

How CQC monitors, inspects and regulates independent doctors and clinics providing primary medical, mental health and non-hospital acute services

August 2021

Updates to this guidance:

 Removed previous information about the frequency of inspections as this no longer applies

Always check CQC's bulletins and website for the most up-to-date guidance

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HOW WE DEFINE INDEPENDENT DOCTOR AND CLINIC SERVICES

We define independent healthcare services as health care provided by organisations that are not NHS trusts or NHS GP services (that is, private sector services). This guidance explains how we inspect the following independent doctor and clinic services:

- Private GP services, including medical agencies that visit people in their home or other places where they are staying (such as hotels or care homes) and non-NHS primary medical type services.
- Medical practitioners providing consultation and/or treatment. These practitioners should be on the specialist register of the General Medical Council. The care and treatment provided will usually be the same or similar to outpatient consultation and treatment services in an acute, community or mental health hospital. Care and treatment could also include minor cosmetic procedures and minor surgical procedures provided in a treatment room.
- Vaccination clinics (it is possible that some of these services may not be provided by an independent doctor) – this does not include COVID-19 vaccination clinics. If travel or other vaccination is the main purpose of the service, we regulate services under this approach).
- Slimming clinics where the main regulated activity of the clinic is to provide advice or treatment by, or under the supervision of, a medical practitioner, including prescribing medicines for weight reduction.
- Weight management where this is provided by someone on the Health Care Professional (HCP) register, but who is not a medical practitioner. For example, a nurse.
- Vasectomy carried out under local anaesthesia.
- Endoscopy restricted to nasopharyngoscopy, colposcopy and use of auroscope etc.
- · Health screening.
- Circumcision carried out by a medical practitioner.
- Gynaecology, dermatology, cardiology or other healthcare or diagnostic service
 that does not involve any treatment that falls under the acute hospital or single
 specialty category. (Where we refer to single specialty we mean where the sole or
 main purpose of the service is to provide the speciality we have specified, for
 example, termination of pregnancy or dialysis).
- Family planning services involving the insertion or removal of an intrauterine contraceptive device carried out by, or under the supervision of, a healthcare professional. The main purpose of the service must be the regulated activity of family planning services.

Read our separate guidance on how we regulate the following types of service:

- <u>Providers of online primary care</u> as a standalone service (private GPs, registered medical practitioners or other clinicians providing consultation and/or treatment remotely, for example, by telephone or internet).
- NHS GP practices
- <u>GP out-of-hours, NHS 111 and urgent care services</u> (even though these are often provided by independent sector organisations).
- Other independent healthcare services not listed above, including independent doctor services approved and licensed by the Department of Health and Social Care (DHSC) to carry out termination of pregnancy and registered with CQC for that regulated activity.

MONITORING AND INFORMATION SHARING

How we monitor independent doctors and clinics providing primary medical, mental health and non-hospital acute services

We are developing how we monitor services. Read our update on what to expect from our monitoring approach.

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.

We gather information from a range of sources, including:

- people who use services
- · other regulators and oversight bodies
- local organisations
- other stakeholders and service providers.

We expect you to have your own system to gather feedback about the care you deliver and use it to improve the quality of care. Inspection teams will consider this alongside other feedback when making judgements about your service.

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:

- General Medical Council
- NHS England (where independent doctor services provide NHS-funded care)
- Nursing and Midwifery Council
- General Pharmaceutical Council
- Medicines and Healthcare products Regulatory Agency.

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 with us so that we can understand and act on what people tell us. This includes through our national <u>Tell us about your care</u> 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

One of your local CQC inspectors or inspection managers 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 an 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

Our inspection activity will focus on where there is risk. Read our update on our regulatory approach and how we will assess services.

If you are registering with CQC as a new provider, we will normally aim to inspect within 12 months of registration. You will receive your initial rating at this inspection.

Announced inspections

Inspections are normally announced. We feel this is the most appropriate way to make sure that our inspections do not disrupt the care you provide.

When we announce inspections, we will usually give you two weeks' notice. The inspector will telephone you to announce the inspection and send a letter to confirm the date. Throughout the inspection process, the lead inspector will support and communicate with you by letter, email or telephone to help you to prepare for the day so that you know what to expect.

Unannounced inspections

We may also carry out an unannounced inspection, for example if we are responding to a specific issue or concern. This may be something identified at a previous inspection that we are following up, or new information.

At the start of all inspection visits, the inspection team will meet with your registered manager. If the registered manager is not available the inspector will meet with the most senior member of staff on duty, and will feed back to them at the end of the inspection if there are any immediate concerns.

Pre-inspection provider information request

Before we inspect, we will ask you for information that will help us to prepare for our inspection and understand more about the care and the service you provide.

For example, this may include:

- information about your patients and people who use your services
- details of your staff, including numbers of staff by role and hours worked
- details of significant events and serious incidents reported, including the actions you have taken

- for private GP services we may consider evidence and examples of how you have provided care for specific population groups
- evidence to show how you have monitored the quality of treatment and services, including details of completed clinical audit cycles with evidence of actions taken as a result and outcomes achieved
- evidence of how you have addressed the findings from patient feedback
- a summary of complaints received, with details of actions you have taken and any improvements made
- policies, procedures and other documentation.

We may ask for other information depending on what data is available to us.

You will have five working days to respond to our request. We will tell you what information to send, where to send it and who to contact if you have any questions.

The inspection team

Each inspection team is led by a CQC inspector 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. These are clinical and other experts such as GPs, consultants, nurses or practice managers.
- 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.
- A member of CQC's Medicines Optimisation team.

What we will inspect

Information from our monitoring activity helps to determine the type of inspection and what we will look at.

Types of inspection

Comprehensive

Comprehensive inspections address all five key questions and ask: is the service safe, effective, caring, responsive and well-led? We will always carry out a comprehensive inspection of services that have not had a first inspection or received an initial rating. These are usually announced in advance.

Follow up

We will inspect when we need to follow up an area of concern. This could be a concern identified during an inspection that has resulted in enforcement or compliance action, or concerns that the public, staff or other stakeholders have raised with us.

These inspections do not usually look at all five key questions. They usually focus only on the specific areas indicated by the information that triggers the inspection. However, if we have not inspected and rated your service before, we may choose to carry out a comprehensive rated inspection as well as looking at any individual concerns. This means we won't have to carry out any further inspections. The decision will depend on the areas of concern and the inspection team.

Inspecting complex providers

If you deliver services across more than one sector, we try to align our inspections to be more efficient and to make the process simpler for you. For example, some organisations may provide a combination of primary healthcare services, acute hospital services, mental health care, community health services and ambulance services, and may also run care homes. We will use teams of specialists to inspect each of these services.

Site visits

Site visits give us an opportunity to talk to people using your services, your staff and other professionals, to find out about their experiences. They allow us to understand how you deliver care and see how people's needs are managed.

Where services are managed from one location across multiple sites, we are likely to visit a number of the sites during an inspection.

Gathering evidence during the site visit

To structure the site visit, the inspection team refers to the key lines of enquiry (KLOEs) in the <u>assessment framework for healthcare services</u>. They also look at any concerns identified beforehand through our monitoring activity. This enables them to focus on specific areas of concern or potential areas of outstanding practice. They collect evidence against the KLOEs using a variety of methods.

People who use services

We will gather the views of your patients, their family and carers, by:

- speaking with them individually
- using information from complaints and concerns sent through our website.

If we include an Expert by Experience on an inspection, they will talk to people at the premises on the day of the inspection.

Your staff

On all inspections, we are likely to speak to a range of staff including:

- doctors, including locums
- managers
- nurses
- healthcare assistants
- other clinical staff
- administrative staff.

For larger providers, the inspection team may also hold focus groups with separate groups of staff.

Gathering information in other ways

We may also gather information by:

- tracking a patient's journey through their care pathway
- · reviewing records
- reviewing operational policies and supporting documents.

We recognise that there are sensitivities about medical records. The relationship between doctors, nurses and their patients is often a close one, with a very strong expectation of confidentiality. Records may include very private and personal information. A member of the inspection team will review medical records.

The start of the visit

At the start of each inspection the inspector will meet with your registered manager. If the registered manager is not available, they will meet with the most senior member of staff on duty. 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, including CQC's regulatory powers
- the plan for the day
- 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:

- your service, including the context in which you operate
- · any examples of outstanding care and practice
- 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 told us about concerns that you are already aware of, we will reflect this when we assess the well-led key question.

The inspection team will meet to review the emerging findings at least once during the inspection. This keeps the team up-to-date with all issues and allows them to shift the focus of the inspection if they identify new areas of concern. It also enables them to identify any further evidence they might need in relation to a line of enquiry and relevant facts to corroborate a judgement.

Feedback on the visit

At the end of the inspection visit, the lead inspector will meet with you to provide initial feedback only, illustrated with some examples.

At the meeting, the inspector will:

- tell you about any issues that were escalated during the visit or that require immediate action
- tell you if we need additional evidence or if we need to seek further specialist advice in order to make a judgement
- tell you about any plans for follow-up or additional visits (unless they are unannounced)
- explain how we will make judgements against the regulations
- explain the next steps, including how we process the draft inspection report
- answer any questions.

We will need to analyse the evidence further before we can reach final judgements on all the issues and award ratings.

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.

Read more about the Mental Capacity Act.

AFTER INSPECTION

Your inspection report

After each inspection we publish an inspection report on our website, normally within 50 days of the inspection. 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. If we find examples of outstanding practice during inspection, we describe them in the report to enable other providers to learn and improve. We also describe any concerns we find about the quality of care. The report sets 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.

Factual accuracy check

When we have checked the quality of the draft inspection report (and evidence appendix/table, if appropriate), we will send you the draft documents. We will ask you to check the factual accuracy and completeness of the information that we have used to reach our judgements and ratings, where applicable.

The factual accuracy checking process allows you to tell us:

- where information is factually incorrect
- where our evidence in the report may be incomplete.

The factual accuracy process gives inspectors and providers the opportunity to ensure that they see and consider all relevant information that will form the basis of CQC's judgements.

Inspection teams base their judgements and ratings on all the available evidence, using their professional judgement and CQC's published ratings characteristics for health-care and for adult-social care services. The inspection report does not need to reference all the evidence but it should include the best evidence to support our judgements.

We will send an email to the appropriate registered person. This will include:

- a copy of the draft report (and evidence appendix/table, if appropriate)
- a link to download a form to provide your response.

Download the appropriate form to submit your response, as set out in the letter in the email. Once you have received the email with the draft report, you have **10 working** days from the date of the email to submit the form with your comments.

If you do not wish to submit a response tell us immediately. We will then be able to publish the final report.

Providers are responsible for making sure that the factual accuracy of the draft report has been checked by the responsible person and that any factual accuracy comments regarding the draft report have been approved and submitted.

The factual accuracy checking process should not be used to query:

- an inspection rating
- how we carried out an inspection see how to complain about CQC
- enforcement activity that we propose see how to <u>make a representation about</u> proposed enforcement activity

The draft report includes the draft judgements and ratings, where appropriate. If the inspector corrects any factual details in the report or accepts any additional evidence, they will amend the draft report. They will determine whether this has an impact on a judgement or rating(s) and will explain any changes on the form. We may change draft ratings if we determine that the evidence on which they are based is inaccurate or incomplete.

For more details and guidance on how to respond, see Factual accuracy check.

Your ratings

We will rate your service for the quality of care overall and for our five key questions: Is the service safe, effective, caring, responsive and well-led?

We award ratings on a four-point scale: outstanding, good, requires improvement, or inadequate.

It is a legal requirement to <u>display your ratings</u>. If you have an overall rating of good or outstanding, you may like to <u>promote</u> this in your communications.

We decide all ratings using a combination of aggregating the key question ratings and the professional judgement of inspection teams. We provide ratings at <u>different</u> levels and we use a set of <u>ratings principles</u> to help us determine the final ratings.

Ratings characteristics

Your rating is based on our assessment of the evidence we gather against the key lines of enquiry in the <u>assessment framework for healthcare services</u>. Inspectors refer to the corresponding ratings characteristics for the key lines of enquiry and use their professional judgement to decide on the rating.

When deciding on a rating, the inspection team asks:

- Does the evidence demonstrate a potential rating of good?
- If yes does it exceed the standard of good and could it be outstanding?
- If no does it reflect the characteristics of requires improvement or inadequate?

A provider doesn't have to demonstrate every characteristic of a rating for us to give that rating. Inspection teams use the ratings characteristics as a guide, not as a checklist or an exhaustive list. They take into account best practice and recognised guidelines, and assure consistency through CQC's quality control process.

For example, if you demonstrate just one of the characteristics of inadequate but this has a significant impact on the quality of care or on people's experience, this could lead to a rating of inadequate. On the other hand, even providers rated as outstanding are likely to have areas where they could improve. In the same way, you don't need to demonstrate every one of the characteristics of good in order to be rated as good.

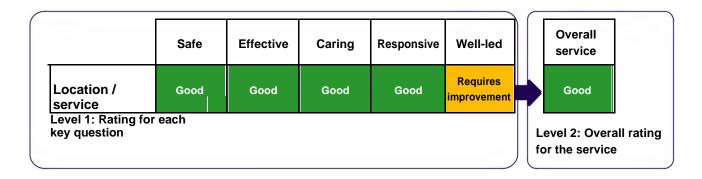
Levels of ratings

We generally rate independent doctor services and clinics at two levels.

Level 1: A rating for each key question for the location/service.

Level 2: An overall rating for the service. This will be an aggregated rating informed by our findings at level 1.

The following example shows how the two levels work together:



Sometimes, we won't be able to award a rating. This could be because:

- the service is new
- we don't have enough evidence
- the service has recently been reconfigured, such as being taken over by a new provider.

In these cases, we will use the term 'inspected but not rated'. We may also suspend a rating at any level. For example, we may have identified significant concerns which, after reviewing but before a full assessment, lead us to reconsider our previous rating. In this case, we would suspend our rating and then investigate the concerns.

How we determine your aggregated ratings

Using professional judgement

To ensure that we make consistent decisions, we follow a set of ratings principles and apply professional judgement when rating at key question level and service level. Our ratings must be proportionate to all available evidence and the specific facts and circumstances.

If we identified concerns in the inspection we will consider the following criteria and use our professional judgement to decide whether to depart from applying the ratings principles – particularly where we need to aggregate ratings that range from inadequate through to outstanding:

- The extent and impact of the concerns on people who use services and the risk to quality and safety, taking into account the type of setting. If concerns have a very limited impact on people, it may reduce the impact on the aggregation of ratings.
- Our confidence in the service to address the concerns, or where action has already been taken.

We can't predict what future models of care and configurations of services will look like. To enable us to be flexible and respond to change, we will base our approach to aggregation for future models of care on these principles.

Where a rating decision is not consistent with the principles, we will record the rationale clearly in the inspection report and the decision will be reviewed using internal quality control and consistency processes.

Updating ratings

When we have re-inspected a service and awarded a new rating for any key question, we carry forward the ratings from the previous inspection and aggregate them with the updated ratings. A change to a key question rating can result in a change to an overall rating for a provider when we apply the ratings aggregation rules.

Where there is a change of ownership or address at an existing location, CQC's website and internal systems will continue to display the provider's 'regulatory history' (rating and inspection report under a previous provider).

After we have published an inspection report, you must <u>display your updated ratings</u> in relevant locations and on your website.

Ratings principles

Our inspection teams use a set of principles when rating services, locations and providers to ensure that we make consistent decisions. The principles will normally apply but will be balanced by inspection teams using their professional judgement. Our ratings must be proportionate to all the available evidence and the specific facts and circumstances.

Reflecting enforcement action in our ratings

Where we are taking enforcement action we will reflect this in the ratings at the key question level.

- 1. Where we have identified a breach of a regulation and we issue a Requirement Notice, the rating linked to the key question relevant to the breach will normally be limited to 'requires improvement' at best.
- 2. Where we have identified a breach of a regulation and we take action under our enforcement powers, such as issuing a Warning Notice or imposing a condition of registration, the rating linked to the key question relevant to the breach will normally be 'inadequate'.

Overarching aggregation principles

The following principles apply when we are aggregating ratings.

- 3. The five key questions are all equally important and should be weighted equally when aggregating.
- 4. All ratings will be treated equally when aggregating unless one of the other principles below applies.

Note: We can adjust the following principles for combinations where it is not appropriate to treat ratings equally, for example, where one of the key questions is rated as inadequate we would not expect the overall rating to be good or outstanding.

Aggregating ratings

There are too many combinations of ratings and the resulting aggregation to show here. However, we use the following principles as the basis of the aggregation and use our professional judgement to apply them to the specific combination of underlying ratings. We will apply the principles in the table below when aggregating the five key questions to an overall service level.

When using the following principles, the number of underlying ratings in most instances will be five (for the key questions). However, there may be circumstances where we do not rate for one or more of these. In these instances, the number of underlying ratings may be fewer.

5. The aggregated rating will normally be 'outstanding' where at least X number of the underlying ratings are 'outstanding' and the other underlying ratings are 'good'.

Number of underlying ratings	Number (X) of underlying outstanding ratings
1 - 3	1 or more
4 - 5	2 or more

6. The aggregated rating will normally be limited to 'requires improvement' where at least X number of the underlying ratings are 'requires improvement'

Number of underlying ratings	Number (X) of underlying requires improvement ratings
1 - 3	1 or more
4 - 5	2 or more

7. The aggregated rating will normally be limited to 'requires improvement' at best where X number of the underlying ratings are 'inadequate'
8. The aggregated rating will normally be limited to 'inadequate' where at least Y number of the underlying ratings are 'inadequate'.

Number of underlying ratings	Principle 7	Principle 8
	Limited to requires improvement where there are (X) number of underlying inadequate ratings	Limited to inadequate where there are (Y) number of underlying inadequate ratings
1 - 3	Not applicable	1 or more
4 - 5	1	2 or more

Request a ratings review

Grounds for review

The only grounds for requesting a rating review after completion of the factual accuracy process and publication are that we have failed to follow our process for making ratings decisions.

You cannot ask for a review of your ratings on the basis that you disagree with our judgements.

Any request for a review must relate solely to your latest final inspection report. We cannot consider references to previous reports or those for other providers.

How to request a review of ratings

All rating review requests must be submitted using our online form by one of:

- the registered manager
- · the nominated individual
- the chief executive (NHS trusts only)

You must submit the request **within 15 working days** of the publication of the report, and you can only submit one request for an inspection report.

There is a limit of 500 words for a request for review across all the ratings you wish to challenge (except for larger NHS trusts and independent hospitals that provide several core services or have multiple locations).

The review process

We will first consider whether your request meets the grounds for review.

If it does not meet these grounds then we'll refuse the request and write to you to explain why.

If it does meet the grounds, CQC staff not involved in the original inspection will review the aspects of the process that were not followed correctly.

As well as our own staff, we may use independent reviewers if their expertise is relevant to your request.

Our review may extend to ratings that you did not challenge. All ratings can go down as well as up as a result of a review.

During the review, we will display a message on the relevant profile page on our website to show it is taking place. The report will remain published on the website

Complaints and appeals

If you are making a complaint against us or challenging our enforcement action, we will pause the review until these are complete.

We will let you know when we start to consider your request – this is usually once the complaint or challenge is complete (including any appeal to the First-tier Tribunal).

The review decision

Where the grounds for a rating review are met, CQC's Chief Inspector of Primary Medical Services and Integrated Care, Chief Inspector of Hospitals or a Deputy Chief Inspector of Adult Social Care makes the final decision.

Once the review is complete, we'll let you know the outcome. We aim to complete all reviews within 50 working days.

We'll make the appropriate changes to your report and ratings as a result of the review on our website as soon as possible.

The review is the final CQC process for challenging a rating. However, you can challenge the ratings elsewhere, such as by applying for a judicial review.

How we publish inspection information

Every time we inspect a health or social care service, we publish information about it on our website, normally within 50 days of the inspection.

This includes:

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

We also send email alerts to people who have registered an interest in a 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 ratings and summaries appear on the webpage, and the report is available as a PDF document.

Email alerts

Visitors to our website can sign up for <u>email alerts</u> 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 <u>enforcement action and representations</u>.

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:

- publish inspection reports with overall outstanding or inadequate ratings
- 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 quidance 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 <u>enforcement policy</u> 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 <u>enforcement policy and enforcement decision tree</u> 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 <u>enforcement policy</u> 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.

Special measures

Responding to inadequate care

Services rated as inadequate overall will be placed straight into special measures.

The purpose of special measures is to:

- Ensure that providers found to be providing inadequate care significantly improve.
- Provide a framework within which we use our enforcement powers in response to inadequate care and work with, or signpost to, other organisations in the system to ensure improvements are made.
- Provide a clear timeframe within which providers must improve the quality of care they provide or we will seek to cancel their registration.

Special measures does not replace CQC's existing enforcement powers: it is likely that we will take enforcement action at the same time as placing a provider into special measures. In some cases we may need to take urgent action to protect people who use the service or to bring about improvement, in accordance with our enforcement policy.

We have published <u>detailed guidance</u> about our approach to special measures.

We want to ensure that services found to be providing inadequate care do not continue to do so.

Responding to care that requires improvement

Where services are rated as requires improvement on more than one consecutive inspection, it shows that they cannot demonstrate the necessary leadership or governance processes to assure and improve quality. In these cases, we will consider whether this may represent a breach of Regulation 17 (good governance). We may also ask the provider for a written report to set out how it will assess, monitor and improve the quality and safety of its services.

If we rate a service as requires improvement for a third time, we will hold a formal management review meeting (MRM) to consider the next steps and the potential use of our enforcement powers.

Where we register larger or complex providers, we will monitor quality across all their services. Where there are concerns across the group, we may consider taking action to hold the provider to account, for example by using our enforcement powers.

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@cgc.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@cgc.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.