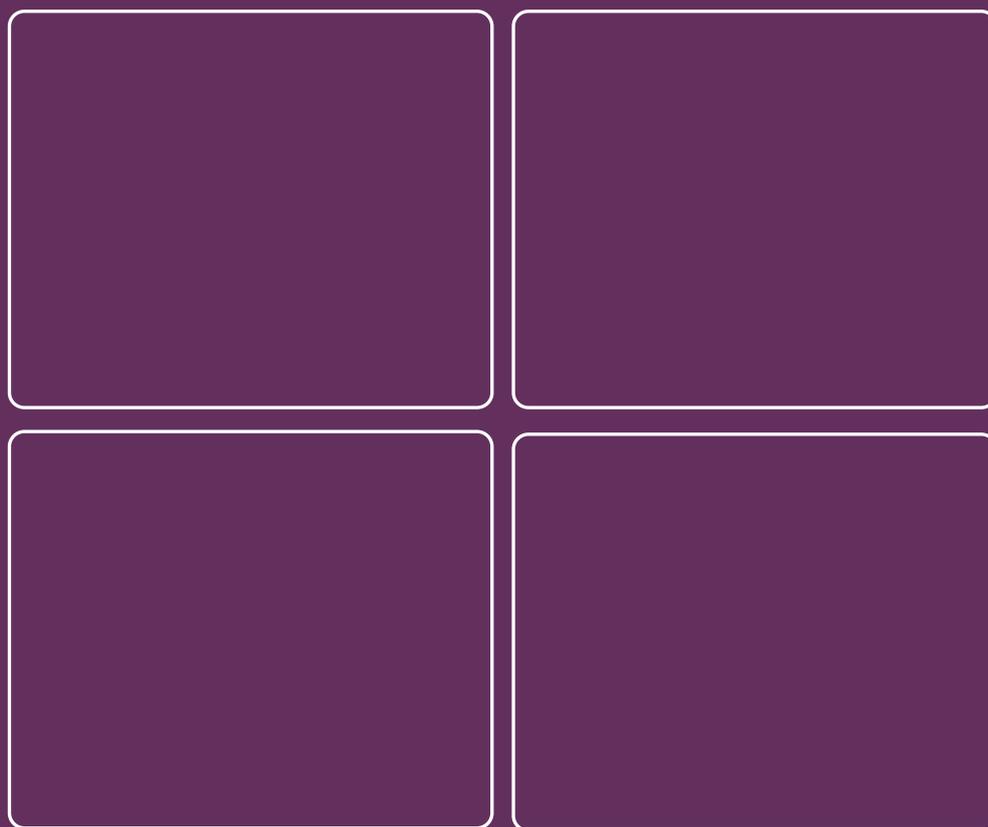


Enforcement policy



About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities or by private or voluntary organisations, we make sure that people get better care. This is because we:

- Focus on quality and act swiftly to eliminate poor quality care.
- Make sure care is centered on people's needs and protects their rights.



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Introduction

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

By this, we mean that registered persons must be compliant with the Health and Social Care Act 2008, Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, and the Care Quality Commission (Registration) Regulations 2009.

In this document, references to "the Act" are to the Health and Social Care Act 2008, while references to "the Regulations" are to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 are referred to as "the regulated activities regulations", and the Care Quality Commission (Registration) Regulations 2009 are referred to as "the registration regulations".

Guidance on how registered persons achieve compliance is expressed in the publication *Guidance about compliance: Essential standards of quality and safety*, which CQC has issued as required under the Act.

This guidance also explains how we measure compliance.

We will continue to monitor the effectiveness of this policy and revise it when necessary.

Context

1. The Care Quality Commission (CQC) is the independent regulator of health and social care services in England. The Health and Social Care Act 2008 established CQC, and sets out the powers we have to regulate services and to take enforcement action. We register services that demonstrate that they meet legal requirements, and after we have registered them, we check that they continue to do this.
2. All services we regulate must comply with the law, but in particular, they must comply with the Health and Social Care Act 2008 and the Regulations made under it, which are the Care Quality Commission (Registration) Regulations 2009 and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

3. We must also issue guidance about the way we will use our powers of enforcement. Where people fail to meet the legal requirements of the Act or where there are breaches of other legislation we have referred to, we can intervene and, if necessary, take action against them. This includes people carrying on a service that has not been registered. The Enforcement policy describes the particular powers we have and the principles behind our approach to applying them. All action will be carried out having regard to the Police and Criminal Evidence Act 1984 principles and Codes of Practice.
4. This policy describes how we will use our enforcement powers and the principles behind our approach, including the use of investigative powers.
5. The revised policy will be published in early 2012 and will replace the policy we published on 1 October 2010.
6. This policy does not apply to the way we use our powers under the Ionising Radiation (Medical Exposure) Regulations 2000; further information is contained in Appendix C.

Background

7. The Health and Social Care Act 2008 and associated regulations give us a variety of powers to intervene and take action where the requirements of the Act and regulations are not being met. We are also able to take action against some other breaches of the law if we see fit.

Registered persons (described as providers and or managers in the Judgement framework) have to comply with different requirements under the Health and Social Care Act 2008. They must apply for registration and show that they can comply with legal requirements. After registration, they must comply with:

- Any conditions of registration.
 - The relevant sections of the Act, the Care Quality Commission (Registration) Regulations 2009, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and any other relevant legislation.
8. Our *Guidance about compliance: Essential standards of quality and safety*:
 - Describes the outcomes we expect people using a service will experience when registered persons are compliant with the regulations. It is designed to help registered persons comply with a legal requirement (which is described as compliance with one or more regulations in the Judgement framework).
 9. The Act and Regulations:
 - Place duties on registered persons.
 - Provide CQC with powers to monitor and inspect regulated activities and to gather information about whether relevant requirements are being met.

- Provide CQC with powers to prosecute unregistered providers of regulated activities.
- Provide CQC with civil powers to ensure compliance by limiting or changing what a registered person is allowed to do, or by temporarily or permanently stopping them from carrying on regulated activities.
- Provide CQC with powers to prosecute, fine and warn registered persons who fail to comply with legal requirements.

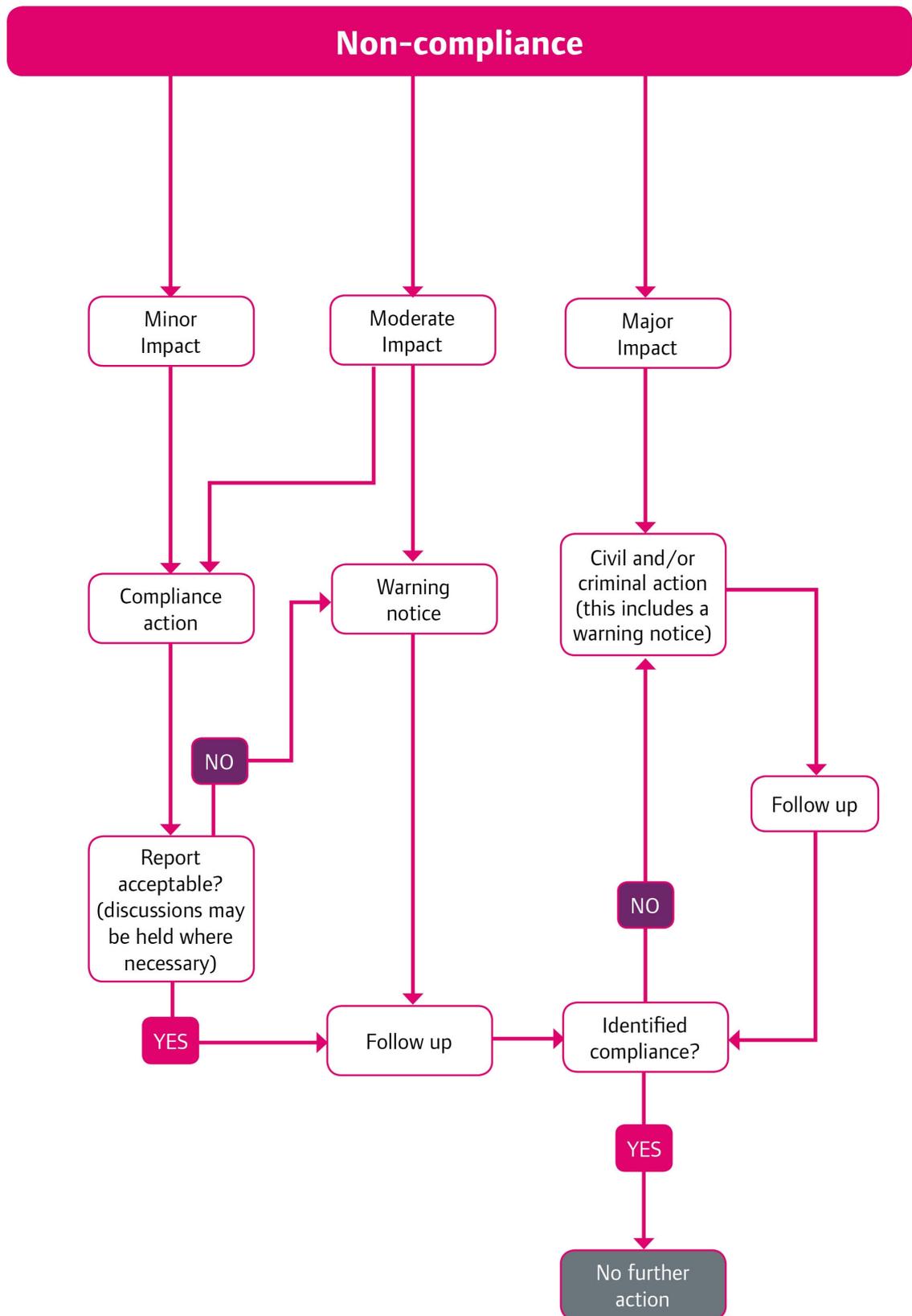
10. Our Judgement framework:

- Helps our inspectors to reach judgements about a registered person's compliance with the essential standards.
- Sets out how we go about determining our regulatory response and how we will make decisions about responding to registered persons who fail to comply with legal requirements (which is described as non-compliance with one or more regulations in the Judgement framework) by taking into account the impact on people using the service (see figure 1).
- Should be used alongside the Enforcement policy to help determine our regulatory response.

11. We will take into account the likely impact of regulatory or enforcement action on people who use services, their carers and families and the wider community when deciding what kind of action to take.

The following diagram is the 'regulatory response escalator' model that helps determine what regulatory response we should take.

Figure 1: Determining our regulatory response – the 'regulatory response escalator' model



Regulatory response

12. Where we have evidence that registered persons are not currently meeting legal requirements, or have demonstrated repeated non-compliance over time (refer to the Judgement framework), we will consider what action to take. This may be a compliance action or enforcement action.
13. We will take account of any ethnic or cultural requirements of individuals when initiating any regulatory response to ensure we manage the process fairly. For example, a minority ethnic healthcare provider may have specific needs around how non-compliance is enforced e.g. translation needs, gender-specific staff, and the appreciation that around religious or cultural festival periods it might take longer to respond to communication.
14. The action we would normally take is set out in our regulatory response escalator. We will use discretion and take account of registered persons' varying circumstances so that we can be proportionate in our response. The use of the escalator may not follow a linear order even in the event of an identified breach of legal requirements, as every breach is judged on an individual basis and our response to it is proportionate to the risk for people who use services. CQC has the right to exercise discretion in determining its regulatory response to any breach of requirements.
15. Table 1 on the following page outlines our options for regulatory response, and the full regulatory response escalator table is set out in Appendix A. For example within the table, multiple breaches with a moderate impact have four possible options of action to consider. In this case, we will consider the circumstances and all information available to us to reach a decision about what is the appropriate action to take. This will include consideration of the risks and harm the breach may have on the people who use the service.
16. Where enforcement is needed, we can take action under 'civil law', 'criminal law' or both.
17. We take civil enforcement action when we need to protect people who use services from **harm** by improving the care they receive or preventing the provision of unsafe care.
18. We take criminal law action when we want to hold a registered person to account for causing **harm** and/or failing to meet legal requirements.
19. Civil enforcement and criminal law can be used together if people who use services need protection from harm and a registered person needs to be held to account.
20. We can use criminal law to prosecute unregistered providers of regulated activities.

Table 1: Our options for regulatory responses

Formal regulatory action	
Compliance actions	

Enforcement action	
Warning Notice	
Civil enforcement	Criminal law
Variation/removal/imposition of condition(s) of registration	Fixed penalty notice
Urgent variation/removal/imposition of condition(s) of registration	
Suspension of registration	
Extend a period of suspension of registration	Simple caution
Urgent suspension of registration/extension of suspension	
Cancellation of registration	Prosecution
Urgent cancellation of registration	

1

Principles of enforcement

21. Our overarching concern and priority is to protect and promote the health, safety and welfare of people who use the services we regulate, and to improve the quality of care they receive.
22. We will be proportionate in how we work with registered persons and others to achieve compliance with the Act and regulations:
 - We will assess any risks to people using, working in and visiting services, and where necessary, take formal regulatory or enforcement action that is proportionate to those risks.
 - Where a service fails to comply with legal requirements, we will take formal regulatory or enforcement action.
 - Where legal requirements are not being met, we will choose the most proportionate way of achieving sustained compliance or we will remove the person's ability to provide or manage care if we consider that compliance could not be promptly achieved or sustained.
 - Where legal requirements continue not to be met despite formal regulatory action being taken (compliance actions), we may escalate to enforcement action (see regulatory response escalator table Appendix A).
23. We will be accountable for our decisions:
 - This policy clearly describes our approach to enforcement, and it can be used when testing our actions and to hold us to account.
 - We positively welcome comments and feedback about our enforcement work and how we have used our powers. We have a complaints procedure that people can use to express concerns about our work and decisions.
 - The law provides the mechanisms for registered persons to make representations and appeals against some of our decisions. We will inform registered persons about how they can use these.
24. We will be consistent in applying our Enforcement policy:
 - Consistency does not mean that we will use the same enforcement option every time a particular legal requirement is not met. It does mean that we will use the same criteria and approach when deciding how to respond to non-compliance and the policy sets out the actions we will normally take.
 - These criteria include taking into account:
 - The impact on and outcomes for people, carers and families, and communities, including the degree of risk to which they have been exposed by the non-compliance.

- Whether we have found non-compliance with the same regulation previously.
 - We will always try to avoid duplicating the work of other bodies that may have contractual relationships, service level agreements, performance management responsibilities or regulatory relationships with us or the registered person.
 - We will seek agreement on processes for identifying the most effective levers for achieving compliance, wherever they are held.
 - We will use our powers whenever this is appropriate.
 - We will collect information about and monitor our enforcement activity to check that we are being fair and consistent in our approach.
25. We will be open and transparent about our approach to enforcement:
- We will consult on any changes to this policy (as required by law) and produce guidance and information about it in plain English and in a variety of formats (on request), so that it is accessible to all people who use services, their families and carers, providers, and the public.
 - We will publish information about our enforcement activity in an annual report.
26. We will target our resources where they are most needed:
- We will gather and review data and trends about our enforcement work, so that we can understand:
 - The scale of non-compliance.
 - How we are responding to it.
 - The outcomes and impact of our enforcement work for people, families and communities.
 - We will take into account equality and diversity in enforcement. To help us, we will develop ways of gathering information about:
 - The enforcement options we choose in circumstances with a relevant diversity concern, and how the diversity concern is recognised.
 - Outcomes for people, carers, families and communities flowing from non-compliance that relates to inequality, direct or indirect discrimination, and barriers associated with the diverse nature of our society, and that breach people's human rights.
 - Whether this policy is being consistently applied with due regard to the age, any disability, gender, gender identity, sexual orientation, race and ethnicity, religion or belief, marriage or civil partnership status or any pregnancy or maternity of providers, managers and people who use their services.
 - We will balance the likely consequences of taking regulatory or enforcement action against the risks of taking no action.

27. We will:

- Ensure that our work is led and undertaken by appropriately trained and skilled staff.
- Be consistent in applying our approach to enforcement across all regulated sectors.
- Follow up enforcement activity in a timely fashion.

2

Our enforcement powers and how we will use them

28. Our enforcement powers under the Health and Social Care Act 2008 are explained in detail below. We have prepared additional detailed operational guidance for individual processes and types of action.
29. Registered persons have a duty to make sure that the regulated activities they are responsible for are carried on and managed in a way that complies with legal requirements.
30. Where we have started taking action against a registered person and subsequently find failure to comply with a different regulation, we can begin additional, separate regulatory or enforcement action against them
31. Where a registered person demonstrates 'low level' but continuous or frequent failure to comply with legal requirements, we will usually escalate our enforcement action so that problems are dealt with swiftly and firmly, using our 'regulatory response escalator'. We will always follow up enforcement action to ensure that compliance is achieved.

Compliance actions

32. Compliance actions are not enforcement action but a precursor to enforcement action and they inform a registered person that they are not compliant with the relevant legislation. Setting compliance actions is not civil or criminal action, but is an important and significant step to take.
33. Where a registered person is not complying with a regulation, but people are not at immediate risk of harm, we will use our power under Regulation 10 (3) of the Regulated Activities Regulations to require a report showing how they will achieve compliance and the action they will take to do so. Failure to send us a report can in itself lead to enforcement action.
34. We will say which regulation is not being met when setting compliance actions, and will give a timescale for the registered person to return a report showing the action they will implement to achieve compliance.
35. Compliance actions are replicated in published reports.

Warning notices

36. Warning notices tell a registered person that they are not complying with a condition of registration, requirement in the Act or a regulation, or any other legal requirement that we think is relevant. We can serve notices about previous

failures to comply with legal requirements or about continuing non-compliance. Where a notice is about continuing non-compliance it will include a timescale by when compliance must be achieved. If a registered person is still not complying with the requirement when the timescale expires, we will consider our response with reference to the regulatory response escalator. This could lead to further action under civil or criminal law.

37. We can also serve warning notices about failures to comply with legal requirements under other Acts of Parliament that we consider are relevant, for example the Mental Capacity Act 2005.
38. There are important rules relating to the way we can use evidence on which warning notices are based. We will take these rules into account when deciding whether a warning notice is appropriate. We cannot use warning notices against unregistered persons.
39. The regulations allow us to publish warning notices as long as registered persons are given the opportunity to make representations where we intend to publish. Note: a provider's representations about warning notices are about the right to publish the warning notice, not about the actual judgement of the warning notice. We will publish a summary of the warning notice if no representations are received, or if any representations we do receive are not upheld.

The factual accuracy check on the draft report provides an opportunity for providers to challenge the content of the report. The factual accuracy process may legitimately challenge facts that directly impact on the judgement arrived at in the report. If such a challenge is upheld through the factual accuracy process and the subject of the challenge goes to the heart of the enforcement action taken, it may consequently lead to a decision not to publish the warning notice. We will not publish any summary of a warning notice until the factual accuracy checking process is complete.

Criminal law

40. Criminal law procedures can be used in response to breaches of certain regulations and sections of the Act. They can be taken against any registered person, or, in the case of a service that is operating without registration, the person who appears to be carrying it on. They can also be used against any person who obstructs us in the course of an inspection and against persons who have applied to us to be registered, where they have made a false or misleading statement.
41. All investigations of criminal offences will be carried out having regard to the Police and Criminal Evidence Act 1984 principles and Code of Practice.
42. We may use these:
 - Where a regulated activity is being carried on without registration.
 - Where a registered person has not responded to a compliance action and continues to fail to meet legal requirements.

- When a registered person is not complying with the requirements of registration under their conditions.
 - Where any people (not just registered persons) are being obstructive to us in the course of inspection.
 - When a registered person or any person who has applied to be registered has been dishonest.
 - When people have or may suffer harm because a registered person has failed to comply with a relevant regulation or requirement of the Act.
 - To fine, caution and/or prosecute registered persons in response to their failures to comply with certain regulations and requirements of the Act.
 - When we have evidence that an offence has taken place.
43. 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.

Penalty notices

44. We can serve a penalty notice when:
- A registered person has failed to comply with certain requirements of the Act or regulations, or
 - A person has carried on a regulated activity without being registered, or
 - A person has obstructed us in the course of inspection, or
 - Where relevant, the offence is continuing when the timescale in a warning notice has expired, and
 - Our evidence meets the standard for a criminal prosecution, and
 - We consider that swiftly achieving compliance without beginning lengthy and costly proceedings is a realistic alternative to prosecution.
45. The registered person can pay the fixed penalty and dispose of liability for the offence, thereby avoiding prosecution. If a registered person decides not to pay the penalty we can consider using our other enforcement powers; this will normally be to prosecute the person.
46. Any fixed penalty paid to CQC under section 86 of the Act must be repaid by CQC to the Secretary of State.
47. The relevant legal requirements and associated fines are set out in Appendix B.

Simple cautions

48. We can offer a simple caution to a registered person, an applicant for registration, any person who appears to be carrying on a regulated activity without being registered, or a person who has obstructed us in the course of inspection instead of prosecuting them for any of the relevant offences where:
 - There is clear evidence that the person has committed an offence, and
 - Our evidence meets the standard for a criminal prosecution, and
 - The code for crown prosecutors has been followed, and
 - Where relevant, the offence is continuing when the timescale in a warning notice has expired, and
 - We consider that swiftly achieving compliance without beginning lengthy and costly proceedings is a realistic alternative to prosecution.
49. The offender must admit the offence and be prepared to accept a caution.
50. When deciding whether to caution a registered person we will consider guidance issued by the Home Office (currently HO Circular 016/2008).

Prosecution

51. We have powers to prosecute for certain offences defined in the Act and the regulations made under it, which includes carrying on a regulated activity without registration. Prosecution is a serious enforcement action. It holds registered persons to account for not complying with legal requirements. It can sometimes be appropriate to prosecute at the same time as taking other enforcement action, for example suspending registration. We may consider prosecuting more than one offence at the same time.
52. Under certain circumstances we will serve a warning notice first to try and get the registered person to achieve compliance before we prosecute.
53. We will not begin prosecution proceedings unless we are satisfied that:
 - It is in the public interest.
 - Our evidence meets the standard for a criminal prosecution.
 - The code for crown prosecutors has been followed.
 - Where relevant the offence is continuing, when the timescale in the warning notice has expired.
 - There is a realistic prospect of conviction.
54. Where another regulator has the power to prosecute, we will coordinate activity at an early stage with them to ensure the right action is taken, to avoid inconsistency, and to ensure that any proceedings taken are for the most appropriate offence (see Section 4).

55. Where we successfully prosecute a provider, the court will decide on the fine that is imposed, and may issue a separate fine in relation to each conviction, where there is more than one. 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.
56. The offences and maximum court fines are set out in Appendix B.

Civil enforcement

57. Civil enforcement procedures follow processes laid down in the Health and Social Care Act 2008. They are used to impose temporary or permanent changes on a person's registered status.
58. We may use these:
 - When registered persons have failed to respond to compliance actions, warning notices, relevant criminal procedures or intervention by our partner agencies, or when people are at risk of harm.
 - To limit how an activity is provided.
 - To stop a registered provider from carrying on an activity, temporarily or permanently.
 - When people have or may suffer harm because a registered person has failed to comply with legal requirements.
 - Where a registered person is not capable of carrying on the regulated activity, either at all or under current registration conditions.
 - Where a registered person or any other person has been convicted of a relevant offence.
59. We are required by law to publish certain details of civil enforcement. We are also required by law to publish details of any action taken under CQC's urgent powers.

Impose, vary or remove conditions of registration

60. Registered persons always have certain routine conditions attached to their registration. These conditions include the locations where the regulated activity can be carried on or managed. For some activities that may include providing accommodation, there will usually be a limit on the number of people who may use the service at any one time. These registration conditions are usually agreed with registered persons when they apply for registration.
61. Imposing, varying and removing conditions of registration is a flexible enforcement process that we can use in a variety of different ways to keep people safe and ensure that legal requirements are met. For example, we may use a condition to stop a regulated activity at one location while the registered person can continue with this regulated activity at their other locations.

62. We begin formal proceedings in relation to amending conditions of registration by sending the registered person(s) a Notice of Proposal and 'evidence bundle' that sets out our case. Registered persons have a right to make representations to us against our proposal before we make a final decision. If we decide to 'adopt' our proposal we send a Notice of Decision. Registered persons have a right of appeal to an independent tribunal against our Notice of Decision. We have written separate detailed guidance about the representations and appeals processes.
63. We also have powers to impose, vary or remove conditions using urgent procedures (see below).

Suspension of registration

64. We can suspend the registration of a registered person for a specified period of time, and also extend a period of suspension. Suspension of registration is a serious step that can have major consequences for a registered person. Suspension affects all of the locations where the relevant regulated activity is carried on or managed by the registered person. We will therefore give particular attention to the likely outcomes of taking this action. Suspension can, however, give a provider the chance to work towards achieving compliance and then resume carrying on or managing an activity. We follow the same notice of proposal and decision procedure described above when we wish to suspend registration.
65. We can also suspend or extend a period of suspension using urgent procedures (see below).

Cancellation of registration

66. Our most powerful sanction is to cancel a registration. As with suspension, this will affect all the locations where the registered person carried on or managed the relevant regulated activity. Cancellation normally follows considerable efforts to get registered persons to comply with legal requirements, but where necessary, we can use the cancellation process without first having followed other processes.
67. We can also cancel registration using urgent procedures (see below).

Urgent procedures

68. When using our urgent powers to vary or impose conditions, or suspend registration, we will issue a Notice of Decision to the registered person. We will only take this step if we believe that if we do not, a person will, or may be, exposed to the risk of harm.

69. We will consider using urgent procedures to cancel a registration as a last resort where the problem cannot be resolved in any other way and where a person(s) is at serious risk to their life, health or wellbeing.
70. When using our powers to cancel a registration using urgent procedures, we must apply to a justice of the peace for a court order. In these circumstances we will wherever possible:
- 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 considerable effort has been made to locate them.
- Where we cannot 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 done so in our application.
71. Action under urgent procedures takes immediate effect. Registered persons have the right of a fast track appeal to an independent tribunal.
72. When serving an Order or Notice of Decision on a registered person using urgent procedures, it will always include information about:
- Our memorandum of understanding with the First-tier Tribunal about a 'fast track' option for appeals when we have used the urgent procedures.
 - How the registered person can appeal against the urgent cancellation order or notice.

Representations and appeals

Representations

73. Registered persons have the right to make representations to us about certain types of enforcement action. We have produced separate detailed guidance which is available on our website about representations on the following:
- Publication of 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.
74. Providers or bodies that are investigated under our section 48 powers can also make representations to us about our subsequent report before it is published.

Appeals

75. Registered persons have the right to appeal to an independent tribunal 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. 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.
76. There is no right of appeal to the Tribunal in relation to warning notices, penalty notices or conviction for offences.

Coordination with partner agencies

77. When we take action to cancel or suspend a registration, or to impose, vary or cancel conditions of registration using either normal or urgent procedures, we will coordinate with other relevant bodies. We will always carefully consider the balance of risk between different options.

3

Publication and notification of enforcement action

78. The Regulations require and authorise us to publish certain information relating to enforcement action.
79. Information about the enforcement action that we take will be included in our review of compliance reports. We will also publish a summary of information about the enforcement action taken against each provider on our website.
80. Section 39 of the Act requires us to send copies of notices relating to enforcement action to prescribed bodies and any other persons CQC considers appropriate.
81. We aim to publish an annual report on our enforcement activity, in order to promote learning and review trends.

4

Working with other organisations

Working with partner agencies and their regulatory, performance management and commissioning processes

82. A number of partner agencies have powers, duties and/or responsibilities in relation to services we regulate. We can work with them to ensure registered persons achieve compliance with the essential standards. This is designed to help registered persons comply with legal requirements.
83. A number of regulators can use their powers and processes to achieve compliance. Before we use our criminal law and civil enforcement powers, we will consider whether another body or bodies may be better placed to intervene. If so, we will arrange a meeting of relevant agencies.
84. Where we and another enforcement body, for example the police or the Health and Safety Executive, have the power to take action about the same circumstances, we will work together to ensure that we coordinate our respective action at an early stage and do not duplicate action against registered persons. This will avoid inconsistencies and ensure that action is taken by the most appropriate body.
85. Where there are allegations of actual abuse involving people in the services we regulate, we will inform the appropriate local authority using our adult safeguarding and child protection procedures. We will work with all other relevant agencies to ensure that people are appropriately protected using relevant local safeguarding procedures.
86. We will work with all appropriate organisations when using our enforcement powers, depending on the kind of provider. For example, we will work with:
 - Monitor, the independent regulator of NHS foundation trusts.
 - Relevant national, regional and local NHS bodies in relation to NHS trusts and services provided or funded by NHS bodies locally.
 - Local authorities in relation to adult social care services.
87. This will help us to take into account what alternative services are available for the people affected by our action, consider alternative action where appropriate, and encourage joint working.
88. Monitor's role is to ensure that NHS foundation trusts operate in an efficient, effective and economic manner. We will not duplicate this role. Failure by an NHS

foundation trust to comply with our legal requirements may also be a breach of Monitor's terms of authorisation, and could lead to intervention by them.

89. Our role in relation to all providers is to ensure that they meet the essential standards of quality and safety. We will always liaise with Monitor before taking enforcement action against an NHS foundation trust. The only exception to this will be where we take immediate action using urgent procedures to protect the safety of people who use services.

5

Investigations

90. Section 48 of the Act gives us powers to carry out investigations into the provision of English NHS health care and social care, including related functions of local authorities. We must also carry out an investigation when asked to do so by the Secretary of State for Health.
91. We may use our powers to investigate where we become aware of evidence of a problem that poses a significant risk to the health, safety or welfare of people receiving health or social care, often due to systemic failings, and where enforcement action has not resulted in the required improvements. Investigations can look specifically or generally at any issue to do with different kinds of health or social care, how particular functions are carried out or the provision by particular people or bodies.
92. Investigations allow us to look into actual or potential serious systemic failings, for example where lack of coordination between sectors and/or services leads to harm.
93. We use investigations to understand problems in delivering care and the contributory factors that give rise to them, both within the body itself and, where appropriate, within the broader care delivery system.
94. We will use our investigation and enforcement powers independently. However, investigations may uncover evidence that leads us to take subsequent enforcement action against individual registered persons/providers or to refer issues to other regulatory/enforcement bodies.
95. Enforcement action following an investigation may include recommending special measures in relation to an English local authority and serving notices on relevant persons requiring action to deal with failures. An investigation may identify suspected non-compliance with the regulations and these may be subject to further enforcement action as a separate exercise.
96. We have developed criteria to help us plan investigations. These are set out in Appendix D.

Appendix A: Regulatory response escalator table

	Type	When to use	Aim of use	Next step if aim is not achieved (or other action where more appropriate)
Formal regulatory action	Compliance action	First breach/offence with minor impact First breach/offence with moderate impact	To gain an acceptable report and achieve compliance through least punitive action	If the report is not acceptable, following discussion with the provider and where required a site visit, issue a warning notice If non-compliance is identified when followed up, issue a warning notice and/or consider civil enforcement action
Enforcement action	Warning notice	First breach/offence with moderate impact Multiple breaches/offences with moderate impact Any breach/offence with a major impact	To demand compliance within timescale (where appropriate)	Civil enforcement and/or criminal law action
Criminal law	Penalty notice	Non-compliance with warning notice Direct offences Multiple breaches/offences with moderate impact Breach/offence(s) with major impact	To dispose of liability for offence or breach efficiently and cost effectively without restricting the registered person's registration	If not accepted, move to prosecution and/or consider civil enforcement action

		Carrying on a regulated activity without registration		
	Simple caution	Non-compliance with warning notice Direct offences Carrying on a regulated activity without registration	To gain an admission of the offence and dispose of liability for offence/breach efficiently and cost effectively without restricting the registered person's registration	If refused, move to prosecution and/or consider civil enforcement action
	Prosecution	Non-compliance with warning notice Direct offences Carrying on a regulated activity without registration	To hold registered person to account for the breach/offence without restricting registration	Consider civil enforcement action or further prosecution
Civil enforcement	Imposition, variation, removal of conditions	Non-compliance with warning notice. Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact With/after prosecution Direct offences	To restrict the registered person's activity	Cancellation of registration Prosecution Further imposition/variation/removal of conditions (which includes variation to remove location)
	Suspension of registration	Non-compliance with warning notice Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact	To prevent the registered person from carrying on the regulated activity/activities for a period of time	Extend suspension Vary to remove regulated activity(ies) Cancellation Prosecution

		With/after prosecution		
	Cancellation of registration	Non-compliance with warning notice Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact Continued non-compliance Variable compliance over time	To prevent the registered person from carrying on regulated activities	Prosecution if regulated activities continue after the cancellation is confirmed
	Urgent imposition, variation, removal of conditions	Non-compliance that will or may expose any person to the risk of harm	To immediately restrict or prevent some regulated activities being provided immediately	Prosecution if registered person fails to abide by the restriction or prevention of regulated activities.
	Urgent cancellation of registration	Non-compliance where there is an immediate risk to a person's life, health or wellbeing	To immediately prevent all regulated activities being provided immediately	Prosecution if regulated activities continue after cancellation confirmed

Note: The use of this regulatory response escalator table may not follow a linear order as every breach is judged on an individual basis and is proportionate to the risk for people using the services. CQC has the right to exercise discretion.

Appendix B: Offences and fines

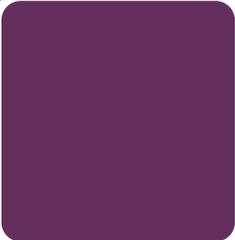
Fixed penalties

Offence	Maximum fine
Failure to comply with regulations about quality and safety (see Regulation 27 of the regulated activities regulations)	Provider £4,000 Manager £2,000
Carrying on a regulated activity without being registered	£4,000
Failure to comply with conditions of registration	Provider £4,000 Manager £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 registration regulations)	Provider £1,250 Manager £625
Failure to make required notifications (see Regulations 14-18 of the registration regulations)	Provider £1,250 Manager £625
Failure to provide a statement about fees chargeable (see Regulation 19 of the registration regulations)	Provider £1,250 Manager £625
Failure to observe certain requirements relating to termination of pregnancy (see Regulation 20 of the registration regulations)	Provider £1,250 Manager £625
Obstructing entry and inspection	£300
Failure to provide documents or information	£300
Failure to provide an explanation of any relevant matter	£300

Offences and fines: Prosecution

Offence	Fine
Failure to comply with regulations about quality and safety (see Regulation 27 of the regulated activities regulations)	£50,000*
Carrying on an activity without being registered	£50,000
Failure to comply with conditions of registration	£50,000
Offences relating to suspension or cancellation	£50,000
False descriptions of concerns	£5,000
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

* Some lesser requirements have a maximum court fine of £2,500



Appendix C: Principles of enforcement under the Ionising Radiation (Medical Exposure) Regulations 2000

The Care Quality Commission has appointed a small number of inspectors with responsibilities for enforcing the Ionising Radiation (Medical Exposure) Regulations 2000 in England. Their powers are derived from the Health and Safety at Work Act 1974.

A separate IR(ME)R Enforcement policy is being developed to describe how these powers are being exercised by CQC.



Appendix D: Criteria for formal investigation

Our role and powers include undertaking investigations into the provision of:

- NHS provided or funded care.
- Adult social services.
- The functions of health authorities and special health authorities in England.

We are required to publish a report following any such investigation and, as well as using our own powers, we can offer advice to the Secretary of State for Health on any of the issues raised – for example, advice on policy issues or changes that we think are necessary to prevent similar problems arising elsewhere.

We will consider using our investigation powers where there has been a serious failing in care or exercise of functions by providers of NHS-funded care, providers of social care and health authorities in England that has or may affect:

- People's basic safety.
- The effectiveness of a service.
- The responsiveness of a service to people's needs.

And one or more of the following criteria are met:

- Providers have failed to respond to conventional enforcement activity with the required improvements in a reasonable timescale.
- Further enforcement activity will result in adverse consequences for people using services, for example as a result of geographical isolation.
- There are indications that there are capacity issues either within the provider itself or across the local care system, which impede the required improvements.
- We become aware of evidence of a significant problem affecting a whole local care system.
- Local commissioning and performance management authorities are not effectively supporting the required improvements in terms of leadership, skills and expertise.
- Broader systemic failures which lie outside the remit of our routine inspection and enforcement powers.

However, we will exercise discretion and can still consider whether an investigation should be started where a situation does not fulfil one or more of these criteria, taking into account its particular circumstances.

We can make recommendations to prevent the failing happening again. When conducting an investigation we will take account of accepted standards or, in their absence, descriptions of good practice (for example from professional bodies).

When we are deciding whether to investigate, we will consider the extent to which local resolution, referral to another body or other action might offer a more effective solution.

Generally, we will not investigate:

- Individual incidents.
- Individual complaints about professional misconduct.
- Changes to how a service is organised (such as mergers).
- Employment or disciplinary matters.
- Matters being considered by a legal process.
- Specific matters already considered by a legal process.
- Issues that fall under the proposed regulations conferred on Monitor, i.e. to investigate complaints against the NHS Commissioning Board or clinical commissioning consortia, the market, competition, and referrals from foundation trust governors (unless explicitly agreed beforehand).
- Investigations and enforcement by or on behalf of professional regulators. However, CQC may refer relevant matters for investigation to professional regulators where appropriate.

This does not prevent us from investigating relevant circumstances associated with or flowing from these situations. A matter that has been dealt with by one of the processes above may, for example, uncover wider concerns about the safety of people using services, or suggest that an organisation is seriously flawed.

We will consider all allegations of serious failings, decide whether rapid or other action is required, and liaise with relevant bodies. Where appropriate we will refer the matter to another agency, such as the police.



Appendix E: Glossary of enforcement terms

Code for Crown Prosecutors: Provides guidance about when it is appropriate for a public body to take criminal action. It can be found at: www.cps.gov.uk/publications/code_for_crown_prosecutors/index.html.

Compliance actions: This is a formal requirement we make of a registered person to submit a report detailing the actions they intend to take to become compliant with legal requirements, including the timeframe.

The registered person will update CQC on progress and completion with those actions.

Direct offences: These are offences set out in the Health and Social Care Act 2008 and any other relevant Act, and in respect of which CQC may prosecute without issuing any prior warning. For example: failure to register to carry on a regulated activity.

First Breach offence: This is when a registered person is non-compliant with the law for the first time (see legal requirements below).

Harm: Harm includes where there has been impairment of the structure of the body or how the body functions, together with any negative effects that this has had. These effects can be seen in many forms but include disease, injury, suffering, disability and death, and can be physical, financial, sexual, social intimidation or psychological.

Impairment is a long-term characteristic of an individual that affects their functioning and/or appearance.

Disease is abnormal functioning in a body's structures (for example lungs or muscles), systems (for example blood circulation and the nervous system) or psychological health.

Injury is damage to any part of the body caused by an agent (for example a poison), incident or event.

Suffering is the experience of anything subjectively unpleasant. Suffering includes pain, feeling unwell, nausea, depression, agitation, alarm, fear and grief.

Disability is the disadvantage experienced by an individual as a result of barriers (attitudinal, physical etc) that impact on people with impairments/ill health.

For regulatory purposes 'harm' also includes abuse as defined in the guidance *No Secrets* (Department of Health, March 2000) and *Working Together* (Department

for Children Schools and Families, March 2010) and its effects and outcomes, for example discriminatory abuse and financial or material abuse.

It does not include harm caused where, for example, a person has surgery that they need.

Legal requirements: These are the requirements of any law that applies to people carrying on or managing a regulated activity. This can include the requirements of the law generally, as well as the specific requirements of the Health and Social Care Act 2008, the Care Quality Commission (Registration) Regulations 2009 and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

Multiple breaches: This is where the registered person is non-compliant with more than one legal requirement.

Notice: A notice is a formal notice in writing given by CQC to a registered person under one of the sections of the Health and Social Care Act. For example, a Notice of Proposal or Notice of Decision in relation to registration, a civil action, a warning notice, or a fixed penalty.

Order: An order means an Order of the Court. An order is a written record of the Court's decision about an application it has considered.

Partner agencies, statutory bodies and other regulators: These are other agencies with whom we work to ensure that the relevant safety and quality standards are maintained. For example, Health and Safety Executive, NHS bodies, local authorities, Independent Safeguarding Authority, General Medical Council, Nursing and Midwifery Council, Monitor.

Registered person: A registered person means an individual, partnership or organisation that is required by law to register with the CQC to carry on or manage regulated activities. This is referenced in the Judgement framework as provider and/or manager.

Regulatory response escalator: This sets out the regulatory responses and steps that CQC can take against any registered person who fails to comply with legal requirements, and illustrates the way CQC might respond to certain situations to achieve compliance and protect people using services. Where registered persons fail to become compliant with legal requirements as a result of one particular response, we will generally take the next appropriate action. This may not always follow the escalator in a linear order as our response depends on particular circumstances and the risk to people who use services.

Prescribed bodies: Section 39 of the Act requires us to send copies of notices relating to enforcement action to certain listed relevant bodies and any other persons CQC considers appropriate. This list is extensive and includes, for example, commissioners from all local areas, all other partner agencies, statutory bodies and other regulators. It may also be just one person who is involved with a provider.

Relevant offence: Offences under the Health and Social Care Act 2008 associated Regulations and any other offence that CQC sees as relevant.

Serving or service of an Order or Notice: These terms refer to the way that documents are formally sent or given to a person. Serving is the way we will carry out that process, while service normally refers to the completed act. We can serve documents by post, in person or sometimes, by email. Where the Act requires us to give a notice to a registered person, we must make sure this is done as described in sections 93 and 94.

Note: Please refer to the glossary in the Judgement framework for further clarification.

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Published April 2012

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