Regulations for service providers and managers

This guidance describes how providers and managers can meet the regulations. These include the fundamental standards – the standards below which care must never fall.

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

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

Regulation 8: General

Regulation 9: Person-centred care

Regulation 9A: Visiting and accompanying in care homes, hospitals and hospices

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

Care Quality Commission (Registration) Regulations

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 21: Death of a service provider

Regulation 22A: Form of notifications to the Commission

Related information

Enforcement

Offences

Regulations on legislation.gov.uk

Each set of regulations listed here is set out in its original wording. The amendments to the regulations are also listed here.

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

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021

Care Quality Commission (Registration) Regulations 2009

Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 (Amendment to Parts 4 & 5)

Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012

Introduction

This guidance was first published on 1 April 2015. It 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)

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. See the 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 a dental care provider we would not assess Regulation 14: Meeting nutrition and hydration needs, as they would not apply to these types of regulated activity.

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 that registered persons must meet, 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.

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 chosen 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 in which providers can show that they meet each component of the regulation.

The following pages provide information that supports the guidance.

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

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 and Social Care, National Institute for Health and Care Excellence, UK Health Security Agency, the former National Patient Safety Agency, NHS England, Skills for Health, Skills for Care and relevant clinical and professional bodies. This section 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 points to 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.

Glossary of terms used in the guidance.

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

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)

(See note 1)

These regulations introduced 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 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.

Part 3 of these regulations has two sections: Section 1 describes the **requirements relating to persons carrying on or managing a regulated activity**. Section 2 includes the **fundamental standards**, which came into force for all health and adult social care services on 1 April 2015.

The requirements in Section 1 (relating to persons carrying on or managing a regulated activity) include a regulation about fit and proper person requirements for directors (Regulation 5). This regulation was 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.

The requirements in Section 2 (fundamental standards) include a statutory duty of candour (Regulation 20) and a requirement for providers to display their CQC rating (Regulation 20A). (see note 2)

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.

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

(See note 3)

The Care Quality Commission (Registration) Regulations 2009 set out requirements that providers must have regard to in relation to their registration, including their financial position, fees, statement of purpose, the circumstances when the need to make notifications to CQC and requirements in relation to termination of pregnancies.

Notes

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

3. 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.

Health and Social Care Act 2008 (Regulated Activities) Regulations

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

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

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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 4

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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;

Guidance on 4(4)(a)

- 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

Guidance on 4(4)(b)

- 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.

Guidance on 4(5)

- 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

Guidance on 4(6)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 5

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 of this guidance for more detail.

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 5(1)

- 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.

Guidance on 5(2)

- 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

Guidance on 5(3)(a)

- 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,

Guidance on 5(3)(b)

- 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,

Guidance on 5(3)(c)

- 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

Guidance on 5(3)(d)

- 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.

Guidance on 5(3)(e)

- 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.

Guidance on 5(6)

- 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.

Related guidance

DBS checks and the fit and proper person requirement: frequently asked questions
DBS checks and the fit and proper person requirement: frequently asked questions
File title
DBS checks and the fit and proper person requirement: frequently asked questions
Keywords
DBS
disclosure
barring
fit and proper
fppr
Audience
Organisations we regulate
Copyright Holder
Care Quality Commission
Teaser

Read our FAQ document to find out more about Disclosure and Barring Service checks and the fit and proper person requirement for directors.
Publisher
Care Quality Commission
Legacy file_id
285450

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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 6

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 for more detail.

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

The regulation in full

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

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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;

Guidance on 6(3)(a)

- 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,

Guidance on 6(3)(b)

- The nominated individual should be appropriately skilled with the necessary qualification(s), knowledge and experience, and demonstrates 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, and

Guidance on 6(3)(c)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 7

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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;

Guidance on 7(2)(a)

- 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,

Guidance on 7(2)(b)

- 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.

Guidance on 7(2)(c)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 8

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.

The regulation in full

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.

Regulation 9: Person-centred care

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 9

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 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

9(1) The care and treatment of service users must – (a) be appropriate, (b) meet their needs and (c) reflect their preferences

Guidance on 9(1)

- 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.

Guidance on 9(2)

- 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;

Guidance on 9(3)(a)

- 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

Guidance on 9(3)(b)

- 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 not 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 not 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 not 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;

Guidance on 9(3)(c)

- 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;

Guidance on 9(3)(d)

- 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;

Guidance on 9(3)(e)

- 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;

Guidance on 9(3)(f)

- 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);

Guidance on 9(3)(g)

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

Guidance on 9(3)(i)

- 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 9A: Visiting and accompanying in care homes, hospitals and hospices

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 9A

This regulation aims to make sure:

- people staying in a care home, hospital or hospice can receive visits from people they want to see
- people living in a care home are not discouraged from taking visits outside the home
- people attending appointments in a hospital or hospice, that do not require an overnight stay, can be accompanied by a family member, friend or advocate if they want someone with them.

The regulation explains what providers must do to make sure they respect the right of each person to receive visits and to be accompanied, following an assessment of their needs and preferences.

Everyone should work on the assumption that in-person visiting and accompaniment to appointments are possible. Providers must put in place any measures or precautions necessary and proportionate to ensure that visiting and accompaniment can continue to happen safely. These must be the least restrictive options and must be decided with the person using the service, and their family, friends or advocates where appropriate. The provider must help people to understand their options and make informed decisions, making reasonable adjustments where necessary. The provider, in partnership with people involved in the decision, should regularly review any precautions that have been implemented and should remove them as soon as possible. It is important that information is communicated clearly to the person using the service and those restricted from visiting throughout the process. The provider should also be clear with those involved who they can contact within the service if they have questions or concerns about any restrictions in place.

Very occasionally, there may be exceptional circumstances where, despite any precautions put in place, a visit or accompaniment may still pose a significant risk to the health, safety or welfare of a person using the service or on the premises. This risk will mean that, despite considering all possible actions and precautions, an in-person visit or accompaniment cannot be safely facilitated and there is no alternative but to restrict visiting or accompaniment at that time. If this is the case, the provider should put in place the necessary restriction and review arrangements regularly. As soon as circumstances change, the provider should remove the restriction and allow in-person visiting or accompaniment again.

A human rights-based approach to decision making can support providers in enabling visiting and accompaniment and when considering restrictions in complex situations. This includes considering the appropriate balance between a person's right to private and family life, independence, choice and control, risk and safety. Providers must consider whether restrictions are lawful, legitimate and proportionate.

Providers must make sure they take people's mental capacity into account. They must make sure that either the person, or someone lawfully acting on their behalf, is involved in planning, managing and reviewing their care and treatment. This includes their right to having visitors and being accompanied to appointments. Providers must make sure decisions are made by those with the legal authority or responsibility to do so. They must work within the requirements of the Mental Capacity Act 2005. The Act includes a duty to consult others, such as families, unpaid carers and advocates, where practicable and appropriate.

Providers must also work within the requirements of the Human Rights Act 1998 and the Equality Act 2010, including the Public Sector Equality Duty, where applicable, and make reasonable adjustments.

See the glossary for clarification of the terms 'needs' and 'preferences'.

CQC cannot prosecute for a breach of this regulation or any of its parts, but we can take regulatory action, including civil enforcement action where this is appropriate.

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

Registered persons maintain overall responsibility for ensuring that all regulations are met.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

9A(1) This regulation applies to a registered person in respect of a relevant regulated activity carried on in a care home, hospital or hospice.

Guidance on 9A(1)

Regulation 9A(6)(a) defines 'regulated activity' for these purposes as **all regulated activities except**:

- personal care
- accommodation for persons who require treatment for substance misuse, and any detoxification services for substance misuse
- management of supply of blood and blood derived products
- transport services, triage and medical advice provided remotely

This regulation does not apply to anyone who is detained in a prison or similar institution to which the Prison Act applies. This regulation also does not apply to anyone detained under the Immigration Acts. However, the requirements of this regulation do apply if someone detained in a prison or under the Immigration Acts is transferred to hospital and detained in that hospital under the Mental Health Act 1983.

'Care home' and 'hospice' are as defined in Regulation 9A(6). Hospital is defined in Regulation 2.

9A(2) Unless there are exceptional circumstances, service users—

(a) whose care or treatment involves an overnight stay or the provision of accommodation in a care home, hospital or hospice, must be facilitated to receive visits at those premises;

(b) who are provided with accommodation in a care home, must not be discouraged from taking visits out of that care home;

(c) who attend a hospital or hospice for the provision of care or treatment which does not involve an overnight stay, must be enabled to be accompanied at those premises by a family member, friend or a person who is otherwise providing support to the service user.

Guidance on 9A(2)(a)

- Providers must support people who use their service to receive visits in person from people they want to see, when they want to see them, unless there are exceptional circumstances that prevent this from being possible. Staff should do all they can to make this possible and easy to arrange. This might look different for different people using different types of service, and providers may need to consider different issues depending on their individual situation and environment. This is why individual risk assessments are important.

Guidance on 9A(2)(b)

- This part of the regulation aims to support people's social contact, to maintain community connections and help them have different experiences.
- Providers must not discourage visits out of the care home or impose unreasonable rules that could effectively act as a restriction when people return after leaving the care home premises for any reason, unless there are exceptional circumstances. For example, unreasonably long periods of isolation which may discourage a resident from deciding to go out.
- Providers should not make the process for taking a visit out difficult by, for example, requiring people to complete lengthy administrative processes before and after visits out.

- Providers should monitor and review visiting policies/arrangements to ensure they are working well for everyone.
- If providers already have contractual arrangements that involve paying for additional staff to support care home residents to go out, this regulation does not change these arrangements.
- Discussions and decisions about visits out should be supported by individual risk assessments and good care planning. This regulation is not about the provider resourcing visits out but ensuring these discussions and decisions do not inhibit or discourage people from going out with their family, friends or advocates.

Guidance on 9A(2)(c)

- If someone attends a hospital or hospice for care or treatment that does not need them to stay in overnight, that service must let the person bring someone with them to those premises and support them. This includes day care treatment and outpatient appointments. This is so people do not have to attend the appointment alone and can help them feel more comfortable and safer when they attend their appointment. It may also help with communication and sharing information where this might otherwise be difficult.
- This regulation does not create any new requirements on transport or other services to physically take friends, family or advocates to an appointment with the person, over or beyond arrangements that may already be in place.

Guidance on 9A(2)(a)(b)(c)

- Providers must (unless there are exceptional circumstances):
    - support people using their service to receive visits
    - not discourage people from taking visits outside the care home
    - support people using their service to be accompanied at the premises when attending appointments.
- 'Visit' means seeing someone in person. The provider should assume visits and accompaniment are possible unless they are confident there are exceptional circumstances. Where a risk has been identified we expect providers to implement appropriate precautions to enable a visit to happen safely, rather than prevent visiting altogether. For example, this may include a visit where the visitors wear a face mask if there is a significant risk of infection.
- If providers are considering taking any precautions or making restrictions to visiting or accompaniment they should continue to apply human rights-based decision making and risk assessment to the individual situation. This should always follow the preferences of the person using the service, wherever possible, and their assessed needs. Providers must consider that any restriction to a person's right to receive visitors is lawful, has a legitimate aim and is proportionate. Proportionate means that there is the least restriction possible to achieve the aim.
- Providers must work in partnership with the person using the service, and should involve those who wish to visit or accompany them, to determine if there is an exceptional circumstance that justifies restricting visiting, discouraging visits out, or restricting accompaniment to an appointment. This could be to protect the person using the service, other people using the service, staff or people visiting, where there is a significant risk to their health, safety or welfare.

- When determining whether there are exceptional circumstances, providers should base their assessment on the health, safety and welfare of people using the service or other people involved. This should include giving consideration to the appropriate balance of a person's rights, the needs of people using their service and any identified risks, including the risk to the person's health and wellbeing resulting from restricting visiting.
- If there is a need for additional precautions or a restriction to be put in place, the provider should apply the most proportionate and least restrictive option. This should be the option least likely to interfere with the person's right to see their visitors when and how they want. For example, if there is a legitimate reason for restricting visits in person because of a significant risk to people's health, safety or welfare, providers should consider ways to mitigate those risks. This could be by implementing additional health and safety measures, or using technology such as video or phone calls to maintain contact until visits in person can be resumed. Options such as these should not be used as alternatives to in-person visiting, where the person wants in-person visits.
- Providers should consider every individual decision as a separate case. Providers should not apply blanket decisions or long-term restrictions. They should review decisions to restrict visiting regularly by working together with the people involved. They should also review these decisions when the circumstances change.

- Providers must keep a record of any assessment and decisions on visiting. They should be able to demonstrate:
    - what are the stated preferences of the person
    - how they have made these decisions and who has been involved
    - how the balance of the person's rights has been considered
    - whether restrictions are lawful, legitimate and proportionate
    - whether they have implemented any mitigations to make sure they have used the least restrictive, most reasonable option when they have reviewed the restrictions.
- As part of this, providers should consider any requirements under Regulation 17: Good governance.

- Providers should always support visits in person to someone who is receiving care at the end of their life. This applies to all types of premises covered by this regulation, including care homes, hospitals and hospices. This guidance is based on the NHS definition of 'end of life care'. "People are considered to be approaching the end of life when they are likely to die within the next 12 months, although this is not always possible to predict. This includes people whose death is imminent, as well as people who:
    - have an advanced incurable condition, such as cancer, dementia or motor neurone disease
    - are generally frail and have co-existing conditions that mean they are expected to die within 12 months
    - have existing conditions if they are at risk of dying from a sudden crisis in their condition
    - have a life-threatening acute condition caused by a sudden catastrophic event, such as an accident or stroke."

9A(3) Without limiting paragraph (2), the things which a registered person must do to comply with that paragraph include—

(a) in relation to paragraph (2)(a), securing that service users are facilitated to receive visits in a way that is appropriate, meets the service user's needs and, so far as reasonably practicable, reflects their preferences;

(b) in relation to paragraph (2)(a) and (c), taking such action, or putting in place such precautions, as is necessary and proportionate to ensure that service users may receive visits or be accompanied safely;

(c) securing that, when making arrangements or decisions in respect of a service user for the purposes of paragraph (2), regard is given to any care or treatment plan for the service user;

(d) involving relevant persons when making any arrangements or decisions in respect of a service user for the purposes of paragraph (2).

Guidance on 9A(3)(a)

- Providers should enable a person using their service to receive visitors in a way that meets their preferences, so far as reasonably practicable.

Guidance on 9A(3)(b)

- Providers must put in place any measures or precautions necessary and proportionate to ensure that visiting and accompaniment can continue to happen safely.

Guidance on 9A(3)(c)

- Any existing care or treatment plans should be considered when making an assessment or decision about visits or accompaniment to appointments.

Guidance on 9A(3)(d)

- If providers cannot meet the person's preferences for a visit, they should consult with the person and their family, friends or advocates and offer them as many options as possible. This is so the person can have as much control as possible over the arrangements.

9A(4) Nothing in this regulation—

(a) requires a service user to receive a visit, take a visit out of a care home or be accompanied—

(i) without the relevant person's consent, or

(ii) where the service user lacks the capacity to give consent, where it would not be in the service user's best interests;

(b) requires or enables a registered person to do anything which would not be in accordance with any court or tribunal order or with any provision (including any direction, power or authorisation) contained in, or made by virtue of, any of the legislation listed in paragraph (5) (including by virtue of any instrument made under that legislation).

Guidance on 9A(4)

- Providers should take all reasonable steps to support people using their service to receive visits, go on visits or to be accompanied when attending appointments that do not require an overnight stay, unless this is against the person's wishes or, if they lack mental capacity to make the relevant decision, it is not in their best interests.
- There may be times when the wishes of the person with the relevant capacity using the service are not the same as those of people who want to visit them. In those circumstances, providers should always give priority to the wishes of people using their service.
- Where a person lacks the relevant capacity, it is important to be aware of legal considerations for that particular circumstance and it may be appropriate to take legal advice. Providers registered with CQC should also be mindful of any considerations under Regulation 11: need for consent

9A(5) The legislation referred to in paragraph (4) is -

(a) the 1983 Act;

(b) the 2005 Act;

(c) so far as relating to high security psychiatric services, the 2006 Act.

Guidance on 9A(5)

- (a) is the Mental Health Act 1983
- (b) is the Mental Capacity Act 2005
- (c) is the National Health Services Act 2006

9A(6)

(a) In this regulation—

"care home" has the meaning given in section 3 (care homes in England) of the Care Standards Act 2000

"hospice" means an establishment other than a hospital whose primary function is the provision of palliative care to persons who attend or are resident there, who are suffering from a progressive disease in its final stages;

"relevant regulated activity" means an activity prescribed in regulation 3 as a regulated activity for the purposes of section 8(1) of the Act, except it does not include -

(i) the regulated activities in paragraphs 1, 3, 8 and 9 of Schedule 1

(ii) any detoxification services for substance misuse provided in the course of carrying on a regulated activity;

(iii) any services provided to a service user (other than a service user who is in receipt of services provided in the carrying on of a regulated activity in paragraph 5 of Schedule 1) who -

(aa) is, or is required to be, detained in a prison or other institution to which the Prison Act 1952 applies,

(bb) is detained under the Immigration Acts,

(cc) is required to be detained in a prison or other institution to which equivalent legislation to that referred to in sub-paragraph (aa) applies in Scotland and Northern Ireland;

"visit", (except in the context of the taking of a visit out of a care home), means a visit from—

(i) a family member of the service user,

(ii) a friend of the service user,

(iii) a person visiting to provide support or companionship to the service user;

(b) in the definition of 'relevant regulated activity' in sub-paragraph (a), "prison" has the same meaning as in section 53(1) of the Prison Act 1952;

(c) a reference to having or lacking capacity, or to a person's best interests, in this regulation is to be interpreted in accordance with the 2005 Act.

Regulation 10: Dignity and respect

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 10

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 10(1)

- 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/sex
- 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—

Guidance on 10(2)

- 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;

Guidance on 10(2)(a)

- 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;

Guidance on 10(2)(b)

- 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 **.**

Guidance on 10(2)(c)

- 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, sex, 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11

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 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 for more detail.

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

The regulation in full

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

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

11(1) Care and treatment of service users must only be provided with the consent of the relevant person.

Guidance on 11(1)

- 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).

Guidance on 11(2), 11(3), 11(4) and 11(5)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12

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 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.

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 12(1)

- 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;

Guidance on 12(2)(a)

- 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;

Guidance on 12(2)(b)

- 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;

Guidance on 12(2)(c)

- 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;

Guidance on 12(2)(d) and 12(2)(e)

- 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;

Guidance on 12(2)(f)

- 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;

Guidance on 12(2)(g)

- 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;

Guidance on 12(2)(h)

- 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.

Guidance on 12(2)(i)

- 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 the legislation page for link to the Civil Contingencies Act 2004).

Regulation 13: Safeguarding service users from abuse and improper treatment

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 13

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

13.—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.

Guidance on 13.—(1)

- 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.

Guidance on 13(2)

- 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.

Guidance on 13(3)

- 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–

Guidance on 13(4)

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; 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

Guidance on 13(4)(c)

- 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.

Guidance on 13(4)(d)

- 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.

Guidance on 13(5)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 14

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 for more detail.

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

The regulation in full

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—
    a. result in a breach of regulation 11, or
    b. not be in the service user's best interests.
4. For the purposes of paragraph (1), "nutritional and hydration needs" means—
    a. receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,
    b. receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,
    c. the meeting of any reasonable requirements of a service user for food and hydration arising from the service user's preferences or their religious or cultural background, and
    d. if necessary, support for a service user to eat or drink.

5. Section 4 of the 2005 Act (best interests) applies for the purposes of determining the best interests of a service user who is 16 or over under this regulation as it applies for the purposes of that Act.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 14(1)

- 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.

Guidance on 14(2)

- 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

Guidance on 14(3)

- 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,

Guidance on 14(4)(a)

- 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,

Guidance on 14(4)(b)

- 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

Guidance on 14(4)(c)

- 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

Guidance on 14(4)(d)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15

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 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.

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

15(1)(a) clean,

Guidance on 15(1)(a)

- 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,

Guidance on 15(1)(b)

- 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,

Guidance on 15(1)(c)

- 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

Guidance on 15(1)(d) and 15(1)(e)

- Providers must make sure that they meet the requirements of relevant legislation so that premises and equipment are properly used and maintained. See the 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.

Guidance on 15(1)(f)

- 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.

Guidance on 15(2)

- Providers must comply with guidance from the Department of Health about the prevention and control of infections: *Health and Social Care Act 2008:* The 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 16

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 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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.

Guidance on 16(1)

- 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.
- Providers that do not have independent review stages should regularly review their complaints resolution processes to ensure they are not disadvantaging complainants as a consequence.
- 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.

Guidance on 16(2)

- 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. This includes considering whether the process needs to be revised, including adding an independent review stage if it is not part of the existing process.

- 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.

Guidance on 16(3)

- 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. This can include requests for details on how the process is administered and reviewed, including whether it has an independent review stage.
- The 28-day period starts the day after the request is received.

Regulation 17: Good governance

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17

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 to 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 17(1)

- 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);

Guidance on 17(2)(a)

- 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;

Guidance on 17(2)(b)

- 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;

Guidance on 17(2)(c)

- 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 2018.
- 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 2018.

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;

Guidance on 17(2)(d)

- 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 2018.

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;

Guidance on 17(2)(e)

- 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).

Guidance on 17(2)(f)

- 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.

Guidance on 17(3)(a) and 17(3)(b)

- This information could include a request for an action plan or a Provider Information Return for adult social care services.

Regulation 18: Staffing

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 18

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 offences section for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 18(1)

- 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,

Guidance on 18(2)(a)

- Providers must ensure that they have an induction programme that prepares staff for their role.
- 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.
- Providers must ensure that all staff receive training in how to interact appropriately with people with a learning disability and autistic people, at a level appropriate to their role.
- 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.
- Staff must receive appropriate supervision in their role to ensure they demonstrate and maintain competence in understanding the needs of people with a learning disability and autistic people, including knowing how to support them in the best way.
- 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

Guidance on 18(2)(b)

- 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.

Guidance on 18(2)(c)

- 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

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 19

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.

It is important to note that "person employed" will include any member of staff who currently works in the service as a **volunteer** or a contractor, as well as agency or bank staff. This is based on the broad meaning of "employment" set out in Regulation 2, which extends the scope to those engaged who are not under a contract.

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 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

19(1) Persons employed for the purposes of carrying on a regulated activity must–

19(1)(a) be of good character,

19(1)(a)

- 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

19(1)(b)

- 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.

19(1)(c)

- 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.

19(2)

- 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. The Schedule 3 requirement for a full employment history does not apply to volunteers except where they are service providers, directors or registered managers. This is on the basis that those roles hold a level of responsibility where it is necessary to have a full employment history to ensure a person's suitability and appropriateness of the role.
- Providers may request employment history for volunteers where they consider this is necessary to the role.
- 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.

19(4)

- 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.

19(5)

- 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.

Meeting our requirements of employment for Regulation 19: frequently asked questions
FAQs for meeting CQC's requirements of employment for Regulation 19
File title
FAQs for meeting CQC's requirements of employment for Regulation 19
Keywords
FAQs for meeting CQC's requirements of employment for Regulation 19
Audience
Organisations we regulate
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Care Quality Commission
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Legacy file_id
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Regulation 20: Duty of candour

Information for patients

AvMA has published a leaflet about the duty of candour for patients and families.
Download AvMA's Duty of Candour leaflet.

For providers

Joint statement on definitions and recording guidance - FutureNHS (requires login)

The duty of candour is a general duty to be open and transparent with people receiving care from you.

It applies to every health and social care provider that CQC regulates.

The duty of candour requires registered providers and registered managers (known as 'registered persons') to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines 'notifiable safety incidents' and specifies how registered persons must apply the duty of candour if these incidents occur.

- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Statutory and professional duties of candour

There are two types of duty of candour, statutory and professional.

Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.

This guidance is about the statutory duty of candour. We regulate the statutory duty, while the professional duty is overseen by regulators of specific healthcare professions such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).

The statutory duty also includes specific requirements for certain situations known as 'notifiable safety incidents'. If something qualifies as a notifiable safety incident, carrying out the professional duty alone will not be enough to meet the requirements of the statutory duty.

Saying sorry is not admitting fault

A crucial part of the duty of candour is the apology. Apologising is not an admission of liability. This is the case, regardless of whether you are in the health or social care, or public or private sectors.

In many cases it is the lack of timely apology that pushes people to take legal action. To fulfil the duty of candour, you must apologise for the harm caused, regardless of fault, as well as being open and transparent about what has happened.

NHS Resolution is the organisation that manages clinical negligence claims against the NHS. Their 'Saying Sorry' leaflet confirms that apologising will not affect indemnity cover:

"Saying sorry is:

- always the right thing to do
- not an admission of liability
- acknowledges that something could have gone better
- the first step to learning from what happened and preventing it recurring."

Background to the duty of candour

Guidance updated 30 June 2022

The changes clarify how you should apply the term "unexpected or unintended" to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifable safety incidents**
- **Examples of notifiable safety incidents**

Until 2014 there was no legal duty on care providers to share information with the people who had been harmed, or their families.

The tragic case of Robbie Powell and the perseverance of his parents through the UK courts and then the European Court of Human Rights exposed the absence of this legal duty.

In 2013, the Francis Inquiry also found serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust:

“The way in which the Trust handled the matter can be viewed as an object lesson in how the tragedy of an avoidable death can be exacerbated by inappropriate handling of the case. It demonstrates the sad fact that, for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism.” (Francis Inquiry into the failings at Mid-Staffordshire NHS Foundation Trust, 2013)

The Francis Inquiry recommended that a statutory duty of candour be introduced for all health and care providers, in addition to the existing professional duty of candour and the requirement for candour in the NHS standard contract.

This statutory duty of candour was brought into law in 2014 for NHS Trusts and 2015 for all other providers and is now seen as a crucial, underpinning aspect of a safe, open and transparent culture. It is so fundamentally linked to concepts of openness and transparency that often the policies and procedures related to it have come to be known by staff by other names, for example, “Being Open”, “Saying Sorry”, and “Just Culture”.

Notifiable safety incidents

Guidance updated 30 June 2022

The changes clarify how you should apply the term “unexpected or unintended” to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifiable safety incidents**

- **Examples of notifiable safety incidents**

‘Notifiable safety incident’ is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all 3 of the following criteria:

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity we regulate.
3. In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care. This element varies slightly depending on the type of provider.

If any of these three criteria are not met, it is not a notifiable safety incident (but remember that the overarching duty of candour, to be open and transparent, always applies).

You should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" we mean the care or treatment provided. By "outcome" we mean the harm that occurred or could have occurred. So, if the treatment or care provided went as intended, and as expected, an incident may not qualify as a Notifiable Safety Incident, even if harm occurred.

This does not mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended.

The definitions of harm vary slightly between health service bodies and all other providers. This is because when the regulation was written, harm thresholds were aligned with existing notification systems to reduce the burden on providers.

It is possible for an incident to trigger the harm threshold for NHS trusts, but not for other service types, or vice versa.

It is helpful to remember that the statutory duty relates to the provision of regulated activities, and so you should follow the notifiable safety incident definition relating to the type of organisation or provider you are working within.

Health service body

Section 9 of the National Health Service Act 2006 defines a 'health service body'. For the purposes of the duty of candour, a health service body means either an:

- NHS trust
- NHS Foundation trust.

Paragraph 8 of Regulation 20 defines the harm thresholds for Health Service Bodies:

In the reasonable opinion of a healthcare professional, the incident could result in or appears to have:

- resulted in the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
- led to the person experiencing severe harm, moderate harm or prolonged psychological harm.

These definitions of harm are linked to the National Reporting and Learning System (NRLS) definitions.

All other services we regulate

Paragraph 9 of Regulation 20 defines the notifiable safety incident harm thresholds for all other services we regulate:

In the reasonable opinion of a healthcare professional, the incident appears to have resulted in, or requires treatment to prevent:

- the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
- the person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last, for a continuous period of at least 28 days
- changes to the structure of the person's body
- the person experiencing prolonged pain or prolonged psychological harm, or
- a shorter life expectancy for the person using the service.

These definitions of harm are aligned to CQC's notification system for reporting deaths and serious injuries.

Definitions of harm

These definitions are common to all types of service.

- Moderate harm

Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

- Severe harm

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.

- Moderate increase in treatment

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)

- Prolonged pain

Pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

- Prolonged psychological harm

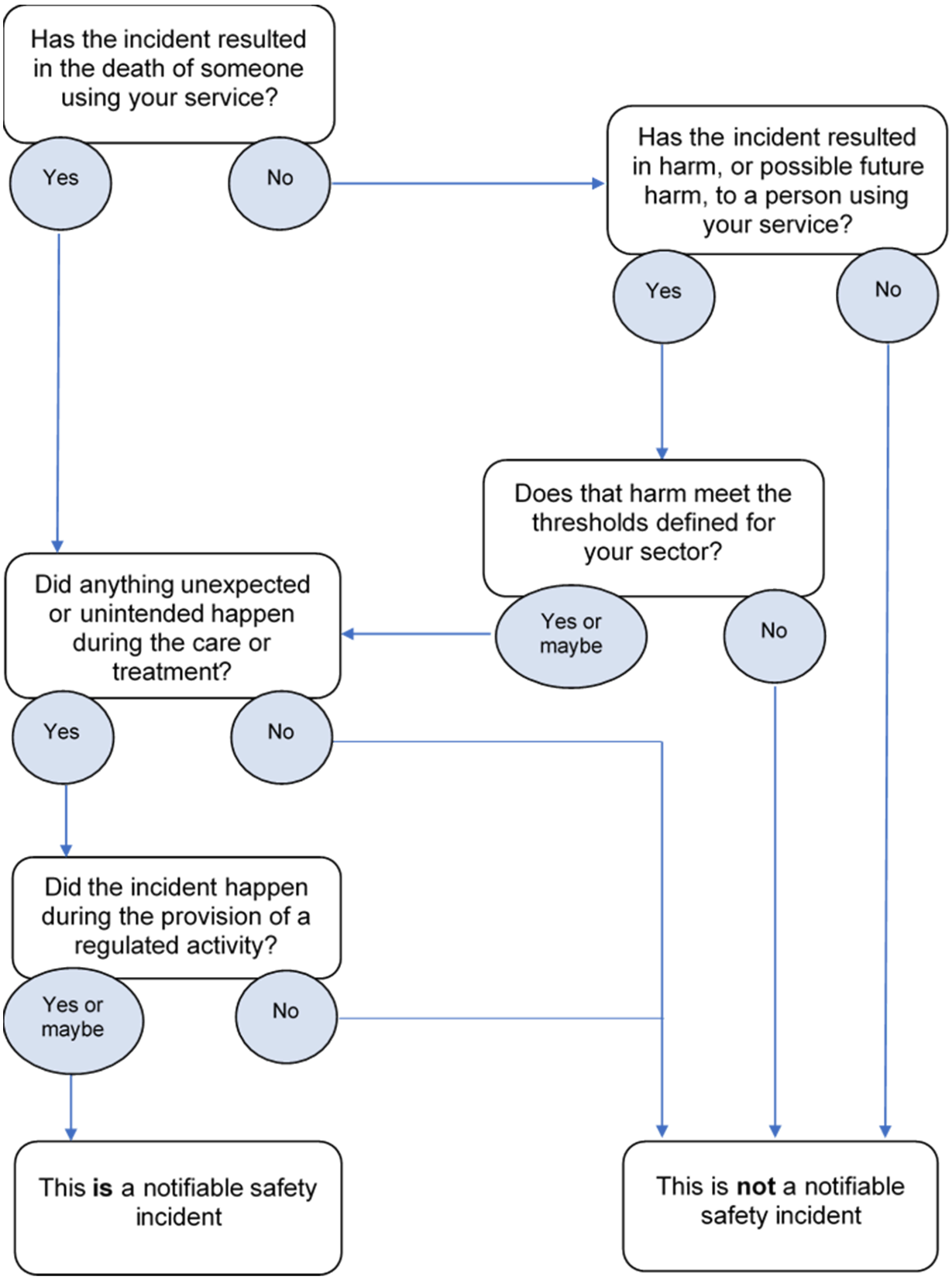
Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Identifying a notifiable safety incident

The presence or absence of fault on the part of a provider has no impact on whether or not something is defined as a notifiable safety incident. **Saying sorry is not admitting fault**.

Even if something does not qualify as a notifiable safety incident, there is always an overarching duty of candour to be open and transparent with people using services.

Flow chart: updated 30 June 2022



Patient gave consent

Something can qualify as a notifiable safety incident even if the patient gave consent for a procedure to be carried out. It all depends on the level of harm and whether something unexpected or unintended happened during the care or treatment, regardless of whether consent was given.

Notifiable safety incident occurred in a different provider

If you discover a notifiable safety incident that occurred in a different provider, you should inform the previous provider.

You must also be open and transparent with the person receiving care about whatever you have discovered. But you do not need to carry out the specific procedures relating to notifiable safety incidents.

The provider where the incident happened must carry out the notifiable safety incidents procedures.

Multiple providers contributed to the harm

If multiple providers contributed to the harm, they should liaise and work together in the investigation that follows as they would for any other incident. Each provider still has its own responsibilities under the duty of candour. They must assure themselves that they have met them.

Incidents that occurred before the duty of candour came into force

There is no legal requirement to carry out the specific requirements laid out in Regulation 20 for something that happened before the regulation existed. However, we would still expect you to carry out the general duty of candour – to apologise and to be open and transparent with people about whatever has been discovered.

Retrospective reviews and patient recalls

If the notifiable safety incident was not realised at the time but was discovered through a retrospective case review, or as part of a large scale patient recall, the duty still applies.

Incidents where there are no staff actively caring for the person

For example, this might be where a person has an unwitnessed fall in a care home.

The care being delivered is described by the regulated activity. In this example that is '**accommodation** for people who require nursing or personal care'. The person fell during the delivery of the accommodation part of the regulated activity. So provided the harm thresholds are met, this could qualify as a notifiable safety incident.

Return to theatre following surgery or a transfer to another treatment area

The term 'moderate increase in treatment' does include situations such as a transfer or an unplanned return to surgery. But 'moderate increase in treatment' is only one part of the overall definition of 'moderate harm'. And it is the description of 'moderate harm' that helps define if something is a notifiable safety incident. To meet the 'moderate harm' threshold the harm must require a moderate increase in treatment **and** there must be significant, but not permanent, harm.

So a transfer or unplanned return to theatre does not automatically qualify as a notifiable safety incident.

Near misses

The intention of the term "could result in harm" in the harm definitions is not to bring near misses into scope as notifiable safety incidents. It is designed to reflect harm that is not apparent at the time of the incident but that may appear later.

See some worked examples of notifiable safety incidents.

Examples of notifiable safety incidents

Guidance updated 30 June 2022

The changes clarify how you should apply the term "unexpected or unintended" to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifable safety incidents**
- **Examples of notifiable safety incidents**

These case studies provide examples of how to apply the notifiable safety incident criteria.

Example 1: Maternity

What happened

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. The woman had not received enough anaesthesia.

2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.

3. Has it resulted in death or severe or moderate harm?
   Yes. The incident has resulted in “prolonged psychological harm” (psychological harm lasting more than 28 days).
   The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 2: Care home

What happened

An occupational therapist completed an assessment with a care home resident whose mobility was deteriorating. They advised that grab rails were needed in his bathroom before it was safe for him to use the bath, and that in the meantime staff should assist him with a wash each morning. The manager failed to update the man’s care plan or inform the care staff of this change, so staff supported him to take a bath the following morning as usual. He slipped when getting out of the bath and broke his arm. The arm was put in a plaster cast and the man needed full assistance for all aspects of his care for six weeks until the cast was removed. He made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. The man slipped getting out of the bath when the occupational therapist's advice was not followed.
2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred during the provision of the regulated activity 'accommodation for persons who require nursing or personal care'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The injury in this case is a broken arm and would fall under Regulation 20(9)(b)(ii) as if the injury was left untreated the person using the service could experience one or more of the scenarios referred to in Regulation 20(9)(a)(i) to (v). The person was receiving care in a care home so the definitions in section 9 rather than 8 apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 3: Surgery

What happened

An elderly woman undergoes a coronary artery bypass operation. The operation is carried out according to plan, with no unexpected or unintended incidences. But the woman suffers a large stroke during the operation and dies soon after.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   No. In this case, nothing unexpected or unintended occurred during the course of treatment.

2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply.

Conclusion

In this case, one of the answers to the three questions is “no”. So, this does not qualify as a notifiable safety incident. Of course the overarching aspect of the duty of candour, to be open and transparent about what happened, always applies, whether or not something is a notifiable safety incident.

Example 4: Mental health

What happened

A prescribing error on a mental health ward resulted in a detained patient being given double her normal dose of lithium for several days. She developed lithium toxicity, which required inpatient admission. She made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. A patient was given the wrong dose of her medication.

2. Did it occur during provision of a regulated activity?
   Yes. It occurred during provision of the regulated activity 'assessment or medical treatment for persons detained under the Mental Health Act 1983'.

3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in moderate harm as defined in 20(7) (significant, but not permanent, harm, and a moderate increase in treatment). The patient was receiving care in an NHS trust so the definitions in Regulation 20(8) apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 5: Dental

What happened

A child with an unknown allergy to latex went for a dental check-up. The dentist wore latex gloves. The child had a very severe anaphylactic reaction which required hospitalisation. The child made a full recovery.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. The child had an allergic reaction.
2. Did it occur during provision of a regulated activity?
   Yes. It occurred during provision of the regulated activity 'diagnostic and screening'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident meant that the person required further treatment to prevent death from anaphylaxis (Regulation 20 (9)(b)(i)). The patient was receiving care in a dentist surgery so the definitions in Regulation 20(9) apply. Note that on the facts provided in this example, there is no suggestion of error or fault on the part of the provider. But neither is required for something to qualify as a notifiable safety incident.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out. Note, there was no fault in this case, but there is no need for someone to have been at fault for an incident to qualify as a notifiable safety incident.

Example 6: General practice

What happened

A young man fell over while playing badminton and goes to his GP the next day with a swollen and painful foot and ankle. His GP decides not to order an x-ray and sends him home with advice to rest, ice, compress and elevate the leg. He tells the man he can weight bear fully. Over the following week, the pain and swelling does not improve, and the man goes back to the GP surgery and sees a different doctor who sends him for an x-ray. He is found to have a fracture of the base of fifth metatarsal that should have been put into a plaster cast and should have been non-weight bearing. Due to this mismanagement, the patient develops a non-union over the following six weeks which causes him ongoing pain and eventually requires surgical intervention in hospital.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. The GP made a misdiagnosis.
2. Did it occur during provision of a regulated activity?
   Yes. It occurred during provision of the regulated activity 'treatment of disease, disorder or injury'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in prolonged pain, impairment of motor functions, and the need for surgical intervention. The patient was receiving care in a GP surgery so the definitions in Regulation 20(9) apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

What you must do when you discover a notifiable safety incident

Guidance updated 30 June 2022

The changes clarify how you should apply the term "unexpected or unintended" to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifable safety incidents**
- **Examples of notifiable safety incidents**

You must start the specific procedure laid out in the duty of candour regulation 'as soon as reasonably practicable'.

We will always expect to see providers acting promptly as soon as a notifiable safety incident has been discovered.

The 'registered person' is responsible for carrying out, or delegating the responsibility for carrying out, the duty and must liaise with the 'relevant person'.

The ‘registered person’ is the registered manager or the registered provider. If you do not need to have a registered manager, such as NHS Trusts, responsibility sits with the leaders of the organisation.

The relevant person is either the person who was harmed or someone acting lawfully on their behalf.

Someone may act on the behalf of the person who was harmed if:

- the person has died
- is under 16 and not competent to make decisions about their care or the consequences of the incident
- is over 16 and lacking mental capacity.

This is in accordance with the Mental Capacity Act 2005.

The regulation states that you must:

1. Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
2. Apologise.
3. Provide a true account of what happened, explaining whatever you know at that point.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
5. Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
6. Keep a secure written record of all meetings and communications with the relevant person.

The purpose of these meetings and communications is to share whatever is known about the incident truthfully, openly and with compassion and support. The person who was harmed has a right to understand what has happened to them. The meeting is not about trying to apportion blame, and in any case, it is likely that investigations will still be underway at this point.

People are sometimes uncertain about how to apologise when an incident is still being investigated. But from the start, simple straightforward expressions of sorrow and regret can and should be made for the harm the person has suffered.

Throughout the process you must give 'reasonable support' to the relevant person, both in relation to the incident itself and when communicating with them about the incident.

'Reasonable support' will vary with every situation, but could include, for example:

- environmental adjustments for someone who has a physical disability
- an interpreter for someone who does not speak English well
- information in accessible formats
- signposting to mental health services
- the support of an advocate
- drawing their attention to other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care.

If the relevant person consents, we would expect to see that you have involved family members and carers in any discussions. It is about taking reasonable steps to make sure you communicate in a way that is as accessible and supportive as possible.

You must keep your own clear records of cases where you have responded to notifiable safety incidents. It may be that the incident also meets the notification thresholds and if so should be reported through the STEIS and NRLS/PSIMS systems or the CQC notification system dependent on care sector.

If the relevant person cannot be, or refuses to be, contacted, you may not be able to carry out paragraphs 2 to 4 of the regulation (the parts relating to notifiable safety incidents), but must keep a written record of all attempts to make contact. You must still report the incident through the appropriate notifications system and investigate it in order to prevent harm occurring to others.

How we regulate the duty of candour

Guidance updated 30 June 2022

The changes clarify how you should apply the term "unexpected or unintended" to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifable safety incidents**
- **Examples of notifiable safety incidents**

The duty of candour is one of the fundamental standards – below which care should never fall. As such it is an area of regulation we pay special attention to.

We do not investigate every notifiable safety incident – this responsibility lies with the provider. Our role is to regulate the provider and ensure it is fulfilling its responsibility to carry out all aspects of the duty of candour. But we will investigate specific notifiable safety incidents where we have concerns.

We do not make judgements about the performance of individual healthcare professionals. In the event of a breach, our judgement will be on the registered person. They are the representative of the care provider.

Every provider should be creating an environment that encourages candour, openness and transparency at all levels. Candour underpins a culture of safety; it is only when organisations are open and honest that they can effectively learn from incidents that cause harm and improve the care that people receive.

During our public consultation in 2018, people shared examples of both poor and good practice that they had experienced. They told us that cover ups (whether real or perceived) and a lack of apology compounded the level of harm they had experienced following the initial incident.

However, when the duty of candour had been carried out well, people talked about how they had received a "heartfelt apology", that the care provider had been "honest from the outset", that "it was not a tick-box exercise", and that assurance was given that things were being put in place to prevent the incident happening to others – that the incidents had been acknowledged and learned from.

Registration

The duty of candour applies to every provider registered with us.

We expect to see evidence during the registration process that the registered person understands their obligations under Regulation 20.

They should understand when and how to carry out the Duty of Candour and have training, policies and systems in place to ensure their employees are able to implement it. Providers should also be able to explain how they will support their staff to be open and transparent when something goes wrong and how this sits within a broader culture of safety.

Monitoring, assessment and inspection

We approach the monitoring of the duty of candour through the lens of the service:

- being well-led
- having an open and safe culture
- meeting the regulatory requirements of the duty of candour

When we hold monitoring calls, assess the data and information we receive, or visit the provider on inspection, we will be looking for evidence that all three factors are met.

It is important to realise that it is possible for the provider to be open and transparent (under Regulation 20(1)) but still not meeting some specific aspects of the duty of candour. This is because Regulation 20(2) is very specific about exactly how the duty must be carried out in relation to:

- the definition of notifiable safety incidents
- the various process steps, meetings and records that must take place
- what those meetings and records should cover
- that the process should be carried out in a timely manner
- that appropriate support should be provided to the person harmed or their representative

There's a range of ways that we assess compliance with the duty. We may:

- Follow up incidents reported through STEIS or CQC notifications that have been marked as triggering the duty of candour to ensure the process was followed through appropriately.

- Follow up incidents reported through STEIS or CQC notifications that were not marked as triggering the duty of candour but appear from the descriptions and harm levels to have required it.
- Ask providers to tell us about recent incidents.
- Follow up on reports of incidents from the public or people using services that appear to have met the threshold of a notifiable safety incident to ensure the specific requirements in the duty of candour took place.
- Ask people who have experienced a notifiable safety incident how the provider responded.
- Question frontline staff about their understanding of the duty of candour and notifiable safety incidents.
- Question the registered person about their policies and processes for recording and carrying out the duty, and for training staff.
- Investigate senior staff and board members' level of understanding of the duty and how they ensure staff feel supported to speak up and be open and honest about incidents.

Not all forms of monitoring and assessment undertaken by CQC will result in a published report, but whenever we do write such reports, we will reference our findings in relation to the duty of candour.

Enforcement

The ultimate responsibility for ensuring the duty of candour is carried out rests with the registered person (in the form of the registered manager or provider).

Where we believe this is not happening, we can use our powers of enforcement, and can prosecute breaches of the regulation.

Regulation 20 also allows us to move directly to criminal enforcement action.

Where an inspector considers a breach may have taken place, they will follow CQC's enforcement policy and decision tree.

All options are open to us, including warning and requirement notices, imposition of conditions and criminal prosecution.

Regulation 20: Duty of candour (regulation in full)

Guidance updated 30 June 2022

The changes clarify how you should apply the term "unexpected or unintended" to decide if something qualifies as a notifiable safety incident or not.

See updated pages:

- **Notifable safety incidents**
- **Examples of notifiable safety incidents**

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

The regulation in full

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).

Regulation 20A: Requirement as to display of performance assessments

We've also published more detailed guidance on the requirement to display ratings, which includes details about how to use our widget and download posters from our site.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20A

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 has developed 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

20A(1) This regulation applies —

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).

Guidance on 20A(1)

- 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 particular premises or activities may be accessed.

Guidance on 20A(2)

- Providers must display their ratings on their websites. CQC has provided 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.

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.

Guidance on 20A(3)

- If a regulated activity is provided at a premises, and the service provider has been rated by CQC, then the rating must be displayed.
- CQC has developed 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.

Guidance on 20A(7)

- 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 (Registration) Regulations

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

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 (AdditionalFunctions) and Health and SocialCare 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

Care Quality Commission (Registration) Regulations 2009: Regulation 12

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 12(1)

- 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.

Guidance on 12(3)

- If a provider changes their 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

Care Quality Commission (Registration) Regulations 2009: Regulation 13

The intention of this regulation is to require providers to make sure 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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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;

Guidance on 13(1)(a)

- 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

Care Quality Commission (Registration) Regulations 2009: Regulation 14

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 here.

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 for more detail.

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

The regulation in full

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.

Regulation 15: Notice of changes

Care Quality Commission (Registration) Regulations 2009: Regulation 15

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 here.

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 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.

The regulation in full

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.

Regulation 16: Notification of death of service user

Care Quality Commission (Registration) Regulations 2009: Regulation 16

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 here.

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 for more detail.

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

The regulation in full

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

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

16(5) This regulation does not apply where regulation 17 applies.

Guidance on 16(5)

- 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

Care Quality Commission (Registration) Regulations 2009: Regulation 17

The intention of this regulation is that CQC is notified of certain events in relation to patients detained under the Mental Health Act 1983, so that we can take follow-up action where needed.

These events are:

- (a) the death of any person liable to be detained under the Mental Health Act 1983, wherever that death takes place;

- (b) the unauthorised absence of any person liable to be detained under the Mental Health Act 1983 from an inpatient psychiatric unit classed as low, medium or high security, when that absence occurs past midnight on any given day; and
- (c) The return from unauthorised leave of any person reported under (b) above.

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

Guidance on 17

Unauthorised absences of a person liable to be detained under the Mental Health Act 1983 (also known as absence without leave or AWOL) are notifiable ONLY when:

- (a) the absence is from an inpatient unit designed as low, medium or high security (Reg 17(3)(ca)); AND
- (b) the person is still absent after midnight on the day their absence began.

Services should remember to report the return to hospital of a patient previously reported as on unauthorised absence (Reg 17(2a)).

The death of any patient liable to be detained must be notified to CQC under this regulation. This is not dependent on the security level of the inpatient unit which was the detaining authority for the patient, nor where nor how that death occurred.

Regulations require notifications to be made 'without delay'. Services may note that CQC operates office hours in respect of such notifications.

Regulation 18: Notification of other incidents

Care Quality Commission (Registration) Regulations 2009: Regulation 18

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.

NHS trusts and NHS Blood and Transplant can report some regulation 18 notifications via LFPSE – these are serious injuries, abuse and allegations of abuse, and events that stop a service running safely and properly. All other providers must send these notifications directly to CQC.

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 for more detail.

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

The regulation in full

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—

   c. the date and nature of the request or application;

   d. 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;

   e. the outcome of the request or application or reason for its withdrawal; and

   f. 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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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,

(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);

Guidance on 18(2)

- 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 that develops after the person has started to use the service
    - 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 judgments
        - 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.

See also

Joint statement on definitions and recording guidance - FutureNHS (requires login)

Regulation 19: Fees

Care Quality Commission (Registration) Regulations 2009: Regulation 19

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 for more detail.

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

The regulation in full

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.

Guidance

This sets out the guidance providers must have regard to against the relevant component of the regulation.

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

Guidance on 19(1)(a)

- 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.

Guidance on 19(1)(b)

- 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.

Guidance on 19(2)(a) and 19(2)(b)

- 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

Care Quality Commission (Registration) Regulations 2009: Regulation 20

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 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.

The regulation in full

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.

Regulation 21: Death of a service provider

Also see our guidance on how to notify us about the death of a registered provider.

Care Quality Commission (Registration) Regulations 2009: Regulation 21

The intention of this regulation is to ensure that CQC is notified in writing and without delay of the death of a service provider who is either:

- an individual
- a partner in a partnership that has only one surviving partner.

If an individual provider dies, the legal entity that registered with CQC no longer exists. This means that no provider is registered to carry on the regulated activity.

The personal representative of an individual provider must notify CQC of their intentions for the future of the service within 28 days of the date of death. They can take responsibility for the regulated activity themselves for up to 28 days without having to register, and CQC can agree to extend this. However, they must appoint someone to take full-time day-to-day charge of the regulated activity over this period.

If the death of a partner leaves a partnership with only one surviving partner, depending on the partnership arrangements, the legal entity may no longer exist. This may mean that no provider is registered to carry on the regulated activity.

Although a failure to inform CQC under this regulation is not an offence, it is an offence to continue to operate as an unregistered provider. This may result in prosecution.

There is no further guidance for this regulation.

The regulation in full

1. Where the service provider is a partnership and a partner dies, the surviving partner shall without delay notify the Commission of the death in writing.
2. Where the service provider is an individual and that individual dies, that individual's personal representative must notify the Commission in writing—
    a. without delay of the death; and
    b. within 28 days of the date of death of their intentions regarding the future carrying on of the regulated activity.
3. The personal representative of the deceased service provider may carry on the regulated activity without being registered in respect of it—
    a. for a period not exceeding 28 days; and
    b. for any future period as may be determined in accordance with paragraph (4).
4. The Commission may extend the period specified in paragraph (3)(a) by such further period, not exceeding one year, as the Commission shall determine, and shall notify any such determination to the personal representative in writing.
5. The personal representative of the deceased service provider shall appoint a person to take full-time day to day charge of the carrying on of the regulated activity during any period in which, in accordance with paragraph (3), they carry on the regulated activity without being registered in respect of it.

Regulation 22A: Form of notifications to the Commission

Care Quality Commission (Registration) Regulations 2009: Regulation 22A

The regulation in full

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.

Related legislation

This page sets out further legislation related to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and Care Quality Commission (Registration) Regulations 2009.

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

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Regulation 5: Fit and proper persons: directors

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

- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Companies Act 2006
- NHS Provider Licence May 2014

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

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Regulation 7: Requirements relating to registered managers

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Regulation 8: General

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Regulation 9: Person-centred care

- The Care Act 2014

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Autism Act 2009
- Children Act 1989
- Children Act 2004
- Children and Young Persons Act 1933
- Equality Act 2010
- Human Rights Act 1998
- Medicines Act 1968

The Medicines Act 1968 is still the current Act of legislation but there has also been a further piece of work carried out to consolidate all the amendments made to the Act which was completed in 2012. This is:

- The Human Medicines Regulations 2012
- The Human Medicines Regulations 2012
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)

Regulation 10: Dignity and respect

- The Care Act 2014

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Data Protection Act 2018
- Equality Act 2010
- The General Data Protection Regulation
- Human Rights Act 1998
- The Human Tissue Act 2004
- The Human Tissue Authority codes of practice
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)

Regulation 11: Need for consent

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Children Act 1989
- Children Act 2004
- Children and Young Persons Act 1933
- Mental Capacity Act 2005

- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)

Regulation 12: Safe care and treatment

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- The Abortion Act 1967
- Autism Act 2009
- Civil Contingences Act 2004
- The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- Data Protection Act 2018
- The Electricity at Work regulations 1989
- The Gas Safety (Installation and Use) regulations 1998
- The General Data Protection Regulation
- Health and Safety at Work etc. Act 1974
- The Health and Safety (First-Aid) Regulations 1981
- The Health and Safety (Miscellaneous Amendments) 2002
- The Ionising Radiations Regulations 1999
- The Ionising Radiation (Medical Exposure) Regulations 2000

- Management of Health and Safety at Work Regulations 1999
- The Manual Handling Operations Regulations 1992
- The Health and Safety (Miscellaneous Amendments) 2002
- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2012
- Medicines Act 1968

The Medicines Act 1968 is still the current Act of legislation but there has also been a further piece of work carried out to consolidate all the amendments made to the Act which was completed in 2012. See The Human Medicines Regulations 2012.

- The Human Medicines Regulations 2012
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)
- Misuse of Drugs Act 1971
- The Misuse of Drugs (Safe Custody) Regulations 1973
- The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007
- Public Interest Disclosure Act 1998
- The Workplace (Health, Safety and Welfare) Regulations 1992
- The Health and Safety (Miscellaneous Amendments) Regulations 2002

Regulation 13: Safeguarding service users from abuse and improper treatment

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Children Act 1989
- Children Act 2004
- Children and Young Persons Act 1933
- Equality Act 2010
- Equality Act 2010: Chapter 1 (protected characteristics) Chapter 2 (prohibited conduct) and Chapter 3 (services and public functions)
- Human Rights Act 1998
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007 and Code of Practice
- Protection of Freedoms Act 2012 – links to The Protection of Freedoms Act 2012 (Disclosure and Barring Service Transfer of Functions) Order 2012
- Safeguarding Vulnerable Groups Act 2006

Regulation 14: Meeting nutritional and hydration needs

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

- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Food Safety Act 1990
- The Food Safety and Hygiene (England) Regulations 2013
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice

Regulation 15: Premises and equipment

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Control of Substances hazardous to Health regulations 2002
- The Electricity at Work regulations 1989
- Equality Act 2010
- The Gas Safety (Installation and Use) regulations 1998
- The Hazardous Waste (England and Wales) Regulations 2005
- Health and Safety at Work etc. Act 1974
- The Health and Safety (First-Aid) Regulations 1981
- The Health and Safety (Miscellaneous Amendments) 2002
- Human Rights Act 1998
- The Ionising Radiations Regulations 2017
- The Ionising Radiation (Medical Exposure) Regulations 2017
- Management of Health and Safety at Work Regulations 1999

- The Manual Handling Operations Regulations 1992
- The Health and Safety (Miscellaneous Amendments) 2002
- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2012
- Mental Capacity Act 2005
- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)
- The Regulatory Reform (Fire Safety) Order 2005
- The Workplace (Health, Safety and Welfare) Regulations 1992
- The Health and Safety (Miscellaneous Amendments) Regulations 2002

Regulation 16: Receiving and acting on complaints

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Data Protection Act 2018
- The General Data Protection Regulation
- The Local Authority Social Services and National Health Service complaints (England) regulations 2009
- Public Interest Disclosure Act 1998

Regulation 17: Good governance

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Control of Substances hazardous to Health regulations 2002
- Data Protection Act 2018
- The Electricity at Work regulations 1989
- Employment Rights Act 1996
- Equality Act 2010
- Freedom of Information Act 2000
- The Gas Safety (Installation and Use) regulations 1998
- The General Data Protection Regulation
- The Hazardous Waste (England and Wales) Regulations 2005
- Health Professional Council – legal framework
- Health and Safety at Work etc. Act 1974
- The Ionising Radiations Regulations 2017
- The Ionising Radiation (Medical Exposure) Regulations 2017
- Management of Health and Safety at Work Regulations 1999
- The Manual Handling Operations Regulations 1992
- The Health and Safety (Miscellaneous Amendments) 2002
- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2012
- Mental Capacity Act 2005

- Mental Capacity Act Code of Practice
- Mental Health Act 1983
- Mental Health Act 2007
- Code of Practice (Mental Health Act 1983)
- The Regulatory Reform (Fire Safety) Order 2005
- RIDDOR
- Safeguarding Vulnerable Groups Act 2006
- The Workplace (Health, Safety and Welfare) Regulations 1992
- The Health and Safety (Miscellaneous Amendments) Regulations 2002

Regulation 18: Staffing

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Dentists Act 1984
- Employment Rights Act 1996
- Equality Act 2010
- Health and Safety at Work etc. Act 1974
- The Health and Safety (First-Aid) Regulations 1981
- The Health and Safety (Miscellaneous Amendments) 2002
- Health and Social Work Professions Order 2001
- Human Rights Act 1998

- Management of Health and Safety at Work Regulations 1999
- Medical Act 1983
- Nursing and Midwifery Order 2001
- The Pharmacy Order 2010
- Protection of Freedoms Act 2012 – links to The Protection of Freedoms Act 2012 (Disclosure and Barring Service Transfer of Functions) Order 2012
- Safeguarding Vulnerable Groups Act 2006

Regulation 19: Fit and proper persons employed

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
- Employment Rights Act 1996
- Equality Act 2010
- Health Professional Council – legal framework
- Nursing and Midwifery Council (NMC) Legislation
- Protection of Freedoms Act 2012 – links to The Protection of Freedoms Act 2012 (Disclosure and Barring Service Transfer of Functions) Order 2012
- Safeguarding Vulnerable Groups Act 2006

Regulation 20: Duty of candour

There are no related legislation links for this regulation.

Regulation 20A: Requirement as to display of performance assessments

There are no related legislation links for this regulation.

Care Quality Commission (Registration) Regulations 2009: related legislation

- Care Quality Commission (Registration) Regulations 2009
- The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012
- The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012

Related guidance

This page sets out further information and guidance related to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and Care Quality Commission (Registration) Regulations 2009.

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

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

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General resources

- NICE Collaborating Centre for Social Care - Social Care Institute for Excellence
- SCIE at-a-glance summaries - Social Care Institute for Excellence
- SCIE guides - Social Care Institute for Excellence
- SCIE resources and services - Social Care Institute for Excellence
- Social Care TV (requires registration) - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Regulation 5: Fit and proper persons: directors

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Conduct, ethics and performance

- The seven principals of public life - GOV.UK (Committee on standards for public life)
- Standards - General Pharmaceutical Council

- Standards of conduct, performance and ethics - Health and Care Professions Council

Disclosure and Barring (DBS)

- Disclosure and Barring Service
- Disclosure and Barring identity checking guidelines
- DBS checks for CQC registration

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Equality and human rights

- EHRC employment statutory code of practice: sections on reasonable adjustments and pre-employment health checks - Equality and Human Rights Commission
- Equality Act 2010 guidance - GOV.UK
- Guidance about age discrimination - Equality and Human Rights Commission
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

General resources

- Health and Care Professions Council

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance

- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Our Standards - Professional Standards Authority
- Setting up and running a charity: detailed information - GOV.UK

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

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

General resources

- NICE Collaborating Centre for Social Care - Social Care Institute for Excellence
- SCIE at-a-glance summaries - Social Care Institute for Excellence
- SCIE guides - Social Care Institute for Excellence
- SCIE resources and services - Social Care Institute for Excellence
- Social Care TV (requires registration) - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Regulation 7: Requirements relating to registered managers

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

General resources

- NICE Collaborating Centre for Social Care - Social Care Institute for Excellence
- SCIE at-a-glance summaries - Social Care Institute for Excellence
- SCIE guides - Social Care Institute for Excellence
- SCIE resources and services - Social Care Institute for Excellence
- Social Care TV (requires registration) - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Regulation 8: General

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence

- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

General resources

- NICE Collaborating Centre for Social Care - Social Care Institute for Excellence
- SCIE at-a-glance summaries - Social Care Institute for Excellence
- SCIE guides - Social Care Institute for Excellence
- SCIE resources and services - Social Care Institute for Excellence
- Social Care TV (requires registration) - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Regulation 9: Person-centred care

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Care, treatment and support

- A better life for older people with high support needs: At a glance summary 65 - Social Care Institute for Excellence

- Adult social care outcomes framework 2018/19: handbook of definitions - Department of Health and Social Care
- GP services for older people: a guide for care home managers – SCIE guide 52 – Social Care Institute for Excellence, December 2013
- Life Story Network resources
- Living well in care homes - Royal College of Occupational Therapists
- Making the move to delivering reablement: At a glance summary 56 - Social Care Institute for Excellence
- Maximising the potential of reablement: SCIE guide 49 – Social Care Institute for Excellence
- NHS choice framework - GOV.UK
- Preventing loneliness and social isolation among older people: At a glance 60 - Social Care Institute for Excellence

Continence

- Continence - Royal College of Nursing
- Faecal incontinence: Quality standard 54 - NICE, February 2014
- Lower urinary tract symptoms: The management of lower urinary tract symptoms in men – NICE clinical guideline 97 - NICE, May 2010
- Urinary incontinence and pelvic organ prolapse in women: management NICE guideline [NG 123] - NICE

Dignity and respect

- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)

End of life care

- Dying well at home: the case for integrated working: SCIE guide 48 - Social Care Institute for Excellence
- End of life care - NHS England
- End of life care for adults: Quality standard [QS13] - NICE
- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People
- Treatment and care towards the end of life: good practice in decision making - General Medical Council

Equality and human rights

- Equality Act 2010 guidance
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

General resources

- National Institute for Health and Care Excellence (NICE)

Medicines

- Managing medicines in care homes - NICE

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK
- Mental Capacity Act resources - Social Care Institute for Excellence

Mental health

- Common core principles for mental health and wellbeing in adult social care - Skills for Care
- Mental wellbeing of older people in care homes: Quality Standard 50 - NICE
- New video to support mental wellbeing of older people in care homes quality standard - NICE

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Patient experience in adult NHS services: improving the experience of care for people using adult NHS services - NICE
- Quality, service improvement and redesign (QSIR) tools - NHS
- Quality standard for patient experience in adult NHS services: NICE quality standard 15 - NICE
- Service user experience in adult mental health: improving the experience of care for people using adult NHS mental health services - NICE
- Service user experience in adult mental health: Quality standard 14 - NICE

Personalised care

- Commitment to care of people living with dementia - Royal College of Nursing
- Dementia Quality Standard (QS184) - NICE
- Introduction to personalisation - Social Care Institute for Excellence
- Personalisation briefing: Implications for advocacy workers: SCIE at a glance summary 12 - Social Care Institute for Excellence

- Personalisation implications for all service user groups - Social Care Institute for Excellence
- Personalisation for specific groups - Social Care Institute for Excellence
- Think Local Act Personal Partnership guidance on personalisation

Restrictive practice/restraint

- SCIE Report 25: Minimising the use of 'restraint' in care homes: challenges, dilemmas and positive approaches - Social Care Institute for Excellence 2009

Safeguarding

- Commissioning care homes: common safeguarding challenges - SCIE guide 46 - Social Care Institute for Excellence

Staff support and training

- Effective supervision in a variety of settings: SCIE guide 50 - Social Care Institute for Excellence

Regulation 9A: Visiting and accompanying in care homes, hospitals and hospices

- Supporting safer visiting in care homes during infectious illness outbreaks - UK Health Security Agency

Regulation 10: Dignity and respect

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014

- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Care, treatment and support

- Compassion in practice nursing, midwifery and care staff: Our vision and strategy - Department of Health/NHS Commissioning Board
- Life Story Network resources
- Living well in care homes - Royal College of Occupational Therapists
- Making the move to delivering reablement: At a glance summary 56 - Social Care Institute for Excellence
- Maximising the potential of reablement: SCIE guide 49 – Social Care Institute for Excellence
- GP services for older people: a guide for care home managers – SCIE guide 52 – Social Care Institute for Excellence, December 2013
- Preventing loneliness and social isolation among older people: At a glance 60 - Social Care Institute for Excellence

Caldicott

- The Caldicott Principles - National Data Guardian
- Caldicott review: information governance in the health and care system (Independent report) - National Data Guardian

Continence

- Continence - Royal College of Nursing
- Faecal incontinence: Quality standard 54 - NICE, February 2014

- Lower urinary tract symptoms: The management of lower urinary tract symptoms in men – NICE clinical guideline 97 - NICE, May 2010
- Urinary incontinence and pelvic organ prolapse in women: management NICE guideline [NG 123] - NICE

Data protection

- Guide to Data Protection - Information Commissioner's Office
- Information sharing advice for safeguarding practitioners - Department for Education

Dignity and respect

- Common core principles for dignity guide - Skills for Care
- Dignity Champions
- Dignity in Care resources - Social Care Institute for Excellence
- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)
- Eliminating mixed sex accommodation: Declaration Exercise, Letter to NHS Chief Executives - Department of Health and Social Care
- Eliminating mixed sex accommodation - PL/CNO/2010/3 (letter from Chief Nursing Officer and Deputy Chief Executive, November 2010) - Department of Health

Equality and human rights

- Equality Act 2010 guidance - GOV.UK
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

End of life care

- Dying well at home: the case for integrated working: SCIE guide 48 - Social Care Institute for Excellence
- End of life care - NHS England
- End of life care for adults: Quality standard [QS13] - NICE
- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People
- Treatment and care towards the end of life: good practice in decision making - General Medical Council

General resources

- National Institute for Health and Care Excellence (NICE)
- NHS Constitution for England - Department of Health and Social Care
- Handbook to the NHS Constitution for England (updated February 2021) - Department of Health and Social Care, Public Health England

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK
- Mental Capacity Act resources - Social Care Institute for Excellence

Mental health

- Common core principles for mental health and wellbeing in adult social care - Skills for Care
- Mental Health Act 1983: Code of Practice - Department of Health
- Mental wellbeing of older people in care homes: Quality Standard 50 - NICE

- New video to support mental wellbeing of older people in care homes quality standard - NICE

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Quality standard for patient experience in adult NHS services: NICE quality standard 15 - NICE
- Service user experience in adult mental health: Quality standard 14 - NICE

Personalised care

- Introduction to personalisation - Social Care Institute for Excellence
- Personalisation briefing: Implications for advocacy workers: SCIE at a glance summary 12 - Social Care Institute for Excellence
- Personalisation implications for all service user groups - Social Care Institute for Excellence
- Personalisation for specific groups - Social Care Institute for Excellence
- Think Local Act Personal Partnership guidance on personalisation

Restrictive practice/restraint

- SCIE Report 25: Minimising the use of 'restraint' in care homes: challenges, dilemmas and positive approaches - Social Care Institute for Excellence 2009

Safeguarding

- Commissioning care homes: common safeguarding challenges - SCIE guide 46 - Social Care Institute for Excellence

Regulation 11: Need for consent

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Care, treatment and support

- GP services for older people: a guide for care home managers – SCIE guide 52 – Social Care Institute for Excellence, December 2013
- NICE interventional procedures guidance - NICE

Consent

- Decision making and consent - General Medical Council
- Gillick competency and Fraser guidelines - NSPCC Learning
- Reference guide to consent for examination or treatment (second edition) - Department of Health and Social Care
- Using surveillance: information for service providers - CQC

Data protection

- In the picture: A data protection code of practice for surveillance cameras and personal information - Information Commissioner's Office

Deprivation of liberty

- Department of Health Guidance: Response to the Supreme Court Judgment/ Deprivation of Liberty Safeguards

End of life care

- Dying well at home: the case for integrated working: SCIE guide 48 - Social Care Institute for Excellence
- End of life care - NHS England
- End of life care for adults: Quality standard [QS13] - NICE
- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People
- Treatment and care towards the end of life: good practice in decision making - General Medical Council

General resources

- NHS Constitution for England - Department of Health and Social Care
- Handbook to the NHS Constitution for England (updated February 2021) - Department of Health and Social Care, Public Health England

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK
- Mental Capacity Act resources - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Quality, service improvement and redesign (QSIR) tools - NHS

Personalised care

- Introduction to personalisation - Social Care Institute for Excellence

Restrictive practice/restraint

- SCIE Report 25: Minimising the use of 'restraint' in care homes: challenges, dilemmas and positive approaches - Social Care Institute for Excellence 2009

Regulation 12: Safe care and treatment

Abortion/termination of pregnancy

- Guidance for doctors on compliance with the Abortion Act - Department of Health and Social Care
- Abortion: procedures for approval of independent providers - Department of Health and Social Care
- Women's heath: termination of pregnancy - Royal College of Nursing
- The care of women requesting induced abortion (Evidence-based Clinical Guideline No. 7) - Royal College of Obstetricians and Gynaecologists

Buildings/premises and equipment

- Building engineering in the health sector (HTM 00) - Department of Health and Social Care
- Central alerting system - Medicines & Healthcare products Regulatory Agency (MHRA)
- DH building notes - Department of Health and Social Care
- Domestic gas health and safety - Health and Safety Executive
- Electrical safety and you: a brief guide - Health and Safety Executive
- Electrical safety at work - Health and Safety Executive

- Have the right workplace facilities - Health and Safety Executive
- Health Building Note 00-10 Part D: Windows and associated hardware - Department of Health
- Health technical memoranda collection - Department of Health and Social Care
- Health technical memoranda series including policies and principles of healthcare engineering (HTM 00) - Department of Health
- Gas safety - Health and Safety Executive
- Good practice guidelines on lighting - Stirling Dementia Service Development Centre
- Lighting at work, HSG38 - Health And Safety Executive
- Medical devices regulation and safety: detailed information - GOV.UK
- PAT: Portable appliance testing FAQs - Health And Safety Executive
- Policies and principles of healthcare engineering (HTM 00) - Department of Health, 2014
- Provision and Use of Work Equipment Regulations 1998 (PUWER)- Health and Safety Executive
- Stirling Dementia Service Development Centre (DSDC)

Caldicott

- The Caldicott Principles - National Data Guardian
- Caldicott review: information governance in the health and care system (Independent report) - National Data Guardian

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Care, treatment and support

- GP services for older people: a guide for care home managers – SCIE guide 52 – Social Care Institute for Excellence, December 2013
- Pressure ulcers: prevention and management - NICE
- Self care: Supporting people to take responsibility for their own health and well being - Skills for Care

Data Protection

- Information sharing advice for safeguarding practitioners - Department for Education
- Guide to Data Protection - Information Commissioner's Office
- The Information Governance Review: To share or not to share

Deprivation of liberty

- Department of Health Guidance: Response to the Supreme Court Judgment/ Deprivation of Liberty Safeguards

Dignity and respect

- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

General resources

- National Institute for Health and Care Excellence (NICE)

Health and safety

- Guidance for health and social care services - Health and Safety Executive
- Health and Safety Executive guidance
- Health and safety in care homes - Health and Safety Executive
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 - Health and Safety Executive
- Leading health and safety at work - Health and Safety Executive
- Managing for health and safety - Health and Safety Executive
- Managing for health and safety (HSG65) guidance - Health and Safety Executive
- Managing risks and risk assessment at work - Health and Safety Executive
- Natural rubber latex sensitisation in health and social care - Health and Safety Executive
- Selecting latex gloves - Health and Safety Executive
- Sharps injuries - Health and Safety Executive

Infection control/cleanliness

- Care homes: infection prevention and control - Department of Health and Social Care, Public Health England
- Health and Social Care Act 2008: code of practice on the prevention and control of infections - Department of Health and Social Care

- The national specifications for cleanliness: Guidance on setting and measuring performance outcomes in care homes - NHS National Patient Safety Agency
- The revised healthcare cleaning manual - National Patient Safety Agency
- Infection control in the built environment (HBN 00-09) - Department of Health and Social Care
- Infection prevention and control Quality standard [QS61] - NICE
- Healthcare-associated infections: prevention and control in primary and community care Clinical guideline [CG139] - NICE
- Prevention and control of healthcare-associated infections: Quality improvement guide - NICE
- Essential practice for infection prevention and control - Royal College of Nursing
- Guidance on decontamination of equipment for gastrointestinal endoscopy - British Society of Gastroenterology

Medicines

- Managing medicines in care homes - NICE
- Medicines management - NICE
- Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes - NICE
- Professional standards for hospital pharmacy - Royal Pharmaceutical Society
- Protocol for ordering, storing and handling vaccines (March 2014) - Public Health England

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK

Moving and handling

- Getting to grips with hoisting people - Health And Safety Executive
- How the Lifting Operations and Lifting Equipment Regulations (LOLER / PUWER) apply to health and social care - Health and Safety Executive
- Moving and handling in health and social care - Health and Safety Executive

Quality monitoring/governance

- NHS Patient Safety Strategy - NHS England
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Quality, service improvement and redesign (QSIR) tools - NHS
- Patient group directions: Medicines practice guideline [MPG2] (Published date: Last updated: 27 March 2017) - NICE
- Security of prescription forms guidance (updated August 2015) - NHS Protect

Personalised care

- Introduction to personalisation - Social Care Institute for Excellence

Restrictive practice/restraint

- SCIE Report 25: Minimising the use of 'restraint' in care homes: challenges, dilemmas and positive approaches - Social Care Institute for Excellence 2009

Risk assessment

- Sensible risk assessment in care settings - Health and Safety Executive
- Bed rail risk management - Sector information minute SIM 07/2012/06 - Health and Safety Executive

- Bed rails: management and safe use (Guidance on managing and using bed rails safely, updated January 2021) - Medicines and Healthcare products Regulatory Agency
- Managing risk from hot water and surfaces in health and social care - Health and Safety Executive

Safeguarding

- Commissioning care homes: common safeguarding challenges - SCIE guide 46 - Social Care Institute for Excellence

Safety

- Cryptic clue or familiar sign?- MHRA
- Our National Patient Safety Alerts - NHS England
- Alerts, recalls and safety information: drugs and medical devices - MHRA

Slips, trips and falls

- Falls from windows or balconies in health and social care - Health and Safety Executive
- Falls in older people: assessing risk and prevention - NICE
- Slips and trips in health and social care - Health and Safety Executive

Staffing and recruitment

- Uniforms and workwear: guidance on uniforms and workwear for NHS employers - Department of Health (2010 archived)

Staff support and training

- 2021 Resuscitation Guidelines - Resuscitation Council UK

Waste mangement

- Safe management of healthcare waste - Department of Health and Social Care

Water systems (including legionella)

- Control of legionella in hot and cold water systems in care services/settings using temperature - Health and Safety Executive
- Safe water in healthcare premises (HTM 04-01) - Department of Health and Social Care

Whistleblowing

- Whistleblowing: Guidance for providers who are registered with the Care Quality Commission
- Whistleblowing: improving organisational practice - Social Care Institute for Excellence
- Raising a concern with NHS England - NHS England
- Raising concerns at work: Whistleblowing guidance for workers and employers in health and social care - The British Association of Social Workers (BASW)

Regulation 13: Safeguarding service users from abuse and improper treatment

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Challenging behaviour

- Ensuring quality services: Core principles for the commissioning of services for children, young people, adults and older people with learning disabilities and/or autism who display or are at risk of displaying behaviour that challenges (NHS England and Local Government Association, 2014)
- Meeting needs and reducing distress: guidance on the prevention and management of clinically related challenging behaviour in NHS settings (NHS Protect, 2013)
- Services for people with learning disabilities and challenging behaviour or mental health needs Mansell report 2007: revised edition - Department of Health (archived)
- Violence and aggression: short-term management in mental health, health and community settings - NICE

Data protection

- Information sharing advice for safeguarding practitioners - Department for Education

Deprivation of liberty

- Department of Health Guidance: Response to the Supreme Court Judgment/ Deprivation of Liberty Safeguards
- Liberty Protection Safeguards factsheets: Information about Liberty Protection Safeguards (LPS) - Department of Health and Social Care

Dignity and respect

- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Equality and human rights

- Equality Act 2010 guidance
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

General resources

- National Institute for Health and Care Excellence (NICE)

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK

Mental health

- Mental Health Act 1983: Code of Practice - Department of Health

Personalised care

- Introduction to personalisation - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Restrictive practice/restraint

- Behaviours which challenge - Skills for Care
- Helping health and care services manage difficult patient behaviour - Department for Health and Social Care

Risk assessment

- Bed rail risk management - Sector information minute SIM 07/2012/06 - Health and Safety Executive
- Bed rails: management and safe use (Guidance on managing and using bed rails safely, updated January 2021) - Medicines and Healthcare products Regulatory Agency
- Managing risks and risk assessment at work - Health and Safety Executive
- Sensible risk assessment in care settings - Health and Safety Executive

Safeguarding

- Child abuse concerns: guide for practitioners - Department for Education
- Child maltreatment: when to suspect maltreatment in under 18s - NICE
- Clinical governance and adult safeguarding - Department of Health (archived)
- Commissioning care homes: common safeguarding challenges - SCIE guide 46 - Social Care Institute for Excellence
- Safeguarding adults - Social Care Institute for Excellence
- Safeguarding adults: A national framework of standards for good practice and outcomes in adult protection work - Association of Directors of Social Services (ADSS)
- Safeguarding children and young people: roles and competencies - Royal College of Paediatrics and Child Health

Whistleblowing

- Raising concerns at work: whistleblowing guidance for workers and employers in health and social care - The British Association of Social Workers (BASW)
- Raising a concern with NHS England - NHS England
- Whistleblowing: guidance for providers who are registered with the Care Quality Commission
- Whistleblowing: improving organisational practice - Social Care Institute for Excellence

Regulation 14: Meeting nutritional and hydration needs

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Dignity and respect

- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Food safety/hygiene

- Alerts, product withdrawals and recalls - Food Standards Agency
- Business guidance: How to run your food business - Food Standards Agency

- Essence of Care 2010: Benchmarks for food and drink - Department of Health
- General food law - Food Standards Agency
- Guidance on food served to older people in residential care - Food Standards Agency (archived)
- Healthier and more sustainable catering - Public Health England
- Sustainable procurement: the GBS for food and catering services - Official Government Buying Standards (GBS) for food and catering services
- The Food Safety Act 1990 – A guide for food businesses - Food Standards Agency

General resources

- National Institute for Health and Care Excellence (NICE)

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK

Nutrition and hydration

- 10 Key Characteristics of good nutritional care in hospitals - Council of Europe
- At a Glance 3: Nutritional care and older people - Social Care Institute for Excellence
- Diet, nutrition and obesity - NICE
- Establishing food standards for NHS hospitals: Independent report - Department of Health and Social Care
- Malnutrition universal screening tool - BAPEN
- Nutrition and hydration: Professional Resources - Royal College of Nursing
- Nutrition for specific groups (Royal College of Nursing)

- Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition - NICE
- Nutrition support in adults: Quality standard 24 - NICE
- Patient-led assessments of the care environment (PLACE) - NHS Digital
- Safer food, better business supplement for residential care homes - Food Standards Agency
- The nutrition and hydration digest: Improving outcomes through food and beverage services - British Dietetic Association

Personalised care

- Introduction to personalisation - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Regulation 15: Premises and equipment

Buildings/premises and equipment

- Bed rails: management and safe use - Medicines and Healthcare products Regulatory Agency
- Building engineering in the health sector (HTM 00) - Department of Health and Social Care
- Devices in Practice: Checklists for using medical devices - Medicines and Healthcare products Regulatory Agency
- Domestic gas health and safety - Health and Safety Executive

- Electrical safety and you: a brief guide - Health and Safety Executive
- Electrical safety at work - Health and Safety Executive
- Gas safety - Health and Safety Executive
- Good practice guidelines on lighting - Stirling Dementia Service Development Centre
- Have the right workplace facilities - Health and Safety Executive
- Health building notes - Department of Health and Social Care
- Health technical memoranda collection - Department of Health and Social Care
- Health technical memoranda series including policies and principles of healthcare engineering (HTM 00) - Department of Health
- Lighting at work, HSG38 - Health And Safety Executive
- Managing medical devices - Medicines and Healthcare products Regulatory Agency
- Medical devices regulation and safety: detailed information - GOV.UK
- Medical gases pipeline systems - Health technical memorandum 02-01 Part A: Design, installation, validation and verification - Department of Health
- PAT: Portable appliance testing FAQs - Health And Safety Executive
- Policies and principles of healthcare engineering (HTM 00) - Department of Health, 2014
- Pressure systems - Health and Safety Executive
- Provision and Use of Work Equipment Regulations 1998 (PUWER) - Health and Safety Executive
- Stirling Dementia Service Development Centre (DSDC)

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Control of Substances Hazardous to Health (COSHH)

- Control of Substances Hazardous to Health (COSHH) - Health and Safety Executive
- The Control of Substances Hazardous to Health Regulations 2002: Approved code of practice and guidance - Health and Safety Executive

Data protection

- In the picture: A data protection code of practice for surveillance cameras and personal information - Information Commissioner's Office

Diginty and respect

- Eliminating Mixed Sex Accommodation: Declaration Exercise, Letter to NHS Chief Executives - Department of Health and Social Care
- Eliminating mixed sex accommodation - PL/CNO/2010/3 (letter from Chief Nursing Officer and Deputy Chief Executive, November 2010) - Department of Health

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Equality and human rights

- Equality Act 2010 guidance

- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

Fire safety

- Fire safety risk assessment: residential care premises - Home Office
- Discover your legal obligations: Regulatory Reform (Fire Safety) Order 2005 - London Fire Brigade

General resources

- NHS Constitution for England - Department of Health and Social Care
- Handbook to the NHS Constitution for England (updated February 2021) - Department of Health and Social Care, Public Health England

Health and safety

- Guidance for health and social care services - Health and Safety Executive
- Health and Safety Executive guidance
- Health and safety in care homes - Health and Safety Executive
- Leading health and safety at work - Health and Safety Executive
- Managing for health and safety - Health and Safety Executive
- Managing for health and safety (HSG65) guidance - Health and Safety Executive
- Ventilation - Health and Safety Executive

Infection control/cleanliness

- Care homes: infection prevention and control - Department of Health and Social Care, Public Health England
- Essential practice for infection prevention and control - Royal College of Nursing
- Guidance on decontamination of equipment for gastrointestinal endoscopy - British Society of Gastroenterology
- Health and Social Care Act 2008: code of practice on the prevention and control of infections - Department of Health and Social Care
- Healthcare-associated infections: prevention and control in primary and community care Clinical guideline [CG139] - NICE
- Infection control in the built environment (HBN 00-09) - Department of Health and Social Care
- Infection prevention and control Quality standard [QS61] - NICE
- PAS 5748:2014 Specification for the planning, application, measurement and review of cleanliness services in hospitals
- Prevention and control of healthcare-associated infections: Quality improvement guide - NICE
- The national specifications for cleanliness: Guidance on setting and measuring performance outcomes in care homes - NHS National Patient Safety Agency
- The revised healthcare cleaning manual - National Patient Safety Agency

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK

Moving and handling

- Getting to grips with hoisting people - Health And Safety Executive

- How the Lifting Operations and Lifting Equipment Regulations (LOLER / PUWER) apply to health and social care - Health and Safety Executive
- Moving and handling in health and social care - Health and Safety Executive

Quality monitoring/governance

- NHS Premises Assurance Model - NHS England
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

Risk assessment

- Bed rail risk management - Sector information minute SIM 07/2012/06 - Health and Safety Executive
- Bed rails: management and safe use (Guidance on managing and using bed rails safely, updated January 2021) - Medicines and Healthcare products Regulatory Agency
- Managing risks and risk assessment at work - Health and Safety Executive
- Sensible risk assessment in care settings - Health and Safety Executive

Safeguarding

- Commissioning care homes: common safeguarding challenges - SCIE guide 46 - Social Care Institute for Excellence

Staffing and recruitment

- People management resources - Social Care Institute for Excellence

Regulation 16: Receiving and acting on complaints

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Complaints

- Adult social care complaint reviews - Local Government and Social Care Ombudsman
- Adult care services: Ombudsman decisions - Local Government and Social Care Ombudsman
- Complaining about health and social care - MIND
- Complaints about health and social care - Local Government and Social CareOmbudsman
- Complaints matter
- Concerns about a care service - Social Care Institute for Excellence
- Improving complaints - The Patients Association
- Independent Sector Complaints Adjudication Service
- My expectations for raising concerns and complaints - Local Government Ombudsman, Healthwatch, Parliamentary and Health Service Ombudsman, November 2014
- NHS complaints guidance - Department for Health and Social Care
- Principles of good complaint handling - Parliamentary and Health Service Ombudsman

Data protection

- Guide to Data Protection - Information Commissioner's Office

Dignity and respect

- Dignity in Care – SCIE guide 15 - Social Care Institute for Excellence, June 2010 (updated May 2013)

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

General resources

- NHS Constitution for England - Department of Health and Social Care
- Handbook to the NHS Constitution for England (updated February 2021) - Department of Health and Social Care, Public Health England

Quality monitoring/governance

- Accessible Information Standard: Making health and social care information accessible - NHS England
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Patient experience in adult NHS services: improving the experience of care for people using adult NHS services - NICE
- Quality standard for patient experience in adult NHS services: NICE quality standard 15 - NICE

- Service user experience in adult mental health: improving the experience of care for people using adult NHS mental health services - NICE
- Service user experience in adult mental health: Quality standard 14 - NICE

Regulation 17: Good governance

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Buildings/premises and equipment

- Building engineering in the health sector (HTM 00) - Department of Health and Social Care
- DH building notes - Department of Health and Social Care
- Domestic gas health and safety - Health and Safety Executive
- Electrical safety and you: a brief guide - Health and Safety Executive
- Electrical safety at work - Health and Safety Executive
- Gas safety - Health and Safety Executive
- Good practice guidelines on lighting - Stirling Dementia Service Development Centre
- Guidance for health and social care services - Health and Safety Executive
- Have the right workplace facilities - Health and Safety Executive
- Health and safety in care homes - Health and Safety Executive

- Health technical memoranda collection - Department of Health and Social Care
- Health technical memoranda series including policies and principles of healthcare engineering (HTM 00) - Department of Health
- Lighting at work, HSG38 - Health And Safety Executive
- PAT: Portable appliance testing FAQs - Health And Safety Executive
- Policies and principles of healthcare engineering (HTM 00) - Department of Health, 2014
- Stirling Dementia Service Development Centre (DSDC)

Care, treatment and support

- Adult social care outcomes framework 2018/19: handbook of definitions - Department of Health and Social Care
- GP services for older people: a guide for care home managers – SCIE guide 52 – Social Care Institute for Excellence, December 2013

Complaints

- Adult care services: Ombudsman decisions - Local Government and Social Care Ombudsman

Conduct, ethics and performance

- Revised Midwives rules and standards come into force - Nursing and Midwifery Council
- Standards for competence for registered nurses Pre-2018 (still valid) - Nursing and Midwifery Council
- Standards for the dental team - General Dental Council

Confidentiality

- A guide to confidentiality in health and social care - NHS Digital
- Confidentiality: NHS code of practice - Department of Health and Social Care

Continuing professional development

- Standards of continuing professional development - Health and Care Professions Council

Control of Substances Hazardous to Health (COSHH)

- Control of Substances Hazardous to Health (COSHH) - Health and Safety Executive
- The Control of Substances Hazardous to Health Regulations 2002: Approved code of practice and guidance - Health and Safety Executive

Data protection

- Guide to Data Protection - Information Commissioner's Office
- In the picture: A data protection code of practice for surveillance cameras and personal information - Information Commissioner's Office
- The Information Governance Review: To share or not to share

Deprivation of liberty

- Liberty Protection Safeguards factsheets: Information about Liberty Protection Safeguards (LPS) - Department of Health and Social Care

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Equality and human rights

- A refreshed equality delivery system for the NHS - NHS England, 2013

- EHRC employment statutory code of practice: sections on reasonable adjustments and pre-employment health checks - Equality and Human Rights Commission
- Equality Act 2010 guidance
- Guidance about age discrimination - Equality and Human Rights Commission
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

General resources

- National Institute for Health and Care Excellence (NICE)
- NHS Constitution for England - Department of Health and Social Care
- Handbook to the NHS Constitution for England (updated February 2021) - Department of Health and Social Care, Public Health England

Health and safety

- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 - Health and Safety Executive
- Natural rubber latex sensitisation in health and social care - Health and Safety Executive
- Selecting latex gloves - Health and Safety Executive
- Sharps injuries - Health and Safety Executive

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK
- Mental Capacity Act resources - Social Care Institute for Excellence

Mental health

- Mental Health Act 1983: Code of Practice - Department of Health

Moving and handling

- Getting to grips with hoisting people - Health And Safety Executive
- How the Lifting Operations and Lifting Equipment Regulations (LOLER / PUWER) apply to health and social care - Health and Safety Executive
- Moving and handling in health and social care - Health and Safety Executive

Quality monitoring/governance

- Accessible Information Standard: Making health and social care information accessible - NHS England
- General Dental Council Governance
- General Medical Council Legislative Framework
- Good medical practice - General Medical Council
- Into practice guide - NICE
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- National NHS staff survey reports
- NHS Patient survey programme
- NHS Patient Safety Strategy - NHS England
- NICE Quality and Outcomes Framework indicator
- Prevention of Future Deaths reports- Courts and Tribunals Judiciary

- Professional Standards Authority
- Records Management Code of Practice 2021 - NHSX
- Revised Never Events policy and framework - NHS England

Records management

- Records Management Code of Practice 2021 - NHSX
- Standards for the clinical structure and content of patient records - Royal College of Physicians

Safety

- Healthcare Professional Alert Notices - NHS Resolution

Staff support and training

- Discover the Adult Social Care Workforce Data Set - Skills for Care
- Effective supervision in a variety of settings: SCIE guide 50 - Social Care Institute for Excellence
- 2021 Resuscitation Guidelines - Resuscitation Council UK
- SCIE resources and services- Social Care Institute for Excellence

Whistleblowing

- Raising concerns at work: Whistleblowing guidance for workers and employers in health and social care - The British Association of Social Workers (BASW)

Regulation 18: Staffing

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care certificate - Health Education England
- Care certificate - Skills for Care
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Care, treatment and support

- GP services for older people: a guide for care home managers: SCIE guide 52 – Social Care Institute for Excellence, December 2013
- Making the move to delivering reablement: At a glance summary 56 - Social Care Institute for Excellence
- Maximising the potential of reablement: SCIE guide 49 – Social Care Institute for Excellence

Conduct, ethics and performance

- Revised Midwives rules and standards come into force - Nursing and Midwifery Council
- Standards - General Pharmaceutical Council
- Standards for competence for registered nurses Pre-2018 (still valid) - Nursing and Midwifery Council
- Standards of conduct, performance and ethics - Health and Care Professions Council

Continuing professional development

- Continuing professional development - General Medical Council
- CPD for dental professionals - General Dental Council

- Professional development - Royal College of Nursing
- Standards of continuing professional development - Health and Care Professions Council

Disclosure and Barring (DBS)

- Disclosure and Barring Service
- Disclosure and Barring identity checking guidelines
- DBS checks for CQC registration

Equality and human rights

- EHRC employment statutory code of practice: sections on reasonable adjustments and pre-employment health checks - Equality and Human Rights Commission
- Guidance about age discrimination - Equality and Human Rights Commission

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Health and safety

- Consulting employees on health and safety: A brief guide to the law - Health and Safety Executive
- Guidance for health and social care services - Health and Safety Executive
- Health and Safety Executive guidance
- Health and safety in care homes - Health and Safety Executive
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 - Health and Safety Executive

- Leading health and safety at work - Health and Safety Executive
- Managing for health and safety - Health and Safety Executive
- Managing for health and safety (HSG65) guidance - Health and Safety Executive
- Natural rubber latex sensitisation in health and social care - Health and Safety Executive
- Selecting latex gloves - Health and Safety Executive
- Sharps injuries - Health and Safety Executive
- Violence at work: A guide for employers - Health and Safety Executive

General resources

- Health and Care Professions Council

Quality monitoring/governance

- Good medical practice - General Medical Council
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Professional Standards Authority
- Recommendations for CQC providers guide - Skills for Care

Restrictive practice/restraint

- SCIE Report 25: Minimising the use of 'restraint' in care homes: challenges, dilemmas and positive approaches - Social Care Institute for Excellence 2009

Staff support and training

- Discover the Adult Social Care Workforce Data Set - Skills for Care

- Effective supervision in a variety of settings: SCIE guide 50 - Social Care Institute for Excellence
- Manager induction standards - Skills for Care
- Review of healthcare assistants and support workers in NHS and social care (The Cavendish Review) - Department of Health and Social Care
- Skills for Care
- What are the Management Standards? - Health and Safety Executive
- Work-related stress - Health and Safety Executive

Staffing and recruitment

- COVID-19 and staffing levels -Royal College of Nursing
- How to ensure the right people, with the right skills, are in the right place at the right time - National Quality Board
- People management resources - Social Care Institute for Excellence
- Planning your workforce - Skills for Care
- Revalidation - General Medical Council
- Safe staffing for nursing in adult inpatient wards in acute hospitals - NICE
- Safe staffing guidance and advice list - NICE

Staff support and training

- National Skills Academy for Social Care

Regulation 19: Fit and proper persons employed

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care certificate - Health Education England
- Care certificate - Skills for Care
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Conduct, ethics and performance

- Revised Midwives rules and standards come into force - Nursing and Midwifery Council
- Standards for competence for registered nurses Pre-2018 (still valid) - Nursing and Midwifery Council
- Standards for the dental team - General Dental Council

Continuing professional development

- Standards of continuing professional development - Health and Care Professions Council

Disclosure and Barring (DBS)

- Disclosure and Barring Service
- Disclosure and Barring identity checking guidelines
- DBS checks for CQC registration

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Equality and human rights

- EHRC employment statutory code of practice: sections on reasonable adjustments and pre-employment health checks - Equality and Human Rights Commission
- Equality Act 2010 guidance
- Guidance about age discrimination - Equality and Human Rights Commission
- Guidance for service providers about their duties under the Equality Act 2010 - Equality and Human Rights Commission
- Services, public functions and associations: Statutory code of practice - Equality and Human Rights Commission

Fees

- Unfair contract terms guidance: OFT311 - Competition and Markets Authority
- Unfair contract terms: CMA37 - Competition and Markets Authority

Quality monitoring/governance

- General Dental Council Governance
- General Medical Council Legislative Framework
- Good medical practice - General Medical Council
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Professional Standards Authority
- Recommendations for CQC providers guide - Skills for Care

Safety

- Healthcare Professional Alert Notices - NHS Resolution

Staffing and recruitment

- People management resources - Social Care Institute for Excellence

Staff support and training

- National Skills Academy for Social Care

Regulation 20: Duty of candour

Care Act and Care Certificate

- Care Act 2014 (Social Care Institute for Excellence resources)
- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

Conduct, ethics and performance

- Revised Midwives rules and standards come into force - Nursing and Midwifery Council
- Standards for competence for registered nurses Pre-2018 (still valid) - Nursing and Midwifery Council
- Standards for the dental team - General Dental Council

Consent

- Gillick competency and Fraser guidelines - NSPCC Learning

Duty of candour

- Openness and honesty when things go wrong: The professional duty of candour - General Medical Council

- NHS Standard Contract 2014/15: Updated Technical Guidance - NHS England

End of life care

- One chance to get it right: improving people's experience of care in the last days and hours of life - Leadership Alliance for the Care of Dying People

Mental capacity

- Mental Capacity Act 2005 code of practice - GOV.UK

Quality monitoring/governance

- General Dental Council Governance
- General Medical Council Legislative Framework
- Good medical practice - General Medical Council
- NHS Patient Safety Strategy - NHS England
- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library
- Professional Standards Authority
- Saying Sorry - NHS Resolution

Safety

- Healthcare Professional Alert Notices - NHS Resolution

Regulation 20A: Requirement as to display of performance assessments

Care Act and Care Certificate

- Care Act 2014 part 1: factsheets - Department of Health, June 2014
- Care Act 2014 resources - Social Care Institute for Excellence
- Statutory Guidance Care Act 2014: supporting implementation Support for local authorities to carry out the implementation for part 1 of the Care Act 2014 - Department of Health and Social Care

General resources

- NICE Collaborating Centre for Social Care - Social Care Institute for Excellence
- SCIE at-a-glance summaries - Social Care Institute for Excellence
- SCIE guides - Social Care Institute for Excellence
- SCIE resources and services - Social Care Institute for Excellence
- Social Care TV (requires registration) - Social Care Institute for Excellence

Quality monitoring/governance

- National Institute for Health and Care Excellence (NICE) guidance
- National Institute for Health and Care Excellence (NICE) quality standards topic library

CQC registration regulations: related guidance

Abortion/termination of pregnancy

- Guidance in relation to requirements of the Abortion Act 1967 - Department of Health, May 2014. This relates to CQC registration regulation 20.
- Procedures for the approval of independent sector places for the termination of pregnancy: Required Standard Operating Procedures (RSOPs) - Department of Health, May 2014. This relates to CQC registration regulation 20.

- Termination of pregnancy: An RCN nursing framework - Royal College of Nursing. This relates to CQC registration regulation 20.
- The care of women seeking induced abortion - Royal College of Obstetricians and Gynaecologists, 2011. This relates to CQC registration regulation 20.

Quality monitoring/governance

- What is registration? - this relates to **all** CQC registration regulations
- Making changes to your registration - this relates to CQC registration regulations 12, 14 and 15
- Notifications for GP providers - this relates to CQC registration regulations 14, 15, 16, 17 and 18
- Notifications for NHS trusts - this relates to CQC registration regulations 14, 15, 16, 17 and 18
- Notifications for non-NHS providers - this relates to CQC registration regulations14, 15, 16, 17 and 18.

Glossary of terms used in the guidance for providers and managers

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

Abuse

Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, 'abuse' means:

- Any behaviour towards a person using services that is an offence under the Sexual Offences Act 2003(a).
- Ill-treatment of a person whether of a physical or psychological nature.
- Theft, misuse or misappropriation of money or property belonging to a person using services, or
- Neglect of a person using services.

Accredited voluntary register

A register that has been accredited by the Professional Standards Authority. This means that the organisation that holds the register meets demanding standards set by the Authority in: governance, setting standards for registrants, education and training, managing the register, providing information and handling complaints. A voluntary register differs from a statutory register because practitioners are not obliged to be registered in order to practise.

Adequate

Sufficient for a specific requirement.

Advance decision

A decision to refuse specified medical treatment, made in advance by a person who has the mental capacity to do so. In this way, people can refuse medical treatment for a time in the future when they may lack the capacity to consent to, or refuse, that treatment.

Advocacy

The action of an advocate, or the services provided by one or more advocates on behalf of another person. It involves taking action to help people to say what they want, securing their rights, representing their interests and obtaining the services they need. Advocacy is most effective when carried out by a person who is independent of the services being provided.

Advocate

Advocate can be used in a general sense, as one who speaks on behalf of another, or it can have special meanings derived from the Mental Health Act 1983 and the Mental Capacity Act 2005.

There are formal and informal advocates and these can be:

- Individuals acting informally:
    - Carers
    - Relatives
    - Partners
    - Neighbours or friends
    - Staff.
- Those prescribed by legislation, such as Independent Mental Health Advocates and Independent Mental Capacity Advocates.
- Those provided by schemes run by local authorities, the NHS and charities.

Agreement (in relation to a signed document)

Usually a document that sets out the understanding between two or more individuals or entities about their enforceable rights and duties regarding their performance and consideration in accordance with their agreement. While an agreement usually leads to a written contract, it can also be recorded in different ways and may also be spoken, rather than written.

Apology

An expression of sorrow or regret in respect of a notifiable safety incident.

Appropriate care and treatment

Making sure that care and treatment is actually what the person needs. Not over-treatment, unnecessary care or treatment, or care or treatment that is disproportionately involved or complicated.

Audit

A thorough examination or evaluation.

Autonomy

Independence or freedom.

Bankruptcy Restriction Order

An order made by a court in a bankruptcy case if it feels that the person who filed for bankruptcy has engaged in culpable or dishonest conduct. A person subject to a Bankruptcy Restriction Order is under certain restrictions for a period of between two and 15 years. A Bankruptcy Restriction Order is not lifted when the bankruptcy is discharged.

Barred lists

Lists maintained by the Disclosure and Barring Service (DBS) of individuals who are unsuitable to work with children or vulnerable adults.

Bind over

An adult accused of an offence may be bound over to appear at a court, or to be of good behaviour, or to keep the peace. If they refuse to accept a bind over, the person may be committed to prison. A bind over may be imposed with other penalties following conviction but is not a conviction and does not go onto a criminal record.

Capacity

The ability by someone to make a specific decision for himself or herself in a given situation. It is assumed that anyone aged 16 or over has capacity unless proven otherwise.

There are no degrees of capacity: either a person has capacity to make a particular decision or does not. People may have the capacity to make some decisions but not others. Children under 16 are assumed not to have capacity unless they have sufficient understanding and intelligence to enable them to understand fully what is proposed.

Capacity is defined by the Mental Capacity Act 2005 as:

"People who lack capacity:

1. For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or disturbance in the functioning of, the mind or brain.
2. It does not matter if the impairment or disturbance is permanent or temporary.
3. A lack of capacity cannot be established merely by reference to:
    1. A person's age or appearance,
    2. A condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity."

Carer

Carers look after their family, partners or friends who are in need of help because they are ill, frail, or have a disability. The care they provide is unpaid.

Carers include young carers.

The term does **not** include paid care workers or people who undertake voluntary work.

Caring

By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.

Carry on

To provide, run or manage the provision of, a regulated activity.

Child/children

The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. However, the Children Act 2004 states that in certain circumstances safeguarding, protection and cooperation between services may be continued through to a young person's 19th birthday or beyond.

Commissioner

A person or organisation that buys services on behalf of the people living in the area that the commissioner covers. This may be for a population as a whole, or for individuals who need specific care, treatment and support.

Competence

The application of the required level of knowledge and skills to a particular task. In applying these, a person demonstrates that they understand and use the required level of knowledge and skills.

Competent persons

People who have the required level of knowledge and skills for a particular task.

Complaint

An expression of dissatisfaction with something. This can relate to any aspect of a person's care, treatment or support and can be expressed verbally, in gesture or in writing.

Compliance

Meeting or conforming with defined requirements.

Composition, arrangement or trust deed with creditors

Various forms of agreement made by an insolvent or financially pressed debtor with two or more creditors to pay part or all of what they owe.

Consent

A person's agreement to, or permission for, a proposed action, particularly any form of examination, care, treatment, or support.

Professionals have their own codes of practice that indicate how they should manage the consent they need from people who use services.

In our guidance, we recognise that the consent of a person who uses services can involve another person, and that it can be obtained, given and recorded in different ways.

Culture

Learned attitudes, beliefs and values that define a group or groups of people.

Dignity

Dignity is concerned with how people feel, think and behave in relation to the worth or value that they place on themselves and others. To treat someone with dignity is to treat them as being of worth and respecting them as a valued person, taking account of their individual views and beliefs.

Director (Regulation 5)

'Director' includes all board level appointments of NHS foundation trusts, NHS trusts and special health authorities and other bodies carrying on a regulated activity that are responsible for the overall quality and safety of care and for making sure that care meets the requirements of the HSCA 2008 (Regulated Activities) Regulations 2014. It includes executive and non-executive, permanent, interim and associate positions, irrespective of their voting rights.

Discharge (in relation to care and treatment)

The point at which a person leaves hospital to return home or be transferred to another service or the formal point when they no longer use a service.

Discharge (in relation to bankruptcy)

A legal release from bankruptcy restrictions.

Diversity

Diversity describes the range of visible and non-visible differences that exist between people. It means understanding that each individual is unique and recognising our individual differences.

Duty of candour

The duty of candour requires providers to be open with the people who use their service. 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 a notification about a safety incident needs to be made to CQC.

Effective

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

Employment

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 defines employment as:

- Employment under a contract of service, an apprenticeship.
- Practising privileges granted to a medical practitioner, which give permission to practise as a medical practitioner in a hospital managed by the service provider.

Although volunteers and Shared Lives carers are not strictly employees, they are included in the definition for the purposes of the regulations and therefore this guidance. References to 'staff' and 'employees' therefore apply to them and temporary or agency workers.

Enforcement action

This is when CQC imposes, varies or removes conditions of registration; when we suspend or cancel a registration whether using urgent procedures or not and issuing Warning Notices, penalty notices, simple cautions; or when we prosecute a provider.

Equipment

Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term 'materials' used in the regulated activity or by people employed by the service provider may refer to aids that could support a person's care, treatment, support, mobility or independence. For example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises. The definition of medical devices above does not include items such as sheets, curtains, pillows and towels.

Experience (of care treatment or support)

Experience can refer to the broad effects that care, treatment or support can have on a person, including their thoughts and feelings about the care, treatment and support they have received, how they interact with staff and others, or any wider impact on their life and those around them.

Experience (in relation to skills and knowledge)

Knowledge and capability gained from previous employment or direct, personal observation, participation or contact in relevant, previous employment related activities.

Fit

The person is of good character, as they are honest, reliable, trustworthy and respectful, and that they have the right qualifications, competence, skills and experience to perform their role.

Good character

A person who is of good character is honest, reliable, trustworthy and respectful. When assessing whether an individual is of good character, providers should make every effort to make sure that as a minimum, they seek all available information to confirm that:

- They have not been convicted of an offence in any country that would be considered an offence in the UK, if the offence relates to the conduct required in carrying on a regulated activity.
- They have not been erased, removed or struck off a professional register.

Harm

Physical or psychological damage or injury.

Healthcare

The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in medical, surgical or social care settings.

Healthcare professional

Individuals regulated and/or licensed to provide some type of health or social care.

Human rights

The basic rights and freedoms contained in the European Convention on Human Rights. The Human Rights Act 1988 means that most of the convention rights are available to everyone in the United Kingdom, regardless of their age, nationality, race, ethnicity, gender or religion and beliefs. It is an offence for a public body to breach any person's human rights, and under the Health and Social Care Act 2008, 'public body' includes any provider that supplies accommodation together with nursing or personal care on behalf of a local authority.

Implied consent

A form of consent that is not expressly granted by a person, but rather inferred from a person's actions and the facts and circumstances of a particular situation (or in some cases, by a person's silence or inaction). The assumed agreement is that the person would approve a course of action if asked in a given situation, but is not presently able to be asked.

Independence

Freedom from the control or influence of others.

Involvement

Enabling people to get involved in the planning and delivery of their own care, treatment and support. This includes people acting on their behalf and groups of people who use services being involved together, for example through local involvement networks or a user forum.

Lawfully acting on their behalf

This refers to authority given under the Mental Capacity Act 2005, such as a valid and applicable advance decision to refuse treatment, Lasting Powers of Attorney for health and welfare containing relevant clauses, Court-Appointed Deputyship including relevant decision-making powers, a decision of a Court, the Mental Health Act 1983, or a best interest assessment in accordance with the Mental Capacity Act 2005. It can also refer to people having parental responsibility for any child aged under 18, which may be a natural or adoptive parent or a local authority if a care order is in place.

Medical device

Any instrument, apparatus, appliance, material or other article (whether used alone or in combination), including the software necessary to use it properly, intended by the manufacturer to be used for people for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, alleviation of or compensation for any injury or disability.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.

This also includes devices intended to administer a medicinal product.

Medicine

A substance or substances administered for the purpose of modifying, controlling, treating or diagnosing a medical condition, disease or illness.

Meeting needs

This term relates to clinical treatment and care outcomes.

Mental health

A person's ability to manage and cope with the stresses and challenges of life.

Misappropriation

Wrongly taking or using something that belongs to another person for your own use.

Moderate harm

For the purposes of Regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 "moderate harm" means—

1. harm that requires a moderate increase in treatment, and
2. significant, but not permanent, harm;

Moratorium period under a debt relief order

A debt relief order is an alternative to bankruptcy, which is intended to give debt relief to people in England and Wales who owe relatively little money, have little or no disposable income and no assets to repay what they owe, and cannot afford to make themselves bankrupt. The main effect of a debt relief order is to place a 'moratorium' period on the debts listed in the order. This means creditors cannot take any action to recover or enforce those debts during this period without a court order. The moratorium usually lasts for 12 months from the date of the order, although there may be exceptions, and after that time the listed debts will be discharged.

Needs

All needs, including emotional, social, cultural, religious and spiritual needs, should be included in assessments about the care and treatment people receive.

Neglect

The failure to meet a person's basic physical and/or psychological needs.

Nominated individual

Nominated individual means the person who is employed as a director, manager or secretary of a body and whose name has been notified to CQC as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Nutritional and hydration needs

In Regulation 14 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, 'nutritional and hydration needs' means:

1. A person's need to receive suitable and nutritious food and hydration that is adequate to sustain life and good health.
2. A person's need to receive parenteral nutrition (feeding intravenously to get nutrition into the body through the veins) and dietary supplements when prescribed by a health care professional.
3. Meeting any reasonable requirements of a person using the service for food and hydration arising from their preferences or their religious or cultural background, and
4. If necessary, supporting people to eat or drink.

Palliative care

The active, holistic care of people who use services who have advanced progressive illness. Managing pain and other symptoms, and providing psychological, social and spiritual support, is paramount. The goal of palliative care is to achieve the best quality of life for people who use services and their families. Many aspects of palliative care are also applicable earlier in the course of the illness, in conjunction with other treatments.

Patient Safety Alerts

Patient safety alerts are issued via the Central Alerting System (CAS), a web-based cascading system for issuing alerts, important public health messages and other safety critical information and guidance to the NHS and other organisations, including independent providers of health and social care.

People who use services

The legislation uses the term "service user", which means a person who receives services from a provider as they carry on a regulated activity.

Personalised

This is when the person using the service leads, with choice being the defining principle in relation to the care or treatment provided to meet their particular needs and preferences.

Person-centred

Putting the person who uses services at the centre of their care, treatment and support, ensuring that everything that is done is based on what is important to that person from their own perspective.

Preferences

This includes those relating to how people's care and treatment are provided or preferences about which provider they choose to provide it. It is recognised that in some circumstances a person's preferences may be limited. For example, when people are detained under the Mental Health Act 1983.

Premises

This is any building or other structure, including any machinery or engineering systems or other objects that are physically affixed and integral to the building or structure, or a vehicle. It includes accommodation provided as part of a person's care or treatment.

Privacy

To respect a person's privacy is to recognise when they wish and need to be alone (or with family or friends), and be protected from others looking at them or overhearing their conversations. It also means respecting their confidentiality and personal information.

Privy to serious misconduct or mismanagement

'Privy to' means that there is evidence that could lead the provider to reasonably conclude that a person was aware of serious misconduct or mismanagement but did not take the appropriate action to ensure that it was addressed.

Professional body

An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in its profession, and the interest of its professional members.

Protected characteristics

The protected equality characteristics are defined in the Equality Act 2010 and are:

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity status
- Race

- Religion or belief
- Sex
- Sexual orientation.

Provider

An individual person, partnership or organisation registered with CQC to carry on one or more regulated activities.

Reasonable adjustments

The duty to make reasonable adjustments is set out in the Equality Act 2010, which says that employers and organisations such as hospitals, care homes and GP surgeries must take steps to remove the barriers people face because of their disabilities. There are three parts to the duty:

- Change the way things are done – a duty to take reasonable steps to change a practice, policy or procedure that makes it more difficult for people with a disability to access or use their services.
- Change a physical feature – a duty to take reasonable steps to remove, change, or provide a reasonable way of avoiding a barrier such as steps, doors, toilets, signs and so on.
- Provide extra aids or services – A duty to take reasonable steps to provide an additional aid or service where it would help people with a disability to benefit. For example, a portable induction loop for people with hearing aids, British Sign Language interpreters, providing information in alternative formats, such as Braille or audio CDs, or extra staff assistance.

Providers must not wait for people to ask them to do something. They should consider in advance what they need to do to make their services accessible to all disabled people.

When is it reasonable to make the changes?

Providers must make changes or adjustments to how they provide their services if it's **reasonable** to. Whether something is reasonable depends on the size, resources of the organisation and type of service they provide. It also depends on what changes or adjustments are needed and how practical or easy it is to do them. It's the courts who decide if something is reasonable or not.

Record

A formal written report or statement of facts, events or information, usually collected over a fairly long period. The act of maintaining individual records is called recording.

Registered person

A person who is the registered provider or registered manager in respect of one or more regulated activities.

Regulatory action

Actions we take as the regulator of health and social care services in England to address a registered person's breach of a regulation, condition of registration or other relevant requirement.

Relevant person (Regulations 9, 11 and 17)

In Regulations 9, 11 and 17, "relevant person" means the person using a service and/or any person who must be consulted when providing person-centred care to a person using a service. Where an adult who uses a service lacks the capacity to make a decision about their care, this would include any person acting lawfully on their behalf under the Mental Capacity Act 2005, such as with authority given by an advance decision to refuse treatment, Lasting Powers of Attorney for health and welfare containing the relevant clauses, or a Court appointed Deputy.

Where a person using a service is subject to the Mental Health Act 1983, it would include any person with the authority to determine care.

Where a person using a service is under 16 and not competent to make a decision about their care, this would include any person with parental responsibility or other legal authority (such as a local authority having a care order), or other recognised family member, carer or advocate.

Relevant person (Regulation 20)

In Regulation 20, "relevant person" means the person using the service or, in the following circumstances, a person lawfully acting on their behalf:

1. When the person using the service dies.
2. Where the person using a service is under 16 and not competent to make a decision in relation to their care or treatment, or
3. Where the person using the service is 16 or over and lacks capacity to make decisions.

Resources

The things needed to carry out a task or piece of work. Resources can include appropriately qualified staff, finances, suitable buildings and sufficient equipment.

Respect

Providers must demonstrate respect for people using their service by:

- Treating people with care and compassion
- Addressing them in the manner they have indicated they prefer, and
- Treating them all equally regardless of their level of understanding or ability to express their views.

Responsible for, contributed to or facilitated serious misconduct or mismanagement

This means that there is evidence that a person has intentionally, or through neglect, behaved in a manner that would be considered to be, or would have led to, serious misconduct or mismanagement.

Responsive

By responsive, we mean that services are organised so that they meet people's needs.

Restraint

In Regulation 13 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, a person controls or restrains a person using services by:

1. Using, or threatening to use, force to enable them to carry out something that the person using the service resists, or

2. Restricting the person's liberty of movement, whether or not they resist, including by using physical, mechanical or chemical means.

Risk

The probability of an adverse event or issue occurring, which is related to a particular condition or treatment and consideration of how severe the consequences are likely to be.

The risk may come directly from the condition itself or indirectly from the process or method involved in the treatment or application. Risk does not mean bad things will happen. It allows people to make decisions about the world in which they live and the choices they have to make, because it is a balanced judgement of danger.

Risk assessment

The process of identifying all the risks to and from an activity, and assessing the potential impact of each risk.

Safe

By safe, we mean that people are protected from abuse and avoidable harm.

Safeguard

To protect and promote people's welfare, including:

- Protecting people from abuse or neglect.
- Preventing impairment of people's health or development.

- Ensuring that people receive care, treatment and support in circumstances consistent with the provision of safe and effective care, treatment and support.

Safeguarding

Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults on independence and choice.

Serious misconduct or mismanagement

Behaviour that would constitute a breach of any duty, responsibility, legislation/ enactment relevant to meeting these regulations or their component parts. "Serious misconduct" may include assault, fraud and theft or breaches of professional duties or codes of practice. "Mismanagement" may include mismanaging funds and/or not adhering to recognised practice, guidance or processes regarding care quality within which the individual is meant to work. These are not exhaustive lists.

Service user

A person who receives services provided in the carrying on of a regulated activity. **Please note:** The regulations refer to 'service users' and where we quote the regulation directly we use this phrase. Elsewhere in the guidance we have used the terms 'people who use services' or 'people'.

Social care

Social care includes all forms of personal care and other practical assistance provided for people who, because of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or any other similar circumstances, are in need of such care or other assistance.

For the purposes of regulation by the Care Quality Commission, this is care provided for, or mainly for, people over 18 years old in England. We sometimes refer to this as adult social care.

Staff

The entire group of people employed for the purposes of carrying on a regulated activity.

Statement of purpose

Schedule 3 of the Care Quality Commission (Registration) Regulations 2009 defines a statement of purpose as a statement that sets out:

1. The aims and objectives of the service provider in carrying on the regulated activity.
2. The types of services provided in order to carry on the regulated activity and the needs of the people who use the service, which those services are intended to meet.
3. In relation to the service provider and any registered manager, their:

- full name
- business address
- business telephone number
- email address where available.

In relation to the registered person:

- The postal address to which CQC may send any document, notice or other communication required to be delivered by these Regulations or the Act, and
- Where the registered person consents to this, an email address to which CQC may send any document, notice or other communication required to be delivered by these Regulations or the Act.

1. The legal status of the service provider.
2. Details of the locations at which the services are provided to carry on the regulated activity.

Supervision

A process to guide, support and assist employees to enable them to carry out the duties they are employed to perform.

Theft

Dishonestly appropriating property belonging to another person with the intention of permanently depriving the other of it.

Third party

A person or organisation other than the principals who are involved in a transaction or direct provision of a service.

Timely

As soon as can be reasonably achieved.

Treatment

In Regulation 2(2) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, treatment includes:

- A diagnostic or screening procedure carried out for medical purposes
- The ongoing assessment of a person's mental or physical state
- Nursing, personal and palliative care, and
- Giving vaccinations and immunisations.

This regulation excludes the regulated activity of assessment or medical treatment for persons detained under the 1983 Act.

Warning Notice

Warning Notices tell a registered person that they are not complying with a condition of registration, requirement in the Act or a regulation, or any other legal requirement that we think is relevant and will usually require a registered person to comply with that requirement by a specified date.

Welfare

A person's state or condition, taking into account their physical, social and financial situation. A person's welfare will also take account of their emotional and spiritual states.

Well-led

By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

Without delay

As soon as can be reasonably achieved.

Service types

The guidance to the regulations applies to all the many different service types that CQC regulates. Some providers' activities will cover more than one service type. The links between service types and regulated activities are set out in our quick guide. This is available in 2 formats:

- Quick guide to regulated activities by type of service: online text version
- Quick reference guide to regulated activities by type of service: chart

The service types and their codes are aligned to CQC's fee structure; this may differ to terms used within the different care settings.

Healthcare services

Acute services (ACS)

These services are complex and vary greatly. Generally, however, they provide medical and/or surgical investigations, diagnosis and treatment for physical illness or condition, injury or disease.

They can provide services to adults, children or both. They may provide services to a broad range of people or to a particular group of people.

They can:

- Admit people on a day case basis or as inpatients.
- Admit people at short notice or in an emergency (whether or not they have a dedicated emergency department).
- See people on an outpatient basis.

They may also provide services such as:

- Surgical operations
- Specialist medical treatments
- Accident and emergency
- Consultations
- Diagnostics
- Maternity and neonatal
- Pathology
- Termination of pregnancy
- Complex dental procedures
- Liaison psychiatry.

People are usually admitted to the service under the care of a medical or clinical practitioner. The service may also employ a broad range of healthcare professionals to meet the needs of the people using the service.

Some services may be smaller than others and may not provide the same range of acute services depending on the size of the hospital (for example, an accident and emergency department).

Examples of services that fit under this category:

- NHS acute hospitals
- Independent acute hospitals
- Termination of pregnancy clinics
- NHS community hospitals
- Independent sector treatment centres (ISTCs)
- Community hospitals
- Cosmetic surgery clinics
- Specialist or single specialty hospitals
- Maternity hospitals.
- IVF clinics providing surgical treatment or endoscopy
- Haemodialysis units
- Minor injuries units.

Hyperbaric chamber services (HBC)

These services involve the administration of oxygen (whether or not combined with one or more other gases) to a person in a sealed chamber that is gradually pressurised with compressed air. The services are carried out by, or under the supervision of, a medical practitioner.
The services help to treat a range of medical conditions including:

- Air or gas embolism

- Decompression illness
- Carbon monoxide poisoning
- Gas gangrene
- Necrotising fasciitis
- Other conditions approved by the Undersea and Hyperbaric Medical Society.

Examples of services that fit under this category:

- Type 1 hyperbaric chambers
- Type 2 hyperbaric chambers.

Hospice services (HPS)

These provide a range of services for conditions where curative treatment is no longer an option, and people are approaching the end of their life. They provide care, treatment and support for people and their families and carers, including respite care for people who live with friends or family at home.

Care, treatment and support can be provided in accommodation or in the community. It can be long or short-term care, on an inpatient basis or provided through day care, day therapy or outreach services.

The services will generally employ or work with a broad range of health and social care professionals to meet the needs of people using the service.

Examples of services that fit under this category:

- Adult hospices
- Children's hospices
- Day hospices

- End of life care teams
- Hospice at home.

Long-term conditions services (LTC)

These services provide a range of highly specialised care, treatment and support to people with physical or neurological illnesses, cognitive impairments or injuries that are unlikely to improve. These conditions may have been inherited or acquired, and may not necessarily be life-limiting. This care, treatment and support is the sole or main purpose of the service.

People may be cared for by these services for many years at a time, and will be 'admitted' and stay at the facility over time. People using these services require the support of medical practitioners and a range of other healthcare professionals, and their care, treatment and support may involve highly technical interventions such as ventilation.

Hospital services for people with mental health needs, and/or learning disabilities, and/or problems with substance misuse (MLS)

These services are for people with **mental health needs**, **a learning disability** or problems with **substance misuse** who are admitted to hospital, involving an overnight stay, for assessment or treatment when there is a need for more intensive support than would typically be provided in the community, or a need for a specialist assessment or intervention.

This is usually because of:

- An acute episode of a severity that requires 24-hour care.
- A need for a higher level of security.
- A need for a specialist assessment, treatment and/or rehabilitation.

This might include providing care, treatment and support for people detained under the Mental Health Act 1983.

Some people with mental health needs or a learning disability may require longer-term accommodation in hospital, while others may be admitted for short periods or treated on a day case basis.

These services **also** cover inpatient treatment for people who have problems with **substance misuse**. They usually involve short periods of hospital-based treatment, including 24-hour medical cover to assess and stabilise the person, and treatment for withdrawal from drugs (legal, illegal and substitute preparations) or detoxification from alcohol.

All the hospital services above will usually comprise one or more wards in which care, treatment and support is provided. There may be a range of other facilities including occupational and arts therapies, psychological therapies, psychosocial interventions, recreational activities and services to address physical health needs.

Examples of services that fit under this category:

- NHS or independent services that provide specialist hospital services for people with mental health needs, people with a learning disability and people who have problems with substance misuse.
- Child and adolescent mental health services (CAMHS) tier 4.

Prison healthcare services (PHS)

This covers all health services provided in prisons, young offender institutions (YOIs) and immigration removal centres (IRCs). Some providers may be permanently based in the prison, YOIs or IRCs; others may be based elsewhere but provide outpatient clinical sessions within the prison.

Prison healthcare services can include a broad range of healthcare, for example general practice, dentistry, mental health, substance misuse, acute and end of life care. We would usually expect providers of prison healthcare services to cover one or more additional service types, depending on the type of service they are providing. They employ a broad range of health and social care professionals to meet the needs of people who use their services.

Examples of services that fit under this category:

- Mental health in-reach teams
- Counselling, assessment, referral, advice and through-care (CARAT) teams
- Prison drug rehabilitation programmes
- Young offenders institutions
- Some immigration removal centres.

Rehabilitation services (RHS)

These services provide, as their sole or main purpose, treatment to people following an illness or injury that impairs their physical, mental or cognitive wellbeing, but for which continued rehabilitative care is likely to bring about improvement.

They may consist of a range of services that promote faster recovery from illness, prevent unnecessary admission to acute services, support timely discharge and maximise independent living.

The services can be provided on a short or long-term basis, in hospital, residential, day care or domiciliary settings. They are mainly provided within healthcare settings but can also be provided in a social care setting.

Examples of services that fit under this category:

- Intermediate care schemes
- Rehabilitation units.

Residential substance misuse treatment/ rehabilitation services (RSM)

These services are provided to adults and young people who have problems with misusing drugs and/or alcohol. They provide care, treatment and support, both pharmacological and psychosocial, and help people to reintegrate into their communities, focusing on the coping strategies and life skills they need to do this.

They often employ a broad range of health and social care professionals to meet the needs of people who use their services.

Some of these services may also provide assessment, stabilisation and treatment for withdrawal from drugs (legal, illegal and substitute preparations) or detoxification from alcohol.

Examples of services that fit under this category:

- Residential substance misuse rehabilitation services
- Crisis and stabilisation intervention units.

Community or integrated healthcare

Community healthcare services (CHC)

These services supply a range of healthcare staff other than doctors, for example, nurses or allied health professionals, to people who need healthcare support in their own home, in community settings or in child development units.

The care provided may be short or long term, and meet acute or chronic healthcare needs. The services may help people to live independently in the community and they are directly responsible for the quality of the care and support provided by the staff they supply, and do not include employment agencies.

Examples of services that fit under this category:

- District nursing
- Nurses agency
- Community physiotherapy team
- Health visiting team
- Support worker team
- Children's community nurses
- Community paediatric therapies
- Community midwifery
- School nursing
- Family planning and sexual health clinics
- Community rehabilitation teams.

Doctors consultation services (DCS)

These services involve doctors working in premises, or a room, designated for medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.

There may be other healthcare professionals, for example nurses, supporting the work of the doctor.

Examples of services that fit under this category:

- Independent doctors consulting rooms
- NHS GP practices
- Slimming clinics.

Doctors treatment services (DTS)

These services involve doctors working in premises, or a room, designated for minor medical treatments as well as medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.

They may also undertake minor invasive investigations or procedures, such as conscious endoscopy, in a treatment room designed for this purpose.
There may be other healthcare professionals, for example practice nurses, supporting the work of the doctor.

Examples of services that fit under this category:

- Independent doctors consulting rooms
- NHS GP practice
- Early medical abortion clinics
- Travel vaccination services
- Polyclinics.

Dental services (DEN)

These services involve registered dentists and dental care professionals usually working in premises designed for consultation and treatments, but they can also be provided in a person's place of residence. Consultations and examinations will involve discussion of the treatment options with the patient and may include dental radiography. Treatment is usually provided in a dedicated room and, in consultation with the patient, may be under local anaesthetic or use a laser. Medicines may be prescribed as part of the treatment.

Examples of services that fit under this category:

- Primary care dental services (dentists on the high street, NHS funded, private or both)
- Dental out-of-hours services.

Diagnostic and/or screening services (DSS)

These services provide individual health assessment and/or screening to people, using:

- Diagnostic imaging, such as:
    - X-rays
    - Computed tomography (CT)
    - Magnetic resonance imaging (MRI)
    - Ultrasound scanning
    - Gamma cameras
    - PET scanners
- Pathology
- Physiological measurement

- Genetic screening services
- Endoscopy.

They provide, as the sole or main purpose, diagnosis or screening. They do not usually provide any other health or social care services. While large acute hospitals will have similar services, this category relates only to these dedicated, focused services.

These services undertake investigations on behalf of the person using the service or on behalf of a healthcare professional that the person is consulting (who is legally permitted to request such investigations).

They will involve a range of healthcare professionals that may include:

- Medical practitioners
- Nurses
- Radiographers
- Physiological measurement technicians.

Examples of services that fit under this category:

- Health screening centres
- MRI or CT scanning services (fixed and mobile)
- Baby scanning services
- Endoscopy centres and clinics
- Stand alone or mobile urodynamic services.

Community-based services for people with a learning disability (LDC)

These services provide care, treatment and support in the community for people with a learning disability, through a wide range of service models.

They employ a broad range of health and social care professionals mainly in multi-disciplinary teams.

They help people to live as independently as possible, manage their condition and improve it where this is possible. People using these services may receive support over a long period or for short-term interventions. They may move between the various community teams to ensure that their changing needs are met.

Examples of services that fit under this category:

- Community learning disability teams
- Challenging behaviour/outreach teams.

Mobile doctors services (MBS)

These services involve doctors visiting people in premises where the person using the service is living (on a long or short-term basis). They may also provide services through an internet website or over the phone where the initial consultation is with either non-clinical staff or with a nurse or a doctor.

The doctors provide medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.

There may be other healthcare professionals, for example nurses, supporting the work of the doctor.

Examples of services that fit under this category:

- Independent medical agencies

- GP out-of-hours services
- Community doctors

Community-based services for people with mental health needs (MHC)

These services provide care, treatment and support in the community for people with mental health needs, through a wide range of service models.

They employ a broad range of health and social care professionals mainly in multi-disciplinary teams.

They help people to recover by providing a broad range of interventions reflecting the psychological, social and physical needs of the individual.

People using these services may receive support over a long period or for short-term interventions. They may move between the various community teams to ensure that their changing needs are met, or be in contact with them simultaneously.

This may include providing care, treatment and support to people subject to supervised community treatment under the Mental Health Act 1983 (amended in 2007).

Examples of services that fit under this category:

- Child and adolescent mental health services (CAMHS) (tiers 2, 3 and 4)

- Community-based services that provide assessment and treatment for people with mental health needs including:
    - community mental health teams
    - assertive outreach
    - early intervention teams
    - court diversity teams
    - crisis resolution home treatment teams.

Community-based services for people who misuse substances (SMC)

These services are provided in the community for people who misuse drugs and/or alcohol. They provide care, treatment and support, both pharmacological and psychosocial, and help with social and other needs so that people can reintegrate into their communities. They employ a broad range of health and social care professionals to meet the needs of people who use their services.

Examples of services that fit under this category:

- Community drug and alcohol teams
- Prescribing services.

Urgent care services (UCS)

These services are provided in parallel with an accident and emergency department and vary greatly from one service to another. They generally comprise a triage service, run by doctors and nurses.

They will not usually screen people whose symptoms require immediate, very urgent or emergency care. Instead, they screen standard cases where time is not of the essence, and where possible, refer these for immediate consultation with an on-site primary care provider.

They may provide services such as:

- Consultations with a doctor
- Physical examinations and simple physiological testing and measurement
- Diagnosis and treatment
- Prescribing medicines
- Referrals to other primary care services.

Examples of services that fit under this category:

- Minor injury units
- Urgent care centres
- Walk-in centres.

Residential social care

Care home services with nursing (CHN)

A care home is a place where personal care and accommodation are provided together. People may live in the service for short or long periods. For many people, it is their sole place of residence and so it becomes their home, although they do not legally own or rent it. Both the care that people receive and the premises are regulated.

In addition, qualified nursing care is provided, to ensure that the full needs of the person using the service are met.

Examples of services that fit under this category:

- Nursing home
- Convalescent home with nursing
- Respite care with nursing
- Mental health crisis house with nursing.

Care home services without nursing (CHS)

A care home is a place where personal care and accommodation are provided together. People may live in the service for short or long periods. For many people, it is their sole place of residence and so it becomes their home, although they do not legally own or rent it. Both the care that people receive and the premises are regulated.

Examples of services that fit under this category:

- Residential home
- Rest home
- Convalescent home
- Respite care
- Mental health crisis house
- Therapeutic communities.

Specialist college services (SPC)

These services provide education, care, and training in independence for young people with a learning disability and/or physical disability. The colleges are first and foremost educational establishments and are regulated by Ofsted. The Care Quality Commission regulates the personal care and accommodation that a college provides where 10% or more of the students require personal care.

Community social care

Domiciliary care services including those provided for children (DCC)

These services provide personal care for people living in their own homes. The needs of people using the services may vary greatly, but packages of care are designed to meet individual circumstances.

The person is visited at various times of the day or, in some cases, care is provided over a full 24-hour period. Where care is provided intermittently throughout the day, the person may live independently of any continuous support or care between the visits.

Examples of services that fit under this category:

- Domiciliary care agency.

Extra care housing services (EXC)

These services cover many different arrangements. Usually, they consist of purpose built accommodation in which varying amounts of care and support can be offered, and where some services and facilities are shared.

The care that people receive is regulated by the Care Quality Commission, but the accommodation is not.

Shared Lives (formerly known as Adult Placement) (SHL)

Shared Lives is care and/or support provided by individuals, couples and families who have been approved and trained for that role by the service registered with Care Quality Commission. Care and/or support may also be provided either within or outside of the home of the carer as well as kinship support to people living in their own homes. It is the **service** that is regulated not the individual accommodation that is owned or rented by private residents.

Supported living services (SLS)

These services involve a person living in their own home and receiving care and/or support in order to promote their independence. The care they receive is regulated by the Care Quality Commission, but the accommodation is not. The support that people receive is continuous, but is tailored to their individual needs. It aims to enable the person to be as autonomous and independent as possible, and usually involves social support rather than medical care.

Miscellaneous healthcare

Ambulance services (AMB)

These services respond to emergency 999 calls, providing medical care in emergency and non-emergency settings outside of hospital. This includes the provision of emergency response and transport services for people with serious or life-threatening conditions.

Ambulance services also provide a range of other urgent and planned healthcare and patient transport services. They may provide care, treatment and support and employ a range of healthcare professionals to meet the needs of the people who use the service.

Examples of services that fit under this category:

- Advice, treatment and/or transport of people in emergency situations or with urgent health needs
- Air ambulance service
- Patient transport services.

Blood and transplant services (BTS)

These involve the management of the supply of blood, blood-derived products and biologically derived tissues to a healthcare provider for the purposes of administering, grafting or transplantation into a human being.

Examples of services that fit under this category:

- NHS Blood and Transplant.

Remote clinical advice services (RCA)

These services provide, as their sole or main purpose, a range of clinical services to people from a distance in an urgent or emergency situation. The initial consultation is usually with a non-clinical call handler who may triage to a clinician. They may provide care, treatment and support to people using:

- Telephone systems
- Digital systems
- Email.

The services may include:

- Simple clinical advice and reassurance
- Diagnosis

- Health screening
- Prescription of medicines
- Referral to another clinical service.

Examples of services that fit under this category:

- NHS 111.

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