NHS AI and Digital Regulations Service for health and social care

Adopters guidance

Understanding how the Care Quality Commission (CQC) regulates health and social care services

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This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- England

From:

- Care Quality Commission (CQC)

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The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England. It makes sure health and social care services provide people with safe, effective, compassionate and high-quality care. CQC also encourages care services to improve.

If you provide a regulated health or social care activity in England, you are legally required to register with CQC. This page will help you to understand:

- which regulations you must meet
- when they may apply

CQC regulates health and adult social care services in England only. Check local regulations for delivering health and social care services in the devolved administrations, for example:

- in Wales, the Care Inspectorate Wales
- in Scotland, the Care Inspectorate
- in Northern Ireland, the Regulation and Quality Improvement Authority

When a digital technology is used to provide regulated health and social care services, developers and adopters need to know what regulations apply.

CQC registration

If you provide a regulated activity, you are legally required to register with CQC. Please read the 'Check if you need to register with CQC' guide for further information on when and how to register.

When applying for CQC registration, you must show that you will be able to meet the regulations in the Health and Social Care Act. Once registered, you must show that you will continue to meet them.

CQC's approach

CQC regulates services to make sure they meet:

- the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, (including the fundamental standards)
- the Care Quality Commission Registration Regulations 2009

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This involves using data and on-site inspection activity to assess the quality of care. CQC publishes its findings, including quality ratings.

CQC uses different methods and sources of evidence to assess the quality of care, depending on the type of service provided. This is to understand if services are safe, effective, caring, responsive and well-led.

CQC inspection teams might want to:

- check technologies are safely and effectively deployed in the care pathway (completing a data protection impact assessment before deployment may help demonstrate how data protection risks were considered and mitigated)
- see evidence that relevant staff have been appropriately trained in using any new technologies
- see that processes are in place for appropriate reporting of any issues or incidents relating to new technologies

When do the regulations apply?

If the use of digital technology constitutes an activity regulated by CQC, and you are not already registered to provide that activity, you will need to register and demonstrate that you can meet the fundamental standards.

Check to see if you provide an activity in scope of registration. You'll only need to register with CQC if you do.

CQC's assessment framework

CQC is developing a new single assessment framework to assess whether services meet regulations. It will do this by asking 5 key questions: whether services are safe, effective, caring, responsive and well-led.

Quality statements under each key question describe what good care looks like. The assessment framework sets out the 6 categories for the type of evidence CQC collects. This will depend on the service type (for example, a GP practice) and the level at which CQC is assessing (for example, at registration).

For more information, see:

CQC's key questions and quality statements

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CQC's new single assessment framework

Guidance on meeting regulations

See CQC's guidance for providers on meeting the regulations.

For more information on the inspection process when CQC makes an on-site visit, see CQC's what we do on an inspection.

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