take. For providers, this guidance will help them to make applications to register or vary their registration, and to make sure their services do not fall below acceptable levels.

I hope you will take the time to respond. Your views are important in helping us to refine our new approach and get it right.

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

David Behan
Chief Executive
Care Quality Commission

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Introduction

New fundamental standard regulations – the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 – will come into force for all providers on 1 April 2015, subject to Parliamentary process and approval.

The guidance in this document sets out what providers can do to ensure that they comply with the new regulations (part A of this document), and how CQC will respond and use its enforcement powers where services are in breach of regulations (part B). Providers will particularly want to take account of this guidance when applying for registration and, after they have registered, in their ongoing assurance of quality and safety.

Within the new regulations, the duty of candour and the fit and proper person requirements for directors will come into force earlier for NHS bodies than for other providers – from October 2014, rather than April 2015. Because of this shorter timescale, we are consulting in parallel on the guidance for NHS bodies in respect of those two specific regulations. The same proposed guidance is repeated in this consultation for all providers; the expectation is that these regulations will be extended to them from April 2015, subject to Parliamentary process and approval.

This consultation will lead to the replacement in its entirety, from April 2015, of CQC's current *Guidance about compliance: Essential standards of quality and safety* and the 28 'outcomes' that it contains. It will also replace CQC's current enforcement policy.

In a few cases, we are not proposing new guidance on regulations. This is the case for regulations on notifications, fees, statement of purpose, financial position, nominated individuals, and fitness of providers who are individuals or partnerships. Guidance for these regulations is contained in outcomes 3, 15, 18-20 and 22-28 of the current *Guidance about compliance: Essential standards of quality and safety*. This guidance will be carried over unchanged into the final full version of this document.

The consultation runs from 25 July 2014 to 17 October 2014. The consultation questions we are asking, and details of how to respond, are set out at the end of this section.

CQC's operating model

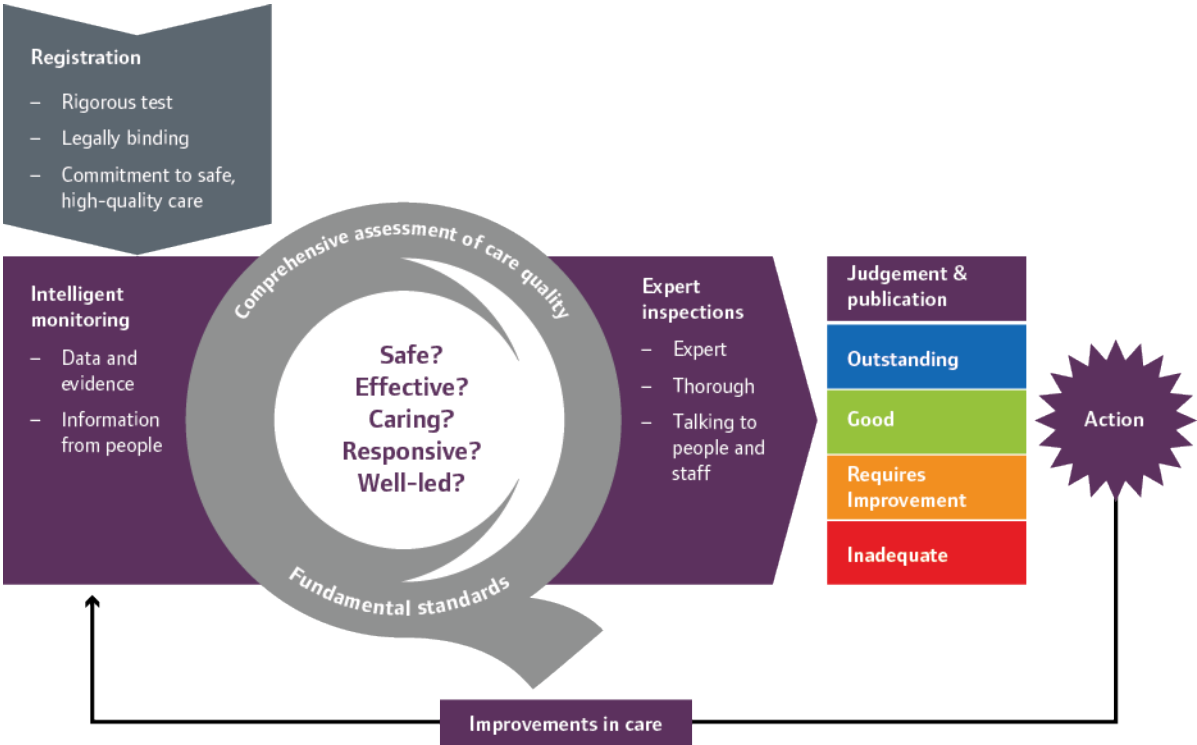
In April 2013, CQC published its new strategy: *Raising standards, putting people first*, setting out CQC's clear purpose and role.

To deliver our purpose, we are introducing significant changes to how we work. Our provider handbooks set out the details of our new approach for each sector we regulate. They describe how we will carry out inspections, make judgements and award ratings to providers. We recently consulted on the handbooks for adult social

care, hospice care, primary medical care, acute services, specialist mental health services and community health services. This consultation closed on 4 June 2014 and we will publish updated handbooks in September and October 2014. We will also publish handbooks for the remaining sectors that we regulate over the coming months.

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

Figure 1: CQC’s overall operating model



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

How our guidance fits into our operating model

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

The law states that we must take into account our guidance on meeting the regulations in:

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

Our guidance on meeting the regulations will therefore be central to:

1. **Registration**

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

2. **Inspection**

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

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

If we find good care, we will also assess whether it meets the characteristics of an outstanding rating.

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

We will also consider whether a regulation has been breached. We will take this guidance into account to determine whether a provider is meeting the new regulations.

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

Our enforcement guidance sets out the approach that we will take to address breaches of regulations. The new regulations enable us to prosecute without first issuing a warning notice. Our guidance also reflects how we may work with other organisations to ensure that people are protected from harm (for example, through special measures regimes).

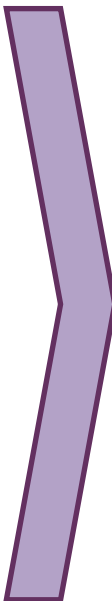
Overview of the new regulations

The 2014 regulations introduce the fundamental standards. These are more focused than the previous regulations, and are clearer about which ones may lead to a prosecution if breached. Where a regulation is not prosecutable, we may use other enforcement powers.

The Department of Health consulted on the new regulations earlier in 2014, and published the regulations and their response to their consultation in July 2014.

The previous 16 regulations (also known as the ‘essential standards’) have been replaced by 11 regulations that set out the fundamental standards of quality and safety. These regulations are clearer statements of the standards of care below which care should never fall. There are joined by two new regulations, on fit and proper person requirements for directors and on a statutory duty of candour. A comparison of the previous and the new regulations is illustrated in figure 2.

Figure 2: Current quality and safety regulations vs new fundamental standards

| Current regulations | | New regulations |
|---|---|--|
| <ul style="list-style-type: none"> • Care and welfare of service users • Assessing and monitoring the quality of service provision • Safeguarding service users from abuse • Cleanliness and infection control • Management of medicines • Meeting nutritional needs • Safety and suitability of premises • Safety and suitability of equipment • Respecting and involving service users • Consent to care and treatment • Complaints • Records • Requirements relating to workers • Staffing • Supporting workers • Cooperating with other providers |  | <ul style="list-style-type: none"> • Person-centred care • Dignity and respect • Need for consent* • Safe care and treatment* • Safeguarding service users from abuse* • Meeting nutritional needs* • Cleanliness, safety and suitability of premises and equipment • Receiving and acting on complaints+ • Good governance+ • Staffing • Fit and proper persons employed <p>and</p> <ul style="list-style-type: none"> • Fit and proper person requirement for directors • Duty of candour* <p>* These regulations have prosecutable clauses relating specifically to harm or the risk of harm. +These have clauses requiring information to be provided to CQC on request. Not providing the information could prevent CQC from identifying and responding to harm/risk of harm in a timely and appropriate manner. Breaching these clauses is therefore prosecutable.</p> |

The regulations and our proposed guidance on what providers could do to meet them are set out in part A of this document.

Our approach to the two new regulations is set out below.

Regulation 5: Fit and proper person requirement for directors

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

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

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

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

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

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

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

The regulation will apply to NHS bodies from October 2014, and the intention is that it will be extended to other providers from April 2015, subject to Parliamentary process and approval.

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

Our approach to the fit and proper person requirement for directors

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

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

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

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

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

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

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

Regulation 20: Duty of candour

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

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

- Make sure it has an open and honest culture across and at all levels within its organisation.
- Tell people in a timely manner when particular incidents have occurred.
- Provide in writing a truthful account of the incident and an explanation about the enquiries and investigations that they will carry out.
- Offer an apology in writing.
- Provide reasonable support to the person after the incident.

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

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

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

For NHS bodies, the regulations adopt the approach suggested by the Dalton/Williams review. Incidents include not only cases of death and severe harm, but also 'moderate harm' in line with providers' existing contractual duty under the NHS Standard Contract. This includes unplanned returns to surgery or unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care). Incidents also include cases of 'prolonged psychological harm' – that is, continuing, or likely to continue, for at least 28 days.

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

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

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

The regulation will apply to NHS bodies from October 2014, and the intention is that it will be extended to other providers from April 2015, subject to Parliamentary process and approval.

Our approach to the duty of candour

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

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

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

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

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

Our approach to guidance on regulations

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

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

The hyperlinks to legislation and guidance relate specifically to each regulation. They are not meant to be exhaustive. We expect providers to meet the requirements of all relevant legislation, even if not hyperlinked in the guidance.

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

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

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

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

Overview of enforcement guidance

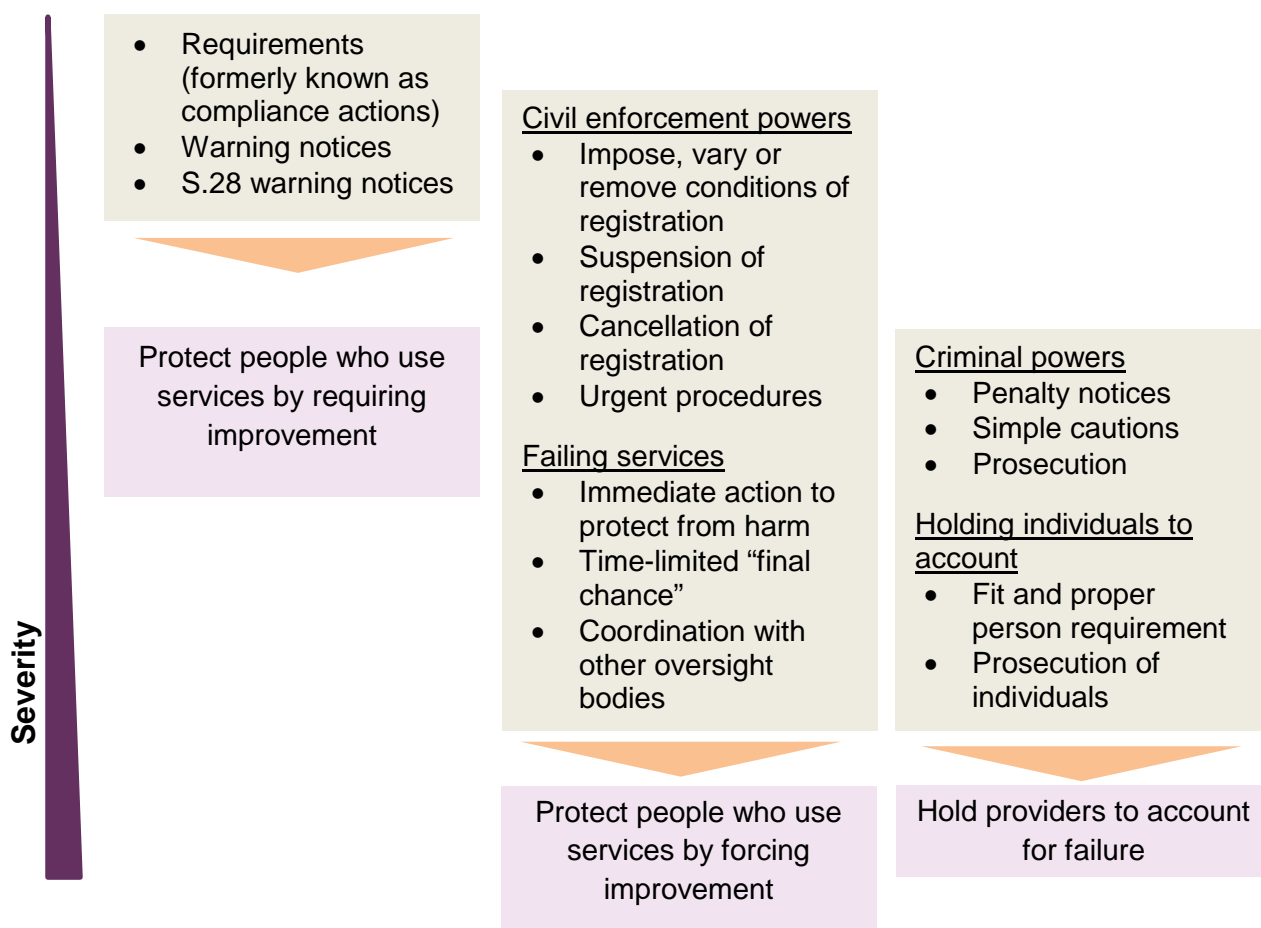
Our proposed guidance on enforcement is set out in part B of this document.

The guidance proposes that when we use our enforcement powers, it will be for one or both of two purposes (figure 3):

- To protect people who use regulated services from harm and the risk of harm.
- To hold providers and individuals to account for failures in how the service is provided.

When a service falls below the required standards, we will consider both purposes. We will often act to hold providers and individuals to account at the same time as we act to secure improvement in the service.

Figure 3: Our enforcement powers



Our approach to enforcement guidance

There are two particular new features of our enforcement guidance.

- From April 2015, when the new regulations come into force, we may prosecute without first issuing a warning notice. This will significantly increase our ability to prosecute breaches of regulations that place people who use services at risk of harm.
- It signals an approach to coordinating our powers with other oversight bodies where organisations are failing, where this will be more effective than acting on our own. An example of this is the special measures regime that CQC operates for NHS bodies with Monitor and the NHS Trust Development Authority.

This consultation

This consultation will run for 12 weeks from 25 July to 17 October 2014. We will then make any amendments required and publish the guidance before we start to use the new regulations.

We are publishing in parallel a shorter six-week consultation that focuses only on the fit and proper person requirement for directors and the duty of candour as they apply to NHS bodies. These regulations will come into force for NHS bodies in October 2014, which is earlier than for other providers.

The guidance proposed in that consultation is identical to the proposals for the fit and proper person requirement and duty of candour in this document. **However, if you are particularly interested in commenting on these two regulations as they apply to NHS bodies, then we recommend you reply to that consultation as well as this one.**

Part A: Guidance for providers about how to meet regulations

Our consultation questions are:

1. Is it clear what providers should do to meet the requirements of the fundamental standards (regulations 9 to 19)? If not, how could it be made clearer?
2. Is it clear what providers should do to meet the fit and proper person requirements for directors (regulation 5)? If not, how could it be made clearer?
3. Is it clear what providers should do to fulfil their duty of candour (regulation 20)? If not, how could it be made clearer?
4. Is the format and layout of the guidance easy to follow and understand?
5. Are the links to key legislation and guidance helpful? How could we promote these links better?
6. Is there anything missing from the guidance?
7. Is there anything that should be taken out of the guidance?

Part B: Enforcement guidance

Our consultation questions are:

8. Do you agree with our approach to using our enforcement powers?
9. How should we reflect the 'serious, multiple or persistent' test in our prosecution criteria?
10. Do you agree with our proposed approach when responding to failure, that it is time-limited but we also work with any partner agencies who may be better placed to secure improvement before we escalate use of our enforcement powers?

How to respond to the consultation

You can respond to our consultation in the following ways. Please send us your views and comments by Friday 17 October 2014.

Online: Use our online form at:

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

By email: Email your response to cqc.consultation@cqc.org.uk.

By post: Write to us at:

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

What we will do with responses to the consultation

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

Part A: Guidance for providers on how to meet the regulations

You can see the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 on this link:

<http://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents>

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

Regulation 5: Fit and proper person: directors

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

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

Summary of the regulation

This regulation applies to health service bodies only from 1 October 2014. It will apply to all other providers from 1 April 2015.

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

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

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

Where a provider is not an NHS trust or foundation trust, the regulation will only apply to the legal entity that holds the CQC registration, because it is a requirement of the registered service. This will be either: a registered individual; members of a registered partnership; or, for a registered organisation, it applies to the persons who are appointed to undertake the role of director or board member. The fitness of other individuals involved in designing and delivering care and treatment is addressed in part through Regulation 19, Fit and proper persons (employed).

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

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

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

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

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

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| <p>(whether unlawful or not) in the course of carrying on a regulated activity</p> | <p>on of a regulated activity; this includes investigating any allegation of such potential behaviour. Where the individual is professionally qualified, it may include fitness to practise proceedings and professional disciplinary cases.</p> <p>Note:</p> <ul style="list-style-type: none"> • Responsible for, contributed to or facilitated means that there is evidence that a person has intentionally or through neglect behaved in a manner which would be considered to be or would have led to serious misconduct or mismanagement. • Privity to means that there is evidence that a person was aware of serious misconduct or mismanagement but did not take the appropriate action to ensure it was addressed. • Serious misconduct or mismanagement means behaviour that would constitute a breach of any legislation/enactment CQC deems relevant to meeting these regulations or their component parts. |
| <p>5(3)(e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual</p> | <ul style="list-style-type: none"> • Only individuals who will be acting in a role that falls within the definition of a ‘regulated activity’ as defined by the Safeguarding Vulnerable Groups Act 2006 will be eligible for a check by the Disclosure and Barring Service (DBS). • As part of the recruitment/appointment process, providers should establish whether the individual is on a relevant barring list. <p>Note:</p> <p>CQC recognises that it may not always be possible for providers to access a DBS check as an individual may not be eligible.</p> |
| <p>5(6) (a) Where a person who holds an office position referred to in paragraph (2)(a) or (b) no longer meets the requirements in</p> | <ul style="list-style-type: none"> • The fitness of directors is regularly reviewed by the provider to ensure that they remain fit for the role they are in; the provider should determine how often fitness must be reviewed based on the assessed risk to business delivery and/or the service users posed by the individual and/or role. • The provider has arrangements in place to respond to concerns about a person’s fitness after they are appointed to a role, identified by itself or others, and these are adhered to. |

paragraph (3), the service provider must—take such action as is necessary and proportionate to ensure that the office or position in question is held by an individual who meets such requirements

- The provider investigates, in a timely manner, any concerns about a person’s fitness or ability to carry out their duties, and where concerns are substantiated, proportionate, timely action is taken; the provider must demonstrate due diligence in all actions.
- Where a person’s fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to service users.
- The provider informs others as appropriate about concerns/findings relating to a person’s fitness; for example, professional regulators, CQC and other relevant bodies, and supports any related enquiries/investigations carried out by others.

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

Regulation 8: General

- 8.—(1) A registered person must comply with regulations 9 to 19 in carrying on a regulated activity.**
- (2) But paragraph (1) does not require a person to do something to the extent that what is required to be done to comply with regulations 9 to 19 has already been done by another person who is a registered person in relation to the regulated activity concerned.**
 - (3) For the purposes of determining under regulations 9 to 19 whether a service user who is 16 or over lacks capacity, sections 2 and 3 of the 2005 Act (people who lack capacity) apply as they apply for the purposes of that Act.**

Note:

The intention of this regulation is to make it clear that, where a provider has more than one registered person, they don't all have to do everything as long as all requirements are met by someone. However, none of them can act in a manner which is contrary to the requirements of the regulations.

We have included the regulation here for clarity, but it does not require guidance.

Regulation 9: Person-centred care

9.—(1) The care and treatment of service users must—

- (a) be appropriate,**
- (b) meet their needs, and**
- (c) reflect their preferences.**

(2) But paragraph (1) does not apply to the extent that the provision of care or treatment would result in a breach of regulation 11.

(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) carrying out, collaboratively with the relevant person, an assessment of the needs and preferences for care and treatment of the service user;**
- (b) designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met;**
- (c) enabling and supporting relevant persons to understand the care or treatment choices available to the service user and to discuss, with a competent health care professional or other competent person, the balance of risks and benefits involved in any particular course of treatment;**
- (d) enabling and supporting relevant persons to make, or participate in making, decisions relating to the service user's care or treatment to the maximum extent possible;**
- (e) providing opportunities for relevant persons to manage the service user's care or treatment;**
- (f) involving relevant persons in decisions relating to the way in which the regulated activity is carried on in so far as it relates to the service user's care or treatment;**
- (g) providing relevant persons with the information they would reasonably need for the purposes of sub-paragraphs (c) to (f);**
- (h) making reasonable adjustments to enable the service user to receive their care or treatment;**
- (i) where meeting a service user's nutritional and hydration needs, having regard to the service user's well-being.**

(4) Paragraphs (1) and (3) apply subject to paragraphs (5) and (6).

(5) If the service user is 16 or over and lacks capacity in relation to a matter to which this regulation applies, paragraphs (1) to (3) are subject to any duty on the registered person under the 2005 Act in relation to that matter.

(6) But if Part 4 or 4A of the 1983 Act applies to a service user, care and treatment must be provided in accordance with the provisions of that Act.

Summary of the regulation

The intention of this regulation is to ensure that each service user receives care that is personalised specifically for them, that meets their needs and reflects their preferences.* Please see the footnote for important clarification of the term “needs”, “preferences” and “relevant person”. For example, relevant person ensures that carers are included in the scope of this regulation.

To meet the requirement of this regulation, the provider must assess each service user’s needs* and preferences* in collaboration with the service user or relevant person,* and must design and deliver care and treatment that is appropriate for each individual, that meets their needs and that they make all reasonable efforts to accommodate preferences. In doing this, the provider must make available information and support that helps people understand the care and treatment options, so they are able to make informed choices and decisions about their care and treatment. Providers must ensure that relevant persons have opportunities and information to be involved with and manage (as appropriate) the service user’s care and treatment if they wish, and the provider should make any reasonable adjustments to facilitate this.

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

Breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC can take regulatory action against breaches of this regulation or any of its component parts. In addition, where CQC deems that a breach of this regulation constitutes a breach of a regulation(s) that carries offence clauses, for example, if care and treatment is provided without the consent of the relevant person(s) and results in any form of abuse or puts the service user at risk of abuse, is unsafe or does not meet their nutritional needs, then CQC can move directly to prosecution without serving a warning notice.

* 'Meeting needs' relates to clinical, treatment and care outcomes.

* 'Preferences' includes those relating to care and treatment and, where applicable, preferences about choice of provider; it is recognised that in some circumstances a service user's preferences may be limited, for example, when service users are detained under the Mental Health Act 1983.

* For the purposes of this regulation, 'relevant person' means the service user or, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf. This could be a family member, friend, carer or advocate etc. 'Lawfully acting on their behalf' means authority given under the Mental Capacity Act 2005, such as a valid and applicable advance decision to refuse treatment, Lasting Powers of Attorney for health and welfare containing relevant clauses, Court-Appointed Deputyship including relevant decision-making powers, a decision of a Court, the Mental Health Act 1983, or a best interest assessment in accordance with the Mental Capacity Act 2005.

| Component of the regulation | What the provider could do to meet the requirement of the component |
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| <p>9(2) But paragraph (1) does not apply to the extent that the provision of care or treatment would result in a breach of regulation 11.</p> | <ul style="list-style-type: none"> • The provider must ensure that it acts in accordance with a person's consent when providing care and treatment; the requirement to provide person-centred care as set out in this regulation cannot be a justification for acting contrary to a person's consent wishes. • The provider must act in accordance with the Mental Capacity Act 2005 and/or the Mental Health Act 1983 where a service user either lacks capacity and/or is detained under the Mental Health Act 1983. |
| <p>9(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include–</p> | <ul style="list-style-type: none"> • The provider must deliver care and treatment to service users that is appropriate, meets their needs and reflects their preferences, whatever they might be. The things that the provider could do described in this component of the regulations should not be considered exhaustive and the provider demonstrate it has done everything reasonably practicable to ensure care is appropriate, meets service users' needs and reflects their preferences. |

9(3)(a) carrying out, collaboratively with the relevant person, an assessment of the needs and preferences for care and treatment of the service user;

- Each service user's care and treatment needs and preferences are assessed by competent persons at appropriate times during the course of their care and treatment, including for transfer/respite/discharge.
- All needs, including emotional and social needs, should be included in assessments and should take into consideration who will deliver the care and treatment.
- Assessments must reflect current legislation and guidance.
- Assessments should be carried out regularly and staff delivering care kept up to date with any changes to a service user's needs and preferences.
- Consideration must be given to the impact on a service user if their preferences are not met.
- Each service user/relevant person(s) is involved in the assessment of needs and preference (as much or as little as they wish to be) and are given support and relevant information to ensure they are able to be involved as much as they would like.
- Where a service user lacks mental capacity to make specific decisions relating to their care and treatment, and no lawful representative has been appointed, their best interests are established in accordance with the Mental Capacity Act 2005, and these are acted upon.
- Where any preferences about the choice of care and treatment can't be met for whatever reason (including as a result of restrictions under the Mental Health Act 1983) this is fully explained in order to: a) allow the service user to make informed decisions that may affect their care and treatment needs or b) understand the reasons why their preferences cannot be met.

9(3)(b) designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met

- Providers should make every reasonable effort to accommodate service users' preferences and be able to demonstrate how the decision was reached if they are not met.
- Where a service user's preferences can't be met, this is fully explained to the service user/relevant person, and documented, so that they can make informed decisions about their care and treatment.
- Care and treatment is designed to ensure it meets all of the service user's needs and if a service user's preferences in any way affect the provider's ability to meet their needs, the impact is

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| | <p>explained to the service user, including exploring any alternatives so that they can make informed decisions about their care and treatment.</p> <ul style="list-style-type: none"> • In accommodating a service user’s preferences, the provider must take into account and make provision for any impact this may have on other service users. • A clear plan of care and treatment should be developed and should be available to all staff and others involved in the delivery of care. |
| <p>9(3)(c) enabling and supporting relevant persons to understand the care or treatment choices available to the service user and to discuss, with a competent health care professional or other competent person, the balance of risks and benefits involved in any particular course of treatment;</p> | <ul style="list-style-type: none"> • Each service user (relevant person) is provided with all the necessary information about their care and treatment, in a way they can understand. • Only competent persons discuss care and treatment choices with the service user (relevant person) and provide the support required to ensure they understand all the risks and benefits of those choices and enable them to make informed decisions about their care and treatment. • Care and treatment choices are discussed on an ongoing basis and service users are supported to make any amendments to their care and treatment they wish, with a full understanding of the risks and benefits associated with the changes. |
| <p>9(3)(d) enabling and supporting relevant persons to make, or participate in making, decisions relating to the service user’s care or treatment to the maximum extent possible;</p> | <ul style="list-style-type: none"> • Service users (relevant persons) are actively encouraged and supported to participate in decision making as much or as little as they wish to be, including taking all steps to maximise their mental capacity to make their own choices. • Service users (relevant persons) are given opportunities to be involved in making decisions, for example, participating in any discussions, invited to meetings, encouraged to ask questions and provide suggestions. • Providers should make every reasonable effort to facilitate the level of support (physical, psychological, emotional or related to content or format) required by the service user to |

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| | <p>participate in making decisions related to care and treatment.</p> <ul style="list-style-type: none"> • Service users' (relevant persons') decisions are recorded. |
| 9(3)(e) providing opportunities for relevant persons to manage the service user's care or treatment; | <ul style="list-style-type: none"> • Service users (relevant persons) are actively encouraged to manage as much of the service user's care and treatment as they wish, for example, manage medication, manage or support personal care, support eating and drinking, etc. • Service users (relevant persons) should be provided with appropriate information, instruction and/or emotional support to help manage the care of the service user, in so far as it would be safe. |
| 9(3)(f) involving relevant persons in decisions relating to the way in which the regulated activity is carried on in so far as it relates to the service user's care or treatment; | <ul style="list-style-type: none"> • Providers should have processes in place to actively seek the views of service users (relevant others) about how care and treatment meets their needs. This may take a number of formats, for example, regular discussions with individuals, encouraging suggestions that could bring about improvements, comment cards, surveys, meetings, etc. Providers should be able to demonstrate that action was taken as a result of feedback. • Providers have mechanisms in place to actively seek the view of a wide range of stakeholders, including service users, members of the public, and other bodies about how the service is delivered, e.g. involvement in decisions about closure or relocation of services etc, and should be able to provide evidence of how these views have been taken into account in any related decisions. |
| 9(3)(g) providing relevant persons with the information they would reasonably need for the purposes of subparagraphs (c) to (f); | <ul style="list-style-type: none"> • Service users (relevant person) should receive information, in the manner that best suits them and that they can understand (this includes oral or written information), that describes: <ul style="list-style-type: none"> ○ all possible care and treatment options ○ risks and benefits of each option ○ the implications of not undertaking any or only undertaking a component of the care and treatment options ○ costs/fees/tariffs associated with care and treatment ○ reasonable expectations of the outcome for each care and treatment options. |

9(3)(h) making reasonable adjustments to enable the service user to receive their care or treatment;

- Providers must make any reasonable adjustments to enable service users to receive care and treatment; reasonable adjustments are set out in the Equality Act 2010.

| Relevant legislation | Relevant guidance |
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| <p>Equality Act 2010 https://www.gov.uk/equality-act-2010-guidance</p> <p>Mental Capacity Act 2005 and associated code of practice http://www.legislation.gov.uk/ukpga/2005/9/contents https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice</p> <p>Mental Health Act 2007 and Code of Practice http://www.legislation.gov.uk/ukpga/2007/12/contents http://www.lbhf.gov.uk/Images/Code%20of%20practice%201983%20rev%202008%20dh_087073%5B1%5D_tcm21-145032.pdf</p> <p>Children Act 1989 http://www.legislation.gov.uk/ukpga/1989/41/contents</p> <p>Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/made http://www.legislation.gov.uk/ukpga/2009/15/section/1 (Autism Act)</p> | <p>Royal College of Nursing Guidance on supporting people with dementia http://www.rcn.org.uk/development/practice/dementia/supporting_people_with_dementia/person-centred_care_planning</p> <p>Social Care Institute for Excellence Guidance on personalisation http://www.scie.org.uk/topic/keyissues/personalisation</p> <p>Think Local Act Personal Partnership guidance on personalisation http://www.thinklocalactpersonal.org.uk/</p> <p>National Institute for Health and Care Excellence (NICE) Assessment and Personalised Care Plan http://www.nice.org.uk/guidance/qualitystandards/dementia/assessmentandpersonalisedcareplan.jsp</p> <p>NHS Institute for Innovation and Improvement, Quality and Service Improvement tools, Pre-operative Assessment and Planning http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/pre-operative_assessment_and_planning.html</p> <p>General Medical Council. End of Life Care guidance http://www.gmc-</p> |

[uk.org/static/documents/content/Treatment and care towards the end of life - English_0414.pdf](http://www.mind.org.uk/static/documents/content/Treatment_and_care_towards_the_end_of_life_-_English_0414.pdf)

Mind – Consent to medical treatment under the Mental Health Act 1983:

<http://www.mind.org.uk/information-support/legal-rights/consent-to-treatment/mental-health-act/>

The Human Tissue Authority Code of Practice

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm>

NHS Choice Framework 2014/15

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299609/2014-15_Choice_Framework.pdf

Department of Health (DH) Adult Social Care Outcomes Framework 2014/15

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/263783/adult_social_care_framework.pdf

NHS England Accessible Information

<http://www.england.nhs.uk/ourwork/patients/accessibleinfo-2/>

Equality and Human Rights Commission: Services, Public functions and Associations: Statutory Code of Practice

<http://www.equalityhumanrights.com/legal-and-policy/legislation/equality-act-2010/equality-act-codes-practice-and-technical-guidance>

Regulation 10: Dignity and respect

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

(2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—

(a) ensuring the privacy of the service user;

(b) supporting the autonomy, independence and involvement in the community of the service user;

(c) having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the service user.

Summary of the regulation

The intention of this regulation is to ensure that service users are treated with respect and dignity at all times while receiving care and treatment.

To meet the requirements of this regulation, the provider must demonstrate respect for service users by treating them with care and compassion, addressing them in the manner they have indicated they prefer and treating all services users equally regardless of their level of understanding or ability to express their views. The provider must maintain service users' privacy at all times, including, for example, if they are asleep or unconscious. The provider must understand the level of autonomy and independence that each service user requires and should enable and promote their involvement in the community that is important to them (where this is relevant to their care and treatment). Providers must have due regard to the age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation of each service user, as defined in the Equality Act 2010.

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

Breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC can take other regulatory action against breaches of this regulation or any of its component parts. In addition, where CQC deems that a breach of this regulation constitutes a breach of a regulation(s) that carries offence clauses, then we can move directly to prosecution without serving a warning notice. For example, if care and treatment is provided without the consent of the relevant person(s), or, where relevant, as a result of a best interest decision-making process in accordance with the Mental Capacity Act 2005, and results in any form of abuse or puts the service user at risk of abuse, is unsafe or if it does not meet the person's nutritional needs.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| <p>10(1) Service users must be treated with dignity and respect.</p> | <ul style="list-style-type: none"> • Service users are treated with dignity and respect and all times, by all staff when receiving care and treatment, including being treated in a caring and compassionate manner. • All communications with services users are carried on in a respectful manner, including using/facilitating the appropriate means of communication and respecting a service user's right to and right not to engage in communications. • Personal preferences, lifestyle choices and choices relating to care and treatment of service users are respected by staff at all times. • The provider should make every reasonable effort to ensure services users' preferences about who their care and treatment is delivered by are respected. For example, staff of a specified gender may be preferred to deliver personal care, or a request may be made for segregated accommodation for men and women, etc. • Service users are addressed in the manner they have indicated they prefer. |

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| <p>10(2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—</p> | <ul style="list-style-type: none"> • The provider must ensure service users are treatment with dignity and respect; the things that the provider could do listed in this component of the regulations should not be considered exhaustive and the provider must demonstrate it has done everything reasonably practicable is done to ensure service users are treated with dignity and respect. |
| <p>10(2)(a) ensuring the privacy of the service user;</p> | <ul style="list-style-type: none"> • The environment is conducive to supporting the privacy of service users when care and treatment are being delivered; for example, there is adequate private space for washing, bathing, using the toilet, holding private conversations or if a service user wishes to spend time alone. Privacy needs and expectations of each service user are identified, recorded and these are met (these may vary in different care settings). • Each service user’s privacy is maintained at all times including, for example, when they are asleep, unconscious or lack capacity. • Service users’ relationships with their visitors, carer, friends, family or relevant other persons are respected and privacy is maintained as far as reasonably practicable during visits. • Discussions about care treatment and support should only take place where they cannot be overheard by people for whom they were not intended. |
| <p>10(2)(b) supporting the autonomy, independence and involvement in the community of the service user;</p> | <ul style="list-style-type: none"> • Service users are offered support in order to maintain their autonomy and independence in accordance with their needs and stated preferences. Service users are offered support when needed; however, staff respect any expressed wishes to act independently. • Where applicable, service users are supported to maintain relationships that are important to them while they are receiving care and treatment. • Service users are supported to be involved or maintain their involvement in their community as much or as little as they wish; the provider must ensure that service users are not left unnecessarily isolated. |

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| | <p>Note:</p> <p>Where service users are detained in high secure settings, ‘the community’ relates to the facility in which they are detained and their level of involvement in it will depend on their care and treatment needs.</p> |
| <p>10(2)(c) having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the service user.</p> | <ul style="list-style-type: none"> • Service users are not discriminated against in any way and the provider must take account of protected characteristics, set out in the Equality Act 2010. <ul style="list-style-type: none"> ○ the protected characteristics are age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation ○ this means that providers must not discriminate, harass or victimise service users on the basis of these protected characteristics. This would include direct and indirect discrimination as set out in the Equality Act 2010. <p>Providers should also ensure that they have due regard to the protected characteristics of service users in the way in which they meet all other regulatory requirements, for example in relation to care and treatment reflecting the service user’s preferences in regulation 9(1)(c) or in relation to community involvement in relation to regulation 10(2)(b).</p> |

| Relevant legislation | Relevant guidance |
|--|---|
| <p>Equality Act 2010 https://www.gov.uk/equality-act-2010-guidance</p> <p>Mental Capacity Act 2005 and associated code of practice http://www.legislation.gov.uk/ukpga/2005/9/contents https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice</p> <p>Mental Health Act 2007 and Code of Practice http://www.legislation.gov.uk/ukpga/2007/12/contents http://www.lbhf.gov.uk/Images/Code%20of%20practice%201983%20rev%202008%20dh_087073%5B1%5D_tcm21-</p> | <p>Equality and Human Rights commission: Services, Public functions and Associations: Statutory Code of Practice http://www.equalityhumanrights.com/legal-and-policy/legislation/equality-act-2010/equality-act-codes-practice-and-technical-guidance</p> <p>Caldicott principles http://informationsharing.co.uk/tools/scoping/how-do-we-decide-the-legal-basis-for-sharing/caldicott-principles/</p> <p>Compassion in Practice Nursing, Midwifery and Care Staff</p> |

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| <p>145032.pdf</p> <p>Data Protection Act 1998 https://www.gov.uk/data-protection/the-data-protection-act</p> <p>Human Rights Act http://www.legislation.gov.uk/ukpga/1998/42/schedule/1</p> <p>The Human Tissue Act 2004 http://www.legislation.gov.uk/ukpga/2004/30/contents</p> <p>The Human Tissue Authority Code of Practice http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</p> | <p>Our Vision and Strategy http://www.england.nhs.uk/wp-content/uploads/2012/12/compassion-in-practice.pdf</p> <p>Consent guidance:</p> <p>Reference guide to consent for examination or treatment (second edition) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1.pdf</p> <p>General Medical Council Consent guidance: patients and doctors making decisions together http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp</p> <p>General Dental Council Principles of Patient Consent http://www.gdc-uk.org/Dentalprofessionals/Standards/Documents/PatientConsent[1].pdf</p> <p>Nursing and Midwifery Council guidance on consent http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Regulation-in-Practice-Topics/consent/</p> <p>National Institute for Health and care Excellence (NICE) quality standards http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> |
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| | <p>National Institute for Health and Care Excellence (NICE) published clinical guidelines http://www.nice.org.uk/Guidance/CG/Published</p> <p>Mental health and well-being guidance for older people National Institute for Health and Care Excellence (NICE) Older people – Mental wellbeing of older people in care homes http://publications.nice.org.uk/mental-wellbeing-of-older-people-in-care-homes-gs50</p> |
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Regulation 11: Need for consent

- 11.—(1) Care and treatment of service users must only be provided with the consent of the relevant person.**
- (2) Paragraph (1) is subject to paragraphs (3) and (4).**
- (3) If the service user is 16 or over and is unable to give such consent because they lack capacity to do so, the registered person must act in accordance with the 2005 Act.**
- (4) But if Part 4 or 4A of the 1983 Act applies to a service user, the registered person must act in accordance with the provisions of that Act.**
- (5) Nothing in this regulation affects the operation of section 5 of the 2005 Act, as read with section 6 of that Act (acts in connection with care or treatment).**

Summary of the regulation

The intention of this regulation is to ensure that all service users (relevant persons*) have given consent in accordance with this regulation before any care or treatment is delivered.

To meet the requirement of this regulation, the provider must ensure that they obtain consent or lawful authority. The person who obtains the consent must have the necessary knowledge and understanding of the care and treatment that they are asking consent for, so that they can discuss the risks and benefits and answer any questions from the service user. They should provide information about the care or treatment in a format that the service user or relevant person understands. The format in which consent is given may depend on the circumstances. For example, where appropriate, consent may be implied from actions such as a person rolling up their sleeve to have their blood pressure taken, or offering their hand when asked if they would like help to move. Expressed consent may be given verbally, although this should be captured in the service user's notes. Consent may be also be formally documented (normally using a form in this case).

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

This regulation relates to all of the fundamental standards, and breaches of it or its components constitute a prosecutable offence. This means that where care and treatment is given without valid consent, and/or it is against the specified wishes of the service user or without lawful authority, CQC can move directly to prosecution without first serving a warning notice. CQC may also take other regulatory action. In addition, adherence to this regulation is relevant when considering how to meet some of the other regulations as consent, or lack of it, can determine the extent to which a provider can meet other regulations.

* For the purposes of this regulation, ‘relevant person’ means the service user or, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf. This could be a family member, friend, carer or advocate. ‘Lawfully acting on their behalf’ means authority given under the Mental Capacity Act 2005 such as a valid and applicable advance decision to refuse treatment, Lasting Powers of Attorney for health and welfare containing relevant clauses, Court-Appointed Deputyship including relevant decision-making powers, a decision of a Court, the Mental Health Act 1983, or a best interest assessment in accordance with the Mental Capacity Act 2005).

| Component of the regulation | What providers could do to meet the requirements of the component |
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| <p>11(1) Care and treatment of service users must only be provided with the consent of the relevant person.</p> | <ul style="list-style-type: none"> • Policies and procedures for obtaining consent to care and treatment reflect current legislation and guidance, and are followed by staff at all times. • Discussions about consent are carried out in accordance with service users’ communication needs. Communications may be provided in different formats, languages and may involve others (e.g. speech language therapist, independent advocate), and may include no-verbal communication (such as sign language). • Information about proposed care and treatment should include information about the risks, complications and alternatives, and be given by a person with the necessary knowledge/ understanding of the care and treatment for which consent is being sought. This information should be given in a way that can be understood by the person being asked to give consent. |

- Consent procedures ensure that service users are not pressured into giving consent.
- Consent is treated as a process that continues throughout the duration of care and treatment, recognising that it may be withheld and/or withdrawn at any time.
- Where a service user or other relevant person refuses to give consent or withdraws it, this is understood and followed by all staff (and others) providing care and treatment. The mental capacity to give consent is understood to include the mental capacity to refuse consent to treatment.
- Where a person lacks capacity to make an informed decision, or give consent, staff act in accordance with the requirements of the Mental Capacity Act (2005) and associated code of practice.

| Relevant legislation | Relevant guidance |
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| <p>Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_2005009_en.pdf</p> <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</p> <p>Ministry of Justice: Mental Capacity Act 2005 Deprivation of liberty safeguards: Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087309.pdf</p> <p>Children Act 1989 http://www.legislation.gov.uk/ukpga/1989/41/contents</p> | <p>NHS Constitution for England https://www.gov.uk/government/publications/the-nhs-constitution-for-england</p> <p>GMC Consent guidance: patients and doctors making decisions together http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp</p> <p>GMC Good medical practice 2013 http://www.gmc-uk.org/guidance/good_medical_practice.asp</p> <p>CQC Supporting note on Consent which includes children and young people</p> |

Mental Health Act 2007
http://www.legislation.gov.uk/ukpga/2007/12/pdfs/ukpga_20070012_en.pdf

Mental Health Act 1983
<http://www.legislation.gov.uk/ukpga/1983/20/contents>

Department of Health, Reference guide to consent for examination or treatment, Second edition:

<https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>

Department of Health, Seeking consent: working with children

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4067204.pdf

Consent: Nursing and Midwifery Council

<http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Regulation-in-Practice-Topics/consent/>

Gillick competencies and Fraser guidelines

http://www.nspcc.org.uk/Inform/research/briefings/gillick_wda101615.html

Regulation 12: Safe care and treatment

12.—(1) Care and treatment must be provided in a safe way for service users.

(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) assessing the risks to the health and safety of service users of receiving the care or treatment;**
- (b) doing all that is reasonably practicable to mitigate any such risks;**
- (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;**
- (d) ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way;**
- (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way;**
- (f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;**
- (g) the proper and safe management of medicines;**
- (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;**
- (i) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.**

Summary of the regulation

The intention of this regulation is to prevent service users from receiving unsafe care and treatment, in order to prevent any avoidable harm or risk of harm. CQC understands that there may be inherent risks in carrying out care and treatment, and will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of service users, and to manage any risks that may arise during care and treatment.

To meet the requirement of this regulation, the provider must take appropriate steps to assure itself that the care and treatment it delivers is safe for all service users. The provider must ensure that care and treatment is designed and delivered with due regard to individual needs and circumstances, and that it is designed and delivered in partnership with other providers where care and treatment is shared or transferred, to ensure the health, safety and welfare of service users. In addition, the provider must ensure that it acts in accordance with relevant legislation in relation to infection prevention and control and the management of medicines. A provider would not be able to meet any of the requirements of this regulation if it did not deploy sufficient numbers of suitably qualified, competent, skilled and experience staff to provide the care and treatment being planned or being delivered, or if it did not have access to the necessary equipment or medicines, or did not use equipment safely.

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

This regulation relates to all of the fundamental standards and breaches of it, or its components, constitute a prosecutable offence. This means that where care and treatment is considered unsafe or there is a risk that it will become so, CQC can move directly to prosecution without first serving a warning notice. Additionally, breaches of other regulations that do not carry prosecutable clauses may be considered to constitute unsafe care and treatment and subsequently will be subject to prosecution under this regulation. CQC may also take any other regulatory action.

Note:

The regulation does not apply to the service user's accommodation where this is not provided as part of their care and treatment.

| Component of the regulation | What providers could do to meet the requirement of the component |
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| <p>12(1) Care and treatment must be provided in a safe way service users.</p> <p>(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—</p> | <ul style="list-style-type: none"> • The provider must provide care and treatment in a safe way; the things that the provider could do listed in this component of the regulations should not be considered exhaustive and the provider must demonstrate it has done everything reasonably practicable to provide care and treatment in a safe way. |
| <p>12(2)(a) assessing the risks to the health and safety of service users of receiving the care or treatment;</p> | <ul style="list-style-type: none"> • Risk assessments relating to the health, safety and welfare of service users are completed and reviewed regularly by people with the qualifications, skills, competence and experience to do so. • Care and treatment assessments, planning and delivery (including when service users start to use the service, are admitted, discharged/transferred or move between services): <ul style="list-style-type: none"> ○ are based on risk assessments that balance service users' needs and safety with their rights and preferences ○ include arrangements to respond appropriately and in a timely manner to service users' changing needs ○ where appropriate, are carried out in accordance with the Mental Capacity Act 2005 (including best interest decisions making, lawful restraint, and where required applying for authorisation for deprivation of liberty through the Mental Capacity Act Deprivation of Liberty Safeguards or the Court of Protection. |

12(2)(b) doing all that is reasonably practicable to mitigate any such risks;

- Providers use risk assessments relating to the health, safety and welfare of service users to make adjustments as required to premises, equipment, staff training, processes and practices etc, which affect any aspect of care and treatment.
- Relevant health and safety concerns are incorporated into service users' care and treatment plans/pathways, for example, allergies, contraindications and other limitations relating to the needs and abilities of the service user.
- Plans and pathways are followed by staff.
- Medication reviews are part of, and align with, service users' care and treatment assessments, plans or pathways and are completed and reviewed regularly in relation to changes in medication.
- The provider complies with relevant Patient Safety Alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and via the Central Alerting System (CAS).
- Incidents that affect the health, safety and welfare of service users are reported internally and to relevant external authorities/bodies, are reviewed and investigated by competent staff using a recognised methodology, and are monitored to ensure that corrective actions, preventative actions and improvements are made as a result. Information about incidents is given to the staff involved and shared with others to promote learning.
- Policies and procedures are in place for anyone to raise concerns about the care and treatment service users receive, and these are in line with current legislation and guidance, and are followed.
- Arrangements are in place to ensure the provider can take appropriate action in the event of a clinical/medical emergency.
- The administration of medications is timely to ensure that service users are not placed at risk.
- The arrangements for giving medicines covertly, where this is thought to be in the service users' best interests, are in accordance with the Mental Capacity Act 2005.
- There are arrangements for requesting a second opinion in relation to medicines for people detained under the Mental Health Act 1983.

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| <p>12(2)(c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;</p> | <ul style="list-style-type: none"> • Staff work only within the scope of their qualifications, competence, skills and experience and are encouraged to seek help when they feel they are being asked to do something they are not prepared for. • Where staff are learning new skills, but are not yet competent, they are appropriately supervised. • Only relevant registered professionals with the appropriate qualifications or suitably skilled and competent staff are deployed to plan, prescribe or deliver care and treatment. |
| <p>12(2)(f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;</p> | <ul style="list-style-type: none"> • Service users' medications should be available at all times in the necessary quantities, in order to prevent risks associated with medication not being administered as prescribed, including when service users manage their own medicines. • Equipment, medicines and/or medical devices necessary to meet service users' needs are available (e.g. at hand when needed/obtainable within a reasonable time without posing a risk) at all times in sufficient quantity, and devices are in full working order. • The equipment, medicines and/or medical devices that are needed to meet service users' needs are available when they are transferred between services or providers. |
| <p>12(2)(g) the proper and safe management of medicines;</p> | <ul style="list-style-type: none"> • The provider has policies and procedures that are in line with current legislation and guidance for: <ul style="list-style-type: none"> ○ obtaining (e.g. only from authorised suppliers) ○ storage (e.g. only accessible by authorised persons, stored at the correct temperature, which is monitored regularly etc) ○ dispensing and preparation (refer to Human Medicines Regulations 2012 (incorporates / amends the Medicines Act 1968 and 1971) ○ administration (in line with safety concerns as detailed in a service user's assessment/care plan) ○ disposal (e.g. in line with expiry dates and relevant legislation) |

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| | <ul style="list-style-type: none"> ○ recording (in line with current guidance and good practice). ● Staff follow policies and procedures related to management of medicines. ● Staff responsible for medicines management and administration are suitably trained and competent. |
| <p>12(2)(h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;</p> | <ul style="list-style-type: none"> ● The provider complies with guidance from the Department of Health about the prevention and control of health care acquired infections <i>The Code of Practice for health and adult social care on the prevention and control of infections and related guidance</i>. |
| <p>12(2)(i) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.</p> | <ul style="list-style-type: none"> ● The provider actively engages with others (both internally and externally) to ensure that care and treatment remain safe for service users. ● Where care is shared between two or more providers, appropriate arrangements are in place to share information, and to plan and deliver care in partnership. ● Arrangements are in place to support service users who are in a transition phase between services and/or other providers. ● When service users move between services or providers (and/or with other bodies e.g. the police), whether registered with CQC or not, appropriate risk assessment should be undertaken to ensure the safety of service users is not compromised. ● Decisions about a move between services or providers relating to service users who may lack mental capacity to make that decision for themselves are made in accordance with the Mental Capacity Act 2005. ● All relevant information relating to care and treatment is shared appropriately, in accordance with current legislation and guidance, in a timely manner when service users move between services and providers. |

- Arrangements are in place to ensure compliance with the Civil Contingences Act 2004 and to respond to and manage major incidents and emergency situations (e.g. having plans in place with other providers/bodies in case of events such as fires, floods, major road traffic accidents/or major incidents, natural disasters such as earth quakes/landslides etc.) to ensure services users are safe and risks to care and treatment are minimised should these situations occur.

| Relevant legislation | Relevant guidance |
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| Health and Safety at Work etc. Act 1974 http://www.legislation.gov.uk/ukpga/1974/37 | The Code of Practice on the prevention and control of infections and related guidance (DH) https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance |
| The Management of Health and Safety at Work Regulations 1999 http://www.legislation.gov.uk/uksi/1999/3242/regulation/3/made e | Infection prevention and control in care homes: Information resource published (DH) https://www.gov.uk/government/publications/infection-prevention-and-control-in-care-homes-information-resource-published |
| The Workplace (Health, Safety and Welfare) Regulations 1992 http://www.legislation.gov.uk/uksi/1992/3004/made/data.pdf | National Institute for Health and Care Excellence (NICE) clinical guidelines https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance |
| The Manual Handling Operations Regulations 1992 http://www.legislation.gov.uk/uksi/1992/2793/contents/made | NICE Guidance for patient group directions http://www.nice.org.uk/mpc/medicinespracticeguidelines/MPG2.jsp |
| The Health and Safety (First Aid) Regulations 1981 http://www.legislation.gov.uk/uksi/1981/917/contents/made | NICE Guidance for medicines reconciliation http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11897 |
| Medicines Act 1968 http://www.legislation.gov.uk/ukpga/1968/67 | |
| The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/contents/made | |

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| <p>The Controlled Drugs (Supervision and Management of Use) Regulations 2013 http://www.legislation.gov.uk/ukxi/2013/373/regulation/11/made</p> <p>Misuse of Drugs Act 1971 http://www.legislation.gov.uk/ukpga/1971/38/contents</p> <p>Safety alerts published by NHS England http://www.england.nhs.uk/ourwork/patientsafety/psa/</p> <p>Safety warnings, alerts and recalls published by the MHRA http://www.mhra.gov.uk/Safetyinformation/Safetywarnings/alertsandrecalls/</p> <p>Central Alerting System https://www.cas.dh.gov.uk/Home.aspx</p> <p>Public Interest Disclosure Act 1998 http://www.legislation.gov.uk/ukpga/1998/23/contents</p> <p>Civil Contingences Act 2004 http://www.legislation.gov.uk/ukpga/2004/36/contents</p> <p>Data Protection Act 1998 http://www.legislation.gov.uk/ukpga/1998/29/contents</p> <p>Information Governance and Caldicott principles (DH) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf</p> | <p>Resuscitation Council UK http://www.resus.org.uk/pages/guide.htm</p> <p>Deprivation of Liberties: Supreme Court Judgements https://www.gov.uk/government/publications/deprivation-of-liberty-safeguards-supreme-court-judgments</p> <p>Royal Pharmaceutical Society guidance on medicines in social care https://www.rpharms.com/social-care-settings-pdfs/the-handling-of-medicines-in-social-care.pdf</p> <p>Nursing and Midwifery Council standards for medicines management http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf</p> <p>CQC whistleblowing guidance for providers http://www.cqc.org.uk/sites/default/files/documents/20131107_100495_v5_00_whistleblowing_guidance_for_providers_registered_with_cqc.pdf</p> <p>CQC whistleblowing guidance for health and care staff http://www.cqc.org.uk/sites/default/files/documents/20120117_whistleblowing_quick_guide_final_update.pdf</p> |
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Regulation 13: Safeguarding service users from abuse and improper treatment

- 13.—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.**
- (2) Systems and processes must be established and operated effectively to prevent abuse of service users.**
- (3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.**
- (4) Care or treatment for service users must not be provided in a way that—**
- (a) includes discrimination against a service user on grounds of any protected characteristic (as defined in section 4 of the Equality Act 2010) of the service user,**
 - (b) includes acts intended to control or restrain a service user that are not necessary to prevent, or not a proportionate response to, a risk of harm posed to the service user or another individual if the service user was not subject to control or restraint,**
 - (c) is degrading for the service user, or**
 - (d) significantly disregards the needs of the service user for care or treatment.**
- (5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.**
- (6) For the purposes of this regulation—**
- “abuse” means—**
- (a) any behaviour towards a service user that is an offence under the Sexual Offences Act 2003(1),**
 - (b) ill-treatment (whether of a physical or psychological nature) of a service user,**
 - (c) theft, misuse or misappropriation of money or property belonging to a service user, or**
 - (d) neglect of a service user.**
- (7) For the purposes of this regulation, a person controls or restrains a service user if that person—**
- (a) uses, or threatens to use, force to secure the doing of an act which the service user resists, or**

(1) 2003 c. 42.

(b) restricts the service user's liberty of movement, whether or not the service user resists, including by use of physical, mechanical or chemical means.

Summary of the regulation

The intention of this regulation is to safeguard service users from suffering any form of abuse or improper treatment, such as discrimination or unlawful restraint, while receiving care and treatment. This would include inappropriate deprivation of liberty under the terms of the Mental Capacity Act 2005.

To meet the requirements of this regulation, the provider must take appropriate steps to ensure a zero tolerance approach to abuse, including neglect and subjecting service users to degrading treatment, and to prevent service users from being abused by its staff or others with whom they come into contact when using the services and those visiting. In addition, the provider must take appropriate steps to ensure a zero tolerance approach to unlawful discrimination or restraint and to unnecessary or disproportionate restraint or deprivation of liberty.

Where any form of abuse is suspected, occurs, is discovered, or reported by a third party (which may be external to the provider) the provider must take timely and appropriate action, including investigation and/or referral to an appropriate body.

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

Where service users suffer abuse or are placed at risk of any form of abuse, CQC can move directly to prosecution without first serving a warning notice. CQC may deem any breaches of other regulations to have led to abuse, or be a major contributory factor in not preventing abuse, and in these cases CQC may move directly to prosecution without serving a warning notice. In addition, CQC can take other regulatory action to breaches of this regulation.

| Component of the regulation | What the provider could do to meet the requirements of the component |
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| <p>13(2) Systems and processes must be established and operated effectively to prevent abuse of service users.</p> | <ul style="list-style-type: none"> • Staff receive safeguarding, including child protection training to the appropriate level for their role, as part of their induction and keep up to date at appropriate intervals and are able to recognise different types of abuse. • Staff are aware of their individual responsibilities in preventing and identifying abuse when delivering care and treatment. • Staff understand their roles and associated responsibilities in relation to any policies, procedures or guidance put in place by the provider to prevent abuse. • Information about current procedures and guidance for raising concerns about abuse are accessible to service users, their lawful representative(s), advocates acting on their behalf, relevant persons and staff. • Incidents and complaints are used to identify potential abuse issues and preventative actions are taken, including escalation where appropriate. • Providers work in partnership with relevant other bodies to contribute to individual risk assessments, the development of child protection and safeguarding adults at risk plans and the implementation of these plans, including the regular review of outcomes for the service user. • Providers and their staff understand and work within the ethos of the Mental Capacity Act 2005 whenever working with service users who may lack mental capacity for some decisions. |
| <p>13(3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of,</p> | <ul style="list-style-type: none"> • The provider takes action as soon as it is alerted to suspected, alleged or actual abuse, or the risk of abuse. • There are policies and procedures that describe the actions to be taken in response to suspicions and allegations of abuse, no matter who raises the concern or who the alleged abuser may be, including timescales for action and the need to investigate. • Staff are aware of and have access to current procedures and guidance for raising and responding |

any allegation or evidence of such abuse.

to concerns of abuse. Staff have access to support or supervision when considering how to respond to concerns of abuse.

- Staff understand their individual responsibilities in responding to concerns of abuse when delivering care and treatment, including investigating concerns.
- Staff understand their roles and associated responsibilities in supporting the actions the provider takes in responding to concerns about abuse.
- There is a system for ensuring that staff are kept up to date about changes to national and local safeguarding arrangements.
- Staff follow local safeguarding arrangements to ensure that allegations are investigated and the provider takes timely action in response to the investigations.
- Support is provided to service users where they allegedly or actually experience or cause abuse.
- Where allegations of abuse are substantiated, providers take corrective action to redress the abuse and implement preventative actions to ensure the abuse is not repeated. This may involve seeking specialist advice or support.
- The provider participates in serious case reviews, any changes to practice are made as a result of the outcomes and any recommendations are implemented.

(4) Care or treatment for service users must not be provided in a way that—

13(4)(a) includes discrimination against a service user on grounds of any protected characteristics (as defined in Section 4 of the Equality Act 2010) of the service user,

- Staff understand their individual responsibilities in preventing discrimination.
- The provider has systems in place for dealing with allegations and acts of discrimination (regardless of who raises the concern or who the perpetrator is), including having policies and procedures in place that describe the actions required and timescales for action to be taken.
- Support is provided to service users where they allegedly or actually experience discrimination, and the provider does not unlawfully victimise service users for making a complaint of discrimination.
- Where allegations of discrimination are substantiated, providers take corrective action and implement preventative actions to ensure the discrimination is not repeated. This may involve

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| | <p>seeking specialist advice or support.</p> |
| <p>13(4)(b) includes acts intended to control or restrain a service user that are not necessary to prevent, or not a proportionate to, a risk of harm posed to the service user or another individual if the service user was not subject to control or restraint,</p> | <ul style="list-style-type: none"> • Staff receive the appropriate level of training to ensure any control, restraint or restrictive practices are only used when absolutely necessary and as a last resort. • The provider must ensure that control restraint and restrictive practices are used proportionately in relation to the risk of harm to the service user, the seriousness of that harm, and that they are applied in line with current legislation and guidance. • Where a service user lacks mental capacity to consent to the arrangements for care or treatment, deprivation of their liberty is implemented and managed in accordance with the Mental Capacity Act 2005, including the use of the Mental Capacity Act Deprivation of Liberty Safeguards where appropriate. |
| <p>13(4)(c) is degrading for the service user, or</p> | <ul style="list-style-type: none"> • The provider and its staff take all reasonably practicable steps to ensure service users are not subjected to any form of degrading treatment and are not treated in a manner that may be degrading. For example, service users are not left in soiled sheets for long periods of time, left on the toilet for long periods and without the means to call for help, left naked or partially or inappropriately covered, made to carry out demeaning tasks, ridiculed in any way by staff, etc. • The provider should consider the views of the service user when defining what is meant by degrading. |
| <p>13(4)(d) significantly disregards the needs of the service user for care or treatment.</p> | <ul style="list-style-type: none"> • Care and treatment is planned and delivered in such a way that all of the service user's needs are able to be met, including ensuring that enough time is allocated to allow staff to deliver care and treatment in accordance with the service user's assessed needs and preferences. • Where a service user lacks the mental capacity to consent to care and treatment, a best interests process should be followed in accordance with the Mental Capacity Act 2005. • Staff can raise any concerns about their ability to deliver planned care with the provider. Where concerns are raised, the provider responds appropriately and in a timely manner. |

| | <ul style="list-style-type: none"> The provider takes all reasonably practicable actions to ensure that staff are able to deliver the planned care to service users and should ensure that they have policies and procedures that support staff to deliver care and treatment in accordance with the requirements detailed in the plan/s of care. |
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| <p>13(5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.</p> | <ul style="list-style-type: none"> The provider must act at all times in accordance with the Mental Capacity Act 2005 Deprivation of Liberty Safeguards: code of Practice and the Mental Capacity Act 2005 Code of Practice. |
| Relevant legislation | Relevant guidance |
| <p>Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf</p> <p>Mental Health Act 2007 http://www.legislation.gov.uk/ukpga/2007/12/pdfs/ukpga_20070012_en.pdf</p> <p>Mental Health Act 1983 http://www.legislation.gov.uk/ukpga/1983/20/contents</p> <p>Care Act 2014 http://www.legislation.gov.uk/ukpga/2014/23/pdfs/ukpga_20140023_en.pdf</p> <p>Children and Young Persons Act 1933 http://www.legislation.gov.uk/ukpga/Geo5/23-24/12/contents</p> | <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</p> <p>Ministry of Justice: Mental Capacity Act 2005 Deprivation of liberty safeguards: Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087309.pdf</p> <p>Department of Health: Code of Practice Mental Health Act 1983 http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087073.pdf</p> |

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| <p>Children Act 1989 http://www.legislation.gov.uk/ukpga/1989/41/contents</p> <p>Children Act 2004 http://www.legislation.gov.uk/ukpga/2004/31/contents</p> <p>Equality Act 2010: Chapter 1 (protected characteristics) Chapter 2 (prohibited conduct) and Chapter 3 (services and public functions) http://www.legislation.gov.uk/ukpga/2010/15/pdfs/ukpga_20100015_en.pdf</p> | <p>Department of Health: Safeguarding Adults: The role of health services https://www.gov.uk/government/publications/safeguarding-adults-the-role-of-health-services</p> <p>Department of Health: Clinical Governance and Adult Safeguarding http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_112341.pdf</p> <p>Department for Education: Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/281368/Working_together_to_safeguard_children.pdf</p> <p>Royal College of Paediatrics and Child Health: Safeguarding children and young people: roles and competences for health care staff http://www.rcpch.ac.uk/system/files/protected/page/Safeguarding%20Children%20-%20Roles%20and%20Competences%20for%20Healthcare%20Staff%20%2002%200%20%20%20%20(3).pdf</p> <p>Department of Health: No secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/194272/No_secrets_guidance_on_developing_and_implementation_multi-agency_policies_and_procedures_to_protect_vulnerable_adults_from_abuse.pdf</p> |
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| | <p>Department of Health: Positive and Proactive Care: reducing the need for restrictive interventions https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300293/JRA DoH Guidance on RP web accessible.pdf</p> <p>Equality and Human Rights Commission: Equality Act 2010 Services, public functions and associations Statutory Code of Practice http://www.equalityhumanrights.com/sites/default/files/publication/pdf/servicescode.pdf</p> <p>Equality and Human Rights Commission: A range of non-statutory guidance for service providers can be accessed from the following webpage: http://www.equalityhumanrights.com/private-and-public-sector-guidance/organisations-and-businesses/guidance-service-providers</p> <p>Department of Health: Care Act 2014 Part 1: factsheets https://www.gov.uk/government/publications/care-act-2014-part-1-factsheets</p> <p>NICE: Violence: The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments (CG25) http://www.nice.org.uk/CG25</p> <p>NICE: When to suspect child maltreatment (CG89) http://www.nice.org.uk/CG89</p> |
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HM Treasury: Every child matters
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/272064/5860.pdf

HM Government: What to do if you're worried a child is being abused
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/190604/DFES-04320-2006-ChildAbuse.pdf

HM Government: Information Sharing: Guidance for practitioners and managers
<https://www.gov.uk/government/publications/information-sharing-for-practitioners-and-managers>

SCIE: Adult safeguarding: Resources
<http://www.scie.org.uk/adults/safeguarding/resources/>

SCIE: At a glance 43: The Deprivation of Liberty Safeguards
<http://www.scie.org.uk/publications/ataglance/ataglance43.asp>

Association of Directors of Adult Social Services: Safeguarding Adults: A National Framework of Standards for good practice and outcomes in adult protection work
<http://www.elderabuse.org.uk/Documents/Other%20Orgs/ADASS%20guide%20-%20SAFEGUARDING%20ADULTS.pdf>

Department of Health: Services for people with learning disabilities and challenging behaviour or mental health needs – Mansell report: revised edition
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080128.pdf

Regulation 14: Meeting nutritional and hydration needs

- 14.—(1) The nutritional and hydration needs of service users must be met.**
- (2) Paragraph (1) applies where—**
- (a) care or treatment involves—**
 - (i) the provision of accommodation by the service provider, or**
 - (ii) an overnight stay for the service user on premises used by the service for the purposes of carrying on a regulated activity, or**
 - (b) the meeting of the nutritional or hydration needs of service users is part of the arrangements made for the provision of care or treatment by the service provider.**
- (3) But paragraph (1) does not apply to the extent that the meeting of such nutritional or hydration needs would—**
- (a) result in a breach of regulation 11, or**
 - (b) not be in the service user’s best interests.**
- (4) For the purposes of paragraph (1), “nutritional and hydration needs” means—**
- (a) receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,**
 - (b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,**
 - (c) the meeting of any reasonable requirements of a service user for food and hydration arising from the service user’s preferences or their religious or cultural background, and**
 - (d) if necessary, support for a service user to eat or drink.**
- (5) Section 4 of the 2005 Act (best interests) applies for the purposes of determining the best interests of a service user who is 16 or over under this regulation as it applies for the purposes of that Act.**

Summary of the regulation

The intention of this regulation is to ensure that service users receive adequate nutrition and hydration to sustain life and good health, and to mitigate the risks of malnutrition and dehydration, while they receive care and treatment.

To meet the requirements of this regulation, the provider must assess each service user's nutrition and hydration needs on an ongoing basis and provide food and drink (including parenteral nutrition and dietary supplements) to meet them, including accommodating any religious/cultural needs and reflecting their preferences. While this regulation is not specifically about the quality of food, the provider is expected to ensure that food is nutritious, presented in an appetising manner, can easily be consumed (the service user can eat it regardless of any limitations they may have) and is easily accessible to the service user. In addition, the provider is expected to provide help if the service user needs support to eat and drink. Adequate water should always be available and accessible to the service user and the provider should help them if they need support to drink. Where appropriate, the provider is expected to engage relevant expertise to ensure that the nutrition and hydration it provides adequately meets the needs of each service user.

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

Breaches of this regulation or its components constitute a prosecutable offence. This means that where service users are not given adequate nutrition and hydration and there is subsequently a risk to their life or good health, CQC can move directly to prosecution without first serving a warning notice. CQC may also consider breaches of this regulation to constitute unsafe or inappropriate care and treatment, and/or to constitute abuse. In addition, CQC may also take other regulatory action in response to breaches of this regulation.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| <p>14(2) Paragraph (1) applies where–</p> <p>14(2)(b) the meeting of the nutritional or hydration needs of service users is part of the arrangements made for the provision of care or treatment by the service provider.</p> <p>14(3) But paragraph (1) does not apply to the extent that the meeting of such nutritional or hydration needs would–</p> <p>14(3)(a) result in a breach of regulation 11, or</p> <p>14(3)(b) not in the service user’s best interests</p> | <ul style="list-style-type: none"> • This regulation does not apply to providers that would not normally provide nutrition and hydration in carrying on the regulated activity. • Providers must follow any consent decisions where people refuse nutrition and hydration unless a best interests decision has been made under the Mental Capacity Act 2005. • It is recognised that the way this regulation is applied in specialist eating disorder services may vary to take account of service users’ needs. |

14(1) The nutritional and hydration needs of service users must be met.

14(4) For the purposes of paragraph (1), “nutritional and hydration needs” means–

14(4)(a) receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,

- Nutrition and hydration assessments are carried out in accordance with recognised guidance by competent persons and identify, as a minimum:
 - requirements to sustain life, support the agreed care and treatment, and support ongoing good health
 - dietary intolerances, allergies, medication contraindications etc.
 - how to support service users’ good health including the level of support required, timing of meals, and sufficient quantities of food and drink.
- Reassessments of nutrition and hydration needs are carried out during the course of care and treatment and any changes in service users’ needs are responded to in a timely manner.
- A variety of nutritious, appetising food is available to meet service users’ needs; it is served at an appropriate temperature, and provided in a manner that can be easily consumed. Where the person using the service lacks capacity, prompts and encouragement to eat are given as appropriate.
- Where a service user is assessed as requiring a specific diet, this is provided in accordance with that assessment e.g. a diabetic diet, low salt diet etc, and takes account of allergies, food intolerance etc.
- Nutritional and hydration intake is monitored to prevent unnecessary weight loss/weight gain and dehydration and timely action is taken to address concerns.
- Staff follow the most up-to-date nutrition and hydration assessment for each service user and take appropriate action if service users are not eating and drinking in accordance with their assessed needs.
- Staff know how to determine whether specialist nutritional advice is required and how to access it, and this advice is accessed when appropriate.
- Water is available and accessible to service users at all times; other drinks are made available periodically throughout the day (and night) and service users receive support to drink if needed.

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| | <ul style="list-style-type: none"> • The availability of food and drink for service users is not compromised if they are absent, for example when receiving care and treatment, or when asleep, etc. |
| 14(4)(b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional, | <ul style="list-style-type: none"> • The provider has systems in place to ensure that prescribed parenteral nutrition and dietary supplements are available at the specified times as required by the service user. • Only appropriately qualified, skilled, competent and experienced staff or relevant persons administer parenteral nutrition and dietary supplements. |
| 14(4)(c) the meeting of any reasonable requirements of a service user for food and hydration arising from the service user's preferences or their religious or cultural background, and | <ul style="list-style-type: none"> • Service users' religious and or cultural needs are recognised in their nutrition and hydration assessment, and these should be met. If there are any clinical contraindications or risks posed as a result of any of these requirements, this is discussed with the service user to allow them to make informed choices about their requirements. • Where a service user has specific dietary requirements relating to moral or ethical issues (vegetarianism, veganism etc), these requirements must be fully considered and every effort is made to meet their requirements. • Service users' preferences are accommodated as far as reasonably practicable, including preference about the time meals are served, quantities, place, etc. |
| 14(4)(d) if necessary, support for a service user to eat or drink | <ul style="list-style-type: none"> • Food is placed within reach of service users and it is presented in an accessible way. • Service users receive appropriate support to eat or drink, if they need it. • Service users are encouraged to eat and drink independently if they are able, but appropriate support, which may include encouragement as well as physical support, is provided when needed. • Service users have appropriate equipment/tools to help them eat and drink independently. • Each service user who requires support is allocated enough time to enable them to take adequate nutrition and hydration to sustain life and good health. |

| Relevant legislation | Relevant guidance |
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| <p>Food Safety Act 1990 http://www.legislation.gov.uk/ukpga/1990/16/contents</p> <p>The Food Safety and Hygiene (England) Regulations 2013 http://www.legislation.gov.uk/uksi/2013/2996/made/data.pdf</p> | <p>Food Standards Agency: Alerts, product withdrawals and recalls http://www.food.gov.uk/enforcement/alerts/#.U5hfiqHTXIU</p> <p>Food Standards Agency: Hygiene and food safety guidance http://www.food.gov.uk/business-industry/guidancenotes/hygguid/#.U5hfw6HTXIU</p> <p>BDA Digest – food quality guidance https://www.bda.uk.com/publications/NutritionHydrationDigest.pdf</p> <p>Social Care Institute for Excellence guidance on nutrition and hydration http://www.scie.org.uk/</p> <p>National Institute for Care Excellence: Clinical guidelines for nutrition support in adults http://www.nice.org.uk/nicemedia/live/10978/29978/29978.pdf</p> <p>Healthier and more sustainable catering: a toolkit for serving food to adults (DH) https://www.gov.uk/government/publications/healthier-and-more-sustainable-catering-a-toolkit-for-serving-food-to-adults</p> <p>Essence of Care 2010: Benchmarks for food and drink (DH) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216696/dh_125313.pdf</p> <p>Royal College of Nursing: Nutrition and hydration http://www.rcn.org.uk/development/practice/nutrition</p> |

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| | <p>Royal College of Nursing: Nutrition for specific groups http://www.rcn.org.uk/development/practice/nutrition/nutrition_for_specific_groups</p> <p><u>PLACE assessment assessors guides relating to food:</u> http://www.england.nhs.uk/wp-content/uploads/2014/01/place-food-assessor-1.pdf</p> <p>http://www.england.nhs.uk/wp-content/uploads/2014/01/place-org-food-1.pdf</p> <p>Council of Europe 10 key characteristics – food quality guidance http://www.bapen.org.uk/pdfs/coe_leaflet.pdf</p> |
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Regulation 15: Premises and equipment

15. —(1) All premises and equipment used by the service provider must be—

- (a) clean,**
- (b) secure,**
- (c) suitable for the purpose for which they are being used,**
- (d) properly used**
- (e) properly maintained, and**
- (f) appropriately located for the purpose for which they are being used.**

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

(3) For the purposes of paragraph (1)(b), (c), (e) and (f), “equipment” does not include equipment at the service user’s accommodation if—

- (a) such accommodation is not provided as part of the service user’s care or treatment, and**
- (b) such equipment is not supplied by the service provider.**

Summary of the regulation

The intention of this regulation is to ensure that the premises and/or equipment used to deliver care and treatment is clean, stored securely and suitable for the intended purpose.

To meet the requirements of this regulation, providers must act in accordance with current legislation and guidance relating to premises and equipment. They must also ensure that premises are located and designed/configured to meet the service user's needs as far as possible, and that they have due regard to make premises accessible to service users. In addition, premises should be appropriately secure so service users feel safe. Providers must ensure that equipment is used for its intended purposes and in accordance with the manufacturer's instructions.

Where the equipment required to deliver care and treatment is owned by the service user, or is supplied by a third party (for example, a different service or an independent supplier) the provider must make every effort to ensure the equipment is suitable for use. If the equipment is unsuitable or not clean, the provider may decide not to provide care and treatment until it is clean (which may mean the provider needs to clean it, if appropriate) and/or suitable, or when replacement(s) are available. CQC would expect the provider to have taken all reasonable steps to ensure that it addressed the issue in a timely manner, and that it made appropriate support or alternative arrangements for the service user to receive their care and treatment.

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

Where premises and equipment are unsafe and put service users at risk of harm, or where harm has occurred, CQC can move directly to prosecution, without first serving a warning notice. Breaches of the sub components of this regulation do not carry prosecutable offence clauses, although CQC may take other regulatory action as it sees appropriate. Where CQC deems that a breach of this regulation constitutes a breach of any other regulations carrying prosecutable offence clauses, then CQC could move directly to prosecution without serving a warning notice. For example, where care and treatment is provided without the consent of the relevant person(s), it results in any form of abuse or puts service users at risk of abuse, is unsafe (as per Regulation 13) or does not meet the nutritional or hydration needs of services users.

Note: The regulation does not apply to the service user's accommodation where such accommodation is not provided as part of their care and treatment. In addition, 'equipment' does not include equipment at the service user's accommodation, where such accommodation is not provided as part of the service user's care or treatment.

The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| 15(1) All premises and equipment used by the service provider must be— | |
| 15(1)(a) clean, | <ul style="list-style-type: none"> • Premises and equipment are kept clean in accordance with current legislation and guidance. • Premises and equipment are visibly clean and free from odours that are offensive or unpleasant. • The provider uses appropriate cleaning methods and agents, operates a cleaning schedule appropriate to the care and treatment being delivered from the premises or by the equipment, monitors the level of cleanliness and takes timely action when any shortfalls are identified. • Equipment is cleaned and/or decontaminated according to the manufacturer’s instructions, and is cleaned/decontaminated after each use and between being used by/for different service users. • Domestic, clinical and hazardous waste and materials are managed in accordance with current legislation and guidance. |
| 15(1)(b) secure, | <ul style="list-style-type: none"> • Security arrangements are in place to ensure service users are safe while receiving care, including: <ul style="list-style-type: none"> ○ protecting personal safety, including restrictive protection required in relation to the Mental Capacity Act 2005 and Mental Health Act 1983, for example appropriate window restrictors or locks on doors used in a way that protects individual service users where lawful and necessary, but does not restrict the liberty of other service users ○ protecting personal property and/or money ○ providing appropriate access to and exit from protected or controlled areas ○ not inadvertently restricting people’s movements and providing appropriate information about access and entry where service users are unable to come and go freely, for example, because of locked doors used to protect some service users ○ when service users move from the premises as part of their care and treatment |

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| | <ul style="list-style-type: none"> ○ operating the appropriate level of security required in relation to the services being delivered. ● If CCTV is used for any purpose, the provider must ensure this is done in the interests of service users and operated in line with relevant guidance. |
| <p>15(1)(c) suitable for the purpose for which they are being used,</p> | <ul style="list-style-type: none"> ● Service users' needs are taken into account when premises are designed, built, renovated or adapted. ● The size, layout and design of premises meets current legislation and guidance and is safe for the care and treatment being delivered. ● Service users can easily access premises, and where this is not the case, reasonable adjustments are made in accordance with the Equalities Act 2010 and other relevant legislation and guidance. ● Premises and equipment have been deemed safe and suitable, for the purpose for which they are being used in accordance with current legislation and guidance. This may include inspection/certification/calibration by relevant authorities. ● Where premises are being used to deliver care and treatment, but this was not the original intended purpose, appropriate alterations have been made and these are in line with current legislation and guidance; where these cannot be met the provider has arrangements in place to mitigate the risks to service users (relevant others) and has appropriate contingency plans in place. ● Premises and equipment used to deliver care and treatment meets the needs of service users and, where possible, their preferences. This includes ensuring that privacy, dignity and confidentiality are not compromised. ● Reasonable adjustments are made in relation to the provision of equipment to meet the needs of service users with disabilities, in line with requirements under the Equality Act 2010. |
| <p>15(1)(d) and properly used</p> <p>15(1)(e) properly maintained, and</p> | <ul style="list-style-type: none"> ● Providers must ensure that they meet the requirement of relevant legislation, including health and safety, fire, electrical, building maintenance, portable appliance testing, etc. to ensure that premises and equipment are properly used and maintained. ● Health and safety risk assessments are regularly carried out of the premises (including grounds) and equipment, and are acted on in a timely manner if improvements are required. |

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| | <ul style="list-style-type: none"> • Arrangements are in place for the purchase, service, maintenance and renewal/replacement of premises (including grounds) and equipment, which ensure that the requirements of current legislation and guidance, as well as manufacturers' instructions and provider policies/procedures, are met. • All equipment is used in accordance with manufacturers' instructions and is only used for the intended purpose and for the intended service user(s). • Providers must ensure that staff and relevant others are trained to use equipment appropriately. |
| <p>15(1)(f) appropriately located for the purpose for which they are being used.</p> | <ul style="list-style-type: none"> • Providers should take the anticipated needs of service users into account when locating services and should ensure easy access to other relevant facilities and the local community. • Equipment, for example, chairs, beds, clinical equipment, and moving and handling equipment, should be accessible (for example, available when needed, or obtained within a reasonable time without posing a risk) at all times to ensure service users' needs can be met. |
| <p>15(2) The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.</p> | <ul style="list-style-type: none"> • The provider complies with guidance from the Department of Health about the prevention and control of health care acquired infections <i>The Code of Practice for health and adult social care on the prevention and control of infections and related guidance</i>. • Where applicable, premises and equipment are decontaminated/sterilised in accordance with current legislation and guidance. • Arrangements are in place to ensure that ancillary services, such as kitchens, laundry rooms, etc. (belonging to the provider), which are used for/by service users, must be used and maintained in accordance with relevant legislation and guidance and that service users and staff using equipment are trained in its use or supervised if necessary. • Multiple use equipment and devices must be cleaned or decontaminated between use and all staff understand the risk to service users of not adhering to this. • Single use and single person devices must not be re-used or shared and all staff understand the risk to service users of not adhering to this. |

| Relevant legislation | Relevant guidance |
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| <p>Health and Safety at Work etc. Act 1974 http://www.legislation.gov.uk/ukpga/1974/37</p> | <p>The Code of Practice on the prevention and control of infections and related guidance (DH) https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance</p> |
| <p>The Management of Health and Safety at Work Regulations 1999 http://www.legislation.gov.uk/uksi/1999/3242/regulation/3/made</p> | |
| <p>The Workplace (Health, Safety and Welfare) Regulations 1992 http://www.legislation.gov.uk/uksi/1992/3004/made/data.pdf</p> | <p>Infection prevention and control in care homes: Information resource published (DH) https://www.gov.uk/government/publications/infection-prevention-and-control-in-care-homes-information-resource-published</p> |
| <p>The Manual Handling Operations Regulations 1992 http://www.legislation.gov.uk/uksi/1992/2793/contents/made</p> | |
| <p>The Regulatory Reform (Fire Safety) Order 2005 http://www.legislation.gov.uk/uksi/2005/1541/contents/made</p> | <p>Health technical memoranda published by the Department of Health (this series brings together all health technical memoranda) https://www.gov.uk/government/collections/health-technical-memorandum-disinfection-and-sterilization</p> |
| <p>Equality Act 2010 http://www.legislation.gov.uk/ukpga/2010/15/contents</p> | |
| <p>Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) https://www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000</p> | <p>DH Health Building notes (this series brings together all health building notes) https://www.gov.uk/government/collections/health-building-notes-core-elements</p> |
| <p>The Medical Devices Regulations 2002 http://www.legislation.gov.uk/uksi/2002/618/contents/made</p> | <p>Guidance published by the Health and Safety Executive http://www.hse.gov.uk/guidance/index.htm</p> |
| <p>The Medical Devices (Amendment) Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1426/made</p> | <p>NHS Premises Assurance Model https://www.gov.uk/government/publications/nhs-premises-assurance-model-launch</p> |
| <p>The Hazardous Waste (England and Wales) Regulations 2005 http://www.legislation.gov.uk/uksi/2005/894/contents/made</p> | |

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| | <p>Information Commissioner’s Office guidance on the use of CCTV http://ico.org.uk/for_organisations/data_protection/topic_guides/~media/documents/library/Data_Protection/Detailed_specialist_guides/ICO_CCTVFINAL_2301.pdf</p> <p>Equality and Human Rights Commission: Equality Act 2010 services, public functions and associations Statutory Code of Practice : http://www.equalityhumanrights.com/publication/services-public-functions-and-associations-statutory-code-practice</p> |
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Regulation 16: Receiving and acting on complaints

16.—(1) Any complaint received must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation.

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

(3) The registered person must provide to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request, 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.**

Summary of the regulation

The intention of this regulation is to ensure that anyone can make a complaint* about any aspect of care and treatment planned and/or provided, and to ensure that providers investigate complaints and take appropriate and timely action to rectify any failures identified by the complainant or investigation.

To meet the requirement of this regulation, providers must promote an open culture in which anyone feels able to raise concerns and, where they feel that they need to, raise it further as a complaint. This will include making information about raising concerns and making complaints accessible, and providing support to enable people to raise concerns and make complaints. Providers must

have systems for assessing, investigating and responding to complaints in a timely manner. The provider must be able to demonstrate that changes have been made as a result of any failure identified by a complaint or related investigation. It should be noted that receiving complaints is not necessarily an indication that a regulation is being breached.

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

Breaches of this regulation do not constitute a prosecutable offence in themselves (other than that outlined above), but where CQC deems a breach of this regulation constitutes a breach of a regulation that carries prosecutable offence clauses, then CQC could move directly to prosecution without serving a warning notice. For example, where care and treatment is provided without the consent of the relevant person(s), results in any form of abuse or puts service users at serious risk of abuse, is unsafe or does not meet the nutritional or hydration needs of services users. In addition, CQC may take any other regulatory action in response to breaches of this regulation.

In addition, the provider must provide CQC with information about the complaint within 28 days when requested to do so. Failure to do so is a prosecutable offence; this may be seen as preventing CQC from taking appropriate action itself in relation to a complaint or putting service users at risk of harm, or of receiving care and treatment that has, or is, causing harm. CQC could move directly to prosecution without first serving a warning notice.

* Complaints can be made verbally or in writing, and complainants do not have to be identified.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| 16(1) Any complaint received must be investigated and necessary and proportionate action must | <ul style="list-style-type: none"> • Complaints should be able to be made to any member of staff, either verbally or in writing. • All staff should be aware of how to respond when they receive a complaint. • All complaints are acknowledged however they are received. • Complainants are not discriminated against or victimised and in particular, service users' care and |

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| <p>be taken in response to any failure identified by the complaint or investigation.</p> | <p>treatment is not affected if a complaint is made by them or on their behalf.</p> <ul style="list-style-type: none"> • The provider operates appropriate systems that ensure all complaints are investigated <ul style="list-style-type: none"> ○ undertaking a review to establish the level of investigation and immediate action required, including referral to appropriate authorities for investigation (e.g. professional regulators and local authority safeguarding teams etc. ○ ensuring appropriate investigations are carried out by competent persons to identify what might have brought about the complaint and actions required as a result. • Timely and appropriate action is taken in response to any failures identified by a complaint or the investigation of a complaint. • Information about how to take action if a complainant is not satisfied with how the provider manages and/ or responds to their complaint is made available, and information is provided about the internal procedures and when complaints should/will be escalated to other relevant bodies. • Where complainants escalate their complaint externally because they are dissatisfied with the local outcome, the provider cooperates with any independent review/process. |
| <p>16(2) The registered person must establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by service users and other persons in relation to the carrying on of the regulated activity.</p> | <ul style="list-style-type: none"> • Information and guidance about how to complain is available and accessible to everyone, including being provided in appropriate languages, formats, etc. • People are made aware of how to complain, are offered support and provided with the level of support required to help them make a complaint, for example, through the use of advocates, interpreter services and any other identified/requested support. • Where a complainant does not wish to identify themselves the provider must still follow its complaints process. • Staff and others who are involved in the assessment and investigation of complaints understand the provider's complaints process and are knowledgeable about current related guidance. • Consent and confidentiality are not compromised at any time during the complaints process. • Complainants, and those about whom complaints are made, are kept informed of the status of their |

complaint and its investigation, and are advised of any changes made as a result.

- The provider maintains a record of complaints, outcomes and actions taken in response and where no action is taken the reasons for this are detailed.
- Providers are required to act in accordance with Regulation 20 Duty of Candour in respect of complaints about care and treatment that has resulted in the occurrence of a notifiable safety incident.

| Relevant legislation | Relevant guidance |
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| <p>Public Interest Disclosure Act 1998 http://www.legislation.gov.uk/ukpga/1998/23/contents</p> <p>Data Protection Act 1998 http://www.legislation.gov.uk/ukpga/1998/29/contents</p> | <p>Department of Health guidance <i>Complaints in the NHS</i> https://www.gov.uk/government/publications/nhs-hospitals-complaints-system-review</p> <p>Principles of Good Complaint Handling (PHSO, 2009) http://www.ombudsman.org.uk/reports-and-consultations/reports/health</p> <p>NHS Constitution https://www.gov.uk/government/publications/the-nhs-constitution-for-england http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx</p> <p>MIND – complaining about health and social care http://www.mind.org.uk/information-support/legal-rights/complaining-about-health-and-social-care/</p> |

Regulation 17: Good governance

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

(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—

- (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (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 securely 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 and of decisions taken in relation to the care and treatment provided;**
- (d) maintain securely such other records as are necessary to be kept in relation to—**
 - (i) persons employed in the carrying on of the regulated activity, and**
 - (ii) the management of the regulated activity;**
- (e) seek and act on feedback from relevant persons 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;**
- (f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).**

(3) The registered person must send to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request—

- (a) a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (2)(a) and (b) are being complied with, and**
- (b) any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.**

Summary of the regulation

The intention of this regulation is to ensure that providers operate systems and processes that enable all other regulatory requirements to be met, as described in Part 3 (Requirements in relation to Regulated Activity) of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014. This includes ensuring that providers are able to meet all the requirements of the fundamental standards described in Regulations 10 to 21.

To meet the requirements of this regulation, providers must have oversight of planning, delivery and monitoring of all care and treatment, what action is taken to mitigate risks to the quality and safety of care and treatment, and what action is taken in response to issues raised by monitoring activities. This includes ensuring that it has access to all relevant information about its service(s), including information about the experience of service users and others, which is necessary to manage the risks to service users if it is not meeting the requirements of the regulations in Part 3. The provider must also take timely and appropriate corrective action where there is a risk of a regulatory breach occurring, or where a regulatory breach has occurred. Additionally, the provider must securely maintain appropriate and accurate records as follows:

- Records about all aspects of the care and treatment of each service user.
- Relevant records about persons it employs for designing and delivering care and treatment.
- Any other records which may be appropriate for managing the carrying on of regulated activities.

The provider must also continually evaluate and make improvements to the systems and processes that are used to achieve the above.

Individuals may be deemed fit under Regulation 5, Fit and proper person: directors and Regulation 19, Fit and proper persons employed, while collectively, a Board (or similar group made up of the individuals to whom this regulation applies) demonstrates a lack of fitness. In these cases, CQC may question whether the provider is meeting the requirements of this regulation as the establishment and effective operation of governance systems and processes are directly dependent on the fitness of the individuals who operate them.

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

Providers must submit to CQC, on request, a written report about how the quality and safety of their services are assessed, monitored, and improved, including how risk to quality and safety are managed. Failure to submit such a report when requested is a prosecutable offence. CQC may consider that this could prevent it from taking appropriate, timely action. CQC could move directly to prosecution without first serving a warning notice.

Other breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC may take other regulatory action in response to a breach of this regulation. Additionally, CQC may consider that a breach of this regulation, or one of its components, constitutes a breach of a regulation which carries an offence. For example, a breach of this regulation may be considered to constitute unsafe or inappropriate care and treatment and/or may constitute abuse.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| <p>17(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—</p> | |
| <p>17(2)(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);</p> | <ul style="list-style-type: none"> • The provider has systems and processes to assess monitor and improve the quality and safety of services provided, and these are continually reviewed to ensure they remain fit for purpose. Fit for purpose means that: <ul style="list-style-type: none"> ○ systems and processes enable the provider to identify where quality and/or safety are being compromised and take appropriate and timely action in response to issues ○ the provider ensures it has access to all necessary information, information is properly analysed, it is considered by a person with the appropriate skills and competence, might need to be escalated and information is understood by those using it |

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| | <ul style="list-style-type: none"> ○ the provider has effective systems to support communications, throughout the organisation (and to others as appropriate) about the quality and safety of services. ● Information about the quality of care and treatment is actively gathered from a range of sources, including service users, professional bodies, commissioners etc, and any other relevant bodies. This information is: <ul style="list-style-type: none"> ○ analysed and responded to, including taking action to address issues where they are raised ○ used by the provider to make and demonstrate improvements have been made in response to information about the quality or the safety of the services. ● The provider identifies and seeks timely, professional/expert advice, as needed, to support it in identifying and making improvements. ● Progress against plans to improve the quality and safety of services is monitored, and appropriate and timely action is taken where progress is not achieved as expected. ● The provider shares relevant information, for example about incidents or risks with other relevant individuals or bodies, e.g. safeguarding boards, coroners, regulators, subject to statutory consent and confidentiality requirements, and where it is identified that improvements are needed these are acted on in a timely manner. |
| <p>17(2)(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;</p> | <ul style="list-style-type: none"> ● The provider has systems and processes that enable it to identify and assess risks to the health, safety and/or welfare of service users. ● The provider has processes to minimise the likelihood that risks will occur and to minimise the impact of risks on service users. ● Risks to the health, safety and/or welfare of service users are escalated within the organisation or to a relevant external body as appropriate. ● Identified risks are continually monitored and appropriate action is taken where a risk is deemed to have increased, i.e. it has become more likely that it will happen. |

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| | <p>Note:</p> <p>'Others' includes anyone who may be put at risk through the carrying on of a regulated activity, such as staff, service users, visitors, tradespeople, students, etc, insofar as their health, safety and/or welfare may have a direct impacts on service users. This regulation does not apply to the general health, safety and welfare of persons other than service users – it applies strictly to service users in the carrying on of a regulated activity.</p> |
| <p>17(2)(c) maintain securely 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 and of decisions taken in relation to the care and treatment provided;</p> | <ul style="list-style-type: none"> • Records relating to service users' care and treatment are created/amended, stored and destroyed in accordance with current legislation and guidance: <ul style="list-style-type: none"> ○ Records are complete, legible, accurate and every effort must be made to ensure records are updated without any delays e.g. results of diagnostic test, correspondence etc., should be added as soon as possible. • Records must be kept secure at all times and only accessed, amended, or destroyed by persons authorised to do so. • Individual service user records are fit for purpose and can be accessed by authorised persons as required in order to deliver their care and treatment in a manner which meets their needs and keeps them safe. • Individual service records should accurately record all decisions taken in relation to care and treatment and may reference to discussions with service users/relevant persons, consent records, advanced decisions to refuse treatment, etc. • Decisions taken on behalf of a service user due to lack of capacity must be recorded and provide evidence that these have been taken in accordance with the requirements of the Mental Capacity Act 2005 or where relevant the Mental Health Act 1983, and their associated Codes of Practice. • Information in all formats is managed in accordance with current legislation and guidance. • Systems and processes support service users' confidentiality and do not contravene the Data Protection Act 1998. |

17(2)(d) maintain securely such other records as are necessary to be kept in relation to–

(i) persons employed in the carrying on of the regulated activity, and

(ii) the management of the regulated activity;

- Records relating to persons employed and the management of regulated activities are created/ amended, stored and destroyed in accordance with current legislation and guidance.
- Records relating to persons employed should include information relevant to their being employed in the role including information relating to the requirements under Regulations 5 (Fit and proper person (directors)) and Regulation 19 (Fit and proper persons employed).
- Records relating to the management of regulated activities mean anything relevant to the design and delivery of care and treatment, and may include governance arrangements such as policies and procedures, service/maintenance records, audits and reviews, purchasing, action plans in response to risks/incidents, etc.
- Records are complete, legible, indelible, accurate and up to date, with no undue delays in adding/ filing information, insofar as is reasonably practicable. Information must not be unduly delayed from being added to/filed in records.
- Records must be kept secure at all times and only accessed, amended or destroyed by authorised persons.
- Information in all formats is managed in accordance with current legislation and guidance.
- Systems and processes support service users' confidentiality and do not contravene the Data Protection Act 1998.

17(2)(e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such

- The provider actively encourages feedback from service users (relevant persons) and others (such as staff, other relevant bodies) about the quality of care and overall experience of engaging with the provider; feedback can be informal or formal, written or verbal.
- All feedback received from service users/relevant persons and others is listened to, recorded and responded to (as appropriate), analysed and used to improve the quality and safety of services and experience of engaging with the provider.
- Improvements are made in a timely manner once they are identified and the provider has systems in place for communicating how feedback has led to improvements.

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| services; | <ul style="list-style-type: none"> The provider should seek the views and act on recommendations and requirements made by external inspectorates such as fire, environmental, health etc, and the provider should be able to demonstrate that any improvements required have been made. |
| 17(2)(f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e). | <ul style="list-style-type: none"> Arrangements to manage quality and risks, and to manage feedback about services, are regularly reviewed to ensure they remain fit for purpose and actions are taken to make improvements as necessary. Arrangements for meeting the requirements referred to in sub-paragraphs (a) to (e) are regularly reviewed to confirm they are being adhered to. Where the provider identifies that arrangements for meeting the requirements referred to in sub-paragraphs (a) to (e) are either not fit for purpose or are not being adhered to, appropriate and timely action is taken in response. |

| Relevant legislation | Relevant guidance |
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| <p>Freedom of Information Act 2000 http://www.legislation.gov.uk/ukpga/2000/36/contents</p> <p>Data Protection Act 1998 http://www.legislation.gov.uk/ukpga/1998/29/contents</p> | <p>NHS Constitution (DH, 2013) https://www.gov.uk/government/publications/the-nhs-constitution-for-england</p> <p>Never events list (update 2013/14) http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf</p> <p>Principles of Good Complaint Handling (PHSO, 2009) http://www.ombudsman.org.uk/reports-and-consultations/reports/health</p> <p>Reports by the Parliamentary and Health Services Ombudsman http://www.ombudsman.org.uk/reports-and-consultations/reports/health</p> |

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| | <p>Local Government Ombudsmen complaints resources for adult social care http://www.lgo.org.uk/adult-social-care/providers/</p> <p>Local Government Ombudsman decisions: adult care services http://www.lgo.org.uk/decisions/adult-care-services/</p> <p>NICE Quality Standard resources http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>SCIE Developing Skills and Services resources http://www.scie.org.uk/topic/developingskillsservices</p> <p>Prevention of future death reports (previously Rule 43 reports) by the Chief Coroner http://www.justice.gov.uk/coroners-burial-cremation/coroners/rule-43</p> <p>National NHS staff survey reports http://www.nhsstaffsurveys.com/Page/1006/Latest-Results/2013-Results/</p> <p>NHS patient survey reports http://www.nhssurveys.org/previousurveys</p> <p>A refreshed Equality Delivery System for the NHS (2013) http://www.england.nhs.uk/wp-content/uploads/2013/11/eds-nov131.pdf</p> |
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| | <p>Records management: NHS Code of Practice (DH, 2006) https://www.gov.uk/government/publications/records-management-nhs-code-of-practice</p> <p>Confidentiality: NHS code of practice (DH, 2003) https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice</p> <p>A guide to confidentiality in health and social care (HSCIC, 2013) http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf</p> <p>ICO guidance on Data Protection etc. http://ico.org.uk/for_organisations/guidance_index/data_protection_and_privacy_and_electronic_communications</p> <p>Health and Social Care Outcomes Frameworks (DH) https://www.gov.uk/government/collections/health-and-social-care-outcomes-frameworks</p> <p>QOF resources (NICE) http://www.nice.org.uk/aboutnice/gof/gof.jsp</p> <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</p> <p>Ministry of Justice: Mental Capacity Act 2005 Deprivation of liberty safeguards: Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice http://webarchive.nationalarchives.gov.uk/20130107105354/http://</p> |
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| | <p>www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087309.pdf</p> <p>Department of Health: Code of Practice Mental Health Act 1983 http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087073.pdf</p> <p>Academy of Medical Royal Colleges (July 2013) Standards for the Structure and Content of patient records.</p> <p>The standards can be accessed online directly at http://www.rcplondon.ac.uk/sites/default/files/standards-for-the-clinical-structure-and-content-of-patient-records.pdf.</p> <p>Full information on them is online at http://www.rcplondon.ac.uk/projects/healthcare-record-standards</p> <p>CQC has an information governance obligation under the Health and Social Care Act 2008</p> |
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Regulation 18: Staffing

18.—(1) Sufficient numbers of suitably qualified, competent, skilled and experienced persons must be deployed in order to meet the requirements of this Part.

(2) Persons employed by the service provider in the provision of a regulated activity must—

- (a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,**
- (b) be enabled where appropriate to obtain further qualifications appropriate to the work they perform, and**
- (c) where such persons are health care professionals, social workers or other professionals registered with a health care or social care regulator, be enabled to provide evidence to the regulator in question demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise or a requirement of their role.**

Summary of the regulation

The intention of this regulation is to ensure that providers deploy enough suitably qualified, competent and experienced staff to enable them to meet all other regulatory requirements described in Part 3 (Requirements in relation to Regulated Activity) of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014. This includes ensuring providers are able to meet all the requirements of the fundamental standards described in Regulations 10 to 21.

To meet the requirements of the regulations, the provider must continually assess whether it is able to deploy enough suitable staff to meet all the needs of service users at all times, including in response to their changing needs. The provider must also support its staff to access training, professional development, supervision and appraisal throughout the duration of employment to enable them to appropriately perform the duties required of their role; this includes supporting them to obtain further qualifications where required for their role. In addition, the provider must enable registered health and social care professionals to demonstrate

to the relevant professional regulator that they meet professional standards (a requirement of their ability to practise) so that they can continue to function effectively in the role for which they are employed.

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

Breaches of this regulation, or its components, do not constitute a prosecutable offence in themselves. However, CQC can take a range of other regulatory action in response to breaches of the regulation. In addition, CQC may consider that a breach of this regulation, or one of its components, constitutes a breach of a regulation that carries a prosecutable offence. For example, a breach of this regulation may be considered to constitute unsafe or inappropriate care and treatment and/or may constitute abuse.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| <p>18(1) Sufficient numbers of suitably qualified, competent, skilled and experienced persons must be deployed in order to meet the requirements of this Part.</p> | <ul style="list-style-type: none"> • The provider must have a systematic approach to determining the number of staff and range of skills required (e.g. different levels of skills and competence, registered professional and support workers, supervision needs and leadership requirements etc.) in order to meet service users' needs and keep them safe at all times, which reflects current legislation and guidance (where available). • Staffing levels and skill mix are reviewed continuously and are adapted to respond to the changing needs and circumstances of service users. • There are policies and procedures in place which ensure that if staff are unavailable to work as scheduled, they are replaced or other staff are re-deployed in a manner which ensures the staffing levels and skill mix remain able to meet service users' needs. <p>Note: Guidance re: Regulation 19 1 (b) (Fit and proper persons employed provides describes what is meant by suitably qualified, competent, skilled and experienced persons).</p> |

18(2) Persons employed by the service provider in the provision of a regulated activity must–

18(2)(a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,

- The provider must ensure that there is an induction programme that prepares staff for their role.
- Training, learning and development needs of individual staff members is carried out at the start of employment and reviewed at appropriate intervals during the course of employment and staff are supported to undertake training, learning and development to enable them to fulfil the requirements of their role.
- Where appropriate, staff are supervised in their role until they can demonstrate required/acceptable levels of competence to function unsupervised.
- Staff receive appropriate ongoing or periodic supervision in their role to ensure competence is maintained.
- Staff are supported during their employment to make sure they are enabled to participate in:
 - statutory training
 - other mandatory training, as defined by the provider for their role
 - any additional training identified as required in order to carry out regulated activities as part of their job duties (particularly to maintain the necessary skills)
 - other learning and development opportunities required to enable them to fulfil their role.
- Completion of all required training, learning and development is monitored and appropriate and timely action is taken where training requirements are not being met.
- Staff receive regular appraisal of their performance in their role and any training, learning and development needs identified, planned for and supported.
- Health, social and other care professionals have access to clinical/professional supervision as required, in accordance with the requirements of the relevant professional regulator.

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| <p>18(2)(b) be enabled where appropriate to obtain further qualifications appropriate to the work they perform, and</p> | <ul style="list-style-type: none"> • Where staff need to obtain further qualifications to continue to perform their role, support is provided for them to do so. • The provider must not act in a manner which prevents or limits staff from obtaining further qualifications which are appropriate to their role. |
| <p>18(2)(c) where such persons are health care professionals, social workers or other professionals registered with a health care or social care regulator, be enabled to provide evidence to the regulator in question demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise or a requirement of their role.</p> | <ul style="list-style-type: none"> • Where registration with a professional body is a requirement of the role, the provider must ensure that staff are enabled to meet the requirements of the relevant professional regulator for the duration of employment (for example, requirements for continuing professional development). • Staff are supported to join Accredited Voluntary Registers should they wish. • Providers must have appropriate systems in place to support this (e.g. revalidation, meeting Codes of Practice). • The provider must not act in a manner which prevents or limits or would result in staff not meeting requirements required by professional regulators. |

| Relevant legislation | Relevant guidance |
|---|--|
| <p>Health and Safety at Work etc. Act 1974 http://www.legislation.gov.uk/ukpga/1974/37</p> | <p>General Dental Council: Standards for the dental team http://www.gdc-uk.org/Dentalprofessionals/Standards/Documents/Standards%20for%20the%20Dental%20Team.pdf</p> |
| <p>Equality Act 2010 http://www.legislation.gov.uk/ukpga/2010/15/contents</p> | <p>General Dental Council: Continuing professional development for dental professionals http://www.gdc-uk.org/dentalprofessionals/cpd/Pages/default.aspx</p> |
| <p>Human Rights Act 1998 http://www.legislation.gov.uk/ukpga/1998/42/contents</p> | <p>General Medical Council: Good medical practice http://www.gmc-uk.org/Good_medical_practice_English_0414.pdf_51527435.pdf</p> |
| <p>Safeguarding Vulnerable Groups Act 2006 http://www.legislation.gov.uk/ukpga/2006/47/contents</p> | <p>General Medical Council: Revalidation http://www.gmc-uk.org/doctors/revalidation.asp</p> |
| <p>Dentists Act 1984 http://www.legislation.gov.uk/ukpga/1984/24</p> | <p>General Medical Council: Continuing professional development http://www.gmc-uk.org/education/continuing_professional_development.asp</p> |
| <p>Medical Act 1983 http://www.legislation.gov.uk/ukpga/1983/54/contents</p> | <p>Nursing and Midwifery Council: The Code – Standards of conduct, performance and ethics for nurses and midwives http://www.nmc-uk.org/Documents/Standards/nmcTheCodeStandardsOfConductPerformanceAndEthicsForNursesAndMidwives_LargePrintVersion.PDF</p> |
| <p>Health and Social Work Professions Order 2001 http://www.legislation.gov.uk/uksi/2002/254/contents/made</p> | <p>Nursing and Midwifery Council: The Prep Handbook http://www.nmc-uk.org/Documents/Standards/NMC_Prepare_handbook_2011.pdf</p> |
| <p>Nursing and Midwifery Order 2001 http://www.legislation.gov.uk/uksi/2002/253/contents/made</p> | |
| <p>The Pharmacy Order 2010 http://www.legislation.gov.uk/ukdsi/2010/9780111487358</p> | |

Nursing and Midwifery Council: Midwives rules and standards 2012
<http://www.nmc-uk.org/Documents/NMC-Publications/Midwives%20Rules%20and%20Standards%202012.pdf>

Nursing and Midwifery Council: Nursing standards for competence
<http://www.nmc-uk.org/Documents/Standards/Standards%20for%20competence.pdf>

Health and Care Professions Council: Standards of conduct, performance and ethics
<http://www.hcpc-uk.org/assets/documents/10003B6EStandardsofconduct,performanceandethics.pdf>

Health and Care Professions Council standards for continuing professional development
<http://www.hpc-uk.org/registrants/cpd/standards/>

General Pharmaceutical Council: Standards of conduct, performance and ethics
<http://www.pharmacyregulation.org/sites/default/files/Standards%20of%20conduct%20ethics%20and%20performance%20July%202012.pdf>

Disclosure and Barring Service
<https://www.gov.uk/government/organisations/disclosure-and-barring-service>

Review of healthcare assistants and support workers in NHS and social care (The Cavendish Review, published by DH July 2013)
<https://www.gov.uk/government/publications/review-of-healthcare-assistants-and-support-workers-in-nhs-and-social-care>

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| | <p>Royal College of Nurses: Mandatory Nurse Staffing Levels http://www.rcn.org.uk/_data/assets/pdf_file/0009/439578/03.12_Mandatory_nurse_staffing_levels_v2_FINAL.pdf</p> <p>National Quality Board: How to ensure the right people, with the right skills, are in the right place at the right time http://www.england.nhs.uk/wp-content/uploads/2013/11/nqb-how-to-guid.pdf</p> <p>Professional Standards Authority http://www.professionalstandards.org.uk/voluntary-registers</p> <p>Skills for Care http://www.skillsforcare.org.uk</p> |
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Regulation 19: Fit and proper persons employed

- 19.—(1) Persons employed for the purposes of carrying on a regulated activity must—**
- (a) be of good character,**
 - (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and**
 - (c) be able by reason of their health, 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—**
- (a) paragraph (1), or**
 - (b) in a case to which regulation 5 applies, paragraph (3) of that regulation.**
- (3) The following information must be available in relation to each such person employed—**
- (a) the information specified in Schedule 3, and**
 - (b) such other information as is required under any enactment to be kept by the registered person in relation to such persons 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) Where a person employed by the registered person no longer meets the criteria in paragraph (1), the registered person must—**
- (a) take such action as is necessary and proportionate to ensure that the requirement in that paragraph is complied with, and**
 - (b) if the person is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.**
- (6) Paragraphs (1) and (3) of this regulation do not apply in a case to which regulation 5 applies.**

Summary of the regulation

The intention of this regulation is to ensure that providers only employ staff who are able to deliver care and treatment (appropriate to their role) that meets the regulatory requirements described in Part 3 (Requirements in relation to Regulated Activity) of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014. This includes meeting the requirements of the fundamental standards detailed in Regulations 10 to 21. This regulation applies to all staff carrying on a regulated activity, including permanent staff, locums, temporary/agency/bank staff, trainees/students/contractors.

To meet the requirements of this regulation, the provider must operate robust recruitment procedures, including undertaking any relevant checks, must have a procedure for ongoing monitoring of staff to ensure they remain able to meet requirements, and appropriate arrangements to deal with staff that are no longer fit to carry out the duties required of them.

Employing unfit persons, or continuing to allow unfit persons to stay in a role, may lead CQC to question the fitness of a provider.

If an aspirant provider cannot demonstrate that it will meet the requirements of this regulation from its first day of business, CQC may refuse its application for registration.

Breaches of this regulation, or its components, do not constitute a prosecutable offence in themselves. However, CQC may take other regulatory action in response to breaches of this regulation. Additionally, CQC may consider that a breach of this regulation, or one of its components, constitutes a breach of a regulation which carries a prosecutable offence. For example, a breach of this regulation may be considered to constitute unsafe care and treatment and/or may constitute have led to abuse or put service users at risk of abuse.

This regulation does not apply to persons covered under the Fit and Proper Person regulation, i.e. a director (including the chairman) of an NHS trust established under section 25 of the National Health Service Act 2006, or a director of an NHS foundation trust.

| Component of the regulation | What providers could do to meet the requirements of the component |
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| 19(1) Persons employed for the purposes of carrying on a regulated activity must– | |
| 19(1)(a) be of good character, | <ul style="list-style-type: none"> • Providers should make every effort to ensure that all available information is sought to confirm that the individual is of good character: <ul style="list-style-type: none"> ○ not having been convicted of an offence in any country which would be considered an offence in the UK, if the offence relates to the conduct required in carrying on a regulated activity ○ not having been removed or struck off a professional register ○ that there is no information about the individual that would suggest they have been responsible for, privy to, contributed to or facilitated any serious misconduct or mismanagement in the course of carrying on a regulated activity. • If information is later identified that suggests the individual is not of good character, (this may have not originally been available or may have been concealed), the provider takes immediate action to investigate and address the situation. • Where a provider deems the individual suitable despite not meeting the characteristics outlined above, the reasons should be recorded and information about this should be made available to those that need to be aware (as appropriate). |
| 19(1)(b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and | <ul style="list-style-type: none"> • Where a qualification is required for a role, either by law or the provider, the provider has means by which it can check that staff hold the appropriate qualification(s). • Where specific skills and experience are a requirement of the role the provider has a means of confirming that staff have these and maintain them. • The provider has systems in place to assess the competence of individuals before they work unsupervised in the role and should provide appropriate supervision (direct or indirect) until deemed competent to carry out the role. This may include demonstrating a caring and |

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| | <p>compassionate nature to required level for the role.</p> <ul style="list-style-type: none"> • The provider may consider that an individual can be employed in a role based on their qualifications, skills and experience with the expectation that they will become competent within a specified timeframe once in the role (i.e. they may be employed and undergo training in order to become competent). |
| <p>19(1)(c) be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.</p> | <ul style="list-style-type: none"> • The provider has clear criteria about what ‘fitness’ means for each role and uses these to determine whether a person is able to carry out their role. • All reasonable efforts are made to make adjustments for individuals in order that they can carry out a role, in line with requirements to make reasonable adjustments for employees under the Equality Act 2010 before they are deemed unfit. This may include offering alternative roles. |
| <p>19(2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in– (a) paragraph (1), or (b) in a case to which regulation 5 applies, paragraph (3) of that regulation.</p> | <ul style="list-style-type: none"> • The provider has effective recruitment and selection procedures in place that comply with relevant legislation and guidance. • Information about candidates (set out in Schedule 3 of the regulations) must be confirmed prior to employment. These include (but are not limited to): <ul style="list-style-type: none"> ○ proof of identify, eligibility to work in the UK, qualifications, registration with professional body (as required) ○ required checks with the Disclosure and Barring Service, ○ declarations of offenses committed in the UK and outside the UK/EU ○ satisfactory evidence of conduct in previous employment/education (specifically information related to conduct in health and social care and with children and vulnerable adults) ○ other checks deemed appropriate by the provider. • Selection/interview processes assess the accuracy of applications and are designed to demonstrate candidates’ suitability for the role, while meeting the requirements of the Equality |

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| | <p>Act 2010 in relation to pre-employment health checks.</p> <ul style="list-style-type: none"> • Recruitment and/or checks may be carried out by a party other than the provider, in which case the provider must have a mechanism of assuring itself that all checks are complete and satisfactory. |
| <p>19(4) Persons employed must be registered with the relevant professional body where such registration is required by, or under, any enactment in relation to–</p> | <ul style="list-style-type: none"> • The provider has means by which it can check that staff have appropriate and current registration with a professional regulator or, where applicable, an accredited voluntary register. |
| <p>19(5) Where a person employed by the registered person no longer meets the criteria in paragraph (1), the registered person must–</p> <p>19(5)(a) take such action as is necessary and proportionate to ensure that the requirement in that paragraph is complied with, and</p> <p>19(5)(b) if the person is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.</p> | <ul style="list-style-type: none"> • The fitness of persons employed is regularly reviewed by the provider. • Arrangements are in place for the provider to respond to concerns about a person’s fitness after they are appointed to a role, raised by themselves or others, and these are adhered to. • The provider responds to concerns about a person’s fitness or ability to carry out their duties in a timely manner, this includes responding immediately if there is an imminent risk to service users. • The response taken to concerns about an individual’s fitness are fair to the individual and demonstrates due diligence. • Where a person’s fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to service users. • The provider informs others as appropriate about concerns/findings relating to a person’s fitness; for example professional regulators, police, safeguarding authorities etc., and supports any related enquiries and investigations carried out by others. |

| Relevant legislation | Relevant guidance |
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| <p>https://www.gov.uk/government/organisations/disclosure-and-barring-service http://www.gdc-uk.org/aboutus/thecouncil/pages/governancemanual.aspx</p> <p>http://www.gmc-uk.org/about/legislation.asp</p> <p>http://www.nmc-uk.org/About-us/legislation/</p> <p>http://www.hpc-uk.org/aboutus/legislation/</p> <p>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf</p> <p>Employment law http://www.legislation.gov.uk/ukpga/1996/18/part/I</p> <p>http://www.legislation.gov.uk/ukpga/2006/47/pdfs/ukpga_20060047_en.pdf</p> <p>Health care professionals Alerts Notices Directions 2006 (DH) http://www.nhsemployers.org/recruitmentandretention/employment-checks/alert-notice-system/pages/alert-notice-system.aspx</p> | <p>https://www.gov.uk/government/publications/dbs-identity-checking-guidelines</p> <p>http://www.hpc-uk.org/aboutregistration/standards/standardsofconductperformanceandethics/</p> <p>http://www.gmc-uk.org/guidance/index.asp?WT.ac=WBPR130422</p> <p>http://www.gdc-uk.org/Dentalprofessionals/Standards/Pages/default.aspx</p> <p>http://www.nmc-uk.org/Publications/Standards/</p> <p>NHS employment checks standard http://www.nhsemployers.org/recruitmentandretention/employment-checks/employment-check-standards/pages/employment-check-standards.aspx</p> <p>Independent Safeguarding Authority (ISA 2009) – this was all individual POVA https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215956/dh_121571.pdf</p> <p>EHRC employment statutory code of practice (sections on reasonable adjustments and pre-employment health checks) http://www.equalityhumanrights.com/sites/default/files/publication_pdf/employercode.pdf</p> |

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| | Accredited voluntary registers http://www.professionalstandards.org.uk/voluntary-registers |
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Regulation 20: Duty of candour

20.—(1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—

- (a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and**
- (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.**

(3) The notification to be given under paragraph (2)(a) must—

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

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

- (a) the information provided under paragraph (3)(b),**
- (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),**
- (c) the results of any further enquiries into the incident, and**
- (d) an apology.**

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—

- (a) paragraphs (2) to (4) are not to apply, and**

- (b) a written record is to be kept of attempts to contact or to speak to the relevant person.**
- (6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).**
- (7) In this regulation—**
- “apology” means an expression of sorrow or regret in respect of a notifiable safety incident;**
- “moderate harm” means—**
- (a) harm that requires a moderate increase in treatment, and**
- (b) significant, but not permanent, harm;**
- “moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);**
- “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—**
- (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or**
- (b) severe harm, moderate harm or prolonged psychological harm to the service user;**
- “prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;**
- “relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—**
- (a) on the death of the service user,**
- (b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or**
- (c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter;**
- “severe harm” means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.**

Summary of the regulation

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

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

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

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

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

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

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

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| <p>20(2)(a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and</p> | <ul style="list-style-type: none"> • Where the service user affected by an incident lacks capacity, or it is felt that it would be counterproductive to disclose information, appropriate arrangements should be in place to support best interest decisions and relevant persons are notified. • Information should only be disclosed to relevant persons other than the person directly suffering the if that person has died, lacks mental capacity or has given their explicit consent. |
| <p>20(2)(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification</p> | <ul style="list-style-type: none"> • Relevant person(s) should be provided with all reasonable practical and emotional support necessary to help overcome the physical, psychological and emotional impact of the incident, including: <ul style="list-style-type: none"> ○ being treated with respect, consideration and empathy ○ offered the option of immediate emotional support during the notifications, for example from a family member, a care professional or a trained advocate ○ offered access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille, etc. ○ providing access to any necessary remedial treatment to minimise or alleviate the harm caused ○ providing the relevant person(s) with information about available impartial advocacy and support services their local Healthwatch and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) to help them deal with the outcome of incident ○ arranging for care and treatment be delivered by another professional/team or provider as far as reasonably practicable should relevant persons wish. |
| <p>20(3) The notification to be given under paragraph (2)(a) must– 20(3)(a) be given in person by one or more representatives of the</p> | <ul style="list-style-type: none"> • A step-by-step account of all relevant facts known about the incident at the time should be given, in person, by one or more appropriate representatives of the provider. This should include as much or as little relevant information as the relevant person(s) want to hear, should be jargon free and explain any complicated terms, and should include an explanation of any further planned enquiries and investigations. This account should be given in a manner that relevant person/s can understand (for example, the provider should consider if appropriate interpreters, advocates, communication aids etc. should be present, but should be conscious of any potential breaches of confidentiality in doing so) |

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| <p>health service body, 20(3)(b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification, 20(3)(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate, 20(3)(d) include and apology, and 20(3)(e) be recorded in a written record which is kept securely by the health service body.</p> | <p>Providers must ensure that an apology is given, in person, by one or more appropriate representatives of the provider to relevant persons.</p> <ul style="list-style-type: none"> • The decision on who is most appropriate to provide the notification and/or apology should consider seniority, relationship to the service user, and experience and expertise in the type of notifiable incident that has occurred • The relevant person should be advised on what further enquiries are appropriate and they should be given all reasonable opportunities to be involved as much as they wish to be in the progress of any enquiries • The provider should explain that new information may emerge during the course of any inquiries into the incident, and must keep the relevant person(s) informed of new information as it arises • Providers should keep relevant person informed (as much or as little as they wish) about the conclusions of its enquiries. The relevant person(s) should also be provided with a single point of contact for any questions or queries and be offered further opportunities to discuss the case: <ul style="list-style-type: none"> ○ on an ongoing basis throughout the course of their ongoing recovery and/or treatment and during any investigation or inquiry ○ at times and amounts of their choosing <p>until they are satisfied that all relevant information has been disclosed</p> <p>Note: On occasion, a provider may discover a notifiable safety incident that happened some time ago, including in relation to care that was delivered by another provider. The provider that discovers the incident should work with any others who might be best placed to notify relevant persons of the incident, and should take responsibility for ensuring this happens.</p> <p>Please see below for guidance regarding 'reasonable attempts'.</p> |
| <p>20(4) The notification given under paragraph (2)(a) must be followed</p> | <ul style="list-style-type: none"> • The provider must ensure that it gives written notification to relevant persons in a timely manner following the notification that was given in person. The written notification should contain all the information provided in person, including an apology. |

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| <p>by a written notification given or sent to the relevant person containing—</p> <p>(a)the information provided under paragraph (3)(b),</p> <p>(b)details of any enquiries to be undertaken in accordance with paragraph (3)(c),</p> <p>(c)the results of any further enquiries into the incident, and</p> <p>(d)an apology.</p> | <ul style="list-style-type: none"> • A record of this written notification must be kept by the provider, along with any enquiries and investigations and the outcome or results of the enquiries or investigations. • The outcomes or results of any inquiries and investigations should also be provided in writing to the relevant persons, should they wish to receive them. • Any correspondence from relevant person(s) relating to the incident should be responded to in an appropriate and timely manner and a record of communications kept. |
| <p>20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—</p> <p>(a) paragraphs (2) to (4) are not to apply, and</p> <p>(b) a written record is to be kept of attempts to contact or to speak to the relevant person.</p> | <ul style="list-style-type: none"> • The provider should make every reasonable effort to contact the relevant person(s) through various communication means. All attempts to contact the relevant person(s) should be documented. • If the relevant person declines to contact the provider, their wishes should be respected and a record of this kept. |

| Relevant legislation | Relevant guidance |
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| <p>Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_2005009_en.pdf</p> <p>Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf</p> <p>Care Quality Commission (Registration Requirements) Regulations 2009 http://www.legislation.gov.uk/uksi/2009/3112/made</p> | <p>NHS National Patient Safety Agency, Being Open Framework http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726</p> <p>NHS England, Serious Incident Framework (note – due to be updated) http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf</p> <p>NHS England Never Events Framework (note – soon to be updated) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213046/never-events-policy-framework-update-to-policy.pdf</p> <p>NHS England Never Events List 2013/14 update http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf</p> <p>National Patient Safety Agency, Seven Steps to Patient Safety: Step 4 Promote reporting http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787</p> <p>Care Quality Commission (Registration Requirement) Regulations 2009: Regulations 16 - 18 http://www.legislation.gov.uk/uksi/2009/3112/made</p> <p>CQC notifications guidance NHS providers: http://www.cqc.org.uk/content/notifications-nhs-trusts</p> <p>GP providers: http://www.cqc.org.uk/content/notifications-gp-providers</p> |

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| | <p>Other providers: http://www.cqc.org.uk/content/notifications-non-nhs-trust-providers</p> <p>General medical Council, Good Medical Practice 2001, Guidance on 'duty of candour' http://www.gmc-uk.org/publications/24152.asp</p> <p>Gillick competence or Fraser guidelines http://www.nspcc.org.uk/Inform/research/briefings/gillick_wda101615.html</p> |
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Consultation questions: Guidance for providers on how to meet the regulations

1. Is it clear what providers should do to meet the requirements of the fundamental standards (regulations 9 to 19)? If not, how could it be made clearer?
2. Is it clear what providers should do to meet the fit and proper person requirements for directors (regulation 5)? If not, how could it be made clearer?
3. Is it clear what providers should do to fulfil their duty of candour (regulation 20)? If not, how could it be made clearer?
4. Is the format and layout of the guidance easy to follow and understand?
5. Are the links to key legislation and guidance helpful? How could we promote these links better?
6. Is there anything missing from the guidance?
7. Is there anything that should be taken out of the guidance?

Part B: Enforcement guidance

This guidance sets out the principles and approach we will follow when using our enforcement powers under the Health and Social Care Act 2008 ('the Act'), as amended by the [Care Act 2014](#), to improve health and adult social care services and protect the health, safety and welfare of people who use them.

It particularly concerns enforcement of the Act, the [Health and Social Care Act 2008 \(Regulation of Regulated Activities\) Regulations 2014](#) and the [Care Quality Commission \(Registration\) Regulations 2009](#).

Our provider handbooks for each care sector describe how we implement our regulatory approach in practice. We consulted on a number of these handbooks between April and June 2014, and we will publish updated handbooks and our consultation response in September and October 2014. We will consult on handbooks for sectors not already covered later in 2014/15.

We will also publish guidance for our inspectors specifically on enforcement (our 'enforcement framework').

This guidance does not cover our enforcement of the [Ionising Radiation \(Medical Exposure\) Regulations 2000](#). These are covered under separate primary legislation and have their own enforcement guidance, available on our website.

1. Purpose and principles of enforcement

Purpose of enforcement

We have two purposes when using our enforcement powers:

- **To protect people who use regulated services from harm and the risk of harm.**
- **To hold providers and individuals to account for failures in how the service is provided.**

When a service falls below the required standards, we will consider both purposes. We will often act to hold providers and individuals to account at the same time as we act to protect people from harm.

Protecting people from harm and the risk of harm

- We may **require** improvement, where the quality or safety of a service is below the required standards but the risk of harm is not immediate, and we expect the provider can improve it on their own, or
- We may **force** improvement, where the quality or safety of a service has fallen to unacceptable levels and the risk of harm means that we are prepared to intervene directly (for example, to restrict a service) or trigger others to intervene.

Holding providers and individuals to account

- We now have regulations that enable us to pursue criminal sanctions significantly more effectively than before, when there has been a failure in the provision of the service. This is because the regulations are clearer on the fundamental standards of quality and safety, which must not be breached, and they no longer require us to issue warning notices before moving to prosecution. CQC will now be the primary prosecution authority at a national level for health and social care.

Principles of enforcement

In considering or using our enforcement powers, we will have regard to our statutory objective of protecting and promoting the health, safety and welfare of people who use health and social care services and the following five principles. These five principles are in line with the regulator's code of practice.

- Equality, diversity and human rights
- Integration
- Proportionality
- Consistency
- Transparency

1. Equality, diversity and human rights

- We will take equality, diversity and human rights into account in our use of enforcement.
- We will have regard to the human rights of people using services in considering enforcement activity.
- We will keep enforcement activity under review to make sure no group is disproportionately or unfairly affected.

2. Integration

- Enforcement is a core part of CQC's regulatory approach. Our approach to enforcement is therefore central to our overall purpose and objectives as a regulator. This means, for example, we will not have separate approaches or a separate workforce for enforcement compared to our other functions. Instead, we will design our various functions so that they are supported by our enforcement role, and we will train and support all inspectors so that their engagement with a provider can cover all aspects of the regulatory relationship, including enforcement.
- Enforcement will particularly join up with our approach to rating providers on overall quality. This means in using our enforcement powers we will take a broader view than just reacting to individual events and concerns. Enforcement must relate to breaches of legislation, but our decision to use enforcement powers will also be influenced by whether a provider has ratings of 'requires improvement' or 'inadequate' and in particular whether there is a history of repeated ratings of 'inadequate'.
- Table 1 below sets out the relationship between the ratings and the regulations. Even though we will now be publishing ratings, the regulations will continue to be part of our approach. We will not hesitate to use them to take action against providers where appropriate where we find breaches of them.

Table 1

| Overall rating | Level of meeting the regulations | High level characteristics of each rating level |
|-----------------------------|---|---|
| Inadequate | Not meeting (with the exception of well-led, which is not completely covered by the regulations). | Significant harm has occurred or is likely to occur, shortfalls in practice, ineffective or no action taken to put things right or improve. |
| Requires improvement | Not meeting or meeting | May have elements of good practice, but inconsistent, potential or actual risk, inconsistent responses when things go wrong. |
| Good | Meeting + (i.e. may be more than the letter of the regulation) | Consistent level of service that people have a right to expect, robust arrangements in place for when things do go wrong. |
| Outstanding | Meeting ++ | Innovative, creative, constantly striving to improve, open and transparent. |

3. Proportionality

- We will take proportionate action. This means that our enforcement response is proportionate to the circumstances of the case. Where appropriate, if the provider is able to improve the service on their own and the risks to people who use services are not immediate, we will expect them to do so rather than intervening ourselves (for example, to restrict a service). We will intervene if people are at risk of harm or providers are ignoring the law.
- However, will not always start with the weakest of our powers and escalate from there. We will stop the previous use of an ‘enforcement escalator’, which placed too much emphasis on issuing successively stronger warnings rather than taking action.
- We will start with whatever level of intervention will achieve our purpose of protecting people who use the service, or holding providers and individuals to account, or both.

4. Consistency

- We will be consistent in applying our enforcement powers:
 - consistency does not mean that we will use the same enforcement option every time a particular legal requirement is not met. It does mean that we will

use the same criteria, triggers and approach when deciding how to respond to breaches of standards or legal requirements.

- we will train and support our staff so as to enable consistency.

5. Transparency

- We will be open and transparent about our approach to enforcement:
 - We will publish our enforcement guidance in plain English and in a variety of formats (on request), so that providers, the public and other oversight organisations can see clearly what we expect of providers and how we approach cases where they do not meet the requirements of the law.
 - We will publish information about our enforcement activity.
 - We will consult on any changes to our enforcement guidance.

2. Our enforcement powers and how we will use them

What we can enforce

Providers of any regulated activity in England must be registered with CQC. We take enforcement against unregistered providers.

We take enforcement against registered persons who breach:

- Conditions of registration.
- Relevant sections of the Act, the [Care Quality Commission \(Registration\) Regulations 2009](#), the [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2010](#), and other legislation that is relevant to achieving registration requirements.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 were updated in 2014 to set out fundamental standards of quality and safety. This was in line with the recommendations of the Francis Inquiry into Mid Staffordshire NHS Foundation Trust. The regulations were also amended to enable CQC to prosecute breaches of fundamental standards without first issuing a warning notice, where appropriate.

Where a breach of a regulation is a criminal offence, it is shown in bold in table 2.

Table 2

| Regulations | Additional notes |
|---|---|
| <p>Person-centred care Dignity and respect Need for consent* Safe care and treatment* Safeguarding service users from abuse* Meeting nutritional needs* Cleanliness, safety and suitability of premises and equipment* Receiving and acting on complaints Good governance Staffing Fit and proper persons employed Duty of candour* Fit and proper person requirement for directors (or equivalent)</p> <p>*These regulations have clauses that allow CQC to move directly to prosecution without first serving a warning notice – they relate specifically to harm or the risk of harm.</p> | <p>In addition, the regulation on good governance and receiving and acting on complaints have clauses that require information to be provided to CQC on request. Not providing the information could prevent CQC from identifying and responding to harm/risk of harm in a timely and appropriate manner. If these clauses are breached, CQC may move to prosecution.</p> |

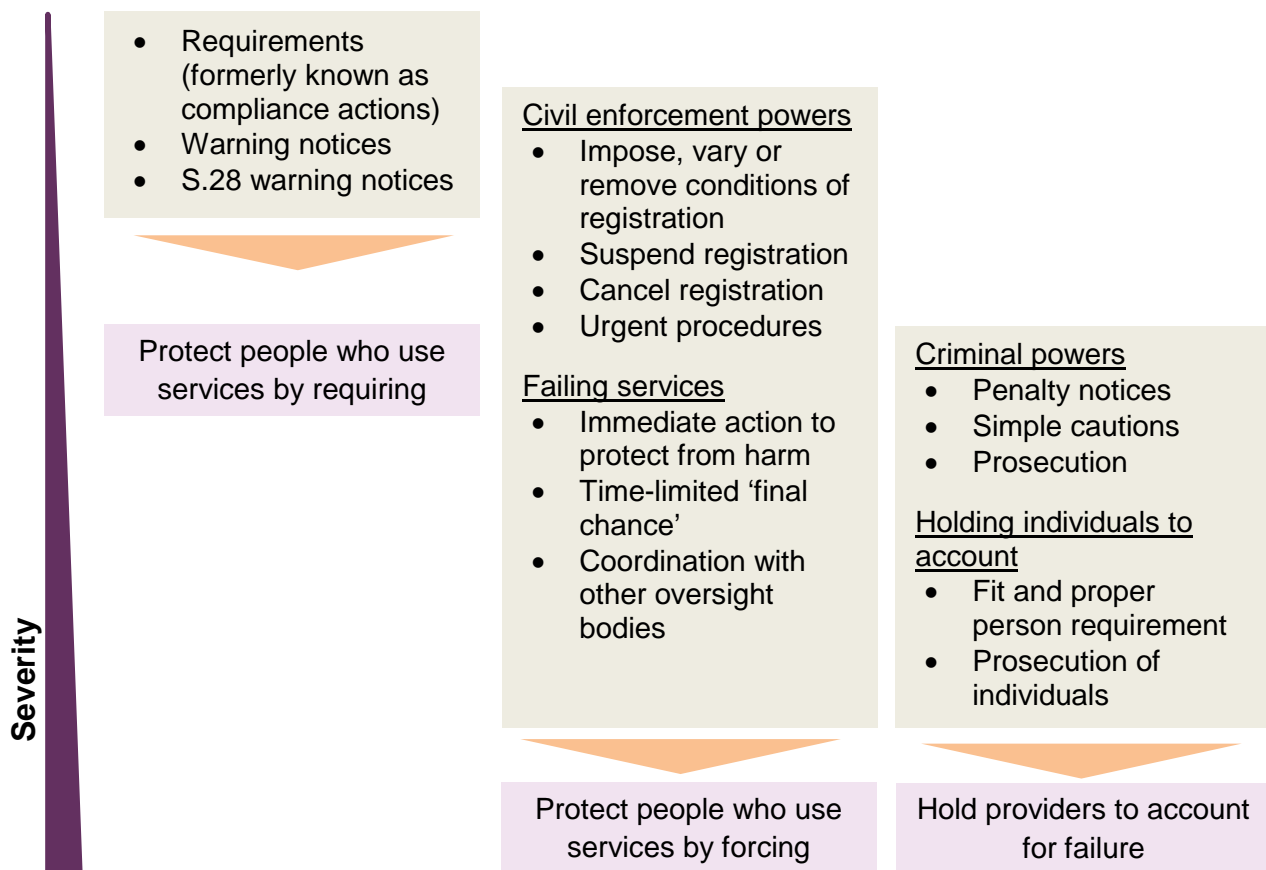
Where breaches of regulations cannot be prosecuted, we will still be able to enforce these through civil powers such as imposing conditions, suspending registration or cancelling registration. Failure to comply with those civil powers would itself be an offence that may result in prosecution.

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 other requirements which are offences, such as abuse or safe care and treatment, and could therefore result in a prosecution via that route.

Our enforcement powers and how they correspond to CQC's purpose of enforcement

Figure 1 sets out the range of enforcement powers we have and how they relate to the purposes of enforcement.

Figure 1: Our enforcement powers*



*S.28 relates to NHS special measures.

In addition to our statutory powers, we also work with other oversight organisations to ensure that they take action on concerns that we have identified, where that is more proportionate or likely to be more effective than CQC acting on its own.

These arrangements are a matter of policy rather than legal powers. Examples include the development of special measures with Monitor and the NHS Trust Development Authority, and the memorandums of understanding, information sharing agreements and operational protocols that CQC has with professional regulators.

How we select the appropriate enforcement power

We will use a four-stage process to make enforcement decisions. We set out below the principles underpinning each stage.

1. Identify non-compliance with a requirement of registration

We will normally carry out a direct check, such as an inspection, to identify concerns where enforcement may be warranted.

2. Apply a 'serious, multiple or persistent' test

We will be increasingly likely to take enforcement, and to use stronger powers, in proportion to how serious, multiple or persistent the identified concerns are.

- **Serious** – we will take progressively stronger action in proportion to the scale of the impact on individuals and, in the case of low impact concerns, also the number of people affected. Similarly, we will take stronger action if a service is carried on in an inappropriate way. For example, a service would be carried on in an inappropriate way if the service has effective mitigations (such as controls, safeguards, precautions or good practice standards) but they are not implemented, despite being reasonably practicable; or if there is disregard for legal requirements, attempts to avoid them or provision of false or misleading information.
- **Multiple** – repeated failures within a service (even if they are in different areas and of different types), the provider's general track record (of enforcement, inspection history and notifications) and the provider's track record of ratings (repeated ratings of 'requires improvement' or 'inadequate') will increase the likelihood and strength of enforcement.
- **Persistent** – repeated instances of a concern and failure to comply with previous requirements or enforcement will increase the likelihood of enforcement and cause us to consider taking stronger action, compared to a first-time failure.

3. Make recommendation for enforcement

Inspectors will set out a recommendation for enforcement, based on the 'serious, multiple or persistent' test. They will do this in the context of their local knowledge:

- The impact of enforcement on people's ability to access the services that they need.
- What we know from our regulatory relationship with the provider or individuals within it, about their capability, capacity and willingness to ensure that the service meets the required standards.
- What we know from previous enforcement experience (for example case law precedents).
- What we know about any activity with the provider by other regulators or commissioners.

To support transparent and consistent decisions on prosecution, we will publish clear prosecution criteria, as follows:

CQC's prosecution criteria

The regulations set a threshold of prosecution of the relevant regulations as:

- Services provided to individuals without proper consent, or
- Failure to provide reports on complaints or good governance, or
- Services which result in:
 - avoidable harm (whether of a physical or psychological nature) to a service user, or
 - a service user being exposed to a significant risk of such harm occurring, or
 - in a case of theft, misuse or misappropriation of money or property, any loss by a service user of the money or property concerned.

CQC also considers that one or more of the following should apply:

- The gravity of the incident, taken together with the seriousness of any actual or potential harm or the general record and approach of the provider, warrant prosecution
- There has been reckless disregard of the requirements on a registered person.
- There have been repeated or multiple breaches, which give rise to significant risk, or persistent and significant poor compliance.
- The service is carried on significantly below the standards that are required for compliance with regulations and is giving rise to significant risk.

In addition, CQC may prosecute where:

- There has been disregard for, and/or attempted avoidance of, the requirement for anyone who carries on regulated activities in England to be registered with CQC.
- There has been a failure to comply with a requirement, warning notice or condition, suspension or cancellation of registration; or there has been a repetition of a breach that was subject to a simple caution.
- False information has been supplied wilfully, information or explanations have been withheld, or there has been an intent to deceive, in relation to a matter which gives rise to significant risk.
- Persons authorised by CQC to enter and inspect have been intentionally obstructed in the lawful course of their duties.

These criteria align with the current policy of the Health and Safety Executive. On their own, they may lead to a higher number of potential prosecution cases than we can reasonably manage. We would particularly welcome views on how they should build on the 'serious, multiple or persistent' test so that we can add more detail and increase transparency about what should cause us to decide to hold providers to account rather than seek improvement. For example:

- How serious should the impact or potential impact on people be? (For example, death, or an accepted definition of serious harm or serious abuse.)
- How should we determine that a pattern of multiple concerns warrants criminal sanctions? (For example, a rating of 'inadequate', or concealment/falsification/failure to act on information about risk.)
- How many times should we seek improvement before deciding that a persistent concern should lead to prosecution?

4. Carry out a management review

Inspectors' recommendations for enforcement will be subject to management review before proceeding. The review will check that the recommendation is in line with the enforcement principles and high-level policy, and ensure that due process is always followed in line with CQC's scheme of delegation and with appropriate legal advice.

3. Requiring improvement to protect people from harm or the risk of harm

Enforcement approaches we will use to require a provider to improve

Requirements

Where a registered person is not achieving the requirements set out in a regulation, but people are not at immediate risk of harm, we will use our power to require a report from the provider. This must show how they will achieve compliance and the action they will take to do so. Failure to send us a report in the timescale we set out is an offence and can in itself lead to enforcement action.

We will tend to use this approach where:

- The provider is not complying with regulations, but the impact on people using the service is not immediately significant, and we expect improving the service to be within the provider's capability within a reasonable time frame, which we will set.
- The provider has no concerning history, in terms of poor performance.

Warning notices

Warning notices tell a registered person that they are not complying with a condition of registration, requirement in the Act or a regulation, or any other legal requirement that we think is relevant. We can serve notices about previous failures to comply with legal requirements or about a continuing breach of regulation(s). Where a notice is about a continuing breach of regulation(s), it will include a timescale by when compliance must be achieved. If a registered person is still not complying with the requirement when the timescale expires, we will consider further enforcement action. This could lead to further action under civil or criminal law. We cannot use warning notices against unregistered persons.

The regulations allow us to publish warning notices as long as registered persons are given the opportunity to make representations where we intend to publish.

The factual accuracy check on a draft report provides an opportunity for providers to challenge the content of the report. We will not publish a warning notice until the factual accuracy checking process is complete.

Warning notice where significant improvement is required in an NHS trust or NHS foundation trust

The Care Act 2014 has created an additional form of warning notice that is specifically for NHS trusts and foundation trusts. We will issue these where we judge that a trust requires significant improvement (not necessarily tied to breaches of regulations). When there are failures in the quality of care within NHS trusts, we work closely with Monitor and the NHS Trust Development Authority. This warning notice can lead to the provider entering the failure regime, which is described in the next section of this guidance on forcing improvement.

We will tend to use these powers where:

- We expect it to be within the provider's capability to improve the service to the required standard within an appropriate time frame, which we will set.
- The nature of the concern, or the potential for it to increase if left unchanged, means that the provider should expect that we will take further, stronger action if improvement is not secured within a set time frame.

4. Forcing improvement to protect people from harm or the risk of harm

Enforcement approaches we will use to force a provider to improve (civil powers)

Impose, vary or remove conditions of registration

Registered persons may have routine conditions attached to their registration. These conditions may include the locations where the regulated activity can be carried on or managed. Registration conditions are usually agreed with registered persons when they apply for registration.

Imposing, varying and removing conditions of registration is a flexible enforcement process that we can use in a variety of different ways to keep people safe and ensure that legal requirements are met. For example, we may use a condition to stop a regulated activity at one location, while the registered person can continue with this regulated activity at their other locations, and we can lift the restriction on the service by removing the condition once the concern has been addressed.

We may also impose conditions that require a registered person to take further action where they, people using their services, commissioners or the public might benefit from some specific improvement. For example, we may use conditions to set certain staffing levels or to ensure that they provide training for staff. We may only impose a condition that is consistent with our objectives under S.3 of the Health and Social Care Act 2008 and which meets the following criteria:

- It is appropriate and proportionate.
- It is relevant to the regulated activities and location at which the registered person provides them.
- It makes clear what the registered person must do, or stop doing, to comply with the condition.
- We can determine whether or not it has been met.
- We consider that the registered person ought to be able to meet the condition.
- The condition is reasonable in all respects.

Whenever possible we will agree the imposition of additional conditions or the variation or removal of existing conditions with the registered person in the first instance. If we cannot reach an agreement with the registered person, or we believe that the level of risk will or may increase, then we may rely on our urgent procedures to amend a registered person's conditions of registration.

Suspend registration

We can suspend the registration of a registered person for a specified period, and also extend a period of suspension, for example where there is a very serious concern but it can realistically be addressed within a fixed period. Suspension affects all of the locations where the registered person carries on or manages the relevant regulated activity. We will therefore give particular attention to the likely outcomes of taking this action. However, suspension can give a provider the chance to work towards achieving compliance and then resume carrying on or managing an activity.

Cancel registration

One of our most powerful sanctions is to cancel a registration. As with suspension, this will affect all the locations where the registered person carries on or manages the relevant regulated activity. Cancellation normally follows considerable efforts to get registered persons to comply with legal requirements, but where appropriate we will use the cancellation process without first having followed other processes.

We will tend to use these powers where:

People have suffered harm or are at risk of harm because a registered person is failing to comply with legal requirements, and in order to protect people we need the provider to cease that activity, and either:

- in our judgement, the registered person will potentially be able to comply with the regulations, any conditions of registration and requirements of the Act at an identifiable time in the future, or
- in the specific case of cancellation of registration, we no longer judge that the registered person has the capability or the capacity to comply with regulations.

Urgent procedures

We can also use the above powers of conditions, suspension and cancellation through urgent procedures, which have immediate effect (providers are able to appeal after our decisions to use urgent procedures).

We decide on our own, when it is appropriate, to impose conditions or suspend registration using urgent procedures, but to cancel a registration using urgent procedures we must apply to a justice of the peace for a court order. In these circumstances we will, wherever possible:

- Tell the registered person in advance about our application to cancel their registration using urgent procedures.
- Only make an application without telling and involving the registered person in exceptional circumstances, such as when their whereabouts are not known and after we have made considerable efforts to locate them.

Where we cannot give the registered person notice of our application to a justice of the peace, we will make a full and frank disclosure of all relevant evidence and confirm that we have done so in our application.

When serving an Order or Notice of Decision on a registered person using any of these urgent procedures, it will always include information about:

- Our memorandum of understanding with the First-tier Tribunal (Care Standards) about a 'fast track' option for appeals when we have used the urgent procedures.
- How the registered person can appeal against the urgent cancellation order or notice.

We will use urgent procedures in line with the thresholds set in the Act. This means that we believe:

- Unless there is an urgent use or amendment of conditions, or urgent suspension of registration, a person will or may be exposed to harm.
- Unless we apply to a justice of the peace for the urgent cancellation of registration, a person will be exposed to serious risk to their life, health or well-being.

Non-compliance with these powers

It is an offence not to comply with conditions of registration, or to continue to provide a regulated activity after registration has been suspended or cancelled. This is reflected in CQC's criteria for prosecution, and can apply to conditions, suspension or regulation for any reason. This means, for example, that in relation to those regulations for which a breach does not in itself amount to a criminal offence, a condition, suspension or cancellation of registration may be imposed. Failure to comply with that registration, suspension or cancellation could result in prosecution.

Responding to failure

While it is the responsibility of the provider to improve the quality of services they provide, there are other organisations that may be able to support failing providers where they are unable to demonstrate that they will improve on their own. One of our options is therefore to bring our serious concerns formally to the attention of other oversight bodies, such as regulators or commissioners. In some cases, these bodies will have powers of intervention and we will recommend that they use their powers where we judge that those will be more proportionate or more effective than the options open to CQC if we acted on our own. In other cases, we will notify these organisations, for example commissioners, that we have serious concerns and they will work with us to monitor improvement made by the provider. However, we will still normally issue a time-limited warning notice and re-inspect at the end of a set period, by when we expect improvements to be made. We will consider further options if improvement has not been made.

A key principle is that in failing services where the purpose of our action is to force improvement then, other than in cases of urgent concern, providers should be given time to improve. Our expectations for this improvement should always be made with clear time limits, after which the provider will have exhausted the possibility of avoiding significant enforcement.

Our high-level approach to failing services will apply in different ways to different types of services. We will set out further detail in our provider handbooks and, where they involve working with other oversight bodies, we will issue joint guidance. An example of this is guidance we have issued with Monitor and the NHS Trust Development Authority for NHS trusts and foundation trusts.

5. Holding providers and individuals to account

Enforcement powers we will use to hold a provider to account (criminal powers)

Penalty notices

Paying a fixed penalty enables a registered person to dispose of liability for an offence, where we might otherwise have prosecuted them. It is at CQC's discretion to decide when to serve a fixed penalty notice and enable this. If a registered person decides not to pay the penalty we can consider using our other enforcement powers; we will normally proceed to prosecution.

Any fixed penalty paid to CQC is not retained but must be repaid by CQC to the Secretary of State.

The relevant legal requirements and associated fines are set out in appendix A.

We will tend to use this power when:

- We have evidence of an offence and that evidence is sufficient that we would be able to bring a criminal prosecution, and
- Although we could prosecute, we consider that swiftly achieving compliance without beginning lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution, and
- The offence has a minor impact on people using the service.

Simple cautions

A simple caution ensures that there is a formal record of an offence when a person has admitted to it, but is not prosecuted.

We will tend to take this approach when:

- We have evidence of an offence and that evidence is sufficient that we would be able to bring a criminal prosecution, and
- Although we could prosecute, we consider that swiftly achieving compliance without beginning lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution, and
- The code for crown prosecutors indicates that this option would be appropriate, and
- The offence has a minor impact on people using the service.

Prosecution

Prosecution can be used to hold any registered person to account for breaches of prosecutable fundamental standards, or for failing to comply with conditions of registration. In the case of a service that is operating without registration, we may prosecute the person who appears to be carrying it on. Prosecution can also be used against any person who obstructs us in the course of an inspection and against persons who have applied to us to be registered, but have made a false or misleading statement.

It will often be appropriate to prosecute at the same time as taking other enforcement action, for example cancellation of a registration. We may also prosecute more than one offence at the same time.

Exceptionally, where we believe it is proportionate, we will serve a warning notice first before we prosecute. For example, if there is doubt over whether the provider could reasonably have been able to avoid non-compliance, we might allow a final chance. However, CQC will generally prosecute providers for serious, multiple or persistent breaches of the fundamental standards (those regulations with prosecutable clauses that specifically relate to harm or the risk of harm) without issuing a warning notice first.

Although we are not required by law to publish details of all criminal law procedures that we undertake, we have a general power to publish this type of information and will normally do so. We must publish information about any offence for which a registered person has been convicted.

All investigations of criminal offences will be carried out with regard to the Police and Criminal Evidence Act 1984 principles and Code of Practice.

Where another regulator has the power to prosecute, we will coordinate activity with them at an early stage to ensure the right action is taken, to avoid inconsistency, and to ensure that any proceedings taken are for the most appropriate offence.

Where we successfully prosecute, the court will decide on the fine that is imposed, and may issue a separate fine in relation to each conviction, where there is more than one. The court may impose a prison sentence as well as, or instead of, a fine following conviction for carrying on a regulated activity without being registered.

The offences and maximum court fines are set out in appendix A.

We will tend to use this power where:

- The concern is serious, multiple or persistent and one or more of the criteria set out on page 136 are met, and:
 - To do so is in the public interest.
 - Our evidence meets the standard for a criminal prosecution.
 - The code for crown prosecutors has been followed.
 - There is a realistic prospect of conviction.

Holding individuals to account

CQC's enforcement activity mostly concerns providers and their liability as the body carrying on regulated activities. However, CQC can use its enforcement powers to hold certain individuals within providers to account. Those individuals are any director, manager or secretary of a body corporate (or a person purporting to act in that capacity), or an officer of an unincorporated association or member of its governing body.

We will tend to hold individuals to account where:

- An offence has been committed with their consent or connivance, or is attributable to neglect on their part.
- There is clarity about the individual's accountability as opposed to the service provider.

We may also hold individuals to account by ensuring that they cannot be employed in a role that we determine they are not fit for. We can do this by cancelling the registration of a registered manager, or by intervening where we consider an individual is not a fit and proper person by refusing a new registration or, for an existing provider, placing a condition on the provider to remove the director. For example, if there is evidence that they have been associated with serious misconduct or responsibility for failure in a previous role. Providers have a general duty only to employ individuals who are fit for their role. The regulations also establish a fit and proper person requirement for directors, and the chair or equivalent of an organisation must carry out that test and confirm the fitness of that individual director in writing to CQC.

6. Representations and appeals

Representations

Registered persons have the right to make representations to us about certain types of enforcement action. We have produced separate detailed guidance, which is available on our website, about representations on the following:

- Warning notices.
- A notice of proposal to impose, vary or remove conditions of registration.
- A notice of proposal to suspend a registration, or to extend the period of a suspension of registration.
- A notice of proposal to cancel a registration.

Appeals

Registered persons have the right to appeal to the First-tier Tribunal against enforcement action using the civil enforcement procedures. (This includes action under urgent procedures, but in those cases the tribunal will ensure any appeal is fast tracked.) We have produced separate detailed guidance about this. Appeals must be lodged within 28 days of the service of:

- A notice of decision.
- A notice of imposed, varied or removed conditions using the urgent procedures.
- A court order to cancel a registration using urgent procedures.

There is no right of appeal to the tribunal in relation to warning notices, penalty notices or conviction for offences.

CQC also offers providers the opportunity to request a review of their ratings. That review is not a statutory right of appeal, but reflects CQC's policy of openness and transparency. It is separate to the procedures for representations and appeals on enforcement and registration decisions.

7. Publication and notification of enforcement action

Publication and notification when we commence enforcement

The regulations require and authorise us to publish certain information relating to enforcement action.

We are required by law to publish certain details of civil enforcement. We are also required by law to publish details of any action taken under CQC's urgent powers.

Information about the enforcement action that we take will be included in our inspection reports. We will also publish a summary of information about the enforcement action taken against each provider on our website, and information about our enforcement activity overall.

We send copies of notices relating to enforcement action to a number of third parties, such as commissioners and other regulators. Generally, these notifications are required in the Care Quality Commission (Registration) Regulations 2009, but we will also inform any other persons that we consider appropriate.

Appendix A: Offences and fines

The Legal Aid, Sentencing and Punishment of Offenders Act 2012 may make changes to the maximum penalties outlined in the table below. This removes the maximum limit on fines that can be imposed on summary conviction. The proposal in the Department of Health's fundamental standards consultation has outlined the proposed changes and the figures in the table below are therefore based on current arrangements. Further information can be found at:

www.gov.uk/government/consultations/fundamental-standards-for-health-and-social-care-providers

Fixed penalties

CQC issues fixed penalties where the provider admits fault, but avoids the greater cost of going to court. When we serve a Fixed Penalty Notice, it is an offer to the provider to discharge their liability for an offence by paying a fine. They do not have to accept that offer, and if they object they should simply refuse it. For serious failings, we reserve the right to prosecute where appropriate.

| Offence | Maximum fine | |
|---|--------------|--------|
| Failure to comply with regulations about quality and safety (see Regulation 27 of the regulated activities regulations) | Provider | £4,000 |
| | Manager | £2,000 |
| Carrying on a regulated activity without being registered | | £4,000 |
| Failure to comply with conditions of registration | Provider | £4,000 |
| | Manager | £2,000 |
| Carrying on a regulated activity while registration is suspended | | £4,000 |
| Managing a regulated activity while registration is cancelled or suspended | | £2,000 |
| Failure to provide an updated statement of purpose (see Regulation 12 of the registration regulations) | Provider | £1,250 |
| | Manager | £625 |
| Failure to make required notifications (see Regulations 14-18 of the registration regulations) | Provider | £1,250 |
| | Manager | £625 |

| | | |
|--|---------------------|----------------|
| Failure to provide a statement about fees chargeable (see Regulation 19 of the registration regulations) | Provider Manager | £1,250 £625 |
| Failure to observe certain requirements relating to termination of pregnancy (see Regulation 20 of the registration regulations) | Provider Manager | £1,250 £625 |
| Obstructing entry and inspection | | £300 |
| Failure to provide documents or information | | £300 |
| Failure to provide an explanation of any relevant matter | | £300 |

Offences and fines: Prosecution

| Offence | Fine |
|---|----------|
| Failure to comply with regulations about quality and safety (see Regulation 27 of the regulated activities regulations) | £50,000* |
| Carrying on an activity without being registered | £50,000 |
| Failure to comply with conditions of registration | £50,000 |
| Offences relating to suspension or cancellation | £50,000 |
| False descriptions of concerns | £5,000 |
| False statements in applications | £2,500 |
| Obstructing entry and inspection | £2,500 |
| Failure to provide documents or information | £2,500 |
| Failure to provide an explanation of any related matter | £2,500 |

* Some lesser requirements have a maximum court fine of £2,500

Consultation questions: Enforcement guidance

8. Do you agree with our approach to using our enforcement powers?
9. How should we reflect the 'serious, multiple or persistent' test in our prosecution criteria?
10. Do you agree with our proposed approach when responding to failure, that it is time-limited but we also work with any partner agencies who may be better placed to secure improvement before we escalate use of our enforcement powers?