Annex 2 to Schedule 1

CQC Guidance for Providers on Meeting the Regulations

Care Quality Commission

Guidance for providers on meeting the regulations

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) (as amended)

Care Quality Commission (Registration) Regulations 2009 (Part 4) (as amended)

March 2015

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

Our purpose

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

Our role

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

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Introduction

This document sets out our guidance for providers on meeting two groups of regulations:

- **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)**
- **Care Quality Commission (Registration) Regulations 2009 (Part 4)**

It applies from 1 April 2015, and will replace in its entirety CQC's *Guidance about Compliance: Essential standards of quality and safety* and its 28 outcomes.

Section 23 of the Health and Social Care Act 2008 (HSCA 2008) says that CQC must produce guidance to help providers to comply with the regulations made under this Act. We therefore developed this guidance with the help of people who use services, organisations that represent them, health and adult social care providers, other regulators and professional bodies.

The regulations set out in this guidance apply to all registered persons (providers and managers) registered with the Care quality Commission (CQC) that carry on regulated activities. There are many different types of services that are governed by the regulations. Annex D shows a full list of service types.

The guidance does not attempt to describe in detail how the regulations apply to each type of service registered with CQC, but we will be proportionate in how we apply the regulations to different types of services. We will consider the size and type of services and the relevance of the regulation to the regulated activity provided. For example, when inspecting providers of personal care to people in their own home we would not assess Regulation 15: Premises and equipment, or when inspecting dentists we would not assess Regulation 14: Meeting nutrition and hydration needs, as they would not apply to these types of regulated activity.

How to use this guidance

Regulation 21 of the HSCA 2008 (Regulated Activity) Regulations 2014 (as amended) says that registered persons "**must have regard**" to this guidance.

If you are a prospective provider or manager applying for registration, this means you must demonstrate that you will be able to meet the requirements set out in these regulations and, once registered, that you will continue to meet them.

Section 25(1) of the HSCA 2008 says that CQC must take this guidance into account when we make our regulatory decisions. We will therefore use this guidance when deciding whether a provider or manager meets the requirements of the regulations when we consider an application for registration. If a prospective provider is not able to demonstrate that they will meet the requirements of the regulations from their first day of business, we may refuse the application.

If you are already registered with CQC as a provider or manager, it is important that you read and consider this guidance in relation to the regulated activities you provide, as it will help you to understand what you need to do to meet the regulations.

You are responsible for meeting the regulations and deciding how to do this. It is not CQC's role to tell providers or managers what they must do to deliver their services. When registered providers and managers do not follow this guidance, we will ask them to provide evidence that their approach enables them to meet the requirements of the regulations.

For each regulation in this guidance, we provide:

1. **A copy of the actual text of the regulation.** It is important to use the text of each regulation as the first source of information about how to meet its requirement. We only provide further guidance on how to meet the individual components of each regulation where we think it needs further clarification and definition. Where we think that the text of the regulation itself is self-explanatory, we do not give any further guidance. There have been a number of amendments to the original regulations on which this guidance is based, but we have used the amended regulations in this guidance.

2. **A summary of the intention of the regulation.**

3. **Guidance on the requirements of specific components of the regulation.** The guidance on specific components of each regulation should not be considered exhaustive as there may be other ways that providers can show that they meet each component of the regulation.

There are also a number of annexes to the guidance:

Annex A: Web links to legislation. The legislation is relevant for all registered providers and managers whatever regulated activity they provide.

Annex B: Web links to guidance. Links to guidance include guidance specific to the different types of activities and services provided and recognised quality standards. We expect registered providers and managers to take account of other nationally recognised guidance that might be specific to the services they deliver. This includes guidance produced by the Department of Health, National Institute for Health and Care Excellence, Public Health England, the former National Patient Safety Agency, NHS England, Skills for Health, Skills for Care and relevant clinical and professional bodies. Annex B also includes guidance from other national organisations that publish guidelines or are recognised by health and social care professionals as producers of high-quality guidance.

The legislation and related guidance in the annexes are listed alphabetically and say which regulation they apply to. The online version enables you to search by specific regulation, sector type (NHS trusts, primary medical services, mental health services and adult social care) and by specific themes.

Annex C: Glossary of terms used in the guidance.

Annex D: List of service types. This sets out the many different types of services that are governed by the regulations and to which the provider guidance applies. Some providers' activities will cover more than one service type.

Annex E: Quick reference chart of offences. This shows which regulations CQC can prosecute against.

The regulations covered by this guidance

This guidance covers two groups of regulations:

1. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)[1]

These regulations introduce the new **fundamental standards**, which describe requirements that reflect the recommendations made by Sir Robert Francis following his inquiry into care at Mid Staffordshire NHS Foundation Trust. They will enable us to pinpoint more clearly the fundamental standards below which the provision of regulated activities and the care provided to people must not fall, and to take appropriate enforcement action where we find it does.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended) has six parts.[2] All of these are relevant to CQC's role, and have informed the development of this guidance. However, we are providing guidance only for Part 3, which contains the Requirements in relation to Regulated Activities.

Part 3 has two sections: Section 1 describes the **requirements relating to persons carrying on or managing a regulated activity.** Section 2 introduces the **fundamental standards** below which the provision of regulated activities and the care people receive must never fall. They come into force for all health and adult social care services on 1 April 2015.

Section 1: Requirements relating to persons carrying on or managing a regulated activity

This contains the following regulations for which this document provides guidance:

Regulation 4: Requirements where the service provider is an individual or partnership

Regulation 5: Fit and proper persons: directors

Regulation 6: Requirement where the service provider is a body other than a partnership

Regulation 7: Requirements relating to registered managers

The requirements in Section 1 introduce a new regulation about fit and proper person requirements for directors (Regulation 5). This regulation has been introduced to ensure that directors are fit to hold their position. Directors must meet certain criteria, including that they are "of good character"; have the qualifications, competence, skills and experience necessary for the relevant position; and are capable of undertaking the relevant position after any reasonable adjustments have been made. They must also not have been responsible for any serious misconduct or mismanagement in the course of carrying on a regulated activity.

1. As amended by a) Health and Social Care Act 2008 (Regulated Activities (Amendment) Regulations 2015 and b) The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012.

2. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended) includes the following parts: Part 1: General; Part 2: Regulated Activities; Part 3: Requirements in relation to Regulated Activities (includes Regulations 4 to 20A, as described in this guidance); Part 4: Compliance and Offences; Part 5: Penalty Notices; Part 6: Miscellaneous.

Section 2: Fundamental standards

This contains the following regulations for which this document provides guidance:

Regulation 8: General

Regulation 9: Person-centred care

Regulation 10: Dignity and respect

Regulation 11: Need for consent

Regulation 12: Safe care and treatment

Regulation 13: Safeguarding service users from abuse and improper treatment

Regulation 14: Meeting nutritional and hydration needs

Regulation 15: Premises and equipment

Regulation 16: Receiving and acting on complaints

Regulation 17: Good governance

Regulation 18: Staffing

Regulation 19: Fit and proper persons employed

Regulation 20: Duty of candour

Regulation 20A: Requirement as to display of performance assessments.

The requirements in Section 2 (fundamental standards) introduce two new regulations. The first introduces a statutory duty of candour (Regulation 20)[3] and the second introduces a requirement for providers to display their CQC rating (Regulation 20A).[4]

The aim of Regulation 20, statutory duty of candour, requires registered persons to be open and honest with the people who use their service when something goes wrong with their care or treatment. When a specified safety incident has occurred in respect of care provided, the regulation sets out a clear set of legal duties on registered providers about how and when to notify people using their service (or their relevant representatives) about those safety incidents. The regulation also describes when notifications about safety incidents need to be made to CQC.

The aim of Regulation 20A, the requirement to display performance assessments, is to require providers who have received a CQC rating to display it conspicuously at their premises and on their website.

Further information about Regulations 5, 20 and 20A will be published in March 2015 for all registered providers.

3. Regulations 5 and 20 were introduced for NHS health service bodies in November 2014, ahead of the remaining regulations coming into force in April 2015. From April 2015, Regulations 5 and 20 will also apply to all registered providers.

4. The Health and Social care Act 2008 (Regulated Activities) (Amendment) Regulations 2015.

2. Care Quality Commission (Registration) Regulations 2009 (Part 4)[5]

The Care Quality Commission (Registration) Regulations 2009 have six parts.[6] We are providing guidance only for Part 4, setting out requirements that providers must have regard to in relation to their registration, including their financial position, fees, statement of purpose, the circumstances when they need to make notifications to CQC and requirements in relation to termination of pregnancies. They are set out in the following regulations:

Regulation 11: General

Regulation 12: Statement of purpose

Regulation 13: Financial position

Regulation 14: Notice of absence

Regulation 15: Notice of changes

Regulation 16: Notification of death of service user

Regulation 17: Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

Regulation 18: Notification of other incidents

Regulation 19: Fees

Regulation 20: Requirements relating to termination of pregnancies

Regulation 22A: Form of notifications to the Commission (although this is in Part 5, it relates to regulations in Part 4).

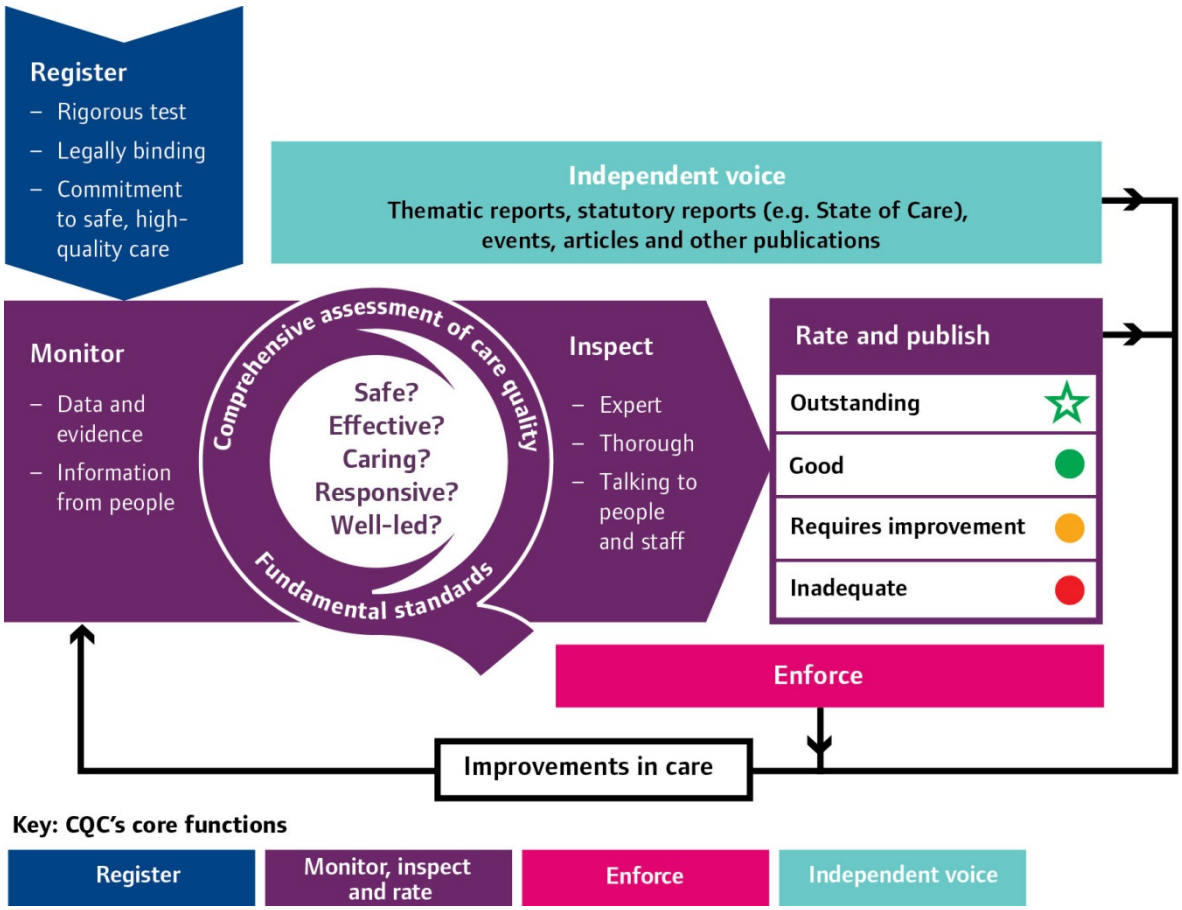
5. As amended by a) The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012.

6. The full CQC (Registration) Regulations (2009) include the following parts: Part 1: General; Part 2: Registration; Part 3: Publication of information and explanations; Part 4: Registration Requirements (includes Regulations 12 to 20 and 22A as described in this guidance); Part 5: Other miscellaneous requirements; Part 6: Compliance, guidance and offences.

How the guidance fits with CQC's operating model

The regulations and this guidance are an essential component of CQC's new approach, as set out in our strategy *Raising Standards, Putting people first*. The diagram of our operating model summarises how we register, monitor, inspect and award ratings to providers, take enforcement action and provide an independent voice on the quality of care.

CQC's overall operating model



Key: CQC's core functions

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

- When we make regulatory decisions about a registered provider or manager's registration. That is, granting a registration, refusing an application for registration, cancelling or suspending a registration, or varying, removing or imposing conditions on a registration.
- In our regulatory decisions when a registered provider or manager may have breached regulations, conditions of registration and in decisions relating to criminal offences.
- In any proceedings for the urgent cancellation of a registration, or for appeals relating to an urgent cancellation.
- In any proceedings for a failure to comply with conditions of registration or for breaches of regulations.

Our guidance on meeting the regulations is therefore central to:

1. Registration

We have strengthened CQC's registration process – particularly for how we assess applications for registration. To be registered with CQC, applicants must demonstrate that they will be able to meet the requirements set out in the regulations. When considering new applications for registration, and variation or cancellation of existing registrations, we now also take account of the duty of candour and the fit and proper person requirement for directors. To help us do this, we draw on the detail included in this guidance.

2. Inspection and ratings

To get to the heart of people's experiences of care and support, the focus of our inspections is on the quality and safety of services, based on the things that matter to people. We therefore ask five key questions about the service, are they:

- Safe?
- Effective?
- Caring?
- Responsive to people's needs?
- Well-led?

To help our inspection teams direct the focus of their inspections, they use a standard set of 'key lines of enquiry' (KLOEs) and prompts. KLOEs help them to form a judgement about the quality of the service, determine a rating for each of the five key questions, and where relevant, produce an overall rating for the service. Ratings are an important part of our inspection process and use a four-point scale: outstanding, good, requires improvement, or inadequate.

Our provider handbooks describe how we carry out inspections, make judgements and, where appropriate, award ratings to providers. They list the KLOEs, which also provide additional information that may help providers to meet the requirements of these regulations. The KLOEs and prompts are specific to each sector and focus on the detail relevant to the sector.

For each of the five key questions we have developed characteristics to describe what care for each of those four rating levels looks like. These characteristics provide a framework, which, together with professional judgement, guide our inspection teams when they make a judgement about a rating.

Our use of ratings and the focus on looking for 'good' are an important part of our model for assessing the overall quality of the care people received. The characteristics of good and outstanding care that we look for in our inspections, as set out in our handbooks, go beyond the fundamental standards as set out in the regulations.

However, our inspections also assess whether the requirements set out in the regulations are met.

3. Enforcement

The regulations set in law a clear minimum standard that registered providers and managers must meet. CQC will be able to take enforcement action against registered providers and managers that do not meet them (the law calls this a breach of regulation(s)).

Enforcement and offences

We have a wide set of powers that allow us to protect the public and hold registered providers and managers to account.

Alongside this guidance about the new regulations, we have a new enforcement policy that explains our approach to taking action where we identify poor care, or where registered providers and managers do not meet the standards required in the regulations. We use our enforcement policy to:

- Protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard.
- Hold registered providers and managers to account for failures in how the service is provided.

Our enforcement policy sets out in full the approach that we take to address breaches of regulations. It also reflects how we may work with other organisations to make sure that people are protected from harm, for example, through special measures regimes.

Offences

Some of the regulations have offences attached, and as part of our enforcement action, CQC will be able to bring prosecutions if these regulations are breached. For regulations that we cannot prosecute against, we can consider using other actions as set out in our enforcement policy.

CQC may prosecute breaches of the following regulations without first issuing a Warning Notice.

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

A breach of the following offences may be prosecuted directly:	
Regulation 11	Need for consent: care and treatment may only be provided with consent.
Regulation 16(3)	Receiving and acting on complaints: a summary of complaints, responses, correspondence and other relevant information identified must be provided to CQC within 28 days of a request.
Regulation 17(3)	Good governance: a report into how the registered person is complying with the good governance requirements and their plans for improvement of services delivered must be provided to CQC within 28 days of a request.
Regulation 20 (2)(a)	Duty of candour: registered persons must as soon as reasonably practicable notify a service user (or person lawfully acting on their behalf) when an unintended or unexpected incident occurs. Notifiable safety incidents are explained further in Regulation 20(8) and 20(9).
Regulation 20(3)	Duty of candour: notifications given under Regulation 20(2)(a) must meet specific requirements.

Regulation 20A	Requirement as to display of performance assessments: providers must display on their website details of CQC's website, the most recent CQC rating and the date it was given. They must also display the most recent rating at each location where regulated activities are provided from and at the provider's principal place of business. Signs must be legible, conspicuously displayed and show the date the rating was given.

A defence to all the above offences is available where the registered persons took all reasonable steps and acted with all due diligence. See Regulation 22(4).

To be able to prosecute for the following offences, they need a further qualification, which is that the breach results in people who use services being exposed to avoidable harm or significant risk of such harm occurring or suffering a loss of money or property as a result of theft, misuse or misappropriation	
Regulation 12	Safe care and treatment: care and treatment must be provided safely.
Regulation 13	Safeguarding service users from abuse and improper treatment: sections 13(1) to 13(4).
Regulation 14	Meeting nutritional and hydration needs: service users' nutritional and hydration needs must be met. This applies where accommodation or an overnight stay on the premises is provided or where meeting a person's nutritional or hydration needs is part of the care and treatment arrangements.

Care Quality Commission (Registration) Regulations 2009

A breach of the following offences may be prosecuted directly:	
Regulation 12	Statement of purpose.
Regulation 14	Notice of absence.
Regulation 15	Notice of changes.
Regulation 16	Notification of death of service user.
Regulation 17	Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983.
Regulation 18	Notification of other incidents.
Regulation 19	Fees etc.
Regulation 20	Requirements relating to termination of pregnancies.
In relation to these offences, there is no requirement for anyone to have been exposed to harm or placed at risk of harm as there is in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A breach of the regulation is an offence without this further qualification.	

For the remaining regulations included in this guidance: (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulations 9; 10; 13(5); 13(6); 13(7); 15; 16(1); 16(2); 17(1); 17(2); 18; 19; 20(1), 20(2)(b); 20(4); 20(5); 20(6); 20(7) and Care Quality Commission (Registration) Regulations 2009, Regulations 13 and 22a), CQC can take other regulatory action.

If the evidence surrounding one of these regulations also demonstrates a breach of another regulation that is identified as an offence, then CQC may also decide to prosecute against the regulation for that other offence.

Annex E to this guidance shows all the above information in a quick reference chart.

Care Quality Commission

Guidance for providers on meeting:

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)

To see the full text of the regulations, click on the following links:

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
http://www.legislation.gov.uk/uksi/2014/2936/contents/made

Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
http://www.legislation.gov.uk/uksi/2015/64/regulation/14/made

Terminology

The regulations refer to 'the service user' or 'relevant person' Where we quote a regulation directly, we use the term 'service user', but elsewhere in the guidance, we use the phrase 'people who use services' or 'people', as our engagement work has shown that this is the term people prefer.

The regulations lay down fundamental standards to be met by registered persons, that is, registered providers and registered managers. This guidance is called *Guidance for providers* and we use that terminology throughout, but it applies equally to registered managers.

Regulation 4: Requirements where the service provider is an individual or partnership

4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.

(2) P must not carry on a regulated activity unless P is fit to do so.

(3) P is not fit to carry on a regulated activity unless P is—

(a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in—

(i) paragraph (4), and

(ii) paragraph (5), or

(b) a partnership and—

(i) each of the partners satisfies the requirements set out in paragraph (4), and

(ii) P satisfies the requirement set out in paragraph (6).

(4) The requirements referred to in paragraph (3)(a)(i) and (b)(i) are that, if P is an individual, that individual or, if P is a partnership, each of the partners—

(a) is of good character,

(b) is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are—

(i) where P is an individual, intrinsic to the carrying on of the regulated activity, or

(ii) where P is a partnership, intrinsic to their role in the carrying on of the regulated activity, and

(c) is able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

(5) The requirement referred to in paragraph (3)(a)(ii) is that P has the necessary qualifications, competence, skills and experience to carry on the regulated activity.

(6) The requirement referred to in paragraph (3)(b)(ii) is that, through the combination of the qualifications, competence, skills and experience of the partners, P has the necessary qualifications, competence, skills and experience to carry on the regulated activity.

(7) In assessing an individual's character for the purposes of paragraph (4)(a), the matters considered must include those listed in Part 2 Schedule 4.

Summary of the regulation

The intention of this regulation is to ensure that people who use services have their needs met because the service is provided by an appropriate person.

To meet the requirements of this regulation, providers must register with CQC under Section 10 of the Health and Social Care Act 2008. The registered provider or partners of the registered provider must:

- Be of good character.
- Be able to properly perform tasks that are intrinsic to their role.
- Have the necessary qualifications, competence, skills and experience to carry on the regulated activity or supervise its management.
- Be able to supply CQC with documents that confirm their suitability (see the information and documents identified in Schedule 3 of the regulations).

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
4(1) This regulation applies where a service provider (P) is an individual or a partnership.	
4(4) The requirements referred to in paragraph (3)(a)(i) and (b)(i) are that, if P is an individual, that individual or, if P is a partnership, each of the partners—	
4(4)(a) be of good character;	• When assessing whether an individual or partner is of good character, providers must follow robust processes to make sure that they gather all available information to confirm that the individual or partner is of good character, and must have regard to the matters outlined in Schedule 4, Part 2 of the regulations. It is not possible to outline every character trait an individual should have, but we would expect to see that the processes followed take account of honesty, trustworthiness, reliability and respectfulness. • If a provider discovers information that suggests an individual or partner is not of good character after they have been appointed to a role, they must take appropriate and timely action to investigate and rectify the matter. • Where a provider considers the individual or partner to be suitable despite the existence of information relevant to issues identified in Schedule 4 Part 2, the provider's reasons should be recorded for future reference.

4(4)(b) is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are— (i) where P is an individual, intrinsic to the carrying on of the regulated activity, or (ii) where P is a partnership, intrinsic to their role in the carrying on of the regulated activity.	• This aspect of the regulation relates to the ability of individuals to carry out their role. This does not mean that people who have a long-term condition, a disability or mental illness cannot be appointed. When appointing relevant individuals the provider must have processes for considering a person's physical and mental health in line with the requirements of the role. • All reasonable steps must be made to make adjustments for individuals to enable them to carry out their role. These must be in line with requirements to make reasonable adjustments for employees under the Equality Act 2010.
4(5) The requirement referred to in paragraph (3)(a)(ii) is that P has the necessary qualifications, competence, skills and experience to carry on the regulated activity.	• Individuals must be appropriately skilled with the necessary qualifications, competence, knowledge and experience. They must be able to demonstrate the competency required to carry on the regulated activity and to manage it where there is no registered manager. • Individuals must have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), relevant best practice and guidance, and understand the consequences of failing to take action on set requirements. • The provider must have appropriate processes for assessing and checking that the individual holds the required qualifications and has the competence, skills and experience required to undertake the role. These processes must be followed in all cases and relevant records kept.
4(6) The requirement referred to in paragraph (3)(b)(ii) is that, through the combination of the qualification, competence, skills and experience of the partners, P has the necessary qualifications, competence, skills and experience to carry on the regulated activity.	• Providers must ensure that the qualifications, competence, skills and experience of all the partners, taken together, will ensure that they are able to carry on the regulated activity in a satisfactory manner. • The partnership should demonstrate that, together, they have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) and understand the consequences of failing to take action on set requirements. • The provider must have appropriate processes for assessing and checking that between them, the partners have the required qualifications and the competence, skills and experience to undertake the role. These processes must be followed in all cases and relevant records kept.

Regulation 5: Fit and proper persons: directors

5.—(1) This regulation applies where a service provider is a body other than a partnership.

(2) Unless the individual satisfies all the requirements set out in paragraph (3), a 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 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

The intention of this regulation is to ensure that people who have director level responsibility for the quality and safety of care, and for meeting the fundamental standards are fit and proper to carry out this important role.

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

Component of the regulation	Providers must have regard to the following guidance
5(1) This regulation applies where a service provider is a body other than a partnership.	• This regulation applies to all providers that are not individuals or partnerships.
5(2) Unless the individual satisfies all the requirements set out in paragraph (3), a 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 a director.	• For NHS bodies it applies to executive and non-executive, permanent, interim and associate positions, irrespective of their voting rights. The requirement will also apply to equivalent director posts in other providers, including trustees of charitable bodies and members of the governing bodies of unincorporated associations. • Where a local authority is a provider, the regulations will not apply to elected members as they are accountable through a different route.
5(3)(a) the individual is of good character,	• When assessing whether a person is of good character, providers must follow robust processes to make sure that they gather all available information to confirm that the person is of good character, and they must have regard to the matters outlined in Schedule 4, Part 2 of the regulations. It is not possible to outline every character trait that a person should have, but we would expect to see that the processes followed take account of a person's honesty, trustworthiness, reliability and respectfulness. • If a provider discovers information that suggests a person 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 considers the individual to be suitable, despite existence of information relevant to issues identified in Schedule 4, Part 2, the provider's reasons should be recorded for future reference and made available.
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,	• Where providers consider that a role requires specific qualifications, they must make this clear and should only appoint those candidates who meet the required specification, including any requirements to be registered with a professional regulator. • Providers must have appropriate processes for assessing and checking that the candidate holds the required qualifications and has the competence, skills and experience required, (which may include appropriate communication and leadership skills and a caring and compassionate nature) to undertake the role. These must be followed in all cases and relevant records kept. • We expect all providers to be aware of, and follow, the various guidelines that cover value-based recruitment, appraisal and development, and disciplinary action, including dismissal for chief executives, chairs and directors, and to have implemented procedures in line with the best practice. This includes the seven principles of public life (Nolan principles).
5(3)(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,	• This aspect of the regulation relates to a person's ability to carry out their role. This does not mean that people who have a long-term condition, a disability or mental illness cannot be appointed. When appointing a person to a role, providers must have processes for considering their physical and mental health in line with the requirements of the role. • All reasonable steps must be made to make adjustments for people to enable them to carry out their role. These must be in line with requirements to make reasonable adjustments for employees under the Equality Act 2010.

5(3)(d) the individual has not been responsible for, been privy to, contributed to or facilitated, any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and	• Providers must have processes in place to assure themselves that a person has not been responsible for, privy to, contributed to, or facilitated any serious misconduct or mismanagement in the carrying on of a regulated activity. This includes investigating any allegation of such and making independent enquiries. • Providers must not appoint any person who has been responsible for, privy to, contributed to, or facilitated any serious misconduct or mismanagement (whether lawful or not) in the carrying on of a regulated activity. • A director may be implicated in a breach of a health and safety requirement or another statutory duty or contractual responsibility because of how the entire management team organised and managed its organisation's activities. In this case, providers must establish what role the director played in the breach so that they can judge whether it means they are unfit. If the evidence shows that the breach is attributable to the director's conduct, CQC would expect the provider to find that they are unfit. • Although providers have information on when convictions, bankruptcies or similar matters are to be considered 'spent' there is no time limit for considering serious misconduct or responsibility for failure in a previous role.
5(3)(e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.	• A person 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 must be subject to a check by the Disclosure and Barring Service (DBS). • Providers must seek all available information to assure themselves that directors do not meet any of the elements of the unfit person test set out in Schedule 4 Part 1. Robust systems should be in place to assess directors in relation to bankruptcy, sequestration, insolvency and arrangements with creditors. In addition, where a director meets the eligibility criteria, providers should establish whether the person is on the children's and/or adults safeguarding barred list and whether they are prohibited from holding the office in question under other laws such as the Companies Act or Charities Act. • If a provider discovers information that suggests an individual is unfit after they have been appointed to a role, the provider must take appropriate and timely action to investigate and rectify the matter.

5(6) Where an individual who holds an office or position referred to in paragraph (2)(a) or (b) no longer meets the requirements in paragraph (3), the service provider must— (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.	• Providers must assess and regularly review the fitness of directors to ensure that they remain fit for the role they are in. Providers must determine how often to review fitness based on the assessed risk to business delivery and/or to the people using the service posed by the individual and/or role. • Providers must have arrangements in place to respond to concerns about a person's fitness in relation to Regulation 5(3) and (4) after they have been appointed to a role, which either they or others have identified, and providers must adhere to these arrangements. • Providers must investigate, in a timely manner, any concerns about a person's fitness or ability to carry out their duties, and where concerns are substantiated, they must take proportionate, timely action. Where a person's fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to people who use the service.

Regulation 6: Requirement where the service provider is a body other than a partnership

6.—(1) This regulation applies where the service provider is a body other than a partnership.

(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as "the nominated individual") who is—

(a) employed as a director, manager or secretary of the body, and

(b) responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual—

(a) is of good character,

(b) has the necessary qualifications, competence, skills and experience to properly supervise the management of the carrying on of the regulated activity,

(c) is able by reason of their health, after reasonable adjustments are made, of properly doing so, and

(d) is able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

(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.

Summary of the regulation

The intention of this regulation is to ensure that the provider is represented by an appropriate person nominated by the organisation to carry out this role on their behalf (nominated individual). The nominated individual is responsible for supervising the management of the regulated activity provided.

This is because providers who comply with this regulation will have appointed as a nominated individual a director, manager or secretary who:

- Is of good character.
- Is able to properly perform tasks that are intrinsic to their role.
- Has the necessary qualifications, competence, skills and experience to supervise the management of the regulated activity.
- Has supplied them with documents that confirm their suitability.

CQC cannot prosecute for a breach of this regulation or any of its parts but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
6(1) This regulation applies where the service provider is a body other than a partnership.	
6(3) The registered person must take all reasonable steps to ensure that the nominated individual is—	
6(3)(a) of good character,	• When assessing whether a nominated individual is of good character, providers must follow robust processes to make sure that they gather all available information to confirm that the individual is of good character, and have regard to the matters outlined in Schedule 4, Part 2 of the regulations. It is not possible to outline every character trait an individual should have, but we would expect to see that the processes followed take account of honesty, trustworthiness, reliability and respectfulness. • If a provider discovers information that suggests a nominated 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 considers the nominated individual to be suitable despite the existence of information relevant to issues identified in Schedule 4, Part 2, the reasons should be recorded for future reference.
6(3)(b) has the necessary qualifications, competence, skills and experience to properly supervise the management of the carrying on of the regulated activity,	• The nominated individual should be appropriately skilled with the necessary qualification(s), knowledge and experience and demonstrate the competency required to supervise the management of the regulated activity. • The nominated individual should demonstrate that they have appropriate knowledge of applicable legislation, including the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, relevant best practice and guidance and understand the consequences of failing to take action on set requirements. • The provider must have appropriate processes for assessing and checking that the nominated individual holds the required qualifications and has the competence, skills and experience required to undertake the role. These processes must be followed in all cases and relevant records kept.
6(3)(c) is able by reason of their health, after reasonable adjustments are made, of properly doing so.	• This aspect of the regulation relates to the ability of nominated individuals to carry out their role. This does not mean that people who have a long-term condition or disability cannot hold such positions. • The provider must have processes for considering the nominated individual's physical and mental health in line with the requirements of the role. • All reasonable steps must be made to make adjustments for nominated individuals to enable them to carry out their role. These must be in line with requirements to make reasonable adjustments for employees under the Equality Act 2010.

Regulation 7: Requirements relating to registered managers

7.—(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

(a) of good character,

(b) has the necessary qualifications, competence, skills and experience to manage the carrying on of the regulated activity,

(c) able by reason of M's health, after reasonable adjustments are made, of doing so, and

(d) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

(3) In assessing an individual's character for the purposes of paragraph (2)(a), the matters considered must include those listed in Part 2 of Schedule 4.

Summary of the regulation

The intention of this regulation is to ensure that people who use services have their needs met because the regulated activity is managed by an appropriate person.

This is because providers who comply with the regulations will have a registered manager who:

- Is of good character.
- Is able to properly perform tasks that are intrinsic to their role.
- Has the necessary qualifications, competence, skills and experience to manage the regulated activity.
- Has supplied them with documents that confirm their suitability.

CQC cannot prosecute for a breach of this regulation or any of its parts but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
7(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so	
7(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—	
7(2)(a) of good character,	• When assessing whether a registered manager is of good character, providers must follow robust processes to make sure that they gather all available information to confirm that the individual is of good character, and have regard to the matters outlined in Schedule 4, Part 2 of the regulations. It is not possible to outline every character trait an individual should have, but we would expect to see that the processes followed take account of honesty, trustworthiness, reliability and respectfulness. • If a provider discovers information that suggests a registered manager is not of good character after they have been appointed to a role, they must take appropriate and timely action to investigate and rectify the matter. Where a provider considers the registered manager to be suitable despite the existence of information relevant to issues identified in Schedule 4, Part 2, the provider's reasons should be recorded for future reference.
7(2)(b) has the necessary qualifications, competence, skills and experience to manage the carrying on of the regulated activity,	• The registered manager should be appropriately skilled with the qualification(s), knowledge and experience and demonstrate the competency required to manage the regulated activity. • The registered manager should demonstrate that they have appropriate knowledge of applicable legislation including the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), relevant best practice and guidance and understand the consequences of failing to take action on set requirements. • The provider must have appropriate processes for assessing and checking that the individual holds the required qualifications and has the competence, skills and experience required to undertake the role. These processes must be followed in all cases and relevant records kept.
7(2)(c) able by reason of M's health, after reasonable adjustments are made, of doing so.	• This aspect of the regulation relates to the ability of registered managers to carry out their role. This does not mean that people who have a long-term condition or disability cannot hold such positions. • The provider must have processes for considering the person's physical and mental health in line with the requirements of the role. • All reasonable steps must be made to make adjustments for registered managers to enable them to carry out their role. These must be in line with requirements to make reasonable adjustments for employees under the Equality Act 2010.

Regulation 8: General

8.—(1) A registered person must comply with regulations 9 to 20A 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 20A 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 20A 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.

Summary of the regulation

This regulation aims to make it clear that if a provider has more than one registered person (for example, a registered provider as well as a registered manager) they do not all individually need to take the same action to meet every regulation. However, they must make sure that they meet every regulation for each regulated activity they provide, and that all the registered people must comply with the requirements of the regulations.

It also states that for Regulations 9 to 20A, sections 2 and 3 of the Mental Capacity Act 2005 must be considered for people who use the service who are aged 16 or over to determine whether they lack the mental capacity to consent.

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 make sure that people using a service have care or treatment that is personalised specifically for them. This regulation describes the action that providers must take to make sure that each person receives appropriate person-centred care and treatment that is based on an assessment of their needs and preferences.

Providers must work in partnership with the person, make any reasonable adjustments and provide support to help them understand and make informed decisions about their care and treatment options, including the extent to which they may wish to manage these options themselves.

Providers must make sure that they take into account people's capacity and ability to consent, and that either they, or a person lawfully acting on their behalf, must be involved in the planning, management and review of their care and treatment. Providers must make sure that decisions are made by those with the legal authority or responsibility to do so, but they must work within the requirements of the Mental Capacity Act 2005, which includes the duty to consult others such as carers, families and/or advocates where appropriate.

Please see the glossary (Annex C) for important clarification of the terms "appropriate care and treatment"; "needs"; "preferences"; and "relevant person".

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
9(1) The care and treatment of service users must – (a) be appropriate, (b) meet their needs and (c) reflect their preferences.	• Providers must do everything reasonably practicable to make sure that people who use the service receive person-centred care and treatment that is appropriate, meets their needs and reflects their personal preferences, whatever they might be.
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.	• Providers must make sure that they provide appropriate care and treatment that meets people's needs, but this does not mean that care and treatment should be given if it would act against the consent of the person using the service. • In some cases, people's preferences for their care or treatment may not meet their needs. Where this is the case, and people lack mental capacity or are detained under mental health legislation, providers must act in accordance with the Mental Capacity Act 2005 and/or the Mental Health Act 1983.

9(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include–	
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 person using a service, and/or the person who is lawfully acting on their behalf, must be involved in an assessment of their needs and preferences as much or as little as they wish to be. Providers should give them relevant information and support when they need it to make sure they understand the choices available to them. • Assessments must take into account current legislation and consider relevant nationally recognised evidence-based guidance. • Where a person lacks the mental capacity to make specific decisions about their care and treatment, and no lawful representative has been appointed, their best interests must be established and acted on in accordance with the Mental Capacity Act 2005. Other forms of authority such as advance decisions must also be taken into account. • Each person's care and treatment needs and preferences should be assessed by people with the required levels of skills and knowledge for the particular task. • Assessments of people's care and treatment needs should include all their needs, including health, personal care, emotional, social, cultural, religious and spiritual needs. • Assessments should take into account specific issues that are common in certain groups of people and can result in poor outcomes for them if not addressed. These include diseases or conditions such as continence support needs and dementia in older people, and diabetes in certain ethnic groups. • Assessments should be reviewed regularly and whenever needed throughout the person's care and treatment. This includes when they transfer between services, use respite care or are re-admitted or discharged. Reviews should make sure that people's goals or plans are being met and are still relevant. • Where providers share responsibility for providing care and treatment with other services through partnership working, integrated care and multidisciplinary assessments, they should also take into account information from all relevant teams, staff and services.
9(3)(b) designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met;	• A person's care and treatment must be designed to make sure it meets all their needs. There may be times when a person's needs and preferences can't be met. In these instances, providers must explain the impact of this to them and explore alternatives so that the person can make informed decisions about their care and treatment.

	• Providers must make every reasonable effort to meet people's preferences. When any preferences about the choice of care and treatment can't be met, providers must fully explain why so that people using the service understand the reasons. The explanation should show how the provider has considered the impact of this on the person. This is so that they can make further informed decisions about their care and treatment. This includes where preferences can't be met because of restrictions under the Mental Health Act 1983. • When planning how to meet a person's preferences, providers should take into account, and make provision for, any impact this may have on other people using the service. • A clear care and/or treatment plan, which includes agreed goals, must be developed and made available to all staff and others involved in providing the care. Where relevant, the plan should include ways in which the person can maintain their independence. • Plans should include an agreed review date. • Providers should use nationally recognised evidence-based guidance when designing, delivering and reviewing care. • Staff providing care must be kept up to date with any changes to a person's needs and preferences.
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;	• Each person, and/or person lawfully acting on their behalf, must have all the necessary information about their care and treatment. This information should be provided in a way that the person understands. • Health care professionals or people with the required level of skills and knowledge must discuss care and treatment choices with the person and/or person lawfully acting on their behalf. They must provide support to make sure the person understands all the risks and benefits associated with those choices and enable them to make informed decisions about their care and treatment. • The person using the service must be able to discuss care and treatment choices continually and have support to make any changes to those choices if they wish. They should be given information about the risks and benefits of any changes in a way they can understand. • Even when the person using the service does not raise the issues themselves, discussions should include all health, care, social and emotional needs.

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;	• Providers must make every reasonable effort to provide opportunities to involve people in making decisions about their care and treatment, and support them to do this. This includes physical, psychological or emotional support, or support to get information in an accessible format or to understand the content. It may include involving people in discussions, inviting them to meetings and encouraging them to ask questions and providing suggestions. • People using the service and/or those lawfully acting on their behalf must be actively encouraged and supported to be involved in making decisions about their care or treatment as much or as little as they wish to be. This includes taking all steps to maximise a person's mental capacity in different ways to make as many of their own choices as possible. • A record must be kept of all assessments, care and treatment plans, and decisions made by people who use the service and/or those acting on their behalf. See Regulation 17 (Good governance).
9(3)(e) providing opportunities for relevant persons to manage the service user's care or treatment;	• People using the service and/or those lawfully acting on their behalf must be given opportunities to manage as much of their care and treatment as they wish and are able to, and should be actively encouraged to do so. 'Manage' in this context may mean being actively involved, overseeing or making decisions about their care or treatment depending on how much they need or want to be involved. This may include managing their medicines, managing or supporting their personal care including eating and drinking, or using appropriate equipment and technology. • People using the service and/or those lawfully acting on their behalf should be given suitable information, advice, instruction and/or emotional support to help manage any care and treatment safely.
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;	• Providers must actively seek the views of people who use their service and those lawfully acting on their behalf, about how care and treatment meets their needs. Providers must be able to demonstrate that they took action in response to any feedback.

9(3)(g) providing relevant persons with the information they would reasonably need for the purposes of sub-paragraphs (c) to (f);	• People using services and those lawfully acting on their behalf must be given relevant information in the most suitable way for them and in a way that they can understand. This includes information that describes: ○ The condition or conditions affecting the person using the service. ○ All possible relevant or appropriate care and treatment options. ○ The risks and benefits of each option. ○ The implications of not undertaking any, or only undertaking a part, of the care and treatment options. ○ Costs/fees/tariffs associated with care and treatment. ○ Reasonable expectations of the outcome of each care and treatment option.
9(3)(i) where meeting a service user's nutritional and hydration needs, having regard to the service user's well being.	• Where food and/or drink are provided for people who use services, they must have a choice that meets their needs and preferences as far as is reasonably practical. • Providers must make sure that they assess each person's nutritional and hydration needs to support their wellbeing and quality of life. This includes when there is no expected cure for an illness.

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 make sure that people using the service are treated with respect and dignity at all times while they are receiving care and treatment. To meet this regulation, providers must make sure that they provide care and treatment in a way that ensures people's dignity and treats them with respect at all times. This includes making sure that people have privacy when they need and want it, treating them as equals and providing any support they might need to be autonomous, independent and involved in their local community.

Providers must have due regard to the protected characteristics as defined in the Equality Act 2010.

CQC cannot prosecute providers for a breach of this regulation or of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
10(1) Service users must be treated with dignity and respect.	• When people receive care and treatment, all staff must treat them with dignity and respect at all times. This includes staff treating them in a caring and compassionate way. • All communication with people using services must be respectful. This includes using or facilitating the most suitable means of communication and respecting a person's right to engage or not to engage in communication. • Staff must respect people's personal preferences, lifestyle and care choices. • When providing intimate or personal care, provider must make every reasonable effort to make sure that they respect people's preferences about who delivers their care and treatment, such as requesting staff of a specified gender.

	• People using the service should be addressed in the way they prefer. • People using the service must not be neglected or left in undignified situations such as those described in the guidance for Regulation 13(4) below.
10(2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—	• Providers must make sure that they treat people using services with dignity and respect. In particular this includes the things listed in 10(2) (a)-(c) but these things are not exhaustive and providers must demonstrate that they take all reasonable steps to make sure that people using their service are always treated with dignity and respect.
10(2)(a) ensuring the privacy of the service user;	• Each person's privacy must be maintained at all times including when they are asleep, unconscious or lack capacity. • All reasonable efforts should be made to make sure that discussions about care treatment and support only take place where they cannot be overheard. • Staff must make sure that people have privacy when they receive treatment and that they are supported to wash, bath, use the toilet and hold private conversations. • Each person's privacy needs and expectations should be identified, recorded, and met as far as is reasonably possible. • People's relationships with their visitors, carer, friends, family or relevant other persons should be respected and privacy maintained as far as reasonably practicable during visits. • People using services should not have to share sleeping accommodation with others of the opposite sex, and should have access to segregated bathroom and toilet facilities without passing through opposite-sex areas to reach their own facilities. Where appropriate, such as in mental health units, women should have access to women-only day spaces. • If any form of surveillance is used for any purpose, providers must make sure this is in the best interests of people using the service, while remaining mindful of their responsibilities for the safety of their staff. Any surveillance should be operated in line with current guidance. Detailed guidance on the use of surveillance is available on CQC's website.

10(2)(b) supporting the autonomy, independence and involvement in the community of the service user;	• People who use services must be offered support to maintain their autonomy and independence in line with their needs and stated preferences. When offering support, staff should respect people's expressed wishes to act independently but also identify and mitigate risks in order to support their continued independence as safely as possible. (See Regulation 12(2)(a) & (b) for more detail). • People must be supported to maintain relationships that are important to them while they are receiving care and treatment. • People must be supported to be involved in their community as much or as little as they wish. Providers must actively work with people who wish to maintain their involvement in their local community as soon as they begin to use a service. The provider must make sure that people are not left unnecessarily isolated. **Note:** Where people are detained in high security settings, 'the community' relates to the facility where they are detained and their level of involvement in it will depend on their care and treatment needs.
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.	• People using services must not be discriminated against in any way and the provider must take account of protected characteristics, set out in the Equality Act 2010. ○ 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 people because of these protected characteristics. This includes direct and indirect discrimination, which is described in the Equality Act 2010. • Providers must also make sure that they have due regard to people's protected characteristics in the way in which they meet all other regulatory requirements. For example, in relation to care and treatment reflecting the person's preferences in Regulation 9(1)(c) or in relation to community involvement in relation to Regulation 10(2)(b).

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).

* Mental Capacity Act 2005 ** Mental Health Act 1983

Summary of the regulation

The intention of this regulation is to make sure that all people using the service, and those lawfully acting on their behalf, have given consent before any care or treatment is provided. Providers must make sure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for.

Consent is an important aspect of providing care and treatment, but in some cases, acting strictly in accordance with consent will mean that some of the other regulations cannot be met. For example, this might apply with regard to nutrition and person-centred care. However, providers must not provide unsafe or inappropriate care just because someone has consented to care or treatment that would be unsafe.

See the glossary (Annex C) for the definition of 'relevant person' in relation to Regulation 11.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
11(1) Care and treatment of service users must only be provided with the consent of the relevant person.	• When a person is asked for their consent, information about the proposed care and treatment must be provided in a way that they can understand. This should include information about the risks, complications and any alternatives. A person with the necessary knowledge and understanding of the care and treatment should provide this information so that they can answer any questions about it to help the person consent to it. • Discussions about consent must be held in a way that meets people's communication needs. This may include the use of different formats or languages and may involve others such as a speech language therapist or independent advocate. Consent may be implied and include non-verbal communication such as sign language or by someone rolling up their sleeve to have their blood pressure taken or offering their hand when asked if they would like help to move. • Consent must be 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. • When a person using a service or a person acting lawfully on their behalf refuses to give consent or withdraws it, all people providing care and treatment must respect this. • Where a person lacks mental capacity to make an informed decision, or give consent, staff must act in accordance with the requirements of the Mental Capacity Act 2005 and associated code of practice. • Consent procedures must make sure that people are not pressured into giving consent and, where possible, plans must be made well in advance to allow time to respond to people's questions and provide adequate information. • Policies and procedures for obtaining consent to care and treatment must reflect current legislation and guidance, and staff must follow them at all times.

11(2) Paragraph (1) is subject to paragraphs (3) and (4). **11(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. **11(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. **11(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).	• Providers must make sure that staff who obtain the consent of people who use the service are familiar with the principles and codes of conduct associated with the Mental Capacity Act 2005, and are able to apply those when appropriate, for any of the people they are caring for.

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 people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staff have the qualifications, competence, skills and experience to keep people safe.

Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.

Providers must prevent and control the spread of infection. Where the responsibility for care and treatment is shared, care planning must be timely to maintain people's health, safety and welfare.

CQC understands that there may be inherent risks in carrying out care and treatment, and we 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 people using their services and to manage risks that may arise during care and treatment.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation if a failure to meet the regulation results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm. We do not have to serve a Warning Notice before prosecution. Additionally, CQC may also take other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Note:

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

Component of the regulation	Providers must have regard to the following guidance
12(1) Care and treatment must be provided in a safe way for service users.	• Providers must provide care and treatment in a safe way. In particular, this includes the areas listed in 12(2) (a) – (i). However, 12(2) is not exhaustive and providers must demonstrate that they have done everything reasonably practicable to provide safe care and treatment. • Providers should consult nationally recognised guidance about delivering safe care and treatment and implement this as appropriate.
12(2) without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include–	

12(2)(a) assessing the risks to the health and safety of service users of receiving the care or treatment;	• Risk assessments relating to the health, safety and welfare of people using services must be completed and reviewed regularly by people with the qualifications, skills, competence and experience to do so. Risk assessments should include plans for managing risks.
	• Assessments, planning and delivery of care and treatment should:
	  ○ Be based on risk assessments that balance the needs and safety of people using the service with their rights and preferences.
	  ○ Include arrangements to respond appropriately and in good time to people's changing needs.
	  ○ Be carried out in accordance with the Mental Capacity Act 2005. This includes best interest decision making; lawful restraint; and, where required, application for authorisation for deprivation of liberty through the Mental Capacity Act 2005 Deprivation of Liberty Safeguards or the Court of Protection.
	All this applies when people use a service. This includes when they are admitted, discharged, transferred or move between services.

12(2)(b) doing all that is reasonably practicable to mitigate any such risks;	• Providers must do all that is reasonably practicable to mitigate risks. They should follow good practice guidance and must adopt control measures to make sure the risk is as low as is reasonably possible. They should review methods and measures and amended them to address changing practice. • Providers should use risk assessments about the health, safety and welfare of people using their service to make required adjustments. These adjustments may be to premises, equipment, staff training, processes, and practices and can affect any aspect of care and treatment. • Relevant health and safety concerns should be included in people's care and treatment plans/pathways. This includes allergies, contraindications and other limitations relating to the person's needs and abilities. • Staff must follow plans and pathways. • Medication reviews must be part of, and align with, people's care and treatment assessments, plans or pathways and should be completed and reviewed regularly when their medication changes. • Providers must comply with relevant Patient Safety Alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and through the Central Alerting System (CAS). • Incidents that affect the health, safety and welfare of people using services must be reported internally and to relevant external authorities/bodies. They must be reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result. Staff who were involved in incidents should receive information about them and this should be shared with others to promote learning. Incidents include those that have potential for harm. • Outcomes of investigations into incidents must be shared with the person concerned and, where relevant, their families, carers and advocates. This is in keeping with Regulation 20, Duty of candour. • There must be policies and procedures in place for anyone to raise concerns about their own care and treatment or the care and treatment of people they care for or represent. The policies and procedures must be in line with current legislation and guidance, and staff must follow them. • The provider must have arrangements to take appropriate action if there is a clinical or medical emergency. • Medicines must be administered accurately, in accordance with any prescriber instructions and at suitable times to make sure that people who use the service are not placed at risk. • When it is agreed to be in a person's best interests, the arrangements for giving medicines covertly must be in accordance with the Mental Capacity Act 2005. • There must be arrangements to request a second opinion in relation to medicines for people who are detained under the Mental Health Act 1983.

12(2)(c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;	• Staff must only work within the scope of their qualifications, competence, skills and experience and should be encouraged to seek help when they feel they are being asked to do something that they are not prepared or trained for. • Staff should be appropriately supervised when they are learning new skills, but are not yet competent. • Only relevant regulated professionals with the appropriate qualifications must plan and prescribe care and treatment, including medicines. Only relevant regulated professionals or suitably skilled and competent staff must deliver care and treatment.
12(2)(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; **12(2)(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 used in a safe way;	• Providers must ensure the safety of their premises and the equipment within it. They should have systems and processes that assure compliance with statutory requirements, national guidance and safety alerts. • Providers retain legal responsibility under these regulations when they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains or contractors. They must therefore make sure that these regulations are adhered to as responsibility for any shortfall rests with the provider. • Providers should have and implement up to date induction and training plans for the safe operation of premises and equipment, including incident reporting and emergency and contingency planning. • Providers should include in their financial planning the capital and revenue costs of maintaining safety. • Providers must make sure that equipment is suitable for its purpose, properly maintained and used correctly and safely. This includes making sure that staff using the equipment have the training, competency and skills needed.
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;	• People's medicines must be available in the necessary quantities at all times to prevent the risks associated with medicines that are not administered as prescribed. This includes when people manage their own medicines. • Sufficient medication should be available in case of emergencies. • Sufficient equipment and/or medical devices that are necessary to meet people's needs should be available at all times and devices should be kept in full working order. They should be available when needed and within a reasonable time without posing a risk. • The equipment, medicines and/or medical devices that are necessary to meet people's needs should be available when they are transferred between services or providers.

12(2)(g) the proper and safe management of medicines;	• Staff responsible for the management and administration of medication must be suitably trained and competent and this should be kept under review.
	• Staff must follow policies and procedures about managing medicines, including those related to infection control.
	• These policies and procedures should be in line with current legislation and guidance and address:
	  ○ Supply and ordering.
	  ○ Storage, dispensing and preparation.
	  ○ Administration.
	  ○ Disposal.
	  ○ Recording.

12(2)(h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;	• The Department of Health has issued a Code of Practice about the prevention and control of healthcare associated infections *Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance*. The law says that CQC must take the Code into account when making decisions about registration and by any court during legal proceedings about registration. By following the Code, providers will be able to show how they meet this regulation but they do not have to comply with the Code by law. A provider may be able to demonstrate that they meet this regulation in a different way (equivalent or better) from that described in the Code. • When assessing risk, providers should consider the link between infection prevention and control, antimicrobial stewardship, how medicines are managed and cleanliness.
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.	• The provider must actively work with others, both internally and externally, to make sure that care and treatment remains safe for people using services. • When care is shared between two or more providers or where there are integrated services, there should be appropriate arrangements to share relevant information promptly and in line with current legislation and guidance, and to plan and deliver care in partnership. • When more than one provider is responsible for the safety of a person using services, the responsibility for providing safe care rests with the principal care provider at the time it is given. • Arrangements should be in place to support people who are in a transition phase between services and/or other providers.

	• When people move between services or providers, appropriate risk assessments must be undertaken to make sure their safety is not compromised. This includes when they move between or with other bodies who may not be registered with CQC, such as the police. Decisions about a move between services or providers relating to people who may lack mental capacity to make that decision for themselves must be made in accordance with the Mental Capacity Act 2005. • To make sure that people who use services are safe and any risks to their care and treatment are minimised, providers must be able to respond to and manage major incidents and emergency situations. This includes having plans with other providers or bodies in case of events such as fires, floods, major road traffic accidents or major incidents, and natural disasters such as earth quakes or landslides (see Annex A for link to the Civil Contingencies Act 2004).

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(a),

(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

(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 people who use services from suffering any form of abuse or improper treatment while receiving care and treatment. Improper treatment includes discrimination or unlawful restraint, which includes inappropriate deprivation of liberty under the terms of the Mental Capacity Act 2005.

To meet the requirements of this regulation, providers must have a zero tolerance approach to abuse, unlawful discrimination and restraint. This includes:

- Neglect.
- Subjecting people to degrading treatment.
- Unnecessary or disproportionate restraint.
- Deprivation of liberty.

Providers must have robust procedures and processes to prevent people using the service from being abused by staff or other people they may have contact with when using the service, including visitors. Abuse and improper treatment includes care or treatment that is degrading for people and care or treatment that significantly disregards their needs or that involves inappropriate recourse to restraint. For these purposes, 'restraint' includes the use or threat of force, and physical, chemical or mechanical methods of restricting liberty to overcome a person's resistance to the treatment in question.

Where any form of abuse is suspected, occurs, is discovered, or reported by a third party, the provider must take appropriate action without delay. The action they must take includes investigation and/or referral to the appropriate body. This applies whether the third party reporting an occurrence is internal or external to the provider.

CQC can prosecute for a breach of some parts of this regulation (13(1) to 13(4)) if a failure to meet those parts results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm. We do not have to serve a Warning Notice before prosecution. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
13(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.	• All providers must make sure that they have, and implement, robust procedures and processes that make sure that people are protected. Safeguarding must have the right level of scrutiny and oversight, with overall responsibility held at board level or equivalent.
13(2) Systems and processes must be established and operated effectively to prevent abuse of service users.	• As part of their induction, staff must receive safeguarding training that is relevant, and at a suitable level for their role. Training should be updated at appropriate intervals and should keep staff up to date and enable them to recognise different types of abuse and the ways they can report concerns. • Staff must be aware of their individual responsibilities to prevent, identify and report abuse when providing care and treatment. This includes referral to other providers. • Staff must understand their roles and associated responsibilities in relation to any of the provider's policies, procedures or guidance to prevent abuse. • Information about current procedures and guidance about raising concerns about abuse should be accessible to people who use the service, advocates, those lawfully acting on their behalf, those close to them and staff. • Providers should use incidents and complaints to identify potential abuse and should take preventative actions, including escalation, where appropriate. • Providers should work in partnership with other relevant bodies to contribute to individual risk assessments, developing plans for safeguarding children and safeguarding adults at risk, and when implementing these plans. This includes regularly reviewing outcomes for people using the service. • Providers and their staff must understand and work within the requirements of the Mental Capacity Act 2005 whenever they work with people who may lack the mental capacity to make some decisions.

13(3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.	• Providers must take action as soon as they are alerted to suspected, alleged or actual abuse, or the risk of abuse. Where appropriate, this action should be in line with the procedures agreed by local Safeguarding Adults or Children Boards. • Providers and staff must know and understand the local safeguarding policy and procedures, and the actions they need to take in response to suspicions and allegations of abuse, no matter who raises the concern or who the alleged abuser may be. These include timescales for action and the local arrangements for investigation. • Staff must be aware of, and have access to, current procedures and guidance for raising and responding to concerns of abuse. Staff should have access to support from line management when considering how to respond to concerns of abuse. • Managers and staff must understand their individual responsibilities to respond to concerns about abuse when providing care and treatment, including investigating concerns. • Staff must understand their roles and associated responsibilities in supporting the actions the provider takes in responding to allegations and concerns about abuse. • Providers should make sure that staff are kept up to date about changes to national and local safeguarding arrangements. • Where appropriate, staff must follow local safeguarding arrangements to make sure that allegations are investigated internally or externally. Providers must make sure that they respond without delay to the findings of any investigations. • When people who use services make allegations of abuse, or actually experience abuse, they must receive the support they need. • Where allegations of abuse are substantiated, providers must take action to redress the abuse and take the necessary steps to ensure the abuse is not repeated. This may involve seeking specialist advice or support. • When required to, providers must participate in serious case reviews. Any changes to practice and/or recommendations relating to the provider must be implemented.
13(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,
 	
13(4)(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,
	• Staff must understand their individual responsibilities in preventing discrimination in relation to the protected characteristics set out in s.4 of the Equality Act 2010. These are: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex; and sexual orientation.
	• Providers should have systems for dealing with allegations and acts of discrimination regardless of who raises the concern or who the allegation is against. This includes policies and procedures that describe the required actions and the timescales in which to take action.
	• Providers must support people who use services when they make allegations of discrimination or actually experience discrimination. They must not unlawfully victimise people who use services for making a complaint about discrimination.
	• When allegations of discrimination are substantiated, providers must take corrective action and make changes to prevent it happening again. This may involve seeking specialist advice or support.
	• See Regulation 13(7) for the meaning of restraint in relation to this regulation.
	• As part of their induction, staff must receive training that is relevant to their role and at a suitable level to make sure any control, restraint or restrictive practices are only used when absolutely necessary, in line with current national guidance and good practice, and as a last resort. The provider should make arrangements to keep staff up to date at appropriate intervals.
	• If using restraint, providers must make sure that restraint:
	  ○ Is only used when absolutely necessary.
	  ○ Is proportionate in relation to the risk of harm and the seriousness of that harm to the person using the service or another person.
	  ○ Takes account of the assessment of the person's needs and their capacity to consent to such treatment.
	  ○ Follows current legislation and guidance.
	• Providers and staff should regularly monitor and review the approach to, and use of, restraint and restrictive practices.
	• Where a person lacks mental capacity to consent to the arrangements for their care or treatment, including depriving them of their liberty, providers must follow a best interest process in accordance with the Mental Capacity Act 2005, including the use of the Mental Capacity Act 2005 Deprivation of Liberty Safeguards, where appropriate.

13(4)(c) is degrading for the service user, or	• Providers and staff must take all reasonable steps to make sure that people who use services are not subjected to any form of degradation or treated in a manner that may reasonably be viewed as degrading, such as: ○ Not providing help and aids so that people can be supported to attend to their continence needs, and ○ Making sure people are not: - Left in soiled sheets for long periods. - 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 or social activities. - Ridiculed in any way by staff. **This list is not exhaustive.** • Providers should consult and consider the views of people using their service when defining the meaning of 'degrading'.
13(4)(d) significantly disregards the needs of the service user for care or treatment.	• Care and treatment must be planned and delivered in a way that enables all a person's needs to be met. This includes making sure that enough time is allocated to allow staff to provide care and treatment in accordance with the person's assessed needs and preferences. There should be policies and procedures that support staff to deliver care and treatment in accordance with the requirements detailed in the plan(s) of care. • When a person lacks the mental capacity to consent to care and treatment, a best interests process must be followed in accordance with the Mental Capacity Act 2005. Other forms of authority such as advance decisions must also be taken into account. • Staff should raise any concerns with the provider about their ability to provide planned care. When concerns are raised, the provider should respond appropriately and without delay.
13(5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.	• Providers 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. • Hospitals and care homes must follow the Deprivation of Liberty Safeguards. • Other types of services must ensure that any deprivation of the liberty of a person who lacks mental capacity is authorised by the Court of Protection.

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—

the provision of accommodation by the service provider, or

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—

result in a breach of regulation 11, or

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 make sure that people who use services have adequate nutrition and hydration to sustain life and good health and reduce the risks of malnutrition and dehydration while they receive care and treatment.

To meet this regulation, where it is part of their role, providers must make sure that people have enough to eat and drink to meet their nutrition and hydration needs and receive the support they need to do so.

People must have their nutritional needs assessed and food must be provided to meet those needs. This includes where people are prescribed nutritional supplements and/or parenteral nutrition. People's preferences, religious and cultural backgrounds must be taken into account when providing food and drink.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation if a failure to meet the regulation results in avoidable harm to a person using the service or a person using the service is exposed to significant risk of harm. In these instances, CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
14(1) The nutritional and hydration needs of service users must be met.	• Providers must include people's nutrition and hydration needs when they make an initial assessment of their care, treatment and support needs and in the ongoing review of these. The assessment and review should include risks related to people's nutritional and hydration needs. • Providers should have a food and drink strategy that addresses the nutritional needs of people using the service.
14(2) Paragraph 1 applies where— (a) care or treatment involves— the provision of accommodation by the service provider, or 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.	• Providers must meet people's nutrition or hydration needs wherever an overnight stay is provided as part of the regulated activity or where nutrition or hydration are provided as part of the arrangements made for the person using the service.

14(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.	• Providers must follow people's consent wishes if they refuse nutrition and hydration unless a best interests decision has been made under the Mental Capacity Act 2005. Other forms of authority such as advance decisions should also be taken into account. • CQC recognises that some services may vary the way they apply this regulation to take account of people's assessed needs and wishes. This includes specialist eating disorder services and some palliative care or end of life situations.
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 must be carried out by people with the required skills and knowledge. The assessments should follow nationally recognised guidance 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.
	  ○ How to support people's good health including the level of support needed, timing of meals, and the provision of appropriate and sufficient quantities of food and drink.
	• Nutrition and hydration needs should be regularly reviewed during the course of care and treatment and any changes in people's needs should be responded to in good time.
	• A variety of nutritious, appetising food should be available to meet people's needs and be served at an appropriate temperature. When the person lacks capacity, they must have prompts, encouragement and help to eat as appropriate.
	• Where a person is assessed as needing a specific diet, this must be provided in line with that assessment. Nutritional and hydration intake should be monitored and recorded to prevent unnecessary dehydration, weight loss or weight gain. Action must be taken without delay to address any concerns.
	• Staff must follow the most up-to-date nutrition and hydration assessment for each person and take appropriate action if people are not eating and drinking in line with their assessed needs.
	• Staff should know how to determine whether specialist nutritional advice is required and how to access and follow it.

	• Water must be available and accessible to people at all times. Other drinks should be made available periodically throughout the day and night and people should be encouraged and supported to drink. • Arrangements should be made for people to receive their meals at a different time if they are absent or asleep when their meals are served. • Snacks or other food should be available between meals for those who prefer to eat 'little and often'.
14(4)(b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,	• Providers must have systems to make sure that people using the service receive their prescribed parenteral nutrition and dietary supplements at the specified times. • Parenteral nutrition and dietary supplements must only be administered by appropriately qualified, skilled, competent and experienced staff.
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	• People should be able to make choices about their diet. • People's religious and cultural needs must be identified in their nutrition and hydration assessment, and these needs must be met. If there are any clinical contraindications or risks posed because of any of these requirements, these should be discussed with the person, to allow them to make informed choices about their requirements. • When a person has specific dietary requirements relating to moral or ethical beliefs, such as vegetarianism, these requirements must be fully considered and met. Every effort should be made to meet people's preferences, including preference about what time meals are served, where they are served and the quantity.
14(4)(d) if necessary, support for a service user to eat or drink.	• People's food must be placed within their reach and presented in a way that is easy to eat, such as liquidised or finger foods where appropriate. • Food must be served and maintained at the right temperature for the whole mealtime. • People should be encouraged to eat and drink independently. They should receive appropriate support, which may include encouragement as well as physical support, when they need it. • People must have appropriate equipment or tools to help them eat and drink independently. • Each person who requires support should have enough time to enable them to take adequate nutrition and hydration to sustain life and good health.

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 make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely and used properly. Providers retain legal responsibility under these regulations when they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains or contractors. They must therefore make sure that they meet the regulation, as responsibility for any shortfall rests with the provider.

Where the person using the service owns the equipment needed to deliver their care and treatment, or the provider does not provide it, the provider should make every effort to make sure that it is clean, safe and suitable for use.

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Note: 'Premises' and 'equipment' are defined in the regulations. The definitions make sure that the term 'premises' does not apply to the person's own accommodation where accommodation is not provided as part of their care and treatment. In addition, 'equipment' does not include equipment at the person's own accommodation, where it is not provided as part of their care or treatment.

Component of the regulation	Providers must have regard to the following guidance
15(1) All premises and equipment used by the service provider must be—	
15(1)(a) clean,	• Premises and equipment must be kept clean and cleaning must be done in line with current legislation and guidance. • Premises and equipment should be visibly clean and free from odours that are offensive or unpleasant. • Providers should: ○ Use appropriate cleaning methods and agents. ○ Operate a cleaning schedule appropriate to the care and treatment being delivered from the premises or by the equipment. ○ Monitor the level of cleanliness. ○ Take action without delay when any shortfalls are identified. ○ Make sure that staff with responsibility for cleaning have appropriate training. • Domestic, clinical and hazardous waste and materials must be managed in line with current legislation and guidance.
15(1)(b) secure,	• Security arrangements must make sure that people are safe while receiving care, including: ○ Protecting personal safety, which includes restrictive protection required in relation to the Mental Capacity Act 2005 and Mental Health Act 1983. This includes the use of window restrictors or locks on doors, which are used in a way that protects people using the service when lawful and necessary, but which does not restrict the liberty of other people using the service. ○ Protecting personal property and/or money. ○ Providing appropriate access to and exit from protected or controlled areas. ○ Not inadvertently restricting people's movements. ○ Providing appropriate information about access and entry when people who use the service are unable to come and go freely and when people using a service move from the premises as part of their care and treatment. ○ Using the appropriate level of security needed in relation to the services being delivered.

	• If any form of surveillance is used for any purpose, the provider must make sure that this is done in the best interests of people using the service, while remaining mindful of their responsibilities for the safety of their staff. Any surveillance should be operated in line with current guidance. Detailed guidance on the use of surveillance is available on CQC's website.
15(1)(c) suitable for the purpose for which they are being used,	• Premises must be fit for purpose in line with statutory requirements and should take account of national best practice. • Premises must be suitable for the service provided, including the layout, and be big enough to accommodate the potential number of people using the service at any one time. There must be sufficient equipment to provide the service. • Adequate support facilities and amenities must be provided where relevant to the service being provided. This includes sufficient toilets and bathrooms for the number of people using the service, adequate storage space, adequate seating and waiting space. • People's needs must be taken into account when premises are designed, built, maintained, renovated or adapted. Their views should also be taken into account when possible. • People should be able to easily enter and exit premises and find their way around easily and independently. If they can't, providers must make reasonable adjustments in accordance with the Equality Act 2010 and other current legislation and guidance. • Any alterations to the premises or the equipment that is used to deliver care and treatment must be made in line with current legislation and guidance. Where the guidance cannot be met, the provider should have appropriate contingency plans and arrangements to mitigate the risks to people using the service. The premises and equipment used to deliver care and treatment must meet people's needs and, where possible, their preferences. This includes making sure that privacy, dignity and confidentiality are not compromised. • Reasonable adjustments must be made when providing equipment to meet the needs of people with disabilities, in line with requirements of the Equality Act 2010.
15(1)(d) properly used, **15(1)(e)** properly maintained, and	• Providers must make sure that they meet the requirements of relevant legislation so that premises and equipment are properly used and maintained. See Annex A for relevant legislation. • The provider's Statement of Purpose and operational policies and procedures for the delivery of care and treatment should specify how the premises and equipment will be used.

	• Any change of use of premises and/or equipment should be informed by a risk assessment and providers must make appropriate alterations to premises and equipment where reasonably practical. Where this is not possible, providers should have appropriate contingency plans and arrangements to mitigate the risks to people using the service. Alterations must be in line with current legislation and guidance. • There should be regular health and safety risk assessments of the premises (including grounds) and equipment. The findings of the assessments must be acted on without delay if improvements are required. • There should be suitable arrangements for the purchase, service, maintenance, renewal and replacement of premises (including grounds) and equipment. These arrangements must make sure that they meet the requirements of current legislation and guidance, manufacturers' instructions and the provider's policies or procedures. • Providers must have operational policies and procedures and maintenance budgets to maintain their equipment, buildings and mechanical engineering and electrical systems so that they are sound, operationally safe and exhibiting only minor deterioration. • All equipment must be used, stored and maintained in line with manufacturers' instructions. It should only be used for its intended purpose and by the person for whom is it provided. • Providers must make sure that staff and others who operate the equipment are trained to use it appropriately.
15(1)(f) appropriately located for the purpose for which they are being used.	• When planning the location of premises, providers must take into account the anticipated needs of the people who will use the service and they should ensure easy access to other relevant facilities and the local community. • Facilities should be appropriately located to suit the accommodation that is being used. This includes short distances between linked facilities, sufficient car parking that is clearly marked and reasonably close, and good access to public transport. • Equipment must be accessible at all times to meet the needs of people using the service. This means it must be available when needed, or obtained in a reasonable time so as not to pose a risk to the person using the service. Equipment includes chairs, beds, clinical equipment, and moving and handling equipment.

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.	• Providers must comply with guidance from the Department of Health about the prevention and control of infections: *Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance*. • Where applicable, premises must be cleaned or decontaminated in line with current legislation and guidance, and equipment must be cleaned, decontaminated and/or sterilised in line with current legislation and guidance and manufacturers' instructions. Equipment must be cleaned or decontaminated after each use and between use by different people who use the service. • Ancillary services belonging to the provider, such as kitchens and laundry rooms, which are used for or by people who use the service, must be used and maintained in line with current legislation and guidance. People using the service and staff using the equipment should be trained to use it or supervised/risk assessed as necessary. • Multiple use equipment and devices must be cleaned or decontaminated between use. Single use and single person devices must not be re-used or shared. All staff must understand the risk to people who use services if they do not adhere to this.

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 make sure that people can make a complaint about their care and treatment. To meet this regulation providers must have an effective and accessible system for identifying, receiving, handling and responding to complaints from people using the service, people acting on their behalf or other stakeholders. All complaints must be investigated thoroughly and any necessary action taken where failures have been identified.

When requested to do so, providers must provide CQC with a summary of complaints, responses and other related correspondence or information.

CQC can prosecute providers for a breach of the part of this regulation (16(3)) that relates to the provision of information to CQC about a complaint within 28 days when requested to do so. CQC can move directly to prosecution without first serving a Warning Notice. In addition, CQC may take any other regulatory action in response to breaches of this regulation. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
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.	• People must be able to make a complaint to any member of staff, either verbally or in writing. • All staff must know how to respond when they receive a complaint. • Unless they are anonymous, all complaints should be acknowledged whether they are written or verbal. • Complainants must not be discriminated against or victimised. In particular, people's care and treatment must not be affected if they make a complaint, or if somebody complains on their behalf. • Appropriate action must be taken without delay to respond to any failures identified by a complaint or the investigation of a complaint. • Information must be available to a complainant about how to take action if they are not satisfied with how the provider manages and/or responds to their complaint. Information should include the internal procedures that the provider must follow and should explain when complaints should/will be escalated to other appropriate bodies. • Where complainants escalate their complaint externally because they are dissatisfied with the local outcome, the provider should cooperate with any independent review or process.
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.	• Information and guidance about how to complain must be available and accessible to everyone who uses the service. It should be available in appropriate languages and formats to meet the needs of the people using the service. • Providers must tell people how to complain, offer support and provide the level of support needed to help them make a complaint. This may be through advocates, interpreter services and any other support identified or requested. • When complainants do not wish to identify themselves, the provider must still follow its complaints process as far as possible. • Providers must have effective systems to make sure that all complaints are investigated without delay. This includes:

- Undertaking a review to establish the level of investigation and immediate action required, including referral to appropriate authorities for investigation. This may include professional regulators or local authority safeguarding teams.
- Making sure appropriate investigations are carried out to identify what might have caused the complaint and the actions required to prevent similar complaints.
- When the complainant has identified themselves, investigating and responding to them and where relevant their family and carers without delay.

- Providers should monitor complaints over time, looking for trends and areas of risk that may be addressed.
- Staff and others who are involved in the assessment and investigation of complaints must have the right level of knowledge and skill. They should understand the provider's complaints process and be knowledgeable about current related guidance.
- Consent and confidentiality must not be compromised during the complaints process unless there are professional or statutory obligations that make this necessary, such as safeguarding.
- Complainants, and those about whom complaints are made, must be kept informed of the status of their complaint and its investigation, and be advised of any changes made as a result.
- Providers must maintain a record of all complaints, outcomes and actions taken in response to complaints. Where no action is taken, the reasons for this should be recorded.
- Providers must act in accordance with Regulation 20: Duty of Candour in respect of complaints about care and treatment that have resulted in a notifiable safety incident.

16(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.	• CQC can ask providers for information about a complaint; if this is not provided within 28 days of our request, it may be seen as preventing CQC from taking appropriate action in relation to a complaint or putting people who use the service at risk of harm, or of receiving care and treatment that has, or is, causing harm. • The 28-day period starts the day after the request is received.

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 make sure that providers have systems and processes that ensure that they are able to meet other requirements in this part of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Regulations 4 to 20A). To meet this regulation; providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.

In addition, providers must securely maintain accurate, complete and detailed records in respect of each person using the service and records relating the employment of staff and the overall management of the regulated activity.

As part of their governance, providers must seek and act on feedback from people using the service, those acting on their behalf, staff and other stakeholders, so that they can continually evaluate the service and drive improvement.

When requested, providers must provide a written report to CQC setting out how they assess, monitor, and where required, improve the quality and safety of their services.

CQC can prosecute for a breach of part of this regulation (17(3)) if a provider fails to submit such a report when requested. CQC may consider that this failure could prevent the provider from taking appropriate, timely action. CQC could therefore move directly to prosecution for a breach of this part of the regulation without first serving a Warning Notice.

Regulatory action can be taken for other parts of the regulation. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
17(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.	• Providers must operate effective systems and processes to make sure they assess and monitor their service against Regulations 4 to 20A of Part 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended). The provider must have a process in place to make sure this happens at all times and in response to the changing needs of people who use the service. • The system must include scrutiny and overall responsibility at board level or equivalent.
17(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—	

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);	• Providers must have systems and processes such as regular audits of the service provided and must assess, monitor and improve the quality and safety of the service. The audits should be baselined against Regulations 4 to 20A of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and should, where possible, include the experiences people who use the service. The systems and processes should be continually reviewed to make sure they remain fit for purpose. Fit for purpose means that:
	  ○ Systems and processes enable the provider to identify where quality and/or safety are being compromised and to respond appropriately and without delay.
	  ○ Providers have access to all necessary information.
	• Information should be up to date, accurate and properly analysed and reviewed by people with the appropriate skills and competence to understand its significance. When required, results should be escalated and appropriate action taken.
	• Providers should have effective communication systems to ensure that people who use the service, those who need to know within the service and, where appropriate, those external to the service, know the results of reviews about the quality and safety of the service and any actions required following the review.
	• Providers should actively seek the views of a wide range of stakeholders, including people who use the service, staff, visiting professionals, professional bodies, commissioners, local groups, members of the public and other bodies, about their experience of, and the quality of care and treatment delivered by the service. Providers must be able to show how they have:
	  ○ Analysed and responded to the information gathered, including taking action to address issues where they are raised, and
	  ○ Used the information to make improvements and demonstrate that they have been made.
	• Providers must seek professional/expert advice as needed and without delay to help them to identify and make improvements.
	• Providers must monitor progress against plans to improve the quality and safety of services, and take appropriate action without delay where progress is not achieved as expected.
	• Subject to statutory consent and applicable confidentiality requirements, providers must share relevant information, such as information about incidents or risks, with other relevant individuals or bodies. These bodies include safeguarding boards, coroners, and regulators. Where they identify that improvements are needed these must be made without delay.

	• Providers should read and implement relevant nationally recognised guidance and be aware that quality and safety standards change over time when new practices are introduced, or because of technological development or other factors.
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;	• Providers must have systems and processes that enable them to identify and assess risks to the health, safety and/or welfare of people who use the service. • Where risks are identified, providers must introduce measures to reduce or remove the risks within a timescale that reflects the level of risk and impact on people using the service. • Providers must have processes to minimise the likelihood of risks and to minimise the impact of risks on people who use services. • Risks to the health, safety and/or welfare of people who use services must be escalated within the organisation or to a relevant external body as appropriate. Identified risks to people who use services and others must be continually monitored and appropriate action taken where a risk has increased. **Note:** In this regulation, 'others' includes anyone who may be put at risk through the carrying on of a regulated activity, such as staff, visitors, tradespeople or students.
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;	• Records relating to the care and treatment of each person using the service must be kept and be fit for purpose. Fit for purpose means they must: ○ Be complete, legible, indelible, accurate and up to date, with no undue delays in adding and filing information, as far as is reasonable. This includes results of diagnostic tests, correspondence and changes to care plans following medical advice. ○ Include an accurate record of all decisions taken in relation to care and treatment and make reference to discussions with people who use the service, their carers and those lawfully acting on their behalf. This includes consent records and advance decisions to refuse treatment. Consent records include when consent changes, why the person changed consent and alternatives offered. ○ Be accessible to authorised people as necessary in order to deliver people's care and treatment in a way that meets their needs and keeps them safe. This applies both internally and externally to other organisations.

	○ Be created, amended, stored and destroyed in line with current legislation and nationally recognised guidance. ○ Be kept secure at all times and only accessed, amended, or securely destroyed by authorised people. • Both paper and electronic records can be held securely providing they meet the requirements of the Data Protection Act 1998. • Decisions made on behalf of a person who lacks capacity must be recorded and provide evidence that these have been taken in line 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 must be managed in line with current legislation and guidance. • Systems and processes must support the confidentiality of people using the service and 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 people employed and the management of regulated activities must be created, amended, stored and destroyed in accordance with current legislation and guidance. • Records relating to people employed must include information relevant to their employment in the role including information relating to the requirements under Regulations 4 to 7 and Regulation 19 of this part (part 3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This applies to all staff, not just newly appointed staff. Providers must observe data protection legislation about the retention of confidential personal information. • Records relating to the management of regulated activities means anything relevant to the planning and delivery of care and treatment. This may include governance arrangements such as policies and procedures, service and maintenance records, audits and reviews, purchasing, action plans in response to risk and incidents. • Records must be kept secure at all times and only accessed, amended or destroyed by people who are authorised to do so. • Information in all formats must be managed in line with current legislation and guidance. • Systems and processes must support the confidentiality of people using the service and 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 services;	• Providers should actively encourage feedback about the quality of care and overall involvement with them. The feedback may be informal or formal, written or verbal. It may be from people using the service, those lawfully acting on their behalf, their carers and others such as staff or other relevant bodies. • All feedback should be listened to, recorded and responded to as appropriate. It should be analysed and used to drive improvements to the quality and safety of services and the experience of engaging with the provider. • Improvements should be made without delay once they are identified, and the provider should have systems in place to communicate how feedback has led to improvements. • Where relevant, the provider should also seek and act on the views of external bodies such as fire, environmental health, royal colleges and other bodies who provide best practice guidance relevant to the service provided.
17(2)(f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).	• Providers must ensure that their audit and governance systems remain effective.
17(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—-	
17(3)(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 **17(3)(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.	• This information could include a request for an action plan or a Provider Information Return or Provider Information Request. There is more information about the Provider Information Request in the provider handbooks.

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 make sure that providers deploy enough suitably qualified, competent and experienced staff to enable them to meet all other regulatory requirements described in this part of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. To meet the regulation, providers must provide sufficient numbers of suitably qualified, competent, skilled and experienced staff to meet the needs of the people using the service at all times and the other regulatory requirements set out in this part of the above regulations. Staff must receive the support, training, professional development, supervision and appraisals that are necessary for them to carry out their role and responsibilities. They should be supported to obtain further qualifications and provide evidence, where required, to the appropriate regulator to show that they meet the professional standards needed to continue to practise.

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offence section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
18(1) Sufficient numbers of suitably qualified, competent, skilled and experienced persons must be deployed in order to meet the requirements of this Part.	• Providers must deploy sufficient numbers of suitably qualified, competent, skilled and experienced staff to make sure that they can meet people's care and treatment needs and therefore meet the requirements of Section 2 of these regulations (the fundamental standards). • Providers should have a systematic approach to determine the number of staff and range of skills required in order to meet the needs of people using the service and keep them safe at all times. The approach they use must reflect current legislation and guidance where it is available. In determining the number of staff and range of skills required to meet people's needs, they should consider the different levels of skills and competence required to meet those needs, the registered professional and support workers needed, supervision needs and leadership requirements. • Staffing levels and skill mix must be reviewed continuously and adapted to respond to the changing needs and circumstances of people using the service. • There should be procedures to follow in an emergency that make sure sufficient and suitable people are deployed to cover both the emergency and the routine work of the service.
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,	• Providers must ensure that they have an induction programme that prepares staff for their role. It is expected that providers that employ healthcare assistants and social care support workers should follow the Care Certificate standards to make sure new staff are supported, skilled and assessed as competent to carry out their roles. • Training, learning and development needs of individual staff members must be carried out at the start of employment and reviewed at appropriate intervals during the course of employment. Staff must be supported to undertake training, learning and development to enable them to fulfil the requirements of their role. • Where appropriate, staff must be supervised until they can demonstrate required/acceptable levels of competence to carry out their role unsupervised. • Staff should receive appropriate ongoing or periodic supervision in their role to make sure competence is maintained. • Staff should be supported to make sure they are can participate in:

	○ Statutory training. ○ Other mandatory training, as defined by the provider for their role. ○ Any additional training identified as necessary to carry out regulated activities as part of their job duties and, in particular, to maintain necessary skills to meet the needs of the people they care for and support. ○ Other learning and development opportunities required to enable them to fulfil their role. This includes first aid training for people working in the adult social care sector. • All learning and development and required training completed should be monitored and appropriate action taken quickly when training requirements are not being met. • Staff should receive regular appraisal of their performance in their role from an appropriately skilled and experienced person and any training, learning and development needs should be identified, planned for and supported. • Health, social and other care professionals must have access to clinical or professional supervision as required, in line with the requirements of the relevant professional regulator.
18(2)(b) be enabled where appropriate to obtain further qualifications appropriate to the work they perform, and	• Providers must support staff to obtain appropriate further qualifications that would enable them to continue to perform their role. • Providers must not act in a way that prevents or limits staff from obtaining further qualifications that are appropriate to their role.
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.	• Where registration with a professional body is a requirement of the role, providers must make sure that staff are able to meet the requirements of the relevant professional regulator throughout their employment, such as requirements for continuing professional development. • Staff should be supported to join Accredited Voluntary Registers if they wish. Providers must have appropriate systems in place to support this, such as revalidation and meeting codes of practice. • Providers must not act in a way that prevents, limits or would result in staff not meeting requirements required by professional regulators.

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 make sure that providers only employ 'fit and proper' staff who are able to provide care and treatment appropriate to their role and to enable them to provide the regulated activity. To meet this regulation, providers must operate robust recruitment procedures, including undertaking any relevant checks. They must have a procedure for ongoing monitoring of staff to make sure they remain able to meet the requirements, and they must have appropriate arrangements in place to deal with staff who are no longer fit to carry out the duties required of them.

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

If CQC considers that a breach of this regulation is also be a breach of another regulation(s) that carries offence clauses, then we can move directly to prosecution without serving a Warning Notice. For example, in situations where the care and treatment is provided without the consent of a person using the service or someone lawfully acting on their behalf, and where it is unsafe, does not meet the person's nutritional needs, results in abuse, or puts the person at risk of abuse.

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
19(1) Persons employed for the purposes of carrying on a regulated activity must–	
19(1)(a) be of good character,	• When assessing whether an applicant is of good character, providers must have robust processes and make every effort to gather all available information to confirm that the person is of good character, and have regard to the matters outlined in Schedule 4, Part 2 of the regulations. It is not possible to outline every character trait that a person should have, but we would expect to see that the processes followed take account of honesty, trust, reliability and respect. • If a provider discovers information that suggests a person is not of good character after they have been employed, they must take appropriate and timely action to meet this regulation. • If a provider considers that an applicant is suitable, despite them having information about anything set out in Schedule 3, the provider's reasons should be recorded for future reference.

19(1)(b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and	• Where a qualification is required for a role, either by law or by a provider, providers should have the means to enable them to check that employees hold the appropriate qualification(s). • Providers must have appropriate processes for assessing and checking that people have the competence, skills and experience required to undertake the role. These processes must be followed in all cases and relevant records kept. • Providers should have systems in place to assess the competence of employees before they work unsupervised in a role. They must provide appropriate direct or indirect supervision until the person is assessed as competent to carry out the role. Competence may include the demonstration of a caring and compassionate approach. It is expected that providers that employ healthcare assistants and social care support workers should follow the Care Certificate standards to assess their competence. • Providers may consider that a person can be engaged 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. This means that they may work for the provider and undergo training at the same time in order to become competent.
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.	• All reasonable steps must be made to make adjustments to enable people to carry out their role. These must be in line with requirements to make reasonable adjustments for employees under the Equality Act 2010. This may include offering alternative roles. • This aspect of the regulation relates to the ability of individuals to carry out their role. This does not mean that people who have a long-term condition or a disability cannot be appointed. • When appointing an employee, providers must have processes for considering their physical and mental health in line with the requirements of the role.
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.	• Providers must have effective recruitment and selection procedures that comply with the requirements of this regulation and ensure that they make appropriate checks for both employees and directors. • Information about candidates set out in Schedule 3 of the regulations must be confirmed before they are employed. • Other checks deemed appropriate by the providers may also be undertaken. • Selection and interview processes should assess the accuracy of applications and be designed to demonstrate candidates' suitability for the role, while meeting the requirements of the Equality Act 2010 in relation to pre-employment health checks. • Recruitment and/or checks on candidates may be carried out by a party other than the provider. In this case, providers must assure themselves that all checks are complete and satisfactory.

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– (a) the work that the person is to perform, or (b) the title that the person takes or uses.	• Providers must have a process to check that staff have appropriate and current registration with a professional regulator or, where applicable, an accredited voluntary register.
19(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.	• Providers must regularly review the fitness of employees. • Providers must follow robust systems to respond to concerns about a person's fitness after they are appointed to a role. This applies whether the concerns are raised by the provider or others. • Providers should respond without delay to concerns about a person's fitness or ability to carry out their duties. This includes responding immediately if there is an imminent risk to people working in and using the service. • The response taken to concerns about a person's fitness should be fair to the person and follow correct procedures. • Where a person's fitness to carry out their role is being investigated, appropriate interim measures must be taken to minimise any risk to people using the service. • Providers must inform others as appropriate about concerns or findings relating to a person's fitness and must support any related enquiries and investigations that others have carried out. They may inform bodies such as professional regulators, police, and safeguarding authorities about concerns.

Regulation 20: Duty of candour

20.— (1) Registered persons 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 registered person 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 registered person,

(b) provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,

(c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate,

(d) include an apology, and

(e) be recorded in a written record which is kept securely by the registered person.

(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 registered person —

(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 registered provider 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" has the meaning given in paragraphs (8) and (9);

"prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"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 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.

(8) In relation to a health service body, "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.

(9) In relation to any other registered person, "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—

(a) appears to have resulted in—

(i.) 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,

(ii.) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,

(iii.) changes to the structure of the service user's body,

(iv.) the service user experiencing prolonged pain or prolonged psychological harm, or

(v.) the shortening of the life expectancy of the service user; or

(b) requires treatment by a health care professional in order to prevent—

(i.) the death of the service user, or

(ii.) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

Summary of the regulation

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

The regulation applies to registered persons when they are carrying on a regulated activity.

CQC can prosecute for a breach of parts 20(2)(a) and 20(3) of this regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

Component of the regulation	Providers must have regard to the following guidance
20(1) Registered persons 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.	• Providers must promote a culture that encourages candour, openness and honesty at all levels. This should be an integral part of a culture of safety that supports organisational and personal learning. There should also be a commitment to being open and transparent at board level or its equivalent, such as a governing body. • Providers should have policies and procedures in place to support a culture of openness and transparency, and ensure that all staff follow them. • Providers should take action to tackle bullying and harassment in relation to duty of candour, and must investigate any instances where a member of staff may have obstructed another in exercising their duty of candour. • Providers should have a system in place to identify and deal with possible breaches of the professional duty of candour by staff who are professionally registered, including the obstruction of another in their professional duty of candour. This is likely to include an investigation and escalation process that may lead to referral to their professional regulator or other relevant body. • Providers should make all reasonable efforts to ensure that staff operating at all levels within the organisation operate within a culture of openness and transparency, understand their individual responsibilities in relation to the duty of candour, and are supported to be open and honest with patients and apologise when things go wrong. • Staff should receive appropriate training, and there should be arrangements in place to support staff who are involved in a notifiable safety incident. • In cases where a provider is made aware that something untoward has happened, they should treat the allegation seriously, immediately consider whether this is a notifiable safety incident and take appropriate action.

20(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must– (a) notify the relevant person that the incident has occurred in accordance with paragraph (3) and **20(3)** The notification to be given under paragraph (2)(a) must– (a) be given in person by one or more representatives of the registered person, (b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification, (c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate, (d) include an apology, and (e) be recorded in a written record which is kept securely by the registered person.	• When a notifiable safety incident has occurred, the relevant person must be informed as soon as reasonably practicable after the incident has been identified. Providers who are subject to the NHS Standard Contract should be aware that the standard contract requires that the notification must be within at most 10 working days of the incident being reported to local systems, and sooner where possible. • All staff working within a provider must have responsibility to adhere to that organisation's policies and procedures around duty of candour, regardless of seniority or permanency. • Regulation 20 defines what constitutes a notifiable safety incident for health service bodies and other providers. It includes incidents that, in the reasonable opinion of a healthcare professional, could result in, or appear to have resulted in, the death of the person using the service or severe harm, moderate harm, or prolonged psychological harm. These terms are defined in the regulation – paragraph 8 for health service bodies and paragraph 9 for other providers (see above). • Where the degree of harm is not yet clear but may fall into the above categories in future, the relevant person must be informed of the notifiable safety incident in line with the requirements of the regulation. • Providers are not required by the regulation to inform a person using the service when a 'near miss' has occurred, and the incident has resulted in no harm to that person. • There must be appropriate arrangements in place to notify the person using the service who is affected by an incident if they are aged 16 and over and lack the mental capacity to make a decision about their care or treatment, including ensuring that a person acting lawfully on their behalf is notified as the relevant person. • A person acting lawfully on behalf of the person using the service must be notified as the relevant person where the person using the service is under 16 and lacks the mental capacity to make a decision regarding their care or treatment. • A person acting lawfully on behalf of the person using the service must be notified as the relevant person, upon the death of the person using the service. • Other than the situations outlined above, information should only be disclosed to family members or carers where the person using the service has given their express or implied consent. • A step-by-step account of all relevant facts known about the incident at the time must be given, in person, by one or more appropriate representatives of the provider. This should include as much or as little information as the relevant person wants to hear, be jargon free and explain any complicated terms.

	• The account of the facts must be given in a manner that the relevant person can understand. For example, providers should consider whether interpreters, advocates, or other communication aids should be used, while being conscious of any potential breaches of confidentiality in doing so. • Providers must also explain to the relevant person what further enquires they will make. • Providers must ensure that one or more appropriate representatives of the provider gives a meaningful apology, in person, to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret. • In making a decision about who is most appropriate to provide the notification and/or apology, the provider should consider seniority, relationship to the person using the service, and experience and expertise in the type of notifiable incident that has occurred.

20(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must–
(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.
	• Providers must give the relevant person all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident. This could include all or some of the following:
	  ○ Treating them with respect, consideration and empathy.
	  ○ Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate.
	  ○ Offering help to understand what is being said, for example, through an interpreter, non-verbal communication aids, written information, Braille etc.
	  ○ Providing access to any necessary treatment and care to recover from or minimise the harm caused where appropriate.
	  ○ Providing the relevant person with details of specialist independent sources of practical advice and support or emotional support/counselling.
	  ○ Providing the relevant person with information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups, for example Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them deal with the outcome of the incident.
	  ○ Arranging for care and treatment from another professional, team or provider if this is possible, if the relevant person wishes.
	  ○ Providing support to access the complaints procedure.

20(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.	• Providers must ensure that they give written notification to the relevant person following the notification that was given in person, even though enquiries may not yet be complete. • The written notification must contain all the information that was provided in person, including an apology, as well as the results of any enquiries that have been made since the notification in person. • The outcomes or results of any further enquiries and investigations must also be provided in writing to the relevant person through further written notifications, if they wish to receive them.
20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person – (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.	• The provider must make every reasonable attempt to contact the relevant person through all available means of communication. All attempts to contact the relevant person must be documented. • If the relevant person does not wish to communicate with the provider, their wishes must be respected and a record of this must be kept. • If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.
20(6) The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).	• Providers must keep a record of the written notification, along with any enquiries and investigations and the outcome or results of the enquiries or investigations. • Any correspondence from the relevant person relating to the incident must be responded to in an appropriate manner and a record of communications should be kept.

Regulation 20A: Requirement as to display of performance assessments

20A.—(1) This regulation applies where, and to the extent that, a service provider has received a rating of its performance by the Commission following an assessment of its performance under section 46(1) of the Act (reviews and performance assessments).[*]

(2) There must be shown on every website maintained by or on behalf of any service provider—

(a) the Commission's website address,

(b) the place on the Commission's website where the most recent assessment of the service provider's overall performance and of its performance in relation to particular premises or activities may be accessed, and

(c) the most recent rating by the Commission of the service provider's overall performance and of its performance in relation to particular premises or activities, in a way which makes it clear to which activities or premises a particular rating relates.

(3) There must be displayed at each premises from which the service provider provides regulated activities at least one sign showing the most recent rating by the Commission that relates to the service provider's performance at those premises.

(4) For the purposes of paragraph (3), where the service provider has not received a rating of its performance at those premises, the rating to be shown is the rating of the service provider's overall performance.

(5) There must be displayed at the service provider's principal place of business at least one sign showing the most recent rating of—

(a) the service provider's overall performance, and

(b) its performance in relation to particular premises or activities, in a way which makes it clear to which activities or premises a particular rating relates.

(6) But paragraph (5) does not apply where the service provider's performance at its principal place of business, or at the premises of which it is part, is itself subject to a separate performance rating given by the Commission (in which case paragraphs (3) and (4) apply).

(7) Any sign displayed, or anything shown on a website, under this regulation must—

(a) be legible,

(b) be displayed conspicuously in a place which is accessible to service users, and

(c) for each rating shown, show the date on which it was given by the Commission.

(8) This regulation does not apply to any premises that are—

(a) the service provider's own home, except where service users have access to it for the purposes of receiving services provided in the carrying on of a regulated activity, or

(b) a service user's accommodation where such accommodation is not provided as part of the service user's care or treatment.

* Section 46 of the 2008 Act was substituted by section 91(2) of the Care Act 2014.

Summary of the regulation

This regulation will apply to all providers when they have received a CQC performance assessment for their regulated activities. Providers must ensure that their rating(s) are displayed conspicuously and legibly at each location delivering a regulated service and on their website (if they have one).

The regulation outlines the information that must be included. CQC will develop posters for providers and digital products to use on websites. Using these will help providers to make sure that they display all the information required under this regulation.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
20A(1) This regulation applies where, and to the extent that, a service provider has received a rating of its performance by the Commission following an assessment of its performance under section 46(1) of the Act (reviews and performance assessments).	• This regulation applies where an organisation has received a CQC rating (outstanding, good, requires improvement or inadequate). This includes those organisations rated before 1 April 2015. In all instances, the most recent CQC rating is the one that should be displayed.
20A(2) There must be shown on every website maintained by or on behalf of any service provider— (a) the Commission's website address, (b) the place on the Commission's website where the most recent assessment of the service provider's overall performance and of its performance in relation to	• Providers must display their ratings on their websites. CQC will provide digital products to enable providers to do this. Using these will ensure that they display all the information required under this regulation. We have published more detailed guidance on what must be displayed on each website.

particular premises or activities may be accessed, (c) the most recent rating by the Commission of the service provider's overall performance and of its performance in relation to particular premises or activities , in a way which makes it clear which activities or premises a particular rating relates to.	
20A(3) There must be displayed at each premises from which the service provider provides regulated activities at least one sign showing the most recent rating by the Commission of the service provider's performance that relates to those premises.	• If a regulated activity is provided at premises, and the service provider has been rated by CQC, then the rating must be displayed. • CQC will develop posters to help providers ensure that all the relevant information is included in an appropriate way. Using these will ensure that providers display all the information required under this regulation. We have published more detailed guidance on what must be displayed in each premises.
20A(7) Any sign displayed, or anything shown on a website, under this regulation must— (b) be displayed conspicuously in a place which is accessible to service users.	• Whether something is conspicuous will depend on the setting. We have therefore published more detailed guidance on where and how to display.

Care Quality Commission

Guidance for providers on meeting:

Care Quality Commission (Registration) Regulations 2009 (Part 4)

To see the full text of the regulations, click on the following links:

Care Quality Commission (Registration) Regulations 2009
http://www.legislation.gov.uk/uksi/2009/3112/contents/made

Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 (Amendment to Parts 4 & 5)
http://www.legislation.gov.uk/uksi/2012/921/contents/made

Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012
http://www.legislation.gov.uk/uksi/2012/1186/contents/made

Where the following regulations refer to making statutory notifications to the Care Quality Commission, please see the further information about this on the Notifications page on our website. There is separate guidance on making statutory notifications for registered providers and managers of: independent healthcare, adult social care, primary dental care and private ambulances, NHS trusts, and GP providers.

Regulation 12: Statement of purpose

12.—(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.

(2) The registered person must keep under review and, where appropriate, revise the statement of purpose.

(3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.

Summary of the regulation

The intention of this regulation is to make sure that providers have produced and sent to CQC a clear statement of all the information listed under Schedule 3.

Providers must notify CQC of any changes to their statement of purpose and ensure it is kept under review, and notify CQC when there are any changes to the information listed in Schedule 3.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
12(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.	• Providers must submit their statement of purpose on first application for registration, together with the registration application form.
12(3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.	• If a provider changes its statement of purpose, it must tell CQC what these changes are within 28 days of making the changes. • If a provider is applying to vary a condition of its registration, it should send CQC a copy of its proposed statement of purpose with its application.

Regulation 13: Financial position

13.—(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity for the purposes of—

(a) achieving the aims and objectives set out in the statement of purpose; and

(b) meeting the registration requirements prescribed pursuant to section 20 of the Act.

(2) This regulation does not apply where the service provider is—

(a) an English local authority; or

(b) a health service body.

Summary of the regulation

The intention of this regulation is to require providers to make sure that they take all reasonable steps to meet the financial demands of providing safe and appropriate services.

To meet this regulation, providers must have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.

CQC cannot prosecute for a breach of this regulation or any of its parts but we can take regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
13.(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity for the purposes of—	
13(1)(a) achieving the aims and objectives set out in the statement of purpose;	• The provider must have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards. • The provider must have insurance and suitable indemnity arrangements to cover potential liabilities arising from death, injury, or other causes, loss or damage to property, and other financial risks.

Regulation 14: Notice of absence

14.—(1) Subject to paragraphs (7) and (8), where—

(a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or

(b) the registered manager,

proposes to be absent from carrying on or managing the regulated activity for a continuous period of 28 days or more, the registered person must give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than 28 days before the proposed absence commences or within such shorter period as may be agreed with the Commission and must contain the following information in relation to the proposed absence—

(a) its length or expected length;

(b) the reason for it;

(c) the arrangements which have been made for the management of the carrying on of the regulated activity during the period of absence;

(d) the name, address and qualifications of the person who will be responsible for the management of the carrying on of the regulated activity during that absence;

(e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the carrying on of the regulated activity during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence referred to in paragraph (1) arises as the result of an emergency, the registered person must give notice of the absence to the Commission within 5 working days of its occurrence specifying the matters set out in paragraph (2)(a) to (e).

(4) Where—

(a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or

(b) the registered manager

has been absent for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall forthwith give notice in writing to the Commission specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person must notify the Commission of the return to duty of the service provider or (as the case may be) the registered manager not later than 7 working days after the date of that return.

(6) In this regulation "working day" means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday in England and Wales within the meaning of the Banking and Financial Dealings Act 1971.

(7) Subject to paragraph (8), this regulation does not apply where the service provider is a health service body.

(8) Where the service provider is a health service body and is subject to a registered manager condition pursuant to regulation 5 or section 12(3) or (5) of the Act, this regulation shall have effect in relation any absence, proposed absence or return to duty of that registered manager.

Summary of the regulation

The intention of this regulation is that CQC can be assured that the service will continue to be properly managed if the person in charge of their service is absent.

To meet the requirements of this regulation, the provider must inform CQC about any planned or unplanned absences from the service that are for a continuous period of 28 days or more, how the service will be run while they are away and when they return from a significant absence.

Providers must use forms provided by CQC to make notifications under this regulation. Further information about how to make any required notification to CQC can be found on CQC's website.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

There is no further guidance for this regulation.

Regulation 15: Notice of changes

15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—

(a) a person other than the registered person carries on or manages the regulated activity;

(b) a registered person ceases to carry on or manage the regulated activity;

(c) the name of a registered person (where that person is an individual) changes;

(d) where the service provider is a partnership, any change in the membership of the partnership;

(e) where the service provider is a body other than a partnership—

(i.) a change in the name or address of the body,

(ii.) a change of director, secretary or other similar officer of the body, or

(iii.) a change of nominated individual;

(f) where the service provider is—

(i.) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or

(ii.) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.

(2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.

(3) In this regulation, "nominated individual" means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Summary of the regulation

The intention of this regulation is to ensure that CQC is notified of specific changes in the running of the service, so that CQC can be assured that the provider has taken appropriate action.

The provider must inform CQC when:

- The person who manages or carries on the service changes.
- There is a change to the registered details of the service and any individual, partnership or organisation who manage or carry it on.

- The registered person becomes financially insolvent.
- The service closes.

Providers must use forms provided by CQC to make notifications under this regulation. Further information about how to make any required notification to CQC can be found on CQC's website.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

There is no further guidance for this regulation.

Regulation 16: Notification of death of service user

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

(a) whilst services were being provided in the carrying on of a regulated activity; or

(b) which has, or may have, resulted from the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, a local authority exercising public health functions (within the meaning of the National Health Service Act 2006) or a provider of primary medical services, the registered person must notify the Commission without delay of the death of a service user where the death—

(a) either—

(i) occurred whilst services were being provided in the carrying on of a regulated activity,

(ii) has, or may have, resulted from the provision of services by a health service body, or local authority exercising public health functions (within the meaning of the National Health Service Act 2006), in the course of carrying on a regulated activity, or

(iii) has, or may have, resulted from the provision of primary medical services in the course of carrying on a regulated activity and those services were provided within the period of two weeks prior to the death of the service user; and

(b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care and treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Health Service Commissioning Board (now known as NHS England).

(a) for the purposes of paragraph (4), where a person has reported a death to the NHS Commissioning Board Authority (now known as NHS England), established under Article 2 of the NHS Commissioning Board Authority (Establishment and Constitution) Order 2011, before the establishing of the National Health Service Commissioning Board ("the Board"), that report is to be treated as having been made to the board.

(5) This regulation does not apply where regulation 17 applies.

(6) In paragraph (2), "provider of primary medical services" means a person who provides primary medical services pursuant to one of the following sections of the National Health Service Act 2006(b)–

(a) section 3A (Secretary of State's duty as to provision of certain services),

(b) section 83(2)(b) (primary medical services),

(c) section 84 (general medical services contracts),

(d) section 92 (arrangements for the provision of primary medical services), and provision of primary medical services shall be construed accordingly.

Summary of the regulation

The intention of this regulation is to ensure that CQC is notified of the deaths of people who use services so that where needed, CQC can take follow-up action.

Notifications include those deaths that:

- Occurred while services were being provided in the carrying on of a regulated activity, or
- Have, or may have, resulted from the carrying on of a regulated activity.

Notifications about deaths must be sent to CQC without delay. All providers must send their notifications directly to CQC unless the provider is a health service body, local authority or provider of primary medical services and it has previously notified the NHS Commissioning Board Authority (now known as NHS England) of the death.

Providers must use forms provided by CQC to make notifications under this regulation. Further information about how to make any required notification to CQC can be found on CQC's website.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
16(5) This regulation does not apply where regulation 17 applies.	• A notification is not required under this regulation where the notification relates to the death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983.

Regulation 17: Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

17.—(1) The registered person must notify the Commission without delay of the death in any location or unauthorised absence from a relevant location of a service user who is liable to be detained by the registered person—

(a) under the Mental Health Act 1983 ("the 1983 Act"); or

(b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) Notification of the death of a service user must include a description of the circumstances of the death.

(2A) The registered person must notify the Commission without delay of the return to a relevant location after a period of unauthorised absence of a service user whose absence is required to be notified under paragraph (1).

(3) In this regulation—

(a) references to persons "liable to be detained" include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;

(b) "community patient" has the same meaning as in section 17A of the 1983 Act;

(c) "hospital" means a hospital within the meaning of Part 2 of that Act; and

(ca) "relevant location" means a location used to provide secure psychiatric services under a contract with an English NHS body(1) or the Secretary of State.

Summary of the regulation

The intention of this regulation is to ensure that CQC is notified of the death or unauthorised absence of a person in any location who is liable to be detained under the Mental Health Act 1983 so that where needed, CQC can take follow-up action.

Notifications about deaths must be sent to CQC without delay. All providers must send their notifications directly to CQC unless the provider is a health service body, local authority or provider of primary medical services and it has previously notified the NHS Commissioning Board Authority (NHS England) of the death.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
17(1) The registered person must notify the Commission without delay of the death in any location or unauthorised absence from a relevant location of a service user who is liable to be detained by the registered person— (a) under the Mental Health Act 1983 ("the 1983 Act"); or (b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.	• Unauthorised absences of a person liable to be detained under the Mental Health Act 1983 become notifiable when the person is still absent after midnight on the day their absence began.

Regulation 18: Notification of other incidents

18.— (1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

(a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—

(i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,

(ii) changes to the structure of a service user's body,

(iii) the service user experiencing prolonged pain or prolonged psychological harm, or

(iv) the shortening of the life expectancy of the service user;

(b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—

(i) the death of the service user, or

(ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);

(c) [omitted]

(d) [omitted]

(e) any abuse or allegation of abuse in relation to a service user;

(f) any incident which is reported to, or investigated by, the police;

(g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—

(i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,

(ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,

(iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and

(iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours;

(h) any placement of a service-user under the age of eighteen in a psychiatric unit whose services are intended for persons over that age where that

placement has lasted for longer than a continuous period of 48 hours.

(3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.

(4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to [the National Health Service Commissioning Board].

[(4ZA) For the purposes of paragraph (4), where a person has reported an incident to the NHS Commissioning Board Authority, established under Article 2 of the NHS Commissioning Board Authority (Establishment and Constitution) Order 2011, before the establishment of the National Health Service Commissioning Board ("the Board"), that report is to be treated as having been made to the Board.]

[(4A) The registered person must notify the Commission of the following events, which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity—

(a) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation:

(b) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act.

(4B) Any notification required to be given in respect of an event in paragraph (4A) shall be given once the outcome of the request or application is known or, if the request or application is withdrawn, at the point of withdrawal and shall include a statement as to—

(a) the date and nature of the request or application;

(b) whether the request or application was preceded by the use of an urgent authorisation, within the meaning of paragraph 9 of Schedule A1 to the 2005 Act;

(c) the outcome of the request or application or reason for its withdrawal; and

(d) the date of the outcome or withdrawal.

(5) In this regulation—

(a) "the 2005 Act" means the Mental Capacity Act 2005;

(b) "abuse", in relation to a service user, means—

(i) sexual abuse,

(ii) physical or psychological ill-treatment,

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

(iv) neglect and acts of omission which cause harm or place at risk of harm;

(c) "health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies;

(d) "registration requirements" means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;

(e) "standard authorisation" has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(f) "supervisory body" has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;

(g) for the purposes of paragraph (2)(a)—

(i) "prolonged pain" and "prolonged psychological harm" means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and

(ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

Summary of the regulation

The intention of this regulation is to specify a range of events or occurrences that must be notified to CQC so that where needed, CQC can take follow-up action.

Providers must notify CQC of all incidents that affect the health, safety and welfare of people who use services. The full list of incidents is in the text of the regulation.

All providers must send their notifications directly to CQC unless the provider is a health service body, local authority or provider of primary medical services and it has previously notified the NHS Commissioning Board Authority (now known as NHS England).

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take any other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
18(2) The incidents referred to in paragraph (1) are— (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in— (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,	• Injuries include those that lead to or that, if untreated, are likely to lead to permanent damage, or damage that lasts, or is likely to last, more than 28 days, to: ○ A person's sight, hearing, touch, smell or taste. ○ Any major organ of the body (including the brain and skin). ○ Bones. ○ Muscles, tendons, joints or vessels. ○ The development after admission of a pressure sore of grade 3 or above, which develops after the person has started to use the service.

(ii) changes to the structure of a service user's body, (iii) the service user experiencing prolonged pain or prolonged psychological harm, or (iv) the shortening of the life expectancy of the service user; (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent— (i) the death of the service user, or (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);	○ Any injury or other event that causes a person pain lasting, or likely to last, for more than 28 days. ○ Intellectual functions, such as: - Intelligence. - Speech. - Thinking. - Remembering. - Making judgements. - Solving problems. • Injuries or events leading to psychological harm, including: ○ Post traumatic stress disorder. ○ Other stress that requires clinical treatment or support. ○ Psychosis. ○ Clinical depression. ○ Clinical anxiety. These lists are not exhaustive.

Regulation 19: Fees

19.— (1) Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user's behalf—

(a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and

(b) including, where applicable, the form of contract for the provision of services by the service provider.

(2) The statement referred to in paragraph (1) must be—

(a) in writing; and

(b) as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

Summary of the regulation

The intention of this regulation is to make sure that providers give timely and accurate information about the cost of their care and treatment to people who use services.

To meet this regulation, providers must make written information available about any fees, contracts and terms and conditions, where people are paying either in full or in part for the cost of their care, treatment and support.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation. This means that CQC can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the offences section on pages 10-11 of this guidance for more detail.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Component of the regulation	Providers must have regard to the following guidance
19(1) Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user's behalf—	
19(1)(a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and	• Providers must give people information about the terms and conditions of their care, treatment or support, including the expected costs and the requirement to pay for their care, treatment and support. This applies to people who pay the provider in full or partially. • Providers must notify people of any changes to their terms and conditions including increases in fees and give them sufficient time to consider whether they wish to continue with the service. • People must be told how they can make payments. • People should be given reasonable notice of when payments are due so they have the opportunity to arrange payment without incurring penalties or late payment fees.
19(1)(b) including, where applicable, the form of contract for the provision of services by the service provider.	• Providers must make sure that they give a copy of any contract detailing the service to be provided to the person using the service and/or the person lawfully acting on their behalf.
19(2) The statement referred to in paragraph (1) must be—	
19(2)(a) in writing; and **19(2)(b)** as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.	• People must be given a written copy of the terms and conditions that they must agree to before their care, treatment or support begins. • Providers must give people using the service information about the costs, terms and conditions of the service, so that they can make decisions about their care, treatment or support. • Providers must give people a written estimate of the costs of the care, treatment or support if a fixed price cannot be given. This should include details of any likely additional costs.

Regulation 20: Requirements relating to termination of pregnancies

20. — (1) This regulation applies to a registered person who—
(a) carries on or manages the regulated activity consisting of the termination of pregnancies; and
(b) is not an English NHS body.
(2) The registered person must ensure that, unless two certificates of opinion have been received in respect of the service user—
(a) no termination of pregnancy is carried out; and
(b) no fee is demanded or accepted from a service user.
(3) The registered person must ensure that a certificate of opinion in respect of a service user undergoing termination of a pregnancy is completed and included with the service user's medical record.
(4) The registered person must ensure that no termination of pregnancy is undertaken after the 20th week of gestation, unless—
(a) the service user is treated by persons who are suitably qualified, skilled and experienced in the late termination of pregnancy; and
(b) appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.
(5) The registered person must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.
(6) The registered person must ensure that a register of service users undergoing a termination of pregnancy is maintained, which is—
(a) completed in respect of each service user at the time the termination is undertaken; and
(b) retained for a period of not less than 3 years beginning on the date of the last entry.
(7) The registered person must ensure that a record is maintained of the total numbers of terminations of pregnancies undertaken.
(8) The registered person must ensure that the record referred to in paragraph (7) (which may be in paper or electronic form) is—
(a) accurate;
(b) kept securely and can be located promptly when required;
(c) retained for an appropriate period of time; and
(d) securely destroyed when it is appropriate to do so.
(9) The registered person must ensure that notice in writing is sent to the Chief Medical Officer of the Department of Health of each termination of pregnancy.
(10) If the registered person—
(a) receives information concerning the death of a service user who has undergone termination of a pregnancy during the period of 12 months ending on the date on which the information is received; and
(b) has reason to believe that the service user's death may be associated with the termination, the registered person must give notice in writing to the Commission of that information, within the period of 14 days beginning on the day on which the information is received.
(11) The registered person must prepare and implement appropriate procedures to ensure that foetal tissue is treated with respect.
(12) In this regulation, "certificate of opinion" means a certificate required by regulations made under section 2(1) of the Abortion Act 1967.

Summary of the regulation

This regulation applies only to registered persons who carry on or manage the regulated activity of termination of pregnancies and are not an English NHS body. To meet this regulation the provider must follow the requirements of the regulation and the procedures and guidance issued by the Department of Health in May 2014 which are:

- Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy (Abortion).
- Guidance in Relation to Requirements of the Abortion Act 1967

The Department of Health's guidance takes account of legal requirements and best practice in relation to termination of pregnancy. We have not provided further guidance in this document as it is either self-explanatory in the regulation or is addressed in the Department of Health's guidance. See the offences section on pages 10-11 of this guidance for more detail about regulatory action CQC can take.

CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

Note: Termination of pregnancy deaths are notified under this regulation rather than under Regulation 16.

Regulation 22A: Form of notifications to the Commission

22A Notifications made pursuant to regulations 14 to 18 and 21 and 22 must be made using the forms provided by the Commission for this purpose.

Where these regulations refer to making statutory notifications to the Care Quality Commission, please see the further information about this on the Notifications page on our website. There is separate guidance on making statutory notifications for registered providers and managers of: independent healthcare, adult social care, primary dental care and private ambulances, NHS trusts, and GP providers.