Care Quality Commission

Care Quality Commission enforcement policy

Consultation

About the Care Quality Commission

The Care Quality Commission (CQC) was established to regulate the quality of health and adult social care and look after the interests of people detained under the Mental Health Act.

Health and social care touches everyone at some point. This gives CQC a powerful and highly responsible role in people's lives. CQC will, from 1 April 2009, bring together the work of the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission, creating for the first time an independent regulator of health, mental health and adult social care in England.

Our vision is of high-quality health and social care that supports people to live healthy and independent lives, empowers individuals, families and carers in making informed decisions about their own care, and is responsive to individual needs.

We will be a leading and innovative regulator and will:

- Focus on outcomes for people
- Harness a range of regulatory approaches to drive improvements in quality
- Prioritise on the basis of risk
- Champion a joined-up approach to care across services, centred on the individual
- Be transparent and open
- Be tough and fair
- Be independent
- Be proportionate
- Coordinate our work with other regulators.

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Foreword

The new Care Quality Commission will bring together independent regulation of health, mental health and adult social care for the first time. This gives the Care Quality Commission the scope to break new ground and to be a world-class regulator.

We will have our own distinctive style and important new powers compared to our predecessor bodies. We will be responsible for registering, reviewing and inspecting health, adult social care and mental health services. We will work with providers to encourage them to improve the quality of their services. Where providers of services let people down, we can take action, including issuing warnings and fines and refusing to register them.

Our primary aim is to put the people who use services first. We will always champion their interests, particularly where services are provided to people who are less able to speak for themselves.

We will be a modern, transparent, tough and fair regulator. Our commitment is to communicate openly about our proposed enforcement policy and listen to what people have to say about it. We are therefore inviting your views on this high-level consultation document that sets out the principles and broad approach of our enforcement policy.

Health and social care touches everyone in England at some point. Increasingly, people move between the sectors when they need help. A high-quality experience isn't about just one service but about how they work together. This also means that we have to be consistent in how we apply our principles of enforcement across the whole system – in health, social care and mental health, and across the public, private and voluntary sectors.

This document does not go into detail about processes. After consultation, we will finalise and publish our policy so that our enforcement role is clear. More detail will follow as we develop our approach. We see this as the start of an ongoing conversation about how we can all work together to help ensure safer, higher quality care for the people who need it.

Barbara Young
Chairman

Cynthia Bower
Chief Executive

1. Introduction

This draft policy sets out how we intend to use our enforcement powers to protect the health, safety and welfare of people who use health and social care services, and to improve the quality of these services. It includes the principles we will follow when doing this.

We are inviting comments on the policy and we welcome your views and suggestions to help us to develop it.

Once we have published the final policy, we will monitor its effectiveness and revise it when necessary.

Context

1. From April 2009, the Care Quality Commission will be the new independent regulator of health and adult social care services across England. We will be responsible for registering, reviewing and inspecting these services. Where providers of services fail to meet the legal requirements of their registration, we may take action against them. This includes those who are operating without being registered.

2. We aim to help services improve by ensuring that essential quality and safety standards are met and that bad practice is stamped out. One of the ways we will do this is by using our enforcement powers.

3. It is important that we are clear from the outset how we intend to use these powers and the principles we will use. This is why we are sharing the draft policy and asking for your views. Chapter 6 has details of how you can send us your comments.

4. When the consultation is complete, we will finalise and publish the policy so that the way we will carry out our enforcement role is clear.

Background

5. The Healthcare Commission can take enforcement action in relation to private and voluntary healthcare providers, under the Care Standards Act 2000 (CSA 2000). The Commission for Social Care Inspection can take similar action under CSA 2000 in relation to adult social care providers.

6. The Care Quality Commission, established in October 2008 by the Health and Social Care Act 2008 (2008 Act), will have enforcement powers that include the CSA 2000 powers and three new powers under the 2008 Act.

7. The enforcement powers in the CSA 2000 and the 2008 Act are:

Power	CSA 2000	2008 Act
Issue a warning notice	×	✓
Impose, vary or remove conditions	✓	✓
Issue a penalty notice in lieu of prosecution	×	✓
Suspend registration	×	✓
Cancel registration	✓	✓
Prosecute for specified offences	✓	✓

8. The 2008 Act will come fully into force in April 2010. However, regulations are being made under Section 20 of the Act that will apply to NHS organisations covered by the *Code of practice for the prevention and control of healthcare associated infections*. These regulations will come into force from April 2009.

9. This will mean that, from April 2009, NHS providers will be required to register with us and comply with the **new** requirements and regulations under the 2008 Act that require them to protect patients, staff and others from identifiable risks of acquiring a healthcare-associated infection.

10. If we take enforcement action against an NHS provider over healthcare-associated infection during 2009/10, we will use the powers in the 2008 Act. This includes the three new powers: issuing warning notices, issuing financial penalty notices, and suspending registration.

11. For all other purposes, during 2009/10 we will use the same powers and the same enforcement frameworks that the Healthcare Commission and the Commission for Social Care Inspection use now (those in the CSA 2000). In relation to enforcement, we may also take account of other acts of Parliament that we consider to be relevant.

12. On 1 April 2010, all health and social care providers, and in some cases managers, will be subject to the full range of enforcement powers under the 2008 Act.

13. The principles that follow explain how we intend to use our powers. They will apply to all our enforcement action from April 2009 onwards, and are based largely on those currently used by the two existing Commissions. The proposed policy is consistent with the principles of the Government's Enforcement Concordat.

14. Following this consultation, we will issue detailed operational guidance on enforcement for 2009/10. We will update this for 2010 when the 2008 Act comes fully into force.

2. Principles of enforcement

15. When a registered provider or manager fails to comply with legislation or its terms of registration, or a person operates without being registered, we can take action against them. This is called enforcement. The purpose of enforcement is to make sure that action is taken to ensure that the provider or manager complies with regulations and requirements. We intend to take a firm but fair approach in carrying out enforcement. Drawing on developments and best practice in better regulation, we intend to follow these general principles:

- Our overarching concern is to protect the safety of service users and improve the quality of care they receive.
- We will take a proportionate approach, based on our assessment of the risk of harm, the quality of care and evidence of non-compliance with the law.
- Our processes will be transparent and accountable.
- We will encourage improvement wherever possible, but if a service fails to fulfil its legal obligations, we may take enforcement action.
- We will put particular emphasis on equality, diversity and human rights, particularly where services are provided to those who are less able to speak for themselves.
- Our work will be led by appropriately trained, skilled staff.
- We will be consistent in the application of these principles across all sectors of care, while tailoring our approach to different types of provider.
- We will follow up all enforcement activity in a timely fashion.
- We will coordinate our work with other regulators.
- We will monitor the operation of the enforcement policy, and take seriously any comments from providers.

We explain more about these key principles below.

16. Our primary concern is to protect the safety of service users. Any enforcement action we take will be **proportionate** to the risks posed to service users and the seriousness of any breach of the law. We may also take other forms of action (such as increasing the frequency of our inspections of a particular provider), or work with other bodies (for example, commissioners or other regulators) that may be in a better position to take action.

17. We aim to be **consistent** in applying the principles across all types of health and adult social care provider: private, public (including NHS foundation trusts) and voluntary. In order to be balanced, we will also take account of the impact of a breach or incident, the attitude and actions of management, and the history of previous breaches/incidents. Decisions on specific enforcement action rely on professional judgement and we will therefore exercise our discretion in each case.

18. We will be **transparent** in order to help providers, managers and the public to understand what is expected of people who provide and manage health and adult social care services and what they should expect from us. This includes making clear why we intend to take, or have taken, enforcement action. As we explain in paragraph 14, further detailed operational guidance will follow.

19. Our approach will ensure that we focus on those providers whose activities cause, or risk causing, serious harm to people using services. We would view persistent non-compliance with regulations as a potentially high risk for people who use services.

20. We will act in the best interests of people who use services and their families and carers, balancing the consequences for these people of taking enforcement action, against the risks of taking no action.

Investigations

21. We will have the power to carry out investigations into NHS healthcare and social care, either as a way of finding out more about serious concerns within a particular service or as a way of finding out more about the quality of service provided. Although investigation is separate from our enforcement powers in the 2008 Act, there are similarities and overlaps between them. Investigation is an alternative open to us which may offer a more effective route than enforcement to resolving potentially serious problems – for example, where a problem may have systemic roots across a whole local economy which enforcement against one provider would not solve, or where serious allegations are made but the extent of the problems are unclear or contested.

22. There are close links to enforcement, because our investigation of serious concerns about care may uncover evidence that subsequently leads us to take enforcement action. The principles that apply to enforcement also apply to the way in which we manage investigations.

23. Investigation enables us to follow up potentially serious systemic failings, publish our findings and ensure that improvements are made, not only within the service under investigation but sometimes more widely. In some instances, we will undertake an investigation to look into a serious allegation or understand the root causes of a problem affecting services generally. We may decide that both enforcement action and systemic improvement are necessary. In any case, we will not delay acting wherever we identify risks to the safety of people who use services.

24. We have discretion to decide what we investigate and we have developed criteria to guide us when making these decisions. These are set out in appendix A. We are required by law to publish a report following an 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 national changes that we think are necessary to prevent similar problems arising elsewhere.

Non-statutory enforcement action

25. We may choose to take non-statutory action in response to a breach of requirements in the 2008 Act and/or the associated regulations. It may be appropriate to take this approach to resolve a relatively low-risk problem, or where a provider voluntarily brings a minor breach to our attention and is already taking (or has taken) appropriate action.

26. Non-statutory action could involve placing a provider or manager under scrutiny for a period, drawing the breach to their attention and giving them an opportunity to put it right within a reasonable period. (We can also do this on a statutory basis by issuing a warning notice – see below.) Non-statutory action can also include asking an unregistered provider to stop operating the service.

27. We may publish details of non-statutory enforcement action, although there is no requirement in law for us to do so.

Consultation question

1. Do you agree with our proposed principles and overall approach to enforcement?

3. How the enforcement powers may be used

28. If we decide to take statutory enforcement action in response to a breach of requirements in the 2008 Act and/or the associated regulations, we can choose the most appropriate action from the range of enforcement powers available to us. For 2009/10, the range of powers from which we can choose for private and voluntary healthcare and adult social care providers are those in the CSA 2000; for NHS providers, they are those in the 2008 Act. From 2010/11 onwards, the powers from which we can choose for **all** providers and managers are those in the 2008 Act.

29. The powers from both Acts are explained below, along with examples of the circumstances in which we might use them. As mentioned in paragraph 14, further detailed operational guidance will follow. It should be noted that, when undertaking enforcement action with a provider, we are able to take additional enforcement action against the same provider at any time, provided this is not related to the issue on which the current enforcement action is being undertaken.

30. In certain situations we may decide to take 'urgent' action as opposed to 'routine' action. This has immediate effect and does not have to allow for the process of representations, although there is a right of appeal. We would usually do this where we feel there is an immediate threat to the safety of patients or service users. We may revert from urgent to routine action, for example if we were taking urgent action to cancel a registration but the provider arranged suitable alternative accommodation for the residents. Where we decide to take routine action, we will allow for representations to be made, before we make our final decision.

31. Where any provider continues to make 'low level' breaches of regulations, we will not hesitate to escalate our enforcement action so that any problems are dealt with swiftly and firmly.

Issue a statutory warning notice (2008 Act only)

32. This notice will provide details of the breach in question and, if it is ongoing, set out a timescale for it to be rectified. At the end of the period specified in the notice, we may take any follow-up action we think necessary if the notice has not been complied with.

33. We may take this action for first-time or minor breaches, or where we believe the situation can be rectified without posing a risk to people who use services in the interim. For example, where there is evidence of a breach of regulations but the provider is judged to have the capacity and willingness to rectify the problem immediately.

Examples

We might use this power where:

- An inspection of an NHS hospital reveals variable standards of cleaning on wards or infringements of hand hygiene practices on an isolation ward, to the extent that the registration requirements may not have been complied with.
- A defect is found in a care home, such as a torn carpet, that could cause an accident, despite the fact that similar concerns had previously been brought to the attention of the provider.
- We find poor procedures in relation to patients who are absent without leave.

Impose, vary or remove conditions (CSA 2000 & 2008 Act)

34. We may, at any time, impose, vary or remove conditions on a provider's registration. We have the power to take this action in urgent cases with immediate effect* if, for example, we feel that a person will or may be exposed to a risk of harm if we do not act immediately.

35. We might use this power when one specific aspect of the service needs to be improved but other services can continue while changes are made. We might also use it to stop further admissions to a service where we have issued a notice to cancel registration, but an appeal is pending.

Examples

We might use this power:

- To close temporarily a hospital decontamination facility that is not fit for purpose.
- To prohibit the admission of a particular group of patients, for example people under 18, where the provider failed to protect this particular group or failed to provide an adequate quality of service to them.
- To prevent a care home from admitting additional residents if we have found that they do not have enough trained staff to look after more people.

* The CSA 2000 requires the Healthcare Commission and the Commission for Social Care Inspection to apply to a Justice of Peace to obtain permission to urgently alter conditions, but under the 2008 Act we do not have to do this.

Issue a financial penalty notice (2008 Act only)

36. We can consider issuing a financial penalty notice for a fixed penalty offence instead of prosecution. If the provider refuses to pay the penalty, we will use our other enforcement actions. The Department of Health will make regulations as to which offences can attract fixed penalty notices (see below) but they may include, for example, carrying on a regulated activity without being properly registered, or failing to comply with a condition of registration.

37. We might use this power when it is clear that the provider is in breach of requirements in the 2008 Act and/or the associated regulations, but where there is evidence that improvements have already been or can be made, and we wish to focus on improvement without a lengthy prosecution. It may be that a penalty notice has a significant impact on a provider's reputation, even where the value of the penalty is relatively small.

Examples

We might use this power where:

- An inspection of an NHS hospital reveals that a number of clinical areas are unclean.
- There has been a failure to comply with Mental Health Act statutory procedures and documentation.
- A domiciliary care agency has had a poor recruitment record, resulting in the use of unsuitable staff, but they have introduced new policies and procedures that we think are likely to bring improvements. In this case, the penalty notice would underline the need for the agency to implement and stick to the new policies.

38. The Department of Health is proposing to make regulations relating to this power, and is currently consulting on:*

- The offences for which it is proposed that penalty notices can be used in 2009/10.
- The value of these penalties.
- The time by which the penalty is to be paid.
- In the event of a refusal to pay, the amount of time that must elapse before we can take further proceedings.

39. The Department of Health will consult again on various regulations for 2010/11 onwards, including those relating to the level of penalty notices.

* *Changes to arrangements for regulating NHS bodies in relation to healthcare-associated infections for 2009/10*, 11 August 2008. Consultation ends 20 October 2008.

Suspend registration (2008 Act only)

40. We can suspend the registration of a provider entirely for a specified period. This will give the provider the opportunity to rectify any breach and then resume service provision. We are able to extend the period of suspension. We are also able to do this in urgent cases as described above (see paragraph 34), and there is a right of appeal. It will be an offence for a provider to operate during a period of suspension.

41. We might use this power when we believe that the breach can be remedied, as long as the provider is judged to have the capacity and willingness to rectify the problem.

Examples

We may use this power where:

- There has been a large-scale outbreak of an infectious disease in a hospital.
- An agency or care home is unable to operate safely because a large proportion of its staff has left. The suspension could be lifted when appropriate staffing levels are resumed.

Cancel registration (CSA 2000 & 2008 Act)

42. As an ultimate sanction, we have the power to cancel registration outright. Although we would aim to ensure that all other options have been exhausted, we do not need to have undertaken any other enforcement action beforehand. We have to follow the process established in the 2008 Act, which builds on the existing CSA 2000 process. We are able to cancel registration in urgent cases as described above, and there is a right of appeal. It is an offence for a provider to operate after this, as they would no longer be registered.

43. We would only consider using this power as a last resort, where people who use services are put at such risk, and where care is so unsafe or of such poor quality, that no other action would be appropriate – for example, in relation to persistent and deliberate non-compliance. Even in these circumstances, any action would be carefully coordinated with other bodies (for example local authorities and health authorities) and the balance of risk would always be considered. In such situations, we would also consider giving advice to the Secretary of State for Health.

Example

We may use this power if we become aware of the sudden and suspicious death of one or more care home residents, and where the providers are not cooperating with investigations that we or other agencies are undertaking.

Prosecute for specified offences (CSA 2000 & 2008 Act)

44. We have the power to prosecute for certain offences. Prosecution is an important part of enforcement. It punishes wrongdoing, avoids recurrence and acts as a deterrent to others. In some cases, it may be appropriate to prosecute in conjunction with other enforcement actions, for example suspension of registration.

45. We would not start a prosecution unless we were satisfied that it is in the public interest, that there is sufficient, admissible and reliable evidence that an offence has been committed and there is a realistic prospect of conviction. In reaching a decision to prosecute, we will have regard to the principles in the Code for Crown Prosecutors (www.cps.gov.uk/victims_witnesses/code.html). Where another organisation has the power to prosecute, we will liaise with them to ensure effective coordination, to avoid inconsistencies, and to ensure that any proceedings are for the most appropriate offence.

46. Where we successfully prosecute a provider, the courts decide on the fine that is imposed and are able to issue a separate fine in relation to each offence that is successfully prosecuted. The courts may decide to impose a prison sentence as well as, or instead of, a fine following conviction for failure to be registered.

47. Under the 2008 Act, the maximum court fines for certain offences have been increased. They apply to NHS providers only in 2009/10, and to all providers and managers from 2010/11 onwards. The offences and maximum court fines from the CSA 2000 and the 2008 Act are as follows:

Offence	CSA 2000 court fine	2008 Act court fine
Failure to be registered	£5,000	£50,000
Failure to comply with conditions in relation to registration	£5,000	£50,000
Offences relating to suspension or cancellation	N/A	£50,000
Failure to comply with registration requirements	£2,500	£50,000*
False descriptions of concerns	£5,000	£5,000
False statements in applications	£2,500	£2,500
Failure to display a certificate of registration	£500	N/A
Obstructing an inspector	£2,500	£2,500
Failure to provide documents or information	£2,500	£2,500
Failure to provide an explanation of any related matter	£2,500	£2,500

* Some lesser requirements have a maximum court fine of £2,500 in the 2008 Act.

Simple cautions

48. We may consider issuing a simple caution as an alternative to prosecution. A simple caution can only be used where there is evidence of guilt, and where the offender admits the offence and is prepared to accept the caution. In deciding whether to issue a caution, we will have to consider these matters, along with guidance issued by the Home Office (currently HO circular 30/2005).

49. We may choose to issue a simple caution where a provider is found not to be complying with guidance (for example, part of the guidance on the prevention and control of healthcare-associated infection), and this constitutes a breach of requirements in the 2008 Act and/or the associated regulations, or where a person was operating a service without being registered but has since applied for and been granted registration

50. Although we are not required by law to publish details of simple cautions, we have a general power to publish this type of information and may therefore choose to do so.

Appeals

51. There will be a right of appeal to a tribunal against some types of enforcement action undertaken by the Care Quality Commission. Any appeal must be made within 28 days of the enforcement action being carried out. Appeals can be made against conditions of registration, or suspension or cancellation of registration.

52. There is no right of appeal to the tribunal in the case of the issuing of warning notices, penalty notices or conviction for offences.

Consultation question

2. Do you agree with the circumstances and manner in which we intend to use each enforcement power?

4. Publication and notification of enforcement action

53. The Department of Health is proposing to make regulations for 2009/10 that require and authorise us to publish certain information relating to enforcement action within set timescales. The proposals are in the consultation document referred to at paragraph 38.

54. The 2008 Act requires us to give copies of notices relating to enforcement action to various bodies, including primary care trusts (PCTs), local authorities, strategic health authorities (SHAs) and Monitor (the independent regulator of NHS foundation trusts). The Department of Health is proposing to make regulations for 2009/10 that specify which PCTs and SHAs should be given copies of notices relating to various aspects of enforcement action, and in which cases we do not need to provide notification of enforcement action. The proposals are in the consultation document referred to at paragraph 38.

55. The Department of Health will consult again on various regulations including those for 2010/11 onwards.

56. We aim to publish an annual report on enforcement, in order to promote learning and review trends.

5. Working with other organisations

57. Where we and another enforcement body, for example the police or the Health and Safety Executive, have the power to take action, we will work together to ensure that we coordinate our respective powers. This will avoid inconsistencies and ensure that any action taken is for the most appropriate offence.

58. Where there are allegations of abuse involving people in services that we regulate, we will inform the local authority in line with safeguarding and child protection procedures and work with the other agencies to ensure that people are appropriately safeguarded.

59. When taking enforcement action, we will work with different organisations depending on the provider's status, for example Monitor for NHS foundation trusts, SHAs for NHS trusts and PCT-provided services, and local authorities for adult social care services. This will help us consider what alternative services are available for the people affected, and to encourage joint working between the relevant authorities.

60. Monitor will continue in its current role, to ensure that NHS foundation trusts operate in an efficient, effective and economic manner. Failure by an NHS foundation trust to comply with our requirements may also be considered to be a breach of their terms of authorisation, and could lead to intervention by Monitor.

61. We will not duplicate Monitor's role. Our role, in relation to all providers, including NHS foundation trusts, is to ensure that they meet safety and quality requirements. We expect to liaise with Monitor before taking enforcement action in relation to an NHS foundation trust. However, occasionally there may be instances where we need to take immediate action in order to protect the safety of people who use services.

Consultation question

3. Does the way in which we propose to work with other organisations ensure a coordinated approach to enforcement?

6. Responding to the consultation and summary of questions

62. This document launches a consultation on our proposals for enforcement action from April 2009 onwards. Your feedback on this consultation will inform our final policy. The consultation period ends on **16 January 2009**.

63. Following the consultation, we will publish a response and our final enforcement policy before it comes into effect on 1 April 2009.

64. The questions asked in this consultation are:

Consultation questions

1. Do you agree with our proposed principles and overall approach to enforcement?

2. Do you agree with the circumstances and manner in which we intend to use each enforcement power?

3. Does the way in which we propose to work with other organisations ensure a coordinated approach to enforcement?

65. We would also welcome comments on the impact assessment at appendix B and views on how the specific proposals in this consultation affect equality, particularly in terms of race, disability, gender and human rights.

66. If you wish to respond to the questions raised in this consultation, please email your response to **consultationresponses@cqc.org.uk**. Alternatively you can complete and return the enclosed reply sheet.

67. This consultation follows the Cabinet Office *Code of Practice on consultation* (see www.berr.gov.uk/files/file44364.pdf). In particular we aim to:

- Consult widely throughout the process, allowing 12 weeks for written consultation at least once during the development of the policy.
- Be clear about what our proposals are, who may be affected, what questions we want to ask and the timescale for responses.
- Ensure that our consultation is clear, concise and widely accessible.

- Ensure that we provide feedback regarding the responses received and how the consultation process influenced the development of the policy.
- Monitor our effectiveness at consultation, including through the use of a designated consultation coordinator.
- Ensure our consultation follows better regulation best practice, including carrying out a regulatory impact assessment if appropriate.

68. If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please use the same contact details as in paragraph 66 above.

Confidentiality of information

69. Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

70. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

71. We will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

7. Regulatory impact

72. We consider it unlikely that the changes to the range of sanctions will cause a significant change in costs, either to ourselves (compared to the current cost of enforcement to the Healthcare Commission and the Commission for Social Care Inspection) or to providers.

73. Any increase in the number or size of providers within the regulatory framework is bound to cause a rise in enforcement costs.

74. The number of enforcement actions overall may increase as we have additional powers at our disposal. However, it is possible that the additional enforcement powers will lower the number of more significant enforcement actions, for example cancelling registration, as the intended effect of our policy is to encourage providers to comply with regulations and requirements earlier in the process. Any savings that may arise as a result should outweigh the additional costs. A regulatory impact assessment is included at appendix C.

Appendix A: Criteria for formal investigation

Our functions include conducting investigations into the provision of NHS care, the provision of adult social services and the exercise of functions of strategic health authorities and special health authorities performing functions in respect of England. We are required to publish a report of any such investigation.

We will conduct an investigation where we become aware of specific concerns. An investigation involves obtaining evidence on, and developing an understanding of, the reasons for a serious failing in the provision of care. We can make recommendations to prevent the failing happening again. When conducting an investigation, we will take account of accepted standards and criteria or, in their absence, other statements of good practice (for example from professional bodies).

Triggers that might alert us to the potential need for an investigation include:

- Direct contact from service users, the public, staff or the media.
- Issues brought to light during our other regulatory activities.
- Requests from the Secretary of State for Health, or from other regulatory bodies.

We have a wide discretion as to the circumstances in which we will undertake an investigation in relation to NHS care or adult social services.

Generally, this will only be where we have credible information that suggests that there may have been, or there may be, a serious failing in the provision of care or the exercise of functions by a strategic health authority or special health authority*, that has, or may result in, a negative impact on the safety of service users, the effectiveness of the service, or responsiveness to people who use the service.

If a case does not feature such a serious failing, we will nevertheless consider whether an investigation should be started, having regard to the particular facts of the case.

* Where the authority is performing functions only or mainly in respect of England.

Factors which might trigger us to commence a formal investigation include:

- A higher number than anticipated of unexplained deaths.
- Serious injury or permanent harm, whether physical, psychological or emotional.
- Events which put at risk public confidence in the care provided, or in the NHS or adult social services more generally.
- A pattern of adverse effects or other evidence of high-risk activity.
- A pattern of failures in service(s), or team(s), or concerns about these.
- In line with multi-agency procedures, allegations of abuse, neglect or discrimination against service users, particularly those less able to speak for themselves or assert their rights.

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

Generally, we will not investigate:

- Individual incidents that have not been pursued through the appropriate complaints procedure, unless it raises an immediate concern.
- Individual complaints about professional misconduct.
- Changes to service configurations (such as mergers).
- Employment or disciplinary matters.
- Matters being considered by legal process.
- Specific matters already determined by legal process.

This does not prevent us from investigating circumstances surrounding such matters. A matter that has been determined under one of the processes outlined above may raise general concerns about the safety of service users or suggest that organisational systems are flawed.

We will consider all allegations of serious failings, identify whether rapid action is required (for example, enforcement action to suspend the service for the protection of people who use services), and liaise with the body concerned and other bodies where necessary. It may be more appropriate in some cases for us to refer the matter to another agency, such as the police.

Appendix B: Equality impact assessment

Context

From April 2009, the Care Quality Commission (CQC) will be the new independent regulator of health and adult social care services across England. It will be responsible for registering, reviewing and inspecting these services. CQC aims to help services improve by ensuring that essential quality and safety standards are met and that bad practice is stamped out.

One of the ways we will do this is by using the enforcement powers set out in the Care Standards Act 2000 (CSA 2000), which have been carried forward, plus three new powers under the Health and Social Care Act 2008 (the 2008 Act). These are:

Power	CSA 2000	2008 Act
Issue a warning notice	×	√
Impose, vary or remove conditions	√	√
Issue a penalty notice in lieu of prosecution	×	√
Suspend registration	×	√
Cancel registration	√	√
Prosecute for specified offences	√	√

The proposed CQC enforcement policy is a high-level document that sets out for consultation the principles underpinning any enforcement and how we plan to use our enforcement powers. The policy seeks to ensure that enforcement decisions made by CQC are consistent, fair and appropriate to the circumstances.

CQC, like any other public body, has a legal duty to promote equality and eliminate discrimination. The equality impact assessment considers the potential impact of the draft enforcement policy in relation to disability, ethnicity, gender identity, age, sexual orientation, and religion or belief.

This paper explains how we looked at the impact on equalities of the policy, and proposes things we can do to ensure that equality issues are addressed when subsequent measures are developed or revised, through regular monitoring and evaluation.

Objective of the policy

The objective of the policy is to set out how we intend to use our enforcement powers to protect and promote the health, safety and welfare of people who use health and social care services, and the principles we will follow in doing so.

The general principles we intend to follow in relation to enforcement are:

- Our overarching concern is to protect the safety of service users and improve the quality of care they receive.
- We will take a proportionate approach, based on our assessment of the risk of harm, the quality of care and the evidence of non-compliance with the law.
- Our processes will be transparent and accountable.
- We will encourage improvement wherever possible, but if a service fails to fulfil its legal obligations, we may take enforcement action.
- We will put particular emphasis on equality, diversity and human rights, particularly where services are provided to those who are less able to speak for themselves.
- Our work will be led by appropriately trained, skilled staff.
- We will be consistent in the application of these principles across all sectors of care, while tailoring our approach to different types of provider.
- We will follow up all enforcement activity in a timely fashion.
- We will coordinate our work with other regulators.
- We will monitor the operation of the enforcement policy, and take seriously any comments from providers.

Enforcement is a powerful tool that is used to change unacceptable behaviour and to redress harm caused by illegal acts. It is important, therefore, to ensure that the enforcement policy is not inherently discriminatory, and that our enforcement in practice will not discriminate against particular groups of the community and will promote equality and human rights.

Equality impact assessment

The policy outlines the approach CQC will take in using its powers when dealing with any breaches of the law. Everyone, irrespective of disability, ethnicity and so on, has to comply with legislation and statutory notices. Enforcement action will

be taken against those organisations and service providers that do not adhere to the law. It will not be aimed at specific groups directly.

The Human Rights Act 1998 covers the basic rights and freedoms we are all entitled to, including equality before the law. These core human rights (principles of dignity, equality, respect, fairness and autonomy) are fundamental to people using health and social care services. Therefore, it is crucial that we adopt a human rights approach to our work. The principles we have laid out in our draft policy seek to put people who use services first and respect people's rights and choices. Our policy makes it clear to our staff and stakeholders that we will make sure that our actions will promote equality and protect all people's human rights and choices.

We will ensure that providers meet their statutory obligations and, where necessary, take enforcement action to improve the safety and quality of health and social care services. By following the legal process laid out in the Human Rights Act and ensuring the processes that underpin our policy promote human rights and choices, we will ensure that human rights are also protected. We can take a range of enforcement actions in order to improve poor or dangerous care practices when we find them. Our powers include urgent cancellation of registration in the most serious cases. We work with others to protect the interests of people who are at risk and cannot protect themselves.

There is no evidence to suggest that this proposed enforcement policy would have an adverse impact in relation to age, disability, race, religion and belief, gender identity or sexual orientation or infringe individual's human rights. The changes outlined in the 2008 Act to create CQC do not, in themselves, introduce any new services. Rather they support plans for the diversification of services available to the users of healthcare (including privately funded care) and adult social care.

However, the assessment has highlighted one particular area of high importance: more factual data is needed in respect of future enforcement activities. A yearly analysis of all enforcement actions taken should highlight any bias towards particular groups and the need for any changes to the policy. This would help CQC to show that it can regulate health and adult social care services effectively and tackle any issues of equality. The Commission for Social Care Inspection and the Healthcare Commission have systems that record enforcement action. These could be developed and used by CQC.

Evidence

- We conducted a literature review and accessed a number of databases to find published evidence.
- We carried out a web search to identify relevant literature, in particular websites of key public sector regulators with enforcement policies in line with their statutory roles – for example the Health and Safety Executive, Local Authorities Trading Standards and the Environment Agency as well as the Healthcare Commission and the Commission for Social Care Inspection.
- We also spoke directly to some regulators to ask about their enforcement policies and their experience of conducting equality impact assessments.
- We had a detailed discussion with the Equality and Human Rights Group of the Department of Health, which helped us to find examples of good practice and to get advice about this assessment.

Quantitative

Due to limited powers and a wide variation in the remit of the existing regulators, there is insufficient data on which to base robust conclusions about the extent to which enforcement may have had an adverse impact on any group, or to which it has promoted equality or protected human rights.

However, a review of the equality impact assessments of the regulatory enforcement policies (such as building control, environmental health, health safety and licensing, planning, private housing and trading standards) of a number of local authorities (for example, Brent Council) has provided good evidence that their policies have no direct adverse impact on any particular group of people.

Qualitative

Within a wider policy context, the Department of Health has already carried out an equality impact assessment of the Health and Social Care Act 2008. This relates to CQC's full scope of regulatory activity, and some specific concerns were raised:

- Firstly, about the ability of a new integrated regulator to adequately monitor and safeguard services for older people (particularly in social care settings) and those with disabilities (particularly learning disabilities).
- Secondly, the role of protecting the rights of users of mental health services who are subject to compulsion could be diminished within an organisation with a wide range of functions that will compete for limited resources. This is particularly

important in light of the new function of monitoring the application of the deprivation of liberty safeguards, as provided for in the Mental Capacity Act 2005.

In relation to the first concern:

- It is our view that the proposals will allow CQC, when compared with the existing regulators, greater flexibility to direct resources and attention where they are most needed. The regulatory regime operated by CQC will build upon the system of targeted and proportionate regulation based on an assessment of risk in relation to safety and other quality of care issues pioneered by the existing commissions. This will allow CQC to ensure that poorly performing providers receive the level of inspection and intervention necessary to maintain the safety and quality of their services.
- To tackle poor or unsafe service delivery, CQC will also have a wider range of sanctions than is available to the bodies it will replace. These sanctions will include new powers to issue penalty notices and suspend registration. This greater range of enforcement powers will allow CQC to safeguard more effectively the quality of services and tackle any equality issues that may become apparent in the provision of those services.

In relation to the second issue:

- We recognise that the Mental Health Act Commission (MHAC) has a somewhat different focus to the other two commissions whose functions will transfer to CQC. The Department of Health has worked with, and will continue to work with, MHAC to ensure that its unique functions and wide range of expertise will be properly maintained in the new organisation. There are significant benefits in bringing MHAC's functions within the remit of CQC. It will enable closer links between monitoring the operation of mental health legislation and the regulation of mental health services more generally. Furthermore, there will be greater flexibility and more effective monitoring of the operation of mental health legislation, as CQC will be able to draw upon a greater range of analytical skills, information and corporate resources than are currently available to MHAC.
- Regulations to be laid under the Mental Capacity Act 2005 will give CQC a new function of monitoring the operation of the deprivation of liberty safeguards contained in the Mental Capacity Act 2005. Through this function, CQC will seek to ensure that the safeguards are working properly, highlight where they are not and, where necessary, require remedial action to be taken. CQC will be able to visit hospitals and care homes and, where necessary, interview any patients who are deprived of their liberty and ask to see the relevant records.

CQC will report once a year to the Secretary of State summarising its activities and findings in relation to these safeguards.

Like the organisations it will replace, CQC will have statutory duties in relation to the promotion of race equality. The Race Equality Duty, which came into force in 2002, requires public authorities to promote equality of opportunity and eliminate discrimination. In addition, CQC will have specific duties to help it ensure that, in the discharge of its functions under the Mental Health and Mental Capacity Acts, it is able to effectively monitor and tackle any instances of unlawful discrimination and adverse impact on the basis of race, gender identity and disability.

Each of the three existing commissions has published and is implementing schemes in relation to the Disability Equality Duty, the Race Equality Duty and the Gender Equality Duty (which came into force in 2007). CQC will need to integrate and build on these, and show a clear commitment to human rights and diversity: not only in terms of how it operates as an organisation (including how it deals with its own staff), develops criteria for assessment and carries out its work programme, but also in how it improves the public's experiences of health and adult social care services. In doing so, the new Commission will build on the good work of the existing commissions and good practice elsewhere.

Future monitoring and evaluation

1. Public consultation

During consultation on its enforcement policy, the CQC will consider whether there is any potential for the policy to disproportionately affect different groups of people. If such a risk is identified, CQC will need to consider what mitigating action it might take and what monitoring is needed.

2. Indirect consequences

Based on our literature search and discussions with other regulators, we found no evidence to raise concerns that the enforcement policy will adversely impact or infringe human rights. However, while the policy in itself is not prone to inequalities, the procedures (registering, reviewing, inspecting, and investigating) that may lead to enforcement decisions do need to be reviewed for evidence of potential adverse impact and monitored for any indirect impact on equality issues.

Similarly a review of how past enforcement has addressed equality and human rights issues raised through investigations will inform future policy development and practice. Therefore, CQC needs to:

- Make sure that its methodologies respond to and promote diversity by consulting with people from diverse groups. CQC should involve a wide diversity of users of services, regulated providers, commissioners and other interested parties. This approach will help to ensure that CQC has appropriate tools built in to its methodologies to tackle any areas where there may be equality issues. The Commission for Social Care Inspection has assessed the impact on equalities of its inspection projects and made a significant number of changes to its tools, methodologies and guidance documents to reduce the likelihood of inequalities in its enforcement actions. The Healthcare Commission is currently undertaking an equality impact assessment of its investigations function and has completed similar assessments of each of the key components of the annual health check, leading to numerous changes to the core standards criteria.
- Train its staff to understand what they need to do to ensure their ways of working fully integrate equality, diversity and human rights. For example, staff should be aware of and respect different cultural requirements and be familiar with legislation on human rights. When necessary, they should use translation services and encourage the use of third parties to translate and mediate with users of services.

3. Annual enforcement reports

This impact assessment has highlighted that more monitoring and analysis is needed to identify and address any equality and human right issues in relation to enforcement actions undertaken by CQC. We recommend that the policy should be monitored by annual reports that collect all enforcement data across the health and social care sector. For example:

- The differences in feedback and complaints between minority groups, age groups, genders, and between people who are and who are not disabled, and the general population.
- More equalities data on who owns and runs different types of business (for example nursing homes and private clinics) that will be regulated by CQC. This will provide baseline data against which more meaningful comparisons can be made. We recognise there are challenges in obtaining such data. CQC needs to ensure that its methodologies do not inadvertently discriminate against registered managers and in some cases providers on the basis of race, gender identity, sexual orientation and so on.

- A breakdown of population profiles to highlight high black and minority ethnic and aged population areas could also help CQC.

To achieve the above, CQC needs to ensure that its staff contribute to the reports. The information, which should include analysis by ethnic group, gender identity and other equality strands and human rights, should be evaluated to establish whether discriminatory practices or adverse impact have occurred and to identify areas where equality and human rights can be better promoted.

4. Regular surveys

In carrying out its functions, CQC will need to show effective involvement of users of services and others affected by its activities. Based on the experience of other regulators, it would be valuable to seek regularly the views of users, carers and public about the services and businesses that the CQC will regulate, on issues such as:

- The speed with which reported breaches of the law are resolved (recognising that enforcement needs to follow due legal process).
- Whether enforcement action is sufficient to address specific problems and bring about improvements.

The representative views should cover age, disability, race, religion and belief, gender identity and sexual orientation.

5. Collaboration with other regulators

CQC should take account of best practice among other regulators who are performing similar enforcement functions. An opportunity to do this is provided through the voluntary Concordat already signed by a number of regulators, including the Commission for Social Care Inspection and the Healthcare Commission, to share their data for regulatory purposes. The analysis of the shared data of enforcement actions might provide some insight of institutional inequalities and help to develop new enforcement approaches.

Appendix C: Regulatory impact assessment

General approach

In our initial manifesto, we have said that, as a leading and innovative regulator, we will:

- Harness a range of regulatory approaches
- Prioritise on the basis of risk
- Be transparent and open
- Be proportionate.

We have also made it clear that providers and commissioners of care will see effective regulation, reducing unnecessary regulatory burdens and bureaucracy.

We intend to be very clear from the start about how we think our approach to regulation will benefit those who use services, and how it will help those who commission and provide services to make sure high quality care is available, while not detracting from their ability to carry out their roles effectively and efficiently.

One way we will do this will be to routinely publish impact assessments when we issue significant consultation or guidance. These assessments will be an important tool in demonstrating our understanding of the costs and benefits of our role as it develops. We will also continually assess the consequences of new proposals and approaches. We will then evaluate over time how far our assessments match up to the experiences of providers, commissioners and people who use services.

We acknowledge that the data immediately available to support this first assessment is limited, and will be working with others to increase the range and quality of the evidence base for future assessments.

Introduction

Our starting point is that organisations responsible for health and adult social care services are accountable for the quality and value of the services they provide. The role of regulation is to reinforce that accountability. CQC will, therefore, be more active where the risks of harm are greater; where people are less able to assert their rights; where commissioning is weaker; where information on quality is poor; or where monopoly providers are failing to improve.

We are consulting on our general approach to enforcement, and highlighting our specific new powers to:

- Issue a warning notice
- Issue a penalty notice in lieu of prosecution
- Suspend registration.

For 2009/10, the only relevant change to the statutory framework is to bring NHS trusts within the scope of all the enforcement powers (including the three new ones above) available to CQC under the Health and Social Care Act 2008, in relation to the registration requirement for healthcare-associated infection. The impacts of this are considered in more detail below.

In 2009/10, independent sector health and adult social care providers will remain subject to enforcement action under the Care Standards Act 2000. NHS trusts and NHS foundation trusts will remain subject to interventions by the Secretary of State and Monitor respectively.

This assessment sets out CQC's initial view of the potential changes in impact in relation to all its enforcement capabilities. We will produce a fuller impact assessment and agree detailed operational guidance for 2009/10 once the current consultation is completed.

We will also publish a further substantial assessment when we consult next year on the implementation of the comprehensive new registration system for health and adult social care, which we will introduce from April 2010. This will take into account any changes to the scope of that registration system that the Government decides to make following its own consultation (see www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625).

Background

The Commission for Social Care Inspection and the Healthcare Commission have operated two forms of enforcement under different legislation. They have the ability to use powers under the Care Standards Act 2000 to:

- Impose, vary or remove conditions
- Cancel registration
- Prosecute for specified offences.

The Commission for Social Care Inspection and the Healthcare Commission have powers under the Health and Social Care Act 2003 to recommend that the Secretary of State takes special measures in relation to local councils and NHS trusts. In practice, these powers have been used sparingly (the Commission for Social Care Inspection has not used the power and the Healthcare Commission has used it on three occasions).

Benefits

Our view is that, where we identify poor quality services, we will be able to provide a more flexible and proportionate response. Change will happen incrementally.

Our future enforcement powers will allow us to issue formal warning notices to encourage breaches of regulatory requirements to be remedied. We will be able to alter registration conditions urgently without applying to a Justice of the Peace. We will be able to issue a financial penalty notice for a fixed penalty offence, instead of prosecution. We will be able to suspend the registration of a provider for a specified period.

All these new powers will enable us to make sure that enforcement is appropriate and proportionate to the need to encourage compliance, without more serious sanctions being invoked except where absolutely necessary in the interests of people who use services. We will have greater flexibility than previous regulators to move up a tiered approach to enforcement, so that our action will be proportionate to what is needed to drive improvement, promote learning and stop poor performance.

It is difficult for us to provide robust estimates of the direct benefits of these changes at this stage. Earlier this year, the Department of Health suggested that such focused enforcement action "…can force providers more readily either to increase their standard to the required level or to close, which in both cases will increase overall quality and safety" and "to the extent that a more targeted approach may diminish the number of providers that have to be closed, access and choice would also improve". In discussion with service providers and others, however, we are confident that we will be able to provide more information on the impact of the new system before the new powers become more generally available to us in April 2010.

Costs

The Department of Health* has suggested that there is likely to be a minimal reduction in costs for the regulator (£0 to £0.5m), and it estimates that there would be no net increase or decrease in the costs incurred by the regulated sector.

We recognise that there will be worries that bringing the NHS into a regulatory enforcement regime for the first time has the potential to increase bureaucracy and distract staff from providing high quality services. We undertake to design and implement enforcement processes that will guard against this happening.

* www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433

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Care Quality Commission

7th Floor, New Kings Beam House
22 Upper Ground
London
SE1 9BW

Telephone 03000 616161
www.cqc.org.uk

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