

# Regulation 11: Need for consent

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

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

Consent is an important aspect of providing care and treatment, but in some cases, acting strictly in accordance with consent will mean that some of the other regulations cannot be met. For example, this might apply with regard to nutrition and person-centred care. However, providers must not provide unsafe or inappropriate care just because someone has consented to care or treatment that would be unsafe. See the [glossary](#) for the definition of 'relevant person' in relation to Regulation 11.

CQC can prosecute for a breach of this regulation or a breach of part of the regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the [offences section](#) for more detail.

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

## The regulation in full

11.—

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

\* Mental Capacity Act 2005

\*\* Mental Health Act 1983

## Guidance

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

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

Guidance on 11(1)

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

- Policies and procedures for obtaining consent to care and treatment must reflect current legislation and guidance, and staff must follow them at all times.

**11(2)** Paragraph (1) is subject to paragraphs (3) and (4).

**11(3)** If the service user is 16 or over and is unable to give such consent because they lack capacity to do so, the registered person must act in accordance with the 2005 Act.

**11(4)** But if Part 4 or 4A of the 1983 Act applies to a service user, the registered person must act in accordance with the provisions of that Act.

**11(5)** Nothing in this regulation affects the operation of section 5 of the 2005 Act, as read with section 6 of that Act (acts in connection with care or treatment).

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

- Providers must make sure that staff who obtain the consent of people who use the service are familiar with the principles and codes of conduct associated with the Mental Capacity Act 2005, and are able to apply those when appropriate, for any of the people they are caring for.