

Guidance about compliance

Summary of regulations, outcomes and judgement framework



About the Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities, private companies or voluntary organisations, we make sure that people get better care. We do this by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

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Introduction

The purpose of this guide

This guide is a summary of the guidance* that we have produced to help providers of health and adult social care to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Part 1 contains the regulations and the outcomes that we expect people using a service will experience if the provider complies with the regulations.

Part 2 summarises the stages and steps in our judgement framework, which we will use to judge compliance with the regulations.

A new system of regulation

As the regulator of health and adult social care in England, we make sure that the care people receive meets essential standards of quality and safety and we encourage ongoing improvements by those who provide or commission care.

The new registration system for health and adult social care will make sure that people can expect services to meet essential standards of quality and safety that respect their dignity and protect their rights. The new system is focused on outcomes rather than systems and processes, and places the views and experiences of people who use services at its centre.

We will continuously monitor compliance with essential standards as part of a new, more dynamic, responsive and robust system of regulation. Our assessors and inspectors will frequently review all available information and intelligence we hold about a provider. We will seek information from patients and public representative groups, and from organisations such as other regulators and the National Patient Safety Agency.

If we have concerns that a provider is not meeting essential standards of quality and safety, we will act quickly, working closely with commissioners and others, and using our new enforcement powers if necessary.

Promoting improvement

In addition to the assurance about compliance with essential standards that registration will provide, we have an important function in promoting improvement by providing independent, reliable and timely information about the quality of care in providers above essential standards, and about the quality of care secured by commissioners for their local communities, which we describe as assessments of quality.

These assessments include: our periodic reviews of the performance of all health and adult social care providers, and of councils and primary care trusts as commissioners of care; our special reviews and studies of particular aspects of care, on economy, efficiency and effectiveness; and information issues.

* The guidance consists of our two main guides 'Essential Standard of Quality and Safety' and 'Judgement Framework' as well as this summary guide.

Part 1: how the outcomes are structured

There are 28 outcomes, each reflecting a specific regulation. Of these 28 regulations and outcomes, there are 16 that relate most directly to the quality and safety of care and which apply to all types of provider. The other 12 regulations may apply differently to different types of provider.

The outcome headings make clear which regulations and outcomes relate to the core 16 quality and safety standards.

We have grouped the 28 outcomes into six key areas:

- Involvement and information
- Personalised care, treatment and support
- Safeguarding and safety
- Suitability of staffing
- Quality and management
- Suitability of management.

Part 1 contains a section for each area, containing:

- A summary of the area and the regulations that it includes.
- For each regulation:
 - the text of the regulation
 - what we think people who use services should experience when providers comply with the regulation (the definition of the outcome). **This is what we will focus on checking that providers are meeting essential standards.**

Why we produced the guidance

Section 23(1) of the Health and Social Care Act 2008 requires us to produce guidance for providers of health and adult social care, to help them comply with the regulations within the Act that govern their activities. This guidance only relates to providers of services that carry out “regulated activities”, who must be registered with us before carrying out these activities.

Part 1: Regulations and outcomes



Involvement and information

This section looks at what providers should do to make sure that people who use services, or those acting on their behalf, are involved in making decisions about their care, treatment and support. It identifies what providers should do to ensure that the views and experiences of people who use services are taken into account when making decisions about how services are delivered and improved in order to meet the registration regulations.

It also looks at the information that providers should make available to people so that they are able to make informed choices, including information about any charges they are expected to pay for their care, treatment and support.

This section covers guidance about compliance for:

1. Respecting and involving people who use services
2. Consent to care and treatment
3. Fees.



Outcome 1: Respecting and involving people who use services

This is one of the core 16 quality and safety standards

What do the regulations say?

Respecting and involving service users

- 17.—(1) The registered person must, so far as reasonably practicable, make suitable arrangements to ensure—
- (a) the dignity, privacy and independence of service users; and
 - (b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.
- (2) For the purposes of paragraph (1), the registered person must—
- (a) treat service users with consideration and respect;
 - (b) provide service users with appropriate information and support in relation to their care or treatment;
 - (c) encourage service users, or those acting on their behalf, to—
 - (i) understand the care or treatment choices available to the service user, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and
 - (ii) express their views as to what is important to them in relation to the care or treatment;
 - (d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in sub-paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;
 - (e) where appropriate, provide opportunities for service users to manage their own care or treatment;
 - (f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on in so far as it relates to their care or treatment;
 - (g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their autonomy, independence and community involvement; and
 - (h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities)

Regulations 2010

What should people who use services experience?

People who use services:

- Understand the care, treatment and support choices available to them.
- Can express their views, so far as they are able to do so, and are involved in making decisions about their care, treatment and support.
- Have their privacy, dignity and independence respected.
- Have their views and experiences taken into account in the way the service is provided and delivered.

Those acting on behalf of people who use services:

- Understand the care, treatment and support choices available to the people who use services.
- Can represent the views of the person using the service by expressing these on their behalf, and are involved appropriately in making decisions about their care, treatment and support.

This is because providers who comply with the regulations will:

- Recognise the diversity, values and human rights of people who use services.
- Uphold and maintain the privacy, dignity and independence of people who use services.
- Put people who use services at the centre of their care, treatment and support by enabling them to make decisions.
- Provide information that supports people who use services, or others acting on their behalf, to make decisions about their care, treatment and support.
- Support people who use services, or others acting on their behalf, to understand the care, treatment and support provided.
- Enable people who use services to care for themselves where this is possible.
- Encourage and enable people who use services to be involved in how the service is run.
- Encourage and enable people who use services to be an active part of their community in appropriate settings.

Outcome 2: Consent to care and treatment

This is one of the core 16 quality and safety standards

What do the regulations say?

Consent to care and treatment

18. The registered person must have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them.

**Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services:

- Where they are able, give valid consent to the examination, care, treatment and support they receive.
- Understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed.
- Can be confident that their human rights are respected and taken into account.

This is because providers who comply with the regulations will:

- Have systems in place to gain and review consent from people who use services, and act on them.

Outcome 3: Fees

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Fees etc.

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.

Regulation 19 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services, or others acting on their behalf, who pay the provider for the services they receive:

- Know how much they are expected to pay, when and how.
- Know what the service will provide for the fee paid.
- Understand their obligations and responsibilities.

This is because providers who comply with the regulations will:

- Be transparent in the information they provide 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.

Personalised care, treatment and support

This section looks at what providers should do to make sure that people who use services get effective, safe and appropriate care, treatment and support that meets their individual needs.

This section covers guidance about compliance for:

4. Care and welfare of people who use services
5. Meeting nutritional needs
6. Cooperating with other providers.



Outcome 4: Care and welfare of people who use services

This is one of the core 16 quality and safety standards

What do the regulations say?

Care and welfare of service users

- 9.**—(1) The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—
- (a) the carrying out of an assessment of the needs of the service user; and
 - (b) the planning and delivery of care and, where appropriate, treatment in such a way as to—
 - (i) meet the service user's individual needs,
 - (ii) ensure the welfare and safety of the service user,
 - (iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and
 - (iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.
- (2) The registered person must have procedures in place for dealing with emergencies which are reasonably expected to arise from time to time and which would, if they arose, affect, or be likely to affect, the provision of services, in order to mitigate the risks arising from such emergencies to service users.

Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

This is because providers who comply with the regulations will:

- Reduce the risk of people receiving unsafe or inappropriate care, treatment and support by:
 - assessing the needs of people who use services
 - planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
 - taking account of published research and guidance
 - making reasonable adjustments to reflect people's needs, values and diversity
 - having arrangements for dealing with foreseeable emergencies.

Outcome 5: Meeting nutritional needs

This is one of the core 16 quality and safety standards

What do the regulations say?

Meeting nutritional needs

14.—(1) Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of—

- (a) a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- (b) food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
- (c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.

(2) For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.

Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Are supported to have adequate nutrition and hydration.

This is because providers who comply with the regulations will:

- Reduce the risk of poor nutrition and dehydration by encouraging and supporting people to receive adequate nutrition and hydration.
- Provide choices of food and drink for people to meet their diverse needs, making sure the food and drink they provide is nutritionally balanced and supports their health.

Outcome 6: Cooperating with other providers

This is one of the core 16 quality and safety standards

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What do the regulations say?

Cooperating with other providers

24.—(1) The registered person must make suitable arrangements to protect the health, welfare and safety of service users in circumstances where responsibility for the care and treatment of service users is shared with, or transferred to, others, by means of—

- (a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;
 - (b) subject to paragraph (2), the sharing of appropriate information in relation to—
 - (i) the admission, discharge and transfer of service users, and
 - (ii) the co-ordination of emergency procedures; and
 - (c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support.
- (2) Nothing in this regulation shall require or permit any disclosure or use of information which is prohibited by or under any enactment, or by court order.

Regulation 24 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Receive safe and coordinated care, treatment and support where more than one provider is involved, or they are moved between services.

This is because providers who comply with the regulations will:

- Cooperate with others involved in the care, treatment and support of a person who uses services when the provider responsibility is shared or transferred to one or more services, individuals, teams or agencies.
- Share information in a confidential manner with all relevant services, individuals, teams or agencies to enable the care, treatment and support needs of people who use services to be met.
- Work with other services, individuals, teams or agencies to respond to emergency situations.
- Support people who use services to access other health and social care services they need.

Safeguarding and safety

This section looks at what providers should do to make sure that people who use the service, workers and others who visit are as safe as they can be and that risks are managed. It looks at what the provider needs to do to ensure that the human rights and dignity of people who use services are respected and how they should identify and respond when people are in vulnerable situations.

It also looks at the things providers should do to make sure that the premises and equipment they use to provide care, treatment and support are safe and suitable.

This section covers guidance about compliance for:

7. Safeguarding people who use services from abuse
8. Cleanliness and infection control
9. Management of medicines
10. Safety and suitability of premises
11. Safety, availability and suitability of equipment.



Outcome 7: Safeguarding people who use services from abuse

This is one of the core 16 quality and safety standards

What do the regulations say?

Safeguarding service users from abuse

11.—(1) The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the carrying on of the regulated activity, the registered person must have suitable arrangements in place to protect service users against the risk of such control or restraint being—

(a) unlawful; or

(b) otherwise excessive.

(3) For the purposes of paragraph (1), “abuse”, in relation to a service user, means—

(a) sexual abuse;

(b) physical or psychological ill-treatment;

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

(d) neglect and acts of omission which cause harm or place at risk of harm.

Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities)

Regulations 2010

What should people who use services experience?

People who use services:

- Are protected from abuse, or the risk of abuse, and their human rights are respected and upheld.

This is because providers who comply with the regulations will:

- Take action to identify and prevent abuse from happening in a service.
- Respond appropriately when it is suspected that abuse has occurred or is at risk of occurring.
- Ensure that Government and local guidance about safeguarding people from abuse is accessible to all staff and put into practice.
- Make sure that the use of restraint is always appropriate, reasonable, proportionate and justifiable to that individual.
- Only use de-escalation or restraint in a way that respects dignity and protects human rights, and where possible respects the preferences of people who use services.
- Understand how diversity, beliefs and values of people who use services may influence the identification, prevention and response to safeguarding concerns.
- Protect others from the negative effect of any behaviour by people who use services.
- Where applicable, only use Deprivation of Liberty Safeguards when it is in the best interests of the person who uses the service and in accordance with the Mental Capacity Act 2005.

Outcome 8: Cleanliness and infection control

This is one of the core 16 quality and safety standards

What do the regulations say?

Cleanliness and infection control

12.—(1) The registered person must, so far as reasonably practicable, ensure that—

- (a) service users;
- (b) persons employed for the purpose of the carrying on of the regulated activity; and
- (c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

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

- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
- (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
- (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
 - (i) premises occupied for the purpose of carrying on the regulated activity,
 - (ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and
 - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

**Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

Cleanliness and infection control

Providers of services comply with the requirements of regulation 12, with regard to the *Code of Practice for health and adult social care on the prevention and control of infections and related guidance*.

Outcome 9: Management of medicines

This is one of the core 16 quality and safety standards

What do the regulations say?

Management of medicines

13. The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

**Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services:

- Will have their medicines at the times they need them, and in a safe way.
- Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

This is because providers who comply with the regulations will:

- Handle medicines safely, securely and appropriately.
- Ensure that medicines are prescribed and given by people safely.
- Follow published guidance about how to use medicines safely.

Outcome 10: Safety and suitability of premises

This is one of the core 16 quality and safety standards

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What do the regulations say?

Safety and suitability of premises

15.—(1) The registered person must ensure that service users and others having access to premises where a regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of—

- (a) suitable design and layout;
- (b) appropriate measures in relation to the security of the premises; and
- (c) adequate maintenance and, where applicable, the proper—
 - (i) operation of the premises, and
 - (ii) use of any surrounding grounds,

which are owned or occupied by the service provider in connection with the carrying on of the regulated activity.

(2) In paragraph (1), the term “premises where a regulated activity is carried on” does not include a service user’s own home.

**Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are in safe, accessible surroundings that promote their wellbeing.

This is because providers who comply with the regulations will:

- Make sure that people who use services, staff and others know they are protected against the risks of unsafe or unsuitable premises by:
 - the design and layout of the premises being suitable for carrying out the regulated activity
 - appropriate measures being in place to ensure the security of the premises
 - the premises and any grounds being adequately maintained
 - compliance with any legal requirements relating to the premises
- Take account of any relevant design, technical and operational standards and manage all risks in relation to the premises.

Outcome 11: Safety, availability and suitability of equipment

This is one of the core 16 quality and safety standards

What do the regulations say?

Safety, availability and suitability of equipment

16.—(1) The registered person must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of the carrying on of a regulated activity is—

- (a) properly maintained and suitable for its purpose; and
- (b) used correctly.

(2) The registered person must ensure that equipment is available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs.

(3) Where equipment is provided to support service users in their day to day living, the registered person must ensure that, as far as reasonably practicable, such equipment promotes the independence and comfort of service users.

(4) For the purposes of this regulation—

- (a) “equipment” includes a medical device; and
- (b) “medical device” has the same meaning as in the Medical Devices Regulations 2002.

Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

This is because providers who comply with the regulations will:

- Make sure that equipment:
 - is suitable for its purpose
 - is available
 - is properly maintained
 - is used correctly and safely
 - promotes independence
 - is comfortable.
- Follow published guidance about how to use medical devices safely.

Suitability of staffing

This section looks at what providers should do to make sure that they have the right staff with the right skills, qualifications, experience and knowledge to support people. It looks at training needs for staff and how they should be supported to carry out their role, including the time they will need away from work in order to take part in learning and development opportunities.

This section covers guidance about compliance for:

12. Requirements relating to workers
13. Staffing
14. Supporting workers.



Outcome 12: Requirements relating to workers

This is one of the core 16 quality and safety standards

What do the regulations say?

Requirements relating to workers

21. The registered person must—

- (a) operate effective recruitment procedures in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person—
 - (i) is of good character,
 - (ii) has the qualifications, skills and experience which are necessary for the work to be performed, and
 - (iii) is physically and mentally fit for that work;
- (b) ensure that information specified in Schedule 3 is available in respect of a person employed for the purposes of carrying on a regulated activity, and such other information as is appropriate;
- (c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—
 - (i) the work that the person is to perform, or
 - (ii) the title that the person takes or uses; and
- (d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—
 - (i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or
 - (ii) where the person is a social care worker registered with the General Social Care Council, informing the Council.

**Regulation 21 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by staff who are fit, appropriately qualified and are physically and mentally able to do their job.

This is because providers who comply with the regulations will:

- Have effective recruitment and selection procedures in place.
- Carry out relevant checks when they employ staff.
- Ensure that staff are registered with the relevant professional regulator or professional body where necessary and are allowed to work by that body.
- Refer staff who are thought to be no longer fit to work in health and adult social care, and meet the requirement for referral, to the appropriate bodies.

Outcome 13: Staffing

This is one of the core 16 quality and safety standards

What do the regulations say?

Staffing

22. In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.

**Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.

This is because providers who comply with the regulations will:

- Make sure that there are sufficient staff with the right knowledge, experience, qualifications and skills to support people.

Outcome 14: Supporting workers

This is one of the core 16 quality and safety standards

What do the regulations say?

Supporting workers

23.—(1) The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

- (a) receiving appropriate training, professional development, supervision and appraisal; and
- (b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

(2) Where the regulated activity carried on involves the provision of health care, the registered person must (as part of a system of clinical governance and audit) ensure that healthcare professionals employed for the purposes of carrying on the regulated activity are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise.

(3) For the purposes of paragraph (2), “system of clinical governance and audit” means a framework through which the registered person endeavours continuously to—

- (a) evaluate and improve the quality of the services provided; and
- (b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Regulation 23 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by competent staff.

This is because providers who comply with the regulations will:

- Ensure that staff are properly supported to provide care and treatment to people who use services.
- Ensure that staff are properly trained, supervised and appraised.
- Enable staff to acquire further skills and qualifications that are relevant to the work they undertake.

Quality and management

This section looks at what providers should do to manage risk in order to ensure that essential standards of quality and safety are maintained, and what information they must give to the Care Quality Commission about certain important events.

This section covers guidance about compliance for:

15. Statement of purpose
16. Assessing and monitoring the quality of service provision
17. Complaints
18. Notification of death of a person who uses services
19. Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983
20. Notification of other incidents
21. Records.

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Outcome 15: Statement of purpose

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Statement of purpose

- 12.—(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.
- (2) The registered person must keep under review and, where appropriate, revise the statement of purpose.
- (3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.

SCHEDULE 3

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

1. The aims and objectives of the service provider in carrying on the regulated activity.
2. The kinds of services provided for the purposes of the carrying on of the regulated activity and the range of service users' needs which those services are intended to meet.
3. The full name of the service provider and of any registered manager, together with their business address, telephone number and, where available, electronic mail addresses.
4. The legal status of the service provider.
5. Details of the locations at which the services provided for the purposes of the regulated activity are carried on.

Regulation 12 and Schedule 3 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services:

- Will benefit from the knowledge that the Care Quality Commission is informed of the services being provided.

This is because providers who comply with the regulations will:

- Have a statement of purpose that is kept under review, and give a copy to the Care Quality Commission.
- Notify the Care Quality Commission of any changes to their statement of purpose.

Outcome 16: Assessing and monitoring the quality of service provision

This is one of the core 16 quality and safety standards

What do the regulations say?

Assessing and monitoring the quality of service provision

10.—(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,
 - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,
 - (iii) the information contained in the records referred to in regulation 20,
 - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),
 - (v) reports prepared by the Commission from time to time relating to the registered person's compliance with the provisions of these Regulations, and
 - (vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;
- (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
 - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and
 - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;

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- (d) establish mechanisms for ensuring that—
- (i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and
 - (ii) P is subject to an appropriate obligation to answer for a decision made by P in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and
- (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to service users.
- (3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with 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.
- Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010**

What should people who use services experience?

People who use services:

- Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

This is because providers who comply with the regulations will:

- Monitor the quality of service that people receive.
- Identify, monitor and manage risks to people who use, work in or visit the service.
- Get professional advice about how to run the service safely, where they do not have the knowledge themselves.
- Take account of:
 - comments and complaints
 - investigations into poor practice
 - records held by the service
 - advice from and reports by the Care Quality Commission.
- Improve the service by learning from adverse events, incidents, errors and near misses that happen, the outcome from comments and complaints, and the advice of other expert bodies where this information shows the service is not fully compliant.
- Have arrangements that say who can make decisions that affect the health, welfare and safety of people who use the service.

Outcome 17: Complaints

This is one of the core 16 quality and safety standards

What do the regulations say?

Complaints

19.—(1) For the purposes of assessing, and preventing or reducing the impact of, unsafe or inappropriate care or treatment, the registered person must have an effective system in place (referred to in this regulation as “the complaints system”) for identifying, receiving, handling and responding appropriately to complaints and comments made by service users, or persons acting on their behalf, in relation to the carrying on of the regulated activity.

(2) In particular, the registered person must—

- (a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;
- (b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary;
- (c) ensure that any complaint made is fully investigated and, so far as reasonably practicable, resolved to the satisfaction of the service user, or the person acting on the service user’s behalf; and
- (d) take appropriate steps to coordinate a response to a complaint where that complaint relates to care or treatment provided to a service user in circumstances where the provision of such care or treatment has been shared with, or transferred to, others.

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

- (a) complaints made pursuant to paragraph (1); and
- (b) responses made by the registered person to such complaints.

**Regulation 19 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services or others acting on their behalf:

- Are sure that their comments and complaints are listened to and acted on effectively.
- Know that they will not be discriminated against for making a complaint.

This is because providers who comply with the regulations will:

- Have systems in place to deal with comments and complaints, including providing people who use services with information about that system.
- Support people who use services or others acting on their behalf to make comments and complaints.
- Consider fully, respond appropriately and resolve, where possible, any comments and complaints.

Outcome 18: Notification of death of a person who uses services

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Notification of death of service user

- 16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—
- (a) whilst services were being provided in the carrying on of a regulated activity; or
 - (b) as a consequence of the carrying on of a regulated activity.
- (2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—
- (a) occurred—
 - (i) whilst services were being provided in the carrying on of a regulated activity, or
 - (ii) as a consequence of the carrying on of a regulated activity; 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 or 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 Patient Safety Agency.
- (5) This regulation does not apply where regulation 17 applies.

Regulation 16 of the Care Quality Commission (Registration) Regulations 2009

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What should people who use services experience?

People who use services:

- Can be confident that deaths of people who use services are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because:

- Providers notify the Care Quality Commission about the death of a person who uses the service.

Outcome 19: Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

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

- 17.—(1) The registered person must notify the Commission without delay of the death or unauthorised absence 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.
- (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
 - (d) “unauthorised absence” means an unauthorised absence from a hospital.

Regulation 17 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People using the service who are detained under the Mental Health Act 1983:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because providers who comply with the regulations will:

- Notify the Care Quality Commission about the death or unauthorised absence of a person detained under the Mental Health Act 1983 who uses services.

Outcome 20: Notification of other incidents

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Notification of other incidents

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

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

- (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—
 - (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
 - (ii) changes to the structure of a service user's body,
 - (iii) the service user experiencing prolonged pain or prolonged psychological harm, or
 - (iv) the shortening of the life expectancy of the service user;
- (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—
 - (i) the death of the service user, or
 - (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);
- (c) 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, including the result of such a request;
- (d) 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;
- (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.
- (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 Patient Safety Agency.
- (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.

Regulation 18 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because providers who comply with the regulations will:

- Notify the Care Quality Commission about incidents that affect the health, safety and welfare of people who use services, including:
 - injuries to people
 - making an application to depriving someone of their liberty
 - events which stop the registered person from running the service as well as they should
 - allegations of abuse
 - a police investigation.

Outcome 21: Records

This is one of the core 16 quality and safety standards

What do the regulations say?

Records

20.—(1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—

- (a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and
- (b) such other records as are appropriate in relation to—
 - (i) persons employed for the purposes of carrying on the regulated activity, and
 - (ii) the management of the regulated activity.

(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—

- (a) kept securely and can be located promptly when required;
- (b) retained for an appropriate period of time; and
- (c) securely destroyed when it is appropriate to do so.

**Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010**

What should people who use services experience?

People who use services can be confident that:

- Their personal records including medical records are accurate, fit for purpose, held securely and remain confidential.
- Other records required to be kept to protect their safety and wellbeing are maintained and held securely where required.

This is because providers who comply with the regulations will:

- Keep accurate personalised care, treatment and support records secure and confidential for each person who uses the service.
- Keep those records for the correct amount of time.
- Keep any other records the Care Quality Commission asks them to in relation to the management of the regulated activity.
- Store records in a secure, accessible way that allows them to be located quickly.
- Securely destroy records taking into account any relevant retention schedules.

Suitability of management

This section looks at what providers and managers must do to show that they are suitable to run the service and that they keep the Care Quality Commission informed about relevant changes.

This section covers guidance about compliance for:

22. Requirements where the service provider is an individual or partnership
23. Requirement where the service provider is a body other than a partnership
24. Requirements relating to registered managers
25. Registered person: training
26. Financial position
27. Notifications – notice of absence
28. Notifications – notice of changes.



Outcome 22: Requirements where the service provider is an individual or partnership

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Requirements where the service provider is an individual or partnership

- 4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.
- (2) P must not carry on a regulated activity unless P is fit to do so.
- (3) P is not fit to carry on a regulated activity unless P is—
 - (a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in paragraph (4); or
 - (b) a partnership and each of the partners satisfies the requirements set out in paragraph (4);
- (4) The requirements referred to are that P or, where applicable, each of the partners is—
 - (a) of good character;
 - (b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
 - (c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

Regulation 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Have their needs met by the service because it is provided by an appropriate person.

This is because providers who comply with the regulations will:

- Register with the Care Quality Commission the appropriate people or persons who:
 - are of good character
 - are physically and mentally able to perform their role
 - have the necessary qualifications, skills and experience to carry on the regulated activity or, where it is an organisation, supervise its management.

Outcome 23: Requirement where the service provider is a body other than a partnership

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Requirement where the service provider is a body other than a partnership

- 5.—(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 employed as a director, manager or secretary of the body and who is 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 is—
- (a) of good character;
 - (b) physically and mentally fit to supervise the management of the carrying on of the regulated activity and has the necessary qualifications, skills and experience to do so; and
 - (c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Have their needs met because the management is supervised by an appropriate person.

This is because providers who comply with the regulations will:

- Have a nominated individual who:
 - is of good character
 - is physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to supervise the management of the regulated activity.

Outcome 24: Requirements relating to registered managers

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Requirements relating to registered managers

- 6.—(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) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
 - (c) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

Regulation 6 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Have their needs met because it 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 physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to manage the regulated activity.

Outcome 25: Registered person: training

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Registered person: training

7.—(1) If the service provider is—

- (a) an individual, the individual must undertake;
- (b) a partnership, it must ensure that one of the partners undertakes; or
- (c) a body other than a partnership, it must ensure that the nominated individual undertakes, from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

(2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.

Regulation 7 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

What should people who use services experience?

People who use services:

- Have their care, treatment and support needs met because there is a competent person leading the service.

This is because providers who comply with the regulations will:

- Undertake appropriate training.

Outcome 26: Financial position

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Financial position

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

- (a) achieving the aims and objectives set out in the statement of purpose; and
 - (b) meeting the registration requirements prescribed pursuant to section 20 of the Act.
- (2)** This regulation does not apply where the service provider is—
- (c) an English local authority; or
 - (d) a health service body.

Regulation 13 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services:

- Can be confident that the service provider is able to meet the financial demands of providing safe and appropriate services.

This is because providers who comply with the regulations will:

- Have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.

Outcome 27: Notifications – notice of absence

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Notice of absence

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

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

(b) the registered manager,

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

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

(a) its length or expected length;

(b) the reason for it;

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

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

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

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

(4) Where—

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

(b) the registered manager,

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

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

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

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

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

Regulation 14 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services:

- Can have confidence that, if the person(s) in charge of their service is absent, it will continue to be properly managed and be able to meet their needs.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - about any significant planned absences from the service
 - about any significant unplanned absences
 - how the service will be run while they are away
 - when they return from a significant absence.

Outcome 28: Notifications – notice of changes

This is NOT one of the core 16 quality and safety standards, and it may apply differently to different providers. Please refer to the full guidance documents.

What do the regulations say?

Notice of changes

- 15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—
- (a) a person other than the registered person carries on or manages the regulated activity;
 - (b) a registered person ceases to carry on or manage the regulated activity;
 - (c) the name of a registered person (where that person is an individual) changes;
 - (d) where the service provider is a partnership, any change in the membership of the partnership;
 - (e) where the service provider is a body other than a partnership—
 - (i) a change in the name or address of the body,
 - (ii) a change of director, secretary or other similar officer of the body, or
 - (iii) a change of nominated individual;
 - (f) where the service provider is—
 - (i) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or
 - (ii) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.
- (2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.
- (3) In this regulation, “nominated individual” means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Regulation 15 of the Care Quality Commission (Registration) Regulations 2009

What should people who use services experience?

People who use services:

- Can be confident that, if there are changes to the service, its quality and safety will not be adversely affected.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - when the person who manages or carries on the service changes
 - when the registered details of the service and any individual, partnership or organisation who manage or carry it on, change
 - when the registered person becomes financially insolvent
 - when the service closes.

Part 2: Summary of the judgement framework



Introduction

Our staff will use the judgement framework when making decisions about compliance and reach judgements about each provider's registration status. Although we will use it to promote consistency, the framework will not be a substitute for the professional judgement of our inspectors and assessors, and we will always take providers' individual circumstances into account.

The framework explains how a decision should be reached by considering evidence about compliance. It focuses on the 16 regulations and associated outcomes that most directly relate to the quality and safety of care.

The framework is split into four stages:

Stage 1: Determining whether there is enough evidence to make a judgement.

Stage 2: Checking whether the evidence demonstrates compliance or whether there are concerns about the provider's compliance with the regulations.

Stage 3: If concerns are found at stage 2, making a judgement about the impact on people using services and the likelihood of the impact occurring.

Stage 4: Validating the judgement.

The regulations that the framework covers

The essential standards of quality and safety consist of the 28 regulations and outcomes that are described in Part 1 of this guide.

Our judgement framework covers the 16 regulations within Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. When checking a provider's compliance, these are the regulations that we will focus on, because they are the ones that focus most directly on the quality and safety of care.

Section	Outcome	Regulation*	Title
Information and involvement	1	17	Respecting and involving people who use services
	2	18	Consent to care and treatment
Personalised care, treatment and support	4	9	Care and welfare of people who use services
	5	14	Meeting nutritional needs
	6	24	Cooperating with other providers
Safeguarding and safety	7	11	Safeguarding people who use services from abuse
	8	12	Cleanliness and infection control
	9	13	Management of medicines
	10	15	Safety and suitability of premises
	11	16	Safety, availability and suitability of equipment
Suitability of staffing	12	21	Requirements relating to workers
	13	22	Staffing
	14	23	Supporting workers
Quality and management	16	10	Assessing and monitoring the quality of service provision
	17	19	Complaints
	21	20	Records
Suitability of management	N/A		

* Regulations of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

Stage 1: Determining whether we have enough evidence to make a judgement about compliance

Is there enough robust evidence to reach a judgement about compliance with the relevant regulations?

To determine whether the evidence is adequate and robust, consider the following points:

- Is it **current**? (within 12 months or longer if a long-term focus)
- Is it **reliable**? (is the source credible, is the evidence consistent, can it be validated or triangulated with another source)
- Is it **relevant**? (is it related to the regulations, the regulated activities and CQC's remit)
- Is it **sufficient**? (is there an adequate amount of evidence with enough detail to make an assessment)
- Does it **demonstrate** the quality of outcomes and/or experiences of people who use services?
- Does it **demonstrate** what controls (processes) the provider has in place?
- Is **specialist input** (eg pharmacy, medical etc) required?

Stage 2: Checking whether the evidence demonstrates compliance with the regulations

Does the evidence demonstrate compliance?

If we are satisfied that the evidence identifies compliance with the outcomes described in the guidance about compliance for providers, we go straight to **stage 4** for validation.

If we think that the provider is not meeting the outcomes described in the guidance about compliance, we will consider whether the provider has done all that is reasonably practicable and that we have made a proportionate decision.

If we still think that the provider is not meeting the outcome statements, **or** it is an assessment of a new application, we will use the prompts in stage 2 of the full judgement framework to identify the concerns.

We will not use the prompts as a tick box exercise. We do not have to have evidence for every prompt.

Once the concerns are identified, we progress to **stage 3** to identify the impact of the concerns on people using the service and the likelihood of the concerns happening or recurring in the future.

Stage 3: Determining the impact on people who use services and the likelihood that this will happen

Step 1: Impact

For stage 3, the first question we need to answer is:

What is the impact on the people who use the service?

The impact can either be “low”, “medium” or “high”, as follows:

Impact	Definition
Low	No or minimal level of impact on people who use services in one or more areas.
Medium	A moderate impact but no long-term effects on people who use services in one or more of the areas.
High	A significant or long-term impact on people who use services in one or more of the areas.

When determining the impact on people who use services, all of the following areas are important:

- Safety
- Independence
- Experience
- Outcomes
- Dignity
- Human rights
- Accessibility.

Also, we consider who is using the service and what their situation is, as these factors may influence the impact. For example:

Capacity: A lack of understanding of the Mental Capacity Act would be more significant in a service providing care to people with dementia than it would in a health screening service that primarily deals with fit, healthy adults.

Diversity: Failing to have information available in an audible format or in Braille would be more significant for a service that specialises in care for people with impaired vision than a service that does not.

Circumstances where people are more vulnerable: A poor and uncomfortable environment would be more significant for people that are detained than for people using an outpatient clinic.

The concern may impact on one or many of the above areas, and all relevant areas should be considered.

Step 2: Likelihood

The second question in stage 3 is:

What is the likelihood that the impact will happen to people using the service?

The likelihood can either be “unlikely”, “possible” or “almost certain”, as follows:

Likelihood	Definition
Unlikely	This will probably never happen/recur, as there are control measures and processes in place.
Possible	This may happen/is probable/recur, but it is not a persisting issue.
Almost certain	This will probably happen/recur frequently. This is could be due to a breakdown in processes, or serious concerns about control measures.

We will consider the evidence using the following prompts to reach a decision about how likely it is that the impact will happen:

- Has the concern happened before?
- How long will the concern last for?
- How many people are exposed to the concern?
- Has the provider identified and assessed the concern?
- Are measures in place to control the concern?
- Are the relevant people involved in managing the concern?

Step 3: Level of concern

When we have determined the impact for people using the service, including any influencing factors, and the likelihood that the impact will happen, we will apply these to the matrix below to determine the overall level of concern.

Likelihood:	Impact:		
	Low	Medium	High
Unlikely	Minor concern	Minor concern	Moderate concern
Possible	Minor concern	Moderate concern	Major concern
Almost certain	Moderate concern	Major concern	Major concern

Stage 4: Validating the judgement

The full version of stage 4 of the judgement framework includes numerous health and social care case studies that show what compliance or concerns may look like in practice. We have included case studies for each variation of concern.

This stage is to validate and confirm that the level of concern is similar to those defined in the descriptors and case studies.

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