Enforcement decision tree

Our enforcement decision tree describes the process that guides how we make decisions about selecting and using appropriate enforcement powers.

Introduction

The Care Quality Commission (CQC) has civil and criminal enforcement powers.

Civil powers focus on reducing the risk to people who use regulated services, while criminal powers hold registered persons to account for serious failures. In some cases, it will be appropriate to use both civil and criminal enforcement powers at the same time.

The decision tree describes the process that guides how CQC makes decision about selecting and using appropriate enforcement powers. Setting a structured decision-making process enables consistency and proportionality.

It has 4 stages:

1. Initial assessment.

2. Legal and evidential review.

3. Selection of the appropriate enforcement action.

4. Final review.

We refer throughout to a breach, or breaches, of legal requirements as this is the legal basis for most civil and all criminal enforcement action, except for powers such as the Section 29A warning notice.

You should also refer to our enforcement policy when using this decision tree.

Stage 1: Initial assessment

We can become aware of incidents and events that could warrant civil and/or criminal enforcement action from several sources. Some examples can include:

- information gathered through our assessment process and/or in notifications from providers.
- safeguarding alerts
- instances of whistleblowing
- RIDDOR or coroners' reports
- complaints
- information from the public.

When this happens, the first stage of the process is to conduct an initial assessment to consider what response is appropriate from the full set of options available.

The options at this stage include:

- gathering more information
- referring the concern or sharing the information of concern with another public body
- progressing to Stage 2 of the decision tree and considering what enforcement action to take.

During the initial assessment stage, we need to ensure that we respond properly to information about a possible breach of a legal requirement. We recognise that each case is different, so we can use a wide range of options where there are potential breaches. It is not feasible or proportionate to follow up every potential breach of a legal requirement. However, information about every potential breach should prompt some action. For example:

- all safeguarding alerts should be reviewed
- notifications and/or incident reports should be reviewed by the appropriate colleague
- any concerns identified should be assessed in more detail before deciding.

Where initial enquiries do not provide assurance that people using regulated services are reasonably protected from harm – and when they suggest that a provider or individual may need to be held to account for a breach – escalation to enforcement and Stage 2 of the decision tree should be considered.

Where a matter is escalated, a Decision-Making Meeting (DMM) or Management Review Meeting (MRM) should be convened to decide on the most appropriate next step.

The DMM or MRM follows a defined decision-making structure that includes mandatory steps and a quality framework to help drive consistency. The process continually reviews decisions about what enforcement action we should take – if any – until we reach a decision. The CQC decision-maker is identified in the appropriate decision-making methodology. This may be either the Scheme of Delegation or the Framework of Operational Delegations and Assurance (FODA). Each process has a defined structure that includes mandatory steps and a quality framework to define consistency. It also prompts us to document the rationale for all decisions, which in turn provides a clear audit trail.

The DMM/MRM will consider the full range of possible responses. We expect that relatively few cases will move from initial assessment straight to Stage 2, as we will need to make further enquiries for most concerns.

In making the decision to move to Stage 2:

- We will bear in mind the importance of working co-operatively with registered persons.
- We will be mindful of our limited enforcement resources.
- We will have regard to criteria set out at Stages 2 and 3.
- We will have regard to any enforcement priorities in our business plan
- We will check whether the facts as we understand them support a case where:
- there has been a serious breach of the provider's legal duties.
- where we are best placed to take the lead
- where it is feasible to collect evidence.

Stage 2: Legal and evidential review

Where a case progresses from Stage 1 to Stage 2, we will conduct a legal and evidential review of the case. This is to determine:

- Whether there is sufficient evidence of a breach of the legal requirements by a registered person.

The review must identify:

- The breach of legal requirement that appears to have taken place.
- Whether enforcement action may be appropriate, having regard to relevant guidance and the Enforcement Policy.

- Whether we possess, or can obtain sufficient, credible and appropriately recorded evidence that is stored and retrievable to support enforcement action. It will usually be necessary to create an 'evidence bundle' at this stage, which may later become the evidence to be disclosed.

The Stage 2 review will usually be conducted by colleagues and their managers who will seek advice where necessary.

If the colleague considers that the evidence demonstrates an identifiable breach of a legal requirement and the evidence is sufficient and robust to prove the breach, the case will continue to Stage 3.

Stage 3: Selecting the appropriate enforcement action

Stage 3 uses a structured decision-making process to decide the appropriate enforcement action. At this stage, decision-makers should consider all civil and criminal enforcement options.

Sections 3A and 3B provide a framework for reaching a decision about what civil enforcement action is appropriate. Section 3C provides a framework for deciding whether it is appropriate to take criminal enforcement action.

Our enforcement criteria take account of CQC's duty to protect and promote the health, safety and welfare of people who use regulated health and social care services by encouraging improvement and focusing on the needs and experiences of people using services.

The criteria also highlight the need for CQC to hold registered persons to account for breaches of regulations.

The decision-making process seeks to guide staff in taking consistent and proportionate decisions without being too prescriptive.

This stage uses 2 criteria to assist CQC staff in deciding which enforcement powers we should use. The criteria are:

- seriousness of the breach
- evidence of multiple and/or persistent breaches

Stage 3A: Seriousness of the breach

We will take progressively stronger action in proportion to:

- the seriousness of the breach
- the potential impact on people using a service
- the number of people affected.

We will take stronger action where a service is carried on in an inappropriate way without effective management of risk.

For example, a registered provider would be ineffective in managing risk if it had not implemented policies and procedures to control risk, despite this being reasonably practicable.

A registered provider would also be ineffective if there was:

- a disregard for legal requirements
- an attempt to avoid them.
- false or misleading information provided.

3A (1): Potential impact of the breach

For civil enforcement, colleagues should assess the level of potential impact that would result if the breach of regulations identified was repeated.

The focus for civil enforcement is on re-occurrence, to assess whether we should act to protect people using regulated services from harm in the future.

Potential impact of the breach: MAJOR

Definition: The breach, if repeated, would result in a serious risk to any person's life, health or wellbeing including:

- permanent disability
- irreversible adverse condition
- significant infringement of any person's rights or welfare (of more than one month's duration)
- major reduction in quality of life.

Potential impact of the breach: MODERATE

Definition: The breach, if repeated, would result in a risk of harm including:

- temporary disability (of more than one week but less than one month's duration)
- reversible adverse health condition
- significant infringement of any person's rights or welfare (of more than one week but less than one month's duration)
- moderate reduction in quality of life.

Potential impact of the breach: MINOR

Definition: The breach, if repeated, would result in a risk of:

- significant infringement of any person's rights or welfare (of less than one week's duration)
- minor reduction in quality of life
- minor reversible health condition.

3A (2): Likelihood that the facts giving rise to the breach will happen again

Colleagues should assess the likelihood that the facts that led to the breach will repeat themselves. The likelihood should be based on the provider's control measures and processes put in place to manage the risks identified, including changes in practice (such as recruiting additional staff or replacing equipment).

Likelihood that the facts giving rise to the breach will happen again: PROBABLE

Definition: It is more probable than not that the facts that gave rise to the breach will repeat themselves, as there are insufficient or ineffective control measures in place to manage the risk identified.

Likelihood that the facts giving rise to the breach will happen again: POSSIBLE

Definition: It is possible that the facts or circumstances that led to the breach will happen again as some control measures have been put in place, but these are not completely effective.

Likelihood that the facts giving rise to the breach will happen again: REMOTE

Definition: It is unlikely that the facts or circumstances that led to the breach will repeat themselves as control measures have been put in place to manage the risk identified, although they may be newly implemented and/or not embedded.

3A (3): Seriousness of the breach

Colleagues need to assess both:

- **the potential impact of the breach**
- **the likelihood that the facts giving rise to the breach will happen again**

They should then apply them to the following table to determine whether the seriousness of the breach is either: **low, medium, high, or extreme**.

	Likelihood: Remote	Likelihood: Possible	Likelihood: Probable
Potential impact: Minor	Low	Low	Medium
Potential impact: Moderate	Low	Medium	High
Potential impact: Major	Medium	High	Extreme

3A (4): Initial recommendation

Colleagues should use the results of 3A (3) to reach an initial recommendation about which civil enforcement powers should be used to protect people using the service from harm or the risk of harm.

This recommendation only takes account of the potential impact of the breach and the likelihood that the facts giving rise to the breach will happen again. We will not reach a final decision on what civil enforcement action to take until we have considered the multiple and persistent criteria, and our enforcement priorities.

Seriousness of the breach: EXTREME

Recommended initial civil enforcement action:

- Urgent cancellation
- Urgent suspension
- Urgent imposition, variation or removal of conditions

Seriousness of the breach: HIGH

Recommended initial civil enforcement action:

- Cancellation
- Suspension
- More significant conditions (impose, vary or remove)

Seriousness of the breach: MEDIUM

Recommended initial civil enforcement action:

- Conditions (impose, vary or remove)
- s29 Warning Notice
- s29a Warning Notice

Seriousness of the breach: LOW

Recommended initial regulatory action:

- Action Plan Request (previously called a Requirement Notice)

Our enforcement policy describes these powers in detail, and it is important to read it along with this decision tree. Registration conditions as part of civil enforcement action can range from imposing minor amendments to registration up to significant restrictions on the carrying on of a regulated activity.

Stage 3B: Identifying multiple and/or persistent breaches

Once an initial recommendation has been reached under Stage 3A, colleagues should then apply the test under Stage 3B to consider whether a more or a less serious level of enforcement than the initial recommendation is appropriate.

This part of the decision-making process considers whether the identified breach and conduct is part of a pattern demonstrating systemic failings.

Where we are considering enforcement against a registered provider, we should assess the provider's ability to identify risks and make and sustain necessary improvements.

Stage 3B considers evidence of multiple or persistent failures. This includes a review of:

- whether there are repeated breaches
- the provider's overall history of performance
- whether there was a failure to assess or act on known risk
- whether there is adequate leadership and governance.

Conclusions reached under Stage 3B can result in a change to the recommended enforcement action by increasing or decreasing the severity.

At this stage, colleagues should work through each of the following questions to identify any adjustments to the initial recommendation made under Stage 3A (4).

3B (1): Has there been a failure to assess or act on past risks?

Colleagues should consider:

- Is there a history of failing to adequately assess risks to people using services, either deliberately, recklessly, through neglect or because ineffective or inadequate action has been taken to make improvements?
- Is there a history of failing to act on identified risks to people using services, including a failure to act on previous CQC assessment reports, requirements, or enforcement actions?

Example 1

A provider of services for people with a learning disability has clear policies for managing patients with epilepsy, including a requirement to carry out an epilepsy risk assessment on admission. A person is admitted to the service with a history of regular and serious epileptic seizures, but an epilepsy risk assessment is not carried out. The person drowns in a bath while being observed in line with the service's general observation policy.

A post-mortem examination report concludes that the person drowned because of an epileptic seizure. His care plan records that he has epilepsy. The patient's death, after an apparent seizure while taking a bath, raises questions about the provider's systems for risk assessment and management overall.

3B (2): Is there evidence of multiple breaches?

Colleagues should consider:

- Is there more than one breach of a regulation or relevant requirements at the same service, different services, or across the whole service, which may indicate that the current conduct is part of a pattern?
- Is there more than one key question rated as inadequate, or are ratings of inadequate more common in the service?
- Are there multiple breaches in a small service? (This may be of greater concern than multiple breaches in a large service, for example, 3 people affected in a 6-bed care home compared with a 600-bed NHS foundation trust.) Colleagues should take account of the proportion of breaches compared with the size of the service and population receiving care.

Example 2

A mental health service provides a range of services in different settings. There is no central system for managing incident reporting and investigation. The overall governance processes are disjointed. The lack of effective governance has resulted in patterns of risk across the service not being properly identified and no action being taken. Ratings of inadequate have been awarded overall and for the safe and responsive key questions. The initial recommendation should be reviewed considering this information.

3B (3): Does the provider's track record show repeated breaches?

Colleagues should consider:

- Is there a history of repeated breaches?
- Are there requirements or enforcement actions that have not been complied with?

- Have necessary improvements been made following breaches identified in reports or enforcement actions?
- Is there evidence that the provider has been unable to improve services? For example, showing that it still has one or more ratings of inadequate at the end of the time-limited period?

If the answer to the fourth question is 'yes', colleagues should consider cancelling the registration or taking action to remove relevant locations unless there is good reason not to do so.

Colleagues should note that a provider's history is taken from the first date of registration of the provider or manager to carry on the regulated activity. If a provider has registered under a new entity, the history should still be considered, but with caution so as not to make unwarranted assumptions.

Example 3

A resident in a care home dies from choking after being helped to eat inappropriate food, despite the risk being clear in her care plan. This is the fourth incident of differing severity at the home in the last few months, in which lack of induction and basic information for agency staff has resulted in them not following care plans. This constitutes a pattern of repeated breaches. Therefore, we would review the initial recommendation and consider criminal proceedings.

Example 4

A GP practice had recruited office staff without carrying out disclosure and barring service (DBS) checks as part of their recruitment and without a risk assessment to determine why a DBS check was not necessary. When this was raised with the practice manager, the practice amended its procedures immediately to include a DBS check for all staff and stipulated that any member of staff who had been recruited previously without a DBS check must now apply for one.

A review of its history showed that the practice had met the regulations and complied with relevant requirements consistently and it was performing well. As the issue was rectified immediately, it would be appropriate to issue an Action Plan Request for recruitment of office staff to involve a DBS check, rather than issuing a Warning Notice or imposing conditions.

Stage 3B (4): Is there adequate leadership and governance?

Colleagues should consider:

- What are the previous ratings or findings for the well-led key question and the competency and capability of the provider's management?

Example 5

The chief executive of an NHS trust leads from the top with a clear mantra that staff work 'for the trust' not 'at the trust' and with the concept of a 'trust family' throughout the hospital. Staff were encouraged to improve patient experience and rewarded for doing so. All levels of staff are empowered to develop their own solutions to enhance services.

There is strong support and alignment between clinicians and managers, who work together to achieve their aim of providing quality patient care. The trust's most recent previous rating was outstanding for well-led at trust level and overall. This demonstrates effective leadership. Therefore, a review of the initial recommendation should be carried out to consider decreasing the severity of the recommended enforcement action.

Stage 3B (5): Change to civil enforcement action due to multiple and persistent criteria

Depending on the answers to each of the above questions (3B (1) to 3B(4)), colleagues should make an overall assessment about the most appropriate civil enforcement action for us to take.

The answers to the questions may increase or decrease the severity of any recommended civil enforcement action.

Severity of civil enforcement action

Less severe civil enforcement action:

- The provider assessed and acted on a known risk.
- There were few or no other breaches.
- There is no history of breaches.
- There is effective leadership and governance.

More severe civil enforcement action:

- There was a failure to assess or act on a known risk.

- There are multiple breaches.
- The provider has a history of breaches.
- There is inadequate leadership and governance.

Section 3C: Consider whether we need to take criminal enforcement action

Criminal enforcement action should be considered in every case where CQC proposes civil enforcement and/or identifies a specific incident of suspected avoidable harm.

Decisions about the most appropriate criminal enforcement action to take will be made in consultation with legal services and following a review of the 2-stage test set out in the Code for Crown Prosecutors. This 2-stage test requires the decision-maker to consider both:

- the sufficiency of evidence gathered
- the public interest to be served in taking criminal enforcement action.

The decision-maker should have regard to CQC's prosecution criteria in the enforcement policy and consider:

- the seriousness of the breach or breaches identified
- the potential impact of the breach or breaches identified on a person using the service and/or the ability of CQC to perform its regulatory functions (breach of conditions or failures to notify).

Example 6

A resident of a care home dies from choking after being helped to eat inappropriate food, despite the risk being clear in their care plan. The lack of induction and basic information for agency staff has resulted in them not following care plans. We should decide whether to gather additional evidence to support criminal enforcement and identify further lines of enquiry.

There is more information about our criminal enforcement powers in the enforcement policy and the list of criminal offences.

Stage 4: Final review

Enforcement priorities and management review

Enforcement priorities are a final check to assist decision-making about what enforcement action we should take.

They can set expectations as part of our overall approach to enforcement. Although they do not dictate decisions under this approach, they are factors to be considered in our decision-making, as they can:

- enable transparent messaging as guidance on broad issues of current interest to CQC's Board: for example, to build our capability in using new powers at a manageable pace, or to spread learning from examples such as using an enforcement case to 'send a message' and influence all providers.

- enable colleagues to be aware of areas of recurrent concern, which they are likely to come across over the year, so they can help to improve standards: for example, absences of registered managers, or failure to submit timely notifications.
- enable CQC's Board to ensure that colleagues are carrying out the Board's priorities: for example, if colleagues do not appear to be using the full range of powers available to them or if there is unexplained variation in the time taken to carry out certain procedures.

A final decision on civil enforcement action and further consideration of criminal enforcement should be taken at either a Decision-making meeting (DMM) or Management review meeting (MRM). These should review the decision making by colleagues at each stage and decide:

- whether civil enforcement action should be taken and if so in what form
- whether criminal enforcement action should be pursued.

The DMM or MRM is the audit trail of the decision-making process for all stages.