

# Enforcement policy

February 2015

# The Care Quality Commission is the independent regulator of health and adult social care in England.

#### Our purpose

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

#### Our role

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

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#### Introduction

Enforcement is one of the core components of the operating model (figure 1) that the Care Quality Commission (CQC) uses to achieve its purpose and perform its role.

This policy sets out the principles and approach we will follow when using our enforcement powers under the Health and Social Care Act 2008, as amended by the Care Act 2014, to improve health and adult social care services and protect the health, safety and welfare of people who use them.

This policy takes effect from 1 April 2015 and replaces the previous enforcement policy. Where we have commenced enforcement action prior to 1 April but it has not been completed, we will be guided by this policy but we may continue to operate under the previous policy if that is more appropriate to the facts of an individual case.

Register - Rigorous test Legally binding Commitment Thematic reports, statutory reports (e.g. State of Care), to safe, highevents, articles and other publications quality care Rate and publish Inspect Monitor Safe? Outstanding Data and Expert Effective? evidence Thorough Caring? Good Information Talking to Responsive? from people people Well-led? Requires improvement and staff Inadequate Enforce Improvements in care Key: CQC's core functions Monitor, inspect Enforce Register

Figure 1: CQC's operating model

The policy particularly concerns enforcement of the Health and Social Care Act 2008, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014<sup>1</sup>, and the Care Quality Commission (Registration) Regulations 2009.<sup>2</sup> In this policy, we refer to both sets of regulations as 'the regulations'.

1 As amended by a) Health and Social Care Act 2008 (Registration and Regulated Activities (Amendment) Regulations 2015 and b) The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012.

**2** As amended by a) The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012.

Note that there will be occasions when, depending on the facts of an individual case, it will not be appropriate to follow the precise steps described in this policy. Therefore it should be read as a general guide to good practice when carrying out or considering to carry out enforcement action. It cannot substitute for judgement in individual cases.

There are many places in this policy where we describe the steps we will take if there has been a breach of the statutory duties of the registrant, a breach of the regulations, or where there are risks to people using services. Decisions about these matters, and whether to proceed to the next state of enforcement action, should be based on the information available to CQC at that time

We accept that there will be occasions when more facts emerge later in the process, or disputes of fact are resolved, and therefore enforcement action is no longer required. If inspectors believe such a stage has been reached, CQC will cease enforcement.

When we refer in this policy to a breach of statutory duties, a breach of the regulations, and risks to people using services this means that it appears to the CQC that there has been a breach of the statutory duties, a breach of the regulations or there are risks to people using services.

When we refer in this policy to 'failures' by a registered provider or others, this means we are referring to a breach of the statutory duties, a breach of the regulations or where the actions or omissions of the provider or others have led to unacceptable risks to people using services.

#### Related guidance documents and legislation

This policy should be read alongside our other key guidance documents:

- Our 'enforcement decision tree' for selecting appropriate enforcement powers.
- Our <u>provider handbooks</u> that describe our approach to inspecting, regulating and, where applicable, rating each of our care sectors.
- Our <u>quidance for providers</u> on meeting the regulations.

This policy does not cover the <u>lonising Radiation (Medical Exposure) Regulations 2000</u>. These are covered under separate primary legislation and have their own enforcement guidance, available on our website. The policy also does not include use of section 48 of the Health and Social Care Act 2008 to carry out investigations.

CQC has powers under the <u>Regulation of Investigatory Powers Act 2000</u> to use directed surveillance and covert human intelligence sources. These powers are subject to <u>additional guidance</u>, available on our website.

#### **Key points**

- We are the primary enforcement body at a national level in England for ensuring that people using health and adult social care services receive safe services of the right quality.
- We have a wide range of enforcement powers and this policy sets out our approach to using our powers.
- We will seek to use a structured decision process to help us decide:
  - Which cases should result in enforcement action.
  - Which enforcement powers we should use.
  - Which approach we should take when using our powers.
- This policy takes effect from 1 April 2015 and replaces the previous enforcement policy.

### 1. Purpose and principles of enforcement

#### **Purpose of enforcement**

We have two primary purposes when using our enforcement powers:

- 1. To protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard.
  - We may work with a provider without using enforcement powers to improve standards where the quality or safety of a service is below the required standards but we assess the risk of harm is not immediate and we consider the provider should be able to improve standards on their own
  - We may **take enforcement action** to compel improvement where the quality or safety of a service has fallen to unacceptable levels, especially where there is a risk of harm to service users. In such cases we may intervene directly (for example, to restrict a service) or trigger others to intervene.

### 2. To hold providers and individuals to account for failures in how the service is provided.

- We have powers to pursue criminal sanctions when there has been a breach of the fundamental standards of quality and safety or some other criminal offence.
- Using the full range of our enforcement powers, including criminal sanctions, should ensure that providers are focused on the need to provide services that meet Parliament's regulatory requirements.

When a service falls below the required standards, we will consider both purposes.

#### Principles that guide the use of our enforcement powers

We will use our enforcement powers to promote our statutory objective of protecting and promoting the health, safety and welfare of people who use health and social care services. The following five principles will guide our decision-making:

#### 1. Being on the side of people who use regulated services

- We recognise that providers often have greater power, control or information than service
  users. Misusing this power can prevent people from receiving high quality care services.
  Where appropriate, we are prepared to use the full range of our powers to ensure that people
  who use regulated services receive safe, effective, compassionate, high quality care to the
  standards set by Parliament.
- The starting point for considering the use of all enforcement powers is to assess the harm or the risk of harm to people using a service.

- We will not tolerate breaches that add up to inadequate care, whether they give rise to a risk
  of harm or not. Where there are failures in care that do not improve, we will be prepared to
  use our enforcement powers.
- We will have regard to the interests of people using care services and others affected by any failure in care as part of considering how to use our enforcement powers.

#### 2. Integrating enforcement into our regulatory model

- Enforcement is a core part of CQC's operating model. Our approach to enforcement is central to our overall purpose and objectives as a regulator. We do not have a separate approach or separate staff for enforcement. Our various functions are designed so they are supported by our enforcement role, and all inspectors are trained so that their engagement with a provider covers all aspects of the regulatory relationship, including enforcement.
- For those providers that we rate, enforcement joins up with (but is not synonymous with) our approach to rating overall quality. We will generally take a broad view when using our enforcement powers as opposed to reacting to individual events and concerns. Enforcement action must relate to specific breaches of legal obligations, but our decision whether to use enforcement powers may take account of a wide range of factors including whether a provider has ratings of requires improvement or inadequate. In particular, we will consider whether the provider has a history of repeated ratings of inadequate.
- Table 1 sets out the relationship between the ratings and the regulations. Our inspections first assess if the care provided is good. Where it is not, we will explore if care requires improvement or is inadequate. At that stage, we will consider whether any of the regulations are being breached. For care to be rated as requires improvement, it does not necessarily mean there is a breach of a regulation. Where care falls below the standard required by the regulations, it will at best be rated as requires improvement. Care rated as inadequate will normally be in breach of regulations.
- While we publish ratings for most providers registered with us, the regulations apply to everyone, including those registered providers for whom we do not publish ratings. We will apply this policy to consider whether we should take enforcement action against providers and others where we find breaches of the regulations.

Table 1: Relationship between the ratings and the regulations

Overall rating	Level of meeting the regulations	High-level characteristics of each rating level
Inadequate	Providers rated as inadequate are generally likely to be not meeting the standards set in the regulations (with the possible exception of the well-led rating, which is not completely covered by the regulations).	Significant harm has occurred or is likely to occur. There are shortfalls in practice and ineffective action or no action has been taken to put things right or improve standards.
Requires improvement	Providers rated as requires improvement may or may not be meeting the standards set out in the regulations.	Providers may have elements of good practice, but provide inconsistent standards of care. This gives rise to potential or actual risk to people using services and/or the provider gives inadequate or inconsistent responses when things go wrong.
Good	Providers rated as good are meeting the standards set out in the regulations and display the characteristics of good care (that is, to be rated good means more than just meeting the standards set out in the regulations).	Providers demonstrate a consistent level of service that meets or exceeds the regulatory standards. The provider has robust arrangements in place for when things go wrong.
Outstanding	Providers rated as outstanding are meeting the regulations and display the characteristics of outstanding care.	Providers are innovative and creative, and are constantly striving to improve standards. They are open and transparent.

#### 3. Proportionality

We will only take action that we judge to be proportionate. This means that our response, including the use of enforcement powers, must be assessed by us to be proportionate to the circumstances of an individual case. Where appropriate, if the provider is able to improve the service on their own and the risks to people who use services are not immediate, we will generally work with them to improve standards rather than taking enforcement action. We generally intervene if people are at an unacceptable risk of harm or providers are repeatedly or seriously failing to comply with their legal obligations.

#### 4. Consistency

- We will seek to be consistent in applying our enforcement powers by, as far as possible, dealing with similar cases in a similar manner. However the facts in one case, including the provider's past history, are rarely replicated precisely in another case. We recognise that, even though we seek to achieve broad consistency, we will take different decisions in cases where the facts are not the same.
  - Consistency does not mean that we will use the same enforcement option every time a
    particular legal requirement is breached. We will seek to use the principles and processes
    set out in this policy to decide how to respond to breaches of regulations or breaches of
    the relevant requirements.
  - We will train and support our staff to promote consistency in our approach and our responses to regulatory breaches.

#### 5. Transparency

- We will strive to be open and transparent about our approach to enforcement, consistent with how we effectively carry out our functions.
  - This enforcement policy is available in a variety of formats, which can be obtained on request. This means providers, the public, and other oversight organisations can easily understand what we expect of providers and how we approach cases where they do not meet the requirements of the law. We will also publish related information including the criteria we use to make decisions and processes for appeals and making representations against our decisions.
  - We will publish information about our enforcement activity and include it in management information reported to our public Board meetings.
  - We will consult on any proposed changes to this enforcement policy.

# 2. Our approach to using our enforcement powers

#### What we can enforce

First, providers of any regulated activity in England must be registered with CQC. We can take enforcement against anyone who provides regulated activities without registration (described in section 5 of this policy).

Second, we can take enforcement against registered persons (meaning registered providers and/or registered managers) who breach:

- Conditions of registration.
- Relevant sections of the Health and Social Care Act 2008, the Care Quality Commission (Registration) Regulations 2009, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and other legislation that is relevant to achieving registration requirements.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 introduced the fundamental standards that come into force for all registered providers on 1 April 2015. These regulations are more focused than the previous regulations, and some allow direct prosecution when the standards are breached. The steps that a provider should have regard to in meeting these standards are set out in our statutory <u>quidance for providers</u>.

Where breaches of regulations do not constitute a criminal offence, we can enforce the standards by using our civil powers to impose conditions, suspend a registration or cancel a registration. Failure to comply with the steps required when we use our civil powers is a criminal offence and so may result in a prosecution.

The breaches of the regulations that constitute criminal offences are shown in bold in table 2.

Table 2: Regulations for which breaches constitute criminal offences (shown in bold)

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	Additional notes	
Regulation 5: Fit and proper persons: directors	In addition, Regulation 16:	
Regulation 9: Person-centred care	Receiving and acting on	
Regulation 10: Dignity and respect	<b>complaints</b> and <b>Regulation 17</b> : <b>Good governance</b> have clauses	
Regulation 11: Need for consent*	that require information to be	
Regulation 12: Safe care and treatment*	provided to CQC on request.	
Regulation 13: Safeguarding service users from abuse and improper treatment*	It is an offence to fail to comply with such a request. Not providing the information could	
Regulation 14: Meeting nutritional and hydration needs*	prevent CQC from identifying	
Regulation 15: Premises and equipment	and responding to harm or risk of harm in a timely and	
Regulation 16: Receiving and acting on complaints	appropriate manner. If these	
Regulation 17: Good governance	clauses are breached, CQC may move to prosecution.	
Regulation 18: Staffing	move to prosecution.	
Regulation 19: Fit and proper persons employed		
Regulation 20: Duty of candour*		
Regulation 20A: Requirement as to display of performance assessments*		
*These regulations relate specifically to harm or the risk of harm, or are requirements imposed by CQC. Breach of these regulations is a criminal offence and CQC is able to move directly to prosecution without first serving a Warning Notice.		
Care Quality Commission (Registration) Regulations 2009		
Regulation 12: Statement of purpose		
Regulation 13: Fees etc		
Regulation 14: Notice of absence		
Regulation 15: Notice of changes		
Regulation 16: Notification of death of service user		
Regulation 17: Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983		
Regulation 18: Notification of other incidents		
Regulation 19: Fees etc		
Regulation 20: Requirements relating to termination of pregnancies		

# Our enforcement powers and how they correspond to the purpose of our enforcement

We have two purposes when we use our enforcement powers (illustrated in figure 2):

- 1. To protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard. We can do this by either requiring or forcing improvement.
- 2. To hold providers and individuals to account for failures in how a service is provided.

Figure 2: CQC's enforcement powers and how they relate to the purpose of our enforcement

#### Increasing severity —

### Purpose: Protecting people who use services by **requiring** improvement

- Requirement Notices (formerly known as 'compliance actions')
- Warning Notices
- Section 29A Warning Notices\*

Purpose: Protecting people who use services by **forcing** improvement

#### **Civil enforcement powers**

- Imposing, varying or removing conditions of registration
- Suspending registration
- Cancelling registration
- Urgent procedures

#### **Special measures**

- Time-limited approach ensures inadequate care is not allowed to continue
- Coordination with other oversight bodies

Purpose: Holding providers and individuals to account for failure

#### **Criminal powers**

- Simple cautions
- Penalty notices
- Prosecution

#### Holding individuals to account

- Fit and proper person requirement
- Prosecution of individuals

<sup>\*</sup>Section 29A only relates to NHS trusts (including foundation trusts).

In addition to our statutory powers, we also work with other oversight organisations to ensure that they take action on concerns that we have identified. We will do so where that is more proportionate or likely to be more effective than CQC acting on its own.

We always retain the option to use our legal enforcement powers as appropriate, for example the development of special measures for NHS trusts with Monitor and the NHS Trust Development Authority, and the memorandums of understanding, information sharing agreements and operational protocols that CQC has with professional regulators. Where we believe that another body is best placed to take action to improve standards we will work with that other body to take that action. However, we will continue to monitor the situation to make sure that improvement does happen. We remain involved and do not assume that a concern has been addressed until we have evidence that this is the case.

#### How we select the appropriate enforcement power

We use a four-stage decision-making process to reach enforcement decisions as described in our 'enforcement decision tree'. We have summarised our approach for each stage of the decision tree below. While this policy sets out our high-level approach, we have published further detail about the decision tree and there is a summary version later in this section (figure 3).

#### 1. Initial assessment

Before commencing enforcement action, the first stage is to consider the case at a structured management review meeting (MRM). The overwhelming majority of cases will be followed up through standard direct checks, such as focused inspections. Urgent cases may proceed directly to evidence collection for potential urgent action or prosecution.

#### 2. Legal and evidential review

This stage checks that the evidence we hold demonstrates a breach of the regulations or relevant requirements. It also ensures we take account of our statutory guidance and any other relevant legislation. It checks that the evidence is sufficient to enable us to proceed to take enforcement action, and that the initial logging and registering of evidence has been done correctly.

#### 3. Selection of the appropriate enforcement action

This stage leads inspectors through a series of tests to assist them to make a decision about which enforcement option to make.

The enforcement decision tree sets out criteria that are used to assist us in this decision-making process. The criteria are:

- Seriousness of the concerns.
- Evidence of multiple and/or persistent breaches.

Stage 3A looks at the seriousness of the concern and the facts that gave rise to that specific concern. It does not take account of other incidents that may have taken place nor the provider's response to them. It is an assessment of the likelihood of the concern happening again, and if so, the impact it would have on people using the service.

Stage 3B takes account of other incidents that may have taken place relating to this provider and the provider's response. It requires inspectors to consider whether there is evidence of systemic failings in the quality of care and/or management, which will result in recurrent issues.

The outcome of the assessment at stage 3B can result in an increase or decrease to the severity of the enforcement action we decide to take, as well as determining whether we need to hold a provider and/or individual to account through criminal sanctions.

#### 4. Final review

The final decision about which enforcement action to pursue is made at an MRM meeting where CQC's sector enforcement priorities are considered. These are the priorities set by CQC's Board and agreed in our business plan. They set expectations for our overall approach to enforcement, providing a transparent message to the sectors as well as to our inspectors.

Consideration of these priorities may result in a change to the type or severity of the enforcement action we intend to take. The final review also checks that the recommendation is in line with this enforcement policy, and that the decision-making process has been followed in line with CQC's scheme of delegation, with appropriate legal advice, and with a robust audit trail of decisions.

#### **Sector enforcement priorities**

Each year, as part of developing the coming year's business plan, we review enforcement activity and consider whether there are priorities that should be reflected in the business plan. These priorities may differ by sector and are set by the CQC board when it agrees the business plan.

Enforcement priorities do not override the terms of this policy, but are taken into account.

Figure 3: Enforcement decision tree

#### Stage

1

#### **Initial assessment:**

• Consider and justify our response to concerns identified

#### Stage

2

#### Legal and evidential review:

- Is there a breach of regulations or relevant requirements? (legal check)
- Is the evidence sufficient, credible and appropriately recorded? (evidential check)

#### Stage

3

# Selection of the appropriate enforcement action:

3A: Seriousness of the concern (the identified concern only)

3B: Multiple or persistent breaches (all other incidents and their management)

#### Stage

4

#### Final review:

- Sector enforcement priorities
- Management review meeting (MRM) to decide enforcement action (consider enforcement principles)

# 3. Requiring improvement to protect people from harm or the risk of harm

We use the following enforcement actions to **require** a provider to protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard. These are:

Purpose: Protecting people who use services by **requiring** improvement

- Requirement Notices (formerly known as 'compliance actions')
- Warning Notices
- Section 29A Warning Notices

#### **Requirement Notices**

Where a registered person is in breach of a regulation or has poor ability to maintain compliance with regulations, but people using the service are not at immediate risk of harm, we may use our power to require a report from the provider. We will do this by serving a Requirement Notice on the provider.

The response from the provider to the Requirement Notice must show how the provider will comply with their legal obligations and must explain the action the provider is taking or proposes to take to do so. Issuing a Requirement Notice notifies a provider that we consider they are in breach of legal requirements and should take steps to improve care standards.

Failure to send us a report in the timescale set out in the Requirement Notice is an offence and could lead to us using other enforcement powers.

We will consider issuing a Requirement Notice where:

- The provider is acting in breach of the regulations; the impact on people using the service is not immediately significant; and we assess that the provider should be able to improve its standards within a reasonable timeframe.
- The provider has no history of poor performance that gives rise to wider concerns.

#### **Warning Notices**

Warning Notices notify a registered person that we consider they are not meeting a condition of registration, a requirement in the Health and Social Care Act 2008, a regulation, or any other legal requirement that we think is relevant. We cannot use Warning Notices against unregistered persons.

We can serve Warning Notices about past failures to meet legal requirements or about a continuing breach of a legal requirement.

Where a Warning Notice concerns a continuing breach of a legal requirement, it will include a timescale by when improvements must be achieved. If a registered person has not made the necessary improvements within the timescale, we will consider further enforcement action. This could lead to further action under civil or criminal law. The enforcement decision tree published alongside this policy specifically prompts inspectors to consider persistent concerns and the ability to improve where concerns are identified.

We aim to follow up every Warning Notice through an appropriate form of check (including unannounced focused inspections where that is proportionate) within three months of the date set in the notice.

The regulations allow us to publish Warning Notices as long as registered persons are given the opportunity in advance to make representations about the proposed publication.

## Warning Notices where significant improvement is required in an NHS trust or NHS foundation trust<sup>3</sup>

There is additional provision in section 29A of the Act for a Warning Notice that is addressed to NHS trusts or foundation trusts. We may issue such a notice where we judge an NHS trust requires significant improvement. Significant improvement is not necessarily restricted to breaches of legislation but could be broader.

Our approach to using these Warning Notices is:

- We will use the same criteria for deciding whether to issue a notice under section 29A as for other Warning Notices.
- Where we do issue a notice under section 29A, we will set a timescale for the significant improvements required to meet the legal obligations of the NHS body or to address the matters set out in the notice.
- We will allow the NHS body to make representations in the same way as other Warning Notices and will have the same expectations for publication and follow-up
- We may use notices under section 29A as part of the NHS single failure regime. This is considered in section 4 of this policy as part of special measures.

**<sup>3</sup>** This power is expected to come into force on 1 April 2015. Until it comes into force, 'normal' Warning Notices as in the section above will apply to NHS trusts and foundation trusts.

# 4. Using civil powers to protect people from harm or the risk of harm and to improve care standards

We use the following **civil enforcement powers** to **force** a provider to protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard.

We can also use the **special measures** framework to manage providers who are failing to comply with their legal requirements.

Purpose: Protecting people who use services by **forcing** improvement

#### Civil enforcement powers

- Imposing, varying or removing conditions of registration
- Suspending registration
- Cancelling registration
- Urgent procedures

#### **Special measures**

- Time-limited approach ensures inadequate care is not allowed to continue
- Coordination with other oversight bodies

#### Impose, vary or remove conditions of registration

Registered persons may have routine conditions attached to their registration. These conditions may include the locations where the regulated activity can be carried on or managed. Registration conditions are usually agreed with registered persons when they apply for registration.

Imposing, varying or removing conditions of registration is a flexible enforcement process that we can use in a variety of different ways to ensure that providers comply with their legal obligations and hence ensure that people who use regulated services are kept safe and receive an acceptable standard of care. For example, we may use a condition to stop a regulated activity at one location but allow the provider to continue providing services at their other locations. We can then remove the condition once our specific concern has been addressed. Conditions may be applied across a whole provider or targeted to specific locations, or to services and activities at one location.

We may also impose conditions that require a registered person to take further action where we consider that some specific improvement is necessary. For example, we may use conditions to ensure that action is taken to manage specific risks.

We will not seek to impose conditions that define precisely how a provider should operate or manage its service. It should remain the provider's choice to decide precisely how to operate its business as long as it complies with all relevant legal requirements.

However, we will retain the right to impose conditions to whatever level of detail and prescriptiveness appear to us to be appropriate in order to ensure that we can be confident that the provider will operate its business in a way that complies with all relevant legal requirements. Usually we will set out our concerns and frame conditions such that they explain what we require to be achieved, but leave the provider to determine exactly how that will be delivered. For example, we may impose a condition requiring staffing levels to take account of national guidance and to require regular returns to us to demonstrate compliance. We will not usually use a condition to define the precise staffing ratio that the provider must achieve.

We will seek to use conditions flexibly. They can be used to formalise administrative arrangements, stop risky activities or require specific improvements. We expect them to be one of our most frequently used powers.

Whenever possible we will seek to agree the imposition of additional conditions or the variation or removal of existing conditions with the registered person in the first instance. If we cannot reach an agreement with the registered person, or we believe that the level of risk will or may increase, then we may rely on our urgent procedures to amend a registered person's conditions of registration.

#### Suspend registration

We can suspend the registration of a registered person for a specified period. We also have the power to extend any period of suspension. We may use this power where there is a very serious concern that we believe can be addressed within a fixed period, for example to construct new buildings or hire new staff.

We anticipate rarely using this power. Suspension affects all of the locations where the registered person carries on or manages the relevant regulated activity. We will therefore pay particular attention to the likely outcomes of suspending registration before taking this action. However, suspension can give a provider the chance to work towards meeting the standards and then resume carrying on or managing an activity, and will be an important proportionate option in specific circumstances.

If providers carry on providing a regulated activity when the registered person has been suspended, this is an offence and we may prosecute.

#### **Cancel registration**

One of our most powerful sanctions is to cancel a registration. As with suspension, this will affect all the locations where the registered person carries on or manages the relevant regulated activity. Cancellation normally follows considerable efforts to get registered persons to meet the legal requirements, including taking special measures as described later in this section. However,

where appropriate, we will use the cancellation process without first having followed other processes.

If providers carry on providing a regulated activity when the registered person has been cancelled, this is an offence and we may prosecute.

#### Deciding when to use conditions, suspension or cancellation

We will consider using conditions, suspension or cancellation where we assess that people receiving regulated services:

• Have suffered harm or are at risk of harm because a registered person is failing to comply with legal requirements.

or

• Are receiving care services that substantially fail to meet the standards set out in the regulations.

We will consider imposing conditions on the provider's registration if we assess that by imposing a condition it is likely to result in the provider addressing the matters of concern within an acceptable timescale.

We will consider suspending a provider's registration if we assess that suspension is reasonably necessary to prevent the breaches of the provider's legal requirements but that the provider will be able to provide a lawful service at an identifiable time in the future.

We will consider the cancellation of a registration if we assess that the registered person does not have the capability or the capacity to substantially comply with regulations, or is likely to fail to do so.

#### **Urgent procedures**

We have the right to exercise the power to impose conditions or suspend a registration on an urgent basis. Where we exercise these powers, our decisions have immediate effect. Providers are entitled to appeal against the use of these urgent powers but this does not prevent the condition or suspension taking effect.

#### Cancelling a provider's registration on an urgent basis

If we wish to cancel a provider's registration using urgent procedures, we must apply to a Justice of the Peace for a court order. In these circumstances we will, where reasonably practicable:

- Tell the registered person in advance about our application to cancel their registration using urgent procedures.
- Only make an application without telling and involving the registered person in exceptional circumstances, such as when their whereabouts are not known and after we have made considerable efforts to locate them.

Where it is not practicable to give the registered person notice of our application to a Justice of the Peace, we will make a full and frank disclosure of all relevant evidence and confirm that we have not given notice to the registered provider as part of our application.

#### General provisions about the use of urgent powers

When serving an Order or Notice of Decision on a registered person using an urgent procedure it will always include information about:

- Our memorandum of understanding with the First-tier Tribunal (Care Standards) about a 'fast track' option for appeals.
- How the registered person can appeal against the urgent cancellation order or notice.

Urgent procedures are an important part of our enforcement powers so that we can act quickly to protect people using a registered service. We expect urgent procedures to be a significant element of our enforcement activity and we will also consider criminal sanctions in serious cases.

We will use urgent procedures in line with the thresholds set out in the Health and Social Care Act 2008. This means that we will only use these powers where we believe that:

- Unless there is an urgent use or amendment of conditions, or urgent suspension of registration, a person will or may be exposed to harm.
- Unless we apply to a Justice of the Peace for the urgent cancellation of registration, a person will be exposed to serious risk to their life, health or wellbeing.

# Non-compliance by a provider following the exercise of these powers

It is a criminal offence not to comply with conditions of registration, or to continue to provide a regulated activity after registration has been suspended or cancelled.

CQC considers breaches of such provisions can amount to a serious offence. This approach is reflected in CQC's criteria for prosecution.

The offence can apply to failure to comply with conditions, suspension or cancellation for any reason. This means, for example, that in relation to those regulations for which a breach does not in itself amount to a criminal offence, a condition, suspension or cancellation of registration may be imposed. Failure to comply with that registration, suspension or cancellation could then result in prosecution.

#### Special administration for NHS trusts and foundation trusts

For NHS foundation trusts, we have powers to require Monitor to appoint an administrator and thereby place the foundation trust in 'special administration'. Special administration is a form of time-limited, rules-based administration that will result in an administrator making recommendations that are designed to ensure that the NHS body improves its standards so that it provides secure, sustainable and high quality services. These powers are set out in the Care

Act 2014. They are mirrored in the Secretary of State's directions to the NHS Trust Development Authority (NHS TDA), so that there are also directly equivalent arrangements for NHS trusts.

To use these powers, we must first have issued a section 29A Warning Notice and be satisfied that the provider has not complied with it. Before requiring appointment of an administrator we will consult the Secretary of State and Monitor or NHS TDA (as appropriate), and then consult the provider, the board, anybody that the trust provides services to, and any other people or organisations that we judge appropriate.

As with cancellation of registration, using this power would normally follow considerable efforts to get the provider to improve, including special measures as described below.

#### **Special measures**

Special measures are an administrative framework which helps CQC to manage providers who are failing to comply with their legal requirements and require a higher than usual level of regulatory supervision. For these providers, special measures assist us to deliver our statutory functions.

Part of any special measures regime is the effective use of enforcement powers to ensure that improvements are made to the standard of care provided by the registered provider. A provider who is operating under special measures may also be working under the close supervision of another oversight body. Where appropriate, we will work closely with relevant oversight bodies to ensure improvements to the standards of service provision are made by the registered provider.

The purpose of special measures is to:

- Ensure that providers found to be providing inadequate care do not continue to do so.
- Provide a framework within which we can use our powers, including enforcement powers, in response to inadequate care standards or other regulatory failures.
- Provide a framework for us to work with other relevant oversight bodies, including signposting the provider to another relevant oversight body or other organisation, to assist in ensuring that improvements in standards and regulatory compliance are achieved.
- Provide a clear and consistent timeframe within which providers are required to improve their
  quality of care so that they meet the regulatory requirements. We are likely to seek to
  exercise our powers to cancel their registration if the required improvements are not made or,
  in the case of NHS trusts and foundation trusts, use our powers to require that they are
  placed in special administration.

Special measures only apply to services we regulate. They are usually triggered by ratings of inadequate care, rather than by individual breaches of regulations. Ratings of inadequate care will generally include a breach of regulations, but they are a rounded assessment of the overall effect for people of how a service is provided, including how the provider meets individual regulations within that.

For services that we do not rate, or where an issue arises in a rated service but it does not change the rating, we will usually continue to use the full the range of our enforcement powers as appropriate, without the special measures framework. We will still be able to use our enforcement powers as appropriate during the period when a provider is in special measures.

Special measures work differently in different types of service areas. For example:

- NHS trusts and foundation trusts, where we work closely with the NHS TDA, Monitor and others
- Primary care, where we work closely with NHS England, professional regulators and others.
- Other services, including adult social care and independent healthcare, that do not all have a
  public sector commissioner, or where services are operated by corporate providers or single
  entities.

For each sector in which we use special measures, we will issue relevant information alongside this policy, in line with its principles and approach. Taking account of the characteristics of the sector, the needs of people who use these services, and the roles of other oversight bodies, improvement agencies and corporate providers, this guidance always includes:

- Clear entry criteria that will trigger special measures, linked to inadequate ratings.
- Time-limited periods for providers to make the necessary improvements so that they are not providing inadequate care.
- Consideration of whether an extension of the time limit will be possible, and if so in what circumstances, through a follow-up inspection.
- Clear criteria for providers exiting special measures, linked to improvement in ratings.
- A clear approach to providers that do not improve and continue to have a rating of inadequate at the end of special measures.

We will work closely with other organisations or oversight bodies in the system to ensure that providers do not continue to provide inadequate care and that they improve during the special measures period. It is the provider's legal responsibility to improve and we will work with the provider to make that happen.

When one or more of a provider's services is placed in special measures, we will assess the wider impact of this on the quality of care provided in its other services.

Special measures are also reflected in the enforcement decision tree that we have published alongside this policy. In particular, the criteria for the use of our power to cancel registration will be triggered where serious concerns are identified and have not been improved within the timeframe that we set.

# 5. Holding providers and individuals to account

We have a variety of methods we can use to hold providers and individuals to account for failures in how the service is provided. We also have new powers in relation to prosecution.

Purpose: Holding providers and individuals to account for failure

#### **Criminal powers**

- Simple cautions
- Penalty notices
- Prosecution

#### Holding individuals to account

- Fit and proper person requirement
- Prosecution of individuals

#### **CQC's new powers in prosecution**

The Health and Safety Executive (HSE) (and for certain services, local authority health and safety inspectors) have a key role in prosecuting serious safety incidents. However, with the coming into force of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, CQC is now able to prosecute cases where people using a registered service are harmed or placed at risk of harm.

We have developed and published a <u>memorandum of understanding</u>, to set out how our roles fit together and principles for managing cases that go across more than one of these roles.

- CQC is the lead inspection and enforcement body for safety and quality of treatment and care matters involving patients and service users in receipt of health or adult social care service from a provider registered with CQC.
- HSE/local authorities are the lead inspection and enforcement bodies for health and safety
  matters involving patients and service users who are in receipt of health or care service from
  providers not registered with CQC.
- HSE/local authorities are the lead inspection and enforcement bodies for health and safety matters involving workers, visitors and contractors.

Our prosecution criteria (set out in the box below) ensure that there is coherence in how we select cases for prosecution, and how HSE/local authorities do so. These criteria are embedded within the enforcement decision tree published alongside this policy.

#### CQC's prosecution criteria

These criteria need to be applied as part of the enforcement decision tree.

We will consider prosecution where there is evidence any of the following apply:

- Services which result in:
  - o Avoidable harm (whether of a physical or psychological nature) to a service user, or
  - o A service user being exposed to a significant risk of such harm occurring, or
  - o In a case of theft, misuse or misappropriation of money or property, any loss by a service user of the money or property concerned.
- Services that have been provided to individuals without informed consent.
- There has been a failure to provide reports on complaints or good governance.
- There has been a failure to legibly display ratings that relate to performance at a provider's premises and overall place of business.
- There has been a failure to notify and offer support to the relevant person following a notifiable safety incident.
- There has been disregard for, and/or attempted avoidance of, the requirement for anyone who carries on regulated activities in England to be registered with CQC.
- There has been a failure to comply with a requirement, Warning Notice or condition, suspension or cancellation of registration; or there has been a repetition of a breach that was subject to a simple caution.
- False information has been supplied wilfully; information or explanations have been withheld; or there has been an intent to deceive, in relation to a matter that gives rise to significant risk.
- Persons authorised by CQC to enter and inspect have been intentionally obstructed in the lawful course of their duties.

We will also consider the following factors when deciding whether to prosecute:

- The gravity of the incident, taken together with the seriousness of any actual or potential harm or the general record and approach of the provider, mean that not holding the provider to account could undermine public confidence in regulation or in that sector of providers.
- There has been disregard for the requirements on a registered person.
- There have been repeated or multiple breaches, which give rise to significant risk, or persistent and significant poor compliance.
- The service is breaching fundamentals of care, namely that it has been carried on significantly below the standards that are required for compliance with regulations and is giving rise to significant risk.
- The potential for wider learning points for providers may mean we will prioritise a single case, so that enforcement sends a broader message to a sector and encourages improvement across it.

# Enforcement powers we will use to hold a provider to account (criminal powers)

#### Simple cautions

A simple caution ensures that there is a formal record of an offence when a person has admitted to it, but is not prosecuted. There is no obligation on a provider to accept a caution and, where the offer of a caution is refused, we will consider prosecution.

We will consider using a simple caution when:

- We have evidence of an offence and that evidence is sufficient that we would be able to bring a criminal prosecution.
- Although we could prosecute, we consider that achieving improvements without initiating lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution.
- The provider has demonstrated to us that they will be able to put these improvements in place within a reasonable timescale.
- The <u>Code for Crown Prosecutors</u> indicates that this option would be appropriate.
- The offence has an insubstantial impact on people using the service.

#### **Penalty notices**

Paying a fixed penalty enables a registered person to avoid a potential prosecution for an offence. It is only appropriate to issue a penalty notice where CQC would have been entitled to prosecute.

CQC has discretion over whether to serve a fixed penalty notice as an alternative to a prosecution. There is no obligation on a registered person to pay the sum under a penalty notice and, if a registered person decides not to pay the penalty, we will consider using other enforcement powers. Failure to pay sums under a penalty notice will normally lead to a prosecution.

The power to issue a penalty notice enables proportionality in specific circumstances. It also enables CQC to 'send a message' where there are recurrent beaches across a sector. Use of fixed penalties to multiple providers within a sector can make it clear that the issue of concern will not be tolerated, but also avoids the need to prosecute every person in breach. It can also signal the importance of the regulatory requirement and that we may proceed to prosecution if there is no improvement.

Any fixed penalty paid to CQC is not retained but must be passed on by CQC to the Secretary of State.

The relevant legal requirements and current levels of penalties are set out in appendix A.

We will consider using the power to issue penalty notices when:

- We have evidence of an offence and that evidence is sufficient to bring a criminal prosecution.
- Although we could prosecute, we consider that achieving improvements without initiating lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution.
- The offence has an insubstantial impact on people using the service.

#### Prosecution

Prosecution can be used to:

- Hold a registered person to account for breaches of prosecutable fundamental standards, or for failing to comply with conditions of registration.
- Enforce the offence of carrying on a service without registration, in which case we may prosecute the person who appears to be carrying it on.
- Ensure accountability for any person who obstructs us in the course of an inspection or any person who makes a false or misleading statement in an application to be registered with us.

Where appropriate, we may prosecute at the same time as taking other enforcement action, for example alongside urgent procedures. We may also prosecute more than one offence at the same time.

There may be occasions where, even if the above criteria are satisfied, we will decide to serve a Warning Notice as an alternative to immediate prosecution. However, CQC will generally prosecute providers where there are serious, multiple or persistent breaches of the fundamental standards (those regulations with prosecutable clauses that specifically relate to harm or the risk of harm) without issuing a Warning Notice first.

Failure to make the improvements set out in a Warning Notice is likely to lead to a prosecution.

Although we are not required by law to publish details of all criminal law procedures that we undertake, we have a general power to publish this type of information and will normally do so. We must publish information about any offence for which a registered person has been convicted.

All investigations of criminal offences will be carried out with regard to the <u>Police and Criminal Evidence Act 1984 (PACE)</u> principles and <u>Codes of Practice</u>.

Where another regulator has the power to prosecute, we will coordinate our activity with them at an early stage to ensure the right action is taken, to avoid inconsistency, and to ensure that any proceedings taken are for the most appropriate offence.

Where we successfully prosecute, the court will decide on the penalty to be imposed. Where someone is charged with more than one offence, the court may order separate penalties in relation to each conviction. The court may impose a prison sentence as well as, or instead of, a fine following conviction for carrying on a regulated activity without being registered.

The offences and current maximum court fines are set out in appendix A.

We will consider using our powers to prosecute where:

• The breach of legislation is assessed by us to be serious and there are multiple or persistent breaches.

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- We have sufficient evidence so there is a realistic prospect of conviction.
- We assess that it is in the public interest for us to use our powers of prosecution.

In making decisions about whether to prosecute, we will be guided by the Code for Crown Prosecutors.

# Holding individuals to account through criminal prosecutions or using other powers

CQC's enforcement activity mostly concerns providers and their liability as the body carrying on regulated activities. However, CQC can use its enforcement powers to hold certain individuals who work for providers to account. Those individuals can be directors, registered managers or the secretary of a corporate body (or a person purporting to act in that capacity), or an officer of an unincorporated association or member of its governing body.

We will consider holding individuals to account by prosecuting them where:

- An offence has been committed with their consent or connivance, or is attributable to neglect on their part.
- There is clarity about the individual's accountability as opposed to the service provider.
- There is a realistic prospect of conviction and we assess that it is in the public interest for us to use our powers of prosecution.

We may also hold individuals to account by ensuring they are not employed in a role they are not fit for. We can do this by cancelling the registration of a registered manager, or by refusing a new registration where we consider an individual is not a fit and proper person. For an existing provider, we can request that they provide assurance that directors are fit for their role.

The regulations also establish a fit and proper person requirement for directors or individuals working in an equivalent role. We may request the chair or equivalent of an organisation to carry out that test and confirm the fitness of the individual director in writing.

#### **Unregistered providers**

It is an offence to provide regulated activities in England without registering with CQC. It is a provider's responsibility to register.

Unless people are at immediate risk of harm, we will usually advise an unregistered provider of the need to register in the first instance. However, in the following instances we will rapidly take enforcement action against all appropriate persons.

- If a provider continues to provide regulated activities without registration.
- If we have grounds to believe that a provider is knowingly choosing not to register.
- If an unregistered provider places people at risk of harm.

This enforcement can include prosecution (which can lead to a fine or imprisonment) and/or other actions such as obtaining an injunction.

### 6. Representations and appeals

#### Representations

Registered persons have the right to make representations to us about certain types of enforcement action. We have produced separate detailed guidance about representations on the following, available on our <u>website</u>:

- Warning Notices.
- A Notice of Proposal to impose, vary or remove conditions of registration.
- A Notice of Proposal to suspend a registration, or to extend the period of a suspension of registration.
- A Notice of Proposal to cancel a registration.

#### **Appeals**

Registered persons have the right to appeal to the First-tier Tribunal (Care Standards) against enforcement action using the civil enforcement procedures. This includes action under urgent procedures but, in those cases, the Tribunal will ensure any appeal is fast tracked. We have produced separate detailed guidance about this on our <u>website</u>.

Appeals must be lodged within 28 days of the service of:

- A Notice of Decision.
- A notice of imposed, varied or removed conditions using the urgent procedures.
- A court order to cancel a registration using urgent procedures.

There is no right of appeal to the Tribunal in relation to Warning Notices, penalty notices or conviction for offences.

CQC offers providers that are rated, the opportunity to request a review of their ratings. That review is not a statutory right of appeal, but a matter of CQC's policy. It is separate to the procedures for representations and appeals on enforcement and registration decisions.

# 7. Publication and notification of enforcement action

The regulations require and authorise us to publish certain information relating to enforcement action.

We are required by law to publish certain details of civil and criminal enforcement. We are also required by law to publish details of any action taken under CQC's urgent powers.

Information about the enforcement action that we take will be included in our inspection reports. We will also publish on our website, a summary of information about the enforcement action taken against each provider and information about our enforcement activity overall.

We send copies of notices relating to enforcement action to a number of third parties, such as commissioners and other regulators. Generally, these notifications are required in the Care Quality Commission (Registration) Regulations 2009, but we will also inform any other persons that we consider appropriate.

We will notify commissioners whenever our activity has an impact on the capacity or configuration of a health and social care economy. Where changes to capacity or configuration are made as a result of our findings but without formal enforcement – for example, if a provider makes rapid changes and we decide that enforcement would no longer be proportionate – we will still endeavour to always notify commissioners.

# **Appendix: Offences and fines**

#### **Fixed penalties**

Offence	Penalty	
Failure to comply with regulations about quality and safety (see Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)	Provider Registered manager	£4,000 £2,000
Carrying on a regulated activity without being registered		£4,000
Failure to comply with conditions of registration	Provider Registered manager	£4,000 £2,000
Carrying on a regulated activity while registration is suspended		£4,000
Managing a regulated activity while registration is cancelled or suspended		£2,000
Failure to provide an updated statement of purpose (see Regulation 12 of the Care Quality Commission (Registration) Regulations 2009)	Provider Registered manager	£1,250 £625
Failure to make required notifications (see Regulations 14-18 of the Care Quality Commission (Registration) Regulations 2009)	Provider Registered manager	£1,250 £625
Failure to provide a statement about fees chargeable (see Regulation 19 of the Care Quality Commission (Registration) Regulations 2009)	Provider Registered manager	£1,250 £625
Failure to observe certain requirements relating to termination of pregnancy (see Regulation 20 of the Care Quality Commission (Registration) Regulations 2009)	Provider Registered manager	£1,250 £625
Obstructing entry and inspection	£300	
Failure to provide documents or information	£300	
Failure to provide an explanation of any relevant matter	£300	

#### **Prosecution**

The Legal Aid, Sentencing and Punishment of Offenders Act 2012 and regulations made under that Act have made changes to the maximum penalties outlined in the table below. The maximum limit on fines previously imposed on summary conviction for amounts of £5,000 or more has been removed.

Offence	Maximum fine
Failure to comply with regulations about quality and safety (see Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)	Unlimited
Carrying on an activity without being registered	Unlimited or 12 months
Failure to comply with conditions of registration	Unlimited
Offences relating to suspension or cancellation	Unlimited
False descriptions of concerns	Unlimited
False statements in applications	£2,500
Obstructing entry and inspection	£2,500
Failure to provide documents or information	£2,500
Failure to provide an explanation of any related matter	£2,500
Failure to display performance assessment (see Regulation 20A of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)	£100

Note: some lesser requirements have a maximum court fine of £2,500.