# Regulations for service providers and managers

Regulations for service providers and managers

Introduction

# 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.—

Health and Social Care Act 2008 (Regulated Activities) Regulations

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

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;

Care Quality Commission (Registration) Regulations

Related legislation

Related guidance

Glossary of terms used in the guidance for providers and managers

Service types

### 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).

‹ Previous
Regulation 11: Need for consent

Next ›
Regulation 13: Safeguarding service users from abuse and improper treatment

© Care Quality Commission 2026