

How CQC monitors, inspects and regulates providers of online primary care

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CONTENTS

| | |
|-------------------------------------------------------------------|-----------|
| MONITORING AND INFORMATION SHARING | 2 |
| How we monitor providers of online primary care | 2 |
| How we work with national partners | 3 |
| How we work with local and regional partners and the public | 4 |
| How we manage our relationship with you | 4 |
| Fit and proper persons requirement: directors..... | 4 |
| INSPECTION | 6 |
| When we will inspect | 6 |
| The inspection team | 6 |
| What we will inspect | 8 |
| Mental Capacity Act..... | 10 |
| AFTER INSPECTION | 11 |
| Your inspection report | 11 |
| Making judgements | 11 |
| Factual accuracy check | 12 |
| How we publish inspection information..... | 12 |
| Enforcement | 14 |
| Make a representation | 15 |
| Complain about CQC | 16 |

MONITORING AND INFORMATION SHARING

How we monitor providers of online primary care

Sources of information

We collect and analyse information about services from a range of sources as part of our intelligence-driven approach to regulation. This helps us to target our resources where the risk to the quality of care is greatest. The information influences what we look at, who we will talk to and how we configure our inspection team.

We gather information from people who use services, other regulators and oversight bodies, and other stakeholders and service providers. We also use this information as evidence when we make our judgements against the legal requirements that you have to meet.

Provider information request

Before an announced inspection, we will ask you to complete a provider information request, which will help us to understand more about the service you provide.

The information we ask for is likely to include:

- details about the services you provide, including the websites through which you deliver regulated activities, and any other companies and websites providing services that you are affiliated with
- the results of any patient feedback survey, and information from patients about how you have used these findings to improve your services
- a summary of any complaints received in the last 12 months, any action you have taken and how you implemented the learning
- a summary of any serious adverse events in the last 12 months, any action you have taken and how you implemented the learning
- evidence of how you monitor the quality of the services provided and examples of quality improvement activity, including clinical audit
- number of consultations in the last 12 months, and a list of medicines prescribed and their volumes

- copies of the templates used when assessing or consulting with patients
- a description of how your service supports clinical staff to operate in line with professional guidance.

This list is not exhaustive.

You will have 10 working days to respond to our request. Over time, we plan to make this an annual information collection.

We may also ask you to use your existing electronic communication channels (email, text, social media) to tell your patients that you are due to be inspected, and to encourage feedback direct to CQC through our [Share Your Experience](#) webform or by phone.

How we work with national partners

We share information about services and people's experiences of them with some of our national partner organisations. These partnerships help us to be more efficient by reducing duplication and making the best use of shared information and resources. Our inspection teams have an ongoing relationship with organisations including:

- Medicines and Healthcare products Regulatory Agency
- General Medical Council
- Healthwatch England
- NHS England
- Nursing and Midwifery Council
- General Pharmaceutical Council
- Parliamentary and Health Service Ombudsman
- Healthcare Inspectorate Wales
- Healthcare Improvement Scotland
- Regulation and Quality Improvement Authority.

How we work with local and regional partners and the public

We use people's experiences of care to help decide when, where and what we inspect.

We encourage people to share their experience of care with us so that we can understand and act on what people tell us. This includes through our national [Tell us about your care](#) partner charities.

We also work in partnership with a range of local and regional groups. We share publicly available information with these groups and ask them to share information with us.

How we manage our relationship with you

Ongoing contact with CQC

A CQC inspector or inspection manager will be designated as your relationship holder.

They should be your first point of contact with CQC. You can contact your relationship holder if you have any queries about your registration or if you need to tell us about any significant changes to your services (for example, if your service begins formally collaborating with others).

Your relationship holder may contact you for a number of reasons. For example, if our monitoring activity suggests a significant improvement or deterioration in the quality of care, your relationship holder may ask you to explain the reasons behind this. Developing an ongoing relationship enables us to have a better understanding of the background and context of your service.

Fit and proper persons requirement: directors

NOTE: this does not apply to providers that are individuals or partnerships.

Providers are responsible for appointing, managing and dismissing directors and board members (or their equivalents). People who have director-level responsibility for the quality and safety of care, treatment and support must meet the fit and proper

persons regulation (FPPR) (Regulation 5 of the Health and Social Care Act 2008). This aims to make sure that directors are fit and proper to carry out their role.

You must carry out appropriate checks to make sure that directors are suitable for their role. Our role is to make sure that you have a proper process to make robust assessments to satisfy the FPPR.

Information of concern

CQC may intervene where there is evidence that you have not followed, or you do not have, proper processes for FPPR. Although we do not investigate individual directors, if we receive information of concern about the fitness of a director, we will pass this on to you as the provider.

We will tell you about all concerns relating to your directors and ask you to assess all the information we send. We will have the consent of the third party referrer to do this, and will protect their anonymity wherever possible. However, there may be occasions when we are concerned about the potential risk to people using services, so we will need to progress without consent. We will also inform the director to whom the case refers, but we will not ask for their consent.

You must detail the steps that you have taken to assure the fitness of the director and provide a full response to CQC.

We will carefully review and consider all information. Where we find that your processes are not robust, or you have made an unreasonable decision, we will either:

- contact you to discuss further
- schedule a focused inspection
- take regulatory action in line with our enforcement policy and decision tree if we identify a clear breach of the regulation.

INSPECTION

When we will inspect

Frequency of inspections

When a new provider of online primary care registers with CQC, we will inspect them within three months of registration. If we do not identify any breaches of regulations in that comprehensive inspection, we will inspect again after approximately two years. If we find any breaches of a regulation, we will base the frequency of our inspections on the level of risk and the significance of our concerns, and any enforcement action we have taken.

The inspection team

Each inspection team is led by a CQC inspector or inspection manager and may include additional expert advisors. The experts who join the team reflect the type of services being inspected, the areas that we want to focus on and the nature of any issues identified before inspection. An inspection team may include:

- Specialist professional advisors with specific relevant expertise, for example clinicians, members of CQC's Medicines Optimisation team or people with knowledge and experience of delivering online health care.
- Experts by Experience. These are people who have experienced care personally or have experience of caring for someone who has received a particular type of care.
- CQC inspection team support staff.

Teams will vary in size and composition depending on the complexity of the services being inspected.

Site visits

As part of the inspection, the inspection team will visit your main office location. They may meet with the registered manager or nominated representative, talk with staff and examine systems, documents and records.

For announced inspections, the lead inspector will contact you in advance to make any necessary logistical arrangements and to ensure that you are prepared for the

visit. We will usually complete the onsite part of the inspection in one day. However, we may need longer for more complex services or if significant issues arise on the day.

Part of the inspection will involve interviewing one or more clinicians. If the clinicians are not office-based, the interviews will be by telephone or video link.

At the start of the site visit, the inspection team will meet with your registered manager, if there is one, and/or the nominated representative. This introductory session will take no longer than 30 minutes. It will introduce the inspection team and explain:

- the scope and purpose of the inspection
- how we will escalate any concerns that we identify during the inspection
- how we will communicate our findings.

You will have an opportunity to:

- tell the inspection team about the service, including the context in which you operate
- share any notable practice that you think goes beyond the requirements of the regulations
- tell the inspection team about any concerns that you have identified about your ability to meet the regulations and what you are doing about it.

If we find that you have not been open with us about issues of concern that you already know about, this will be emphasised and reflected when we assess the well-led key question.

Feedback on the visit

At the end of the inspection visit, the inspector will provide summary feedback. This usually includes:

- explaining our findings to date, including any issues that we escalated during the visit
- any plans for follow-up or additional visits (unless they are to be unannounced)
- explaining how we will make our assessment against the regulations
- explaining the next steps
- answering your questions about the process.

What we will inspect

CQC regulates providers of online primary care services in England where they provide regulated activities, most commonly:

- treatment of disease, disorder or injury
- transport services, triage and medical advice provided remotely
- diagnostic and screening procedures.

By 'providers of online primary care' we mean: healthcare services that provide a regulated activity by an online means. This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis or treatment of disease and to follow up patients' treatment.

This guidance explains how we regulate these providers within primary care, when care is delivered purely as a standalone service by a provider in the independent sector. Examples include providers that deliver healthcare consultations by video link and providers prescribing medicines in response to online forms. Many of the themes and inspection prompts will also be relevant our approach to registering, monitoring and inspecting primary medical services that provide traditional face-to-face services, but also have an online healthcare element, such as carrying out consultations by video call.

Assessment framework

To direct the focus of their inspection, our inspection teams use a set of key lines of enquiry (KLOEs) that directly relate to the five key questions – are services safe, effective, caring, responsive and well-led? For online primary health care inspections, we will use the standard [KLOEs for healthcare services](#).

Each KLOE is accompanied by a number of questions that inspection teams will consider as part of the assessment. We call these prompts. In addition to the prompts that accompany the standard KLOEs, we have also developed a set of prompts specifically tailored for providers of online primary care.

Our inspection teams will consider the information and data gathered in preparing for the inspection to decide which of the prompts they will use to help them make a judgment on the KLOEs.

Types of inspection

Comprehensive

Comprehensive inspections address all five key questions and relevant legal requirements. They ask: is the service safe, effective, caring, responsive and well-led? We will always carry out a comprehensive inspection of services that we have not yet inspected.

Comprehensive inspections will usually be announced, with two to three weeks' notice. We feel that this is the most appropriate way to make sure that the care you provide to patients is not disrupted. It also enables us to obtain and review the information that you send us before inspection as well as information from patients. However, we may also carry out unannounced or short-notice inspections if we have concerns about a service.

On unannounced or short-notice inspections where we do not use a provider information request beforehand, we will ask you at the start of the inspection to use your existing electronic communication channels (email, text, social media) to tell your patients that you are being inspected and encourage feedback direct to CQC through our [Share Your Experience](#) webform or by phone.

Focused

In some circumstances we will carry out a focused inspection rather than a comprehensive inspection.

This will be when we need to follow up on an area of concern. This could be either a concern identified during a previous comprehensive inspection, which has resulted in enforcement action, or concerns that have been raised with us by the public, staff, other regulators or stakeholders, or through our monitoring activity.

Focused inspections do not usually look at all five key questions. They usually focus only on the areas indicated by the information that triggers the inspection.

Although they are smaller in scope, a focused inspection broadly follows the same process as a comprehensive inspection. The reason for the inspection determines many aspects, such as the scale of the inspection, when to visit, what evidence needs to be gathered, the size of the team and which specialist advisors to involve.

These inspections may be announced or unannounced, depending on the focus of the inspection. When a focused inspection identifies further significant concerns, it may trigger a comprehensive inspection.

Mental Capacity Act

Mental Capacity Act

If your service provides care or support for adults who have (or appear to have) difficulty making informed decisions about their care, treatment or support, you may need to refer to the Mental Capacity Act 2005.

The Mental Capacity Act helps to safeguard the human rights of people aged 16 and over who lack (or may lack) mental capacity to make decisions. This may be because of a lifelong learning disability or a more recent short-term or long-term impairment resulting from injury or illness. This includes decisions about whether or not to consent to care or treatment.

Your staff need to be able to identify situations where the Mental Capacity Act may be relevant and know what steps to take to maximise and assess a person's capacity. If a person's capacity is impaired, staff must know how to ensure that decisions made on the person's behalf are in their best interests.

See more about assessing mental capacity in the additional guidance for providers of online primary care.

Read more about the [Mental Capacity Act](#).

AFTER INSPECTION

Your inspection report

After each inspection we publish an inspection report on our website. This presents a summary of our findings, judgements and any enforcement activity that we may have taken.

The report focuses on what our findings mean for the public. It gives details about our judgements on whether services are providing people with care that is safe, effective, caring, responsive and well-led, based on whether regulations are being met. If we find examples of notable practice during inspection, we describe them in the report to enable other providers to learn and improve. Reports also include information about any areas for improvement, even if the service meets the regulations. We describe any concerns we find about the quality of care and clearly set out any evidence we have found about a breach of the regulations and other legal requirements.

Quality checks

Before publishing, we carry out quality and consistency checks on all reports to ensure that our judgements are consistent. This includes internal quality panels where we discuss and ratify a sample of reports.

Making judgements

We do not currently have the legal powers to rate providers of online primary care, although we expect to be granted these powers in the future.

Our inspectors make a judgement on whether your service is meeting the necessary legal requirements based on our assessment of the evidence we gather against the key lines of enquiry in the [assessment framework for healthcare services](#) and the additional specific prompts for providers of online primary care.

We also use information gathered from other sources as evidence when we make our judgements. This includes information that you provide, information from people who use services, other regulators and oversight bodies and other stakeholders and service providers.

When making our judgements, we consider the weight of each piece of relevant evidence. In most cases we seek to verify our evidence with other sources to support our findings. When we have conflicting evidence we will consider its source, how robust it is and which is the strongest. We may conclude that we need to gather additional evidence or seek specialist advice to make a judgement.

Factual accuracy check

When we have completed our quality checks on the inspection report and evidence, we will send the draft report to your nominated individual.

At this stage, we ask you to comment on the factual accuracy of the draft. You can challenge the accuracy and completeness of the evidence that we have used to reach the findings and decide whether you are meeting legal requirements.

You have 10 working days in which to check factual accuracy and submit your comments to CQC.

The factual accuracy process doesn't deal with complaints about CQC or representations about proposed enforcement activity.

For more information please see our [factual accuracy guidance](#).

How we publish inspection information

Every time we inspect a health or social care service, we publish information about it on our website.

This includes:

- details of current and recent inspections
- the inspection report.

We also send email alerts to people who have registered an interest in a particular service, location or area.

Current and recent inspections

When we are inspecting a service, we display a message on its profile webpage. We remove this when we publish the inspection report.

The inspection report

We publish your inspection reports on the appropriate profile webpages. The summaries appear on the webpage, and the report is available as a PDF document.

Email alerts

Visitors to our website can sign up for [email alerts](#) about our inspections related to particular locations.

Anybody who has signed up to receive alerts about one of your locations will get an email:

- when we have inspected the location, and
- when we publish the report.

We send these alerts once a week.

Enforcement action

We only publish information about enforcement action once any representations and appeals processes are complete.

The exception to this is urgent enforcement action, where we update our website with information straightaway. This includes action such as:

- suspending a provider or registered manager
- placing conditions on a provider's registration because of major concerns.

Read more about our [enforcement action and representations](#).

Informing the media

We routinely send summary information about our findings to local, national and trade media.

We will normally send more in-depth details to the media when we:

- take enforcement action
- prosecute.

Enforcement

If the care you provide harms people or puts people at risk of harm, we can take enforcement action to protect them. We do this so that you make improvements to prevent any further harm or risk of harm. If the improvements you need to make are small and low risk, we may work with you without taking enforcement action.

If you provide poor quality care you may be committing an offence. If you do commit an offence we can take criminal enforcement action to hold you to account. Our [guidance](#) helps you to understand the level of care that people should receive. If the level of care falls below this and people are harmed or put at risk, you may be committing an offence and we may take criminal enforcement action.

Types of enforcement action

The type of enforcement action we can take will depend on whether we are protecting people or holding you to account.

- We will take **civil enforcement action** to protect people; and/or
- To hold you to account we will take **criminal enforcement action** if you fail to meet prosecutable fundamental standards.

Our [enforcement policy](#) describes this in more detail.

Deciding which enforcement action to take

This will depend on a number of factors including:

- the level of harm or risk that has occurred
- the actions you have taken to prevent harm from happening again
- the quality of care you have provided previously
- whether you have had any enforcement action taken against you before
- in respect of criminal enforcement, in accordance with the Code for Crown Prosecutors.

Our [enforcement policy and enforcement decision tree](#) explain in more detail how and when we take enforcement action.

Following up enforcement action

We will inspect your services to check whether you have made the changes needed to improve. If you have not made the necessary changes we can take more severe enforcement action. In serious cases we can cancel your registration so you can no longer provide care.

Offences

Certain regulations have offences attached to them. This means that if you breach the regulation, it is an offence and CQC can prosecute as part of our enforcement action.

The offences and our powers to prosecute are set out in the following legislation:

- Health and Social Care Act 2008 as amended
- [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#)
- [Care Quality Commission \(Registration\) Regulations 2009](#)

Our [enforcement policy](#) details the fixed penalties and fines payable for offences.

For the regulations where we cannot prosecute, we can use other regulatory actions, which are set out in our [enforcement policy](#).

Make a representation

If CQC takes civil enforcement action the relevant registered person has the right to make representations to us. You can make a representation if we:

- issue a Warning Notice
- impose, vary or remove conditions of registration
- suspend registration, or extend the period of suspension of registration
- cancel registration.

Warning Notices

A registered person must make representations against a warning notice in writing within 10 working days of CQC serving the notice.

See our guidance on making representations against a Warning Notice:

[Representations against warning notices](#)

Please use this form to make representations: [Notice representations form](#)

Please note: there is no right of appeal to the First-Tier Tribunal against a warning notice; you can only make representations to us about it.

Please send your representations form by email to

HSCA_Representations@cqc.org.uk.

Notice of proposal

A registered person can make a representation against a notice of proposal before we decide whether to adopt it and serve a notice of decision. You must make a representation within 28 days of CQC serving the notice.

If we issue a notice of decision, a provider can appeal about it to the First-tier Tribunal.

See our guidance about making representations against a notice of proposal: [Representations and appeals guidance](#)

Please use this form to make a representation: [Notice representations form](#).

We will consider all representations and aim to respond to them within 20 working days.

Please note: Each form only covers one regulated activity (please specify which one in the appropriate section of the form).

To make representations about more than one regulated activity, you must complete and submit a separate form for each one.

Please send your representations form by email to HSCA_Representations@cqc.org.uk.

Complain about CQC

We aim to provide the best possible service, but we do not always get it right. CQC welcomes your feedback to help us improve our services and ensure we are responding to your concerns as best we can.

Your complaint should be made to the person you have been dealing with because they will usually be the best person to resolve the matter. If you feel unable to do this, or you have tried and were unsuccessful, you can contact our National Customer Service Centre by phone, letter or email.

Post

CQC National Customer Service Centre
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Phone: 03000 616161

Email: enquiries@cqc.org.uk

Opening hours: 8.30am – 5:30pm, Monday to Friday

What will happen next?

Your complaint will be forwarded to our National Complaints Team who will make contact with you to discuss your concerns and confirm how CQC will respond to them.

We will try to resolve your complaint informally within seven working days so that we can address the concerns as soon as possible. If a formal investigation is needed, we will propose a date for response (usually within 30 working days) and agree this with you. Your complaint will be investigated by someone not connected to the issues and the process will be overseen by the National Complaints Team. You will then receive a report detailing our findings and if appropriate, what we have done, or plan to do, to put things right.

What if I am still not happy?

If you remain unhappy with the outcome of your complaint, you can contact the Parliamentary and Health Service Ombudsman (PHSO) via your local Member of Parliament. Visit the [PHSO website](#) to find out how.