Guidance on CQC’s enforcement powers
Changes to enforcement policy and enforcement powers

Impact assessment

This impact assessment has been published alongside our enforcement consultation and covers:

1. Proposed changes to our enforcement guidance

Stakeholders may want to refer to this document before reading this impact assessment; it provides information on the proposed changes to how we will use our enforcement powers.

This document provides an analysis of the potential cost and benefit impacts of our proposals for the way we will use our enforcement powers in future.

Introduction

1. The Care Quality Commission (CQC) is making some major changes to how we will regulate providers of health and social care. A core part of these changes concerns how we will use our enforcement powers in future. This ensures we are better able to use our powers to both protect users of services from harm, and also to hold providers to account following serious failings in the provision of care.

2. The Secretary of State has laid new secondary legislation so that our current regulations will be streamlined so they become 11 fundamental standards of quality and safety, plus new regulations covering two additional fundamental standards – a duty of candour and a fit and proper person requirement for directors1. This will provide us with the legal basis to take targeted enforcement action should providers fall below any of

1 Department of Health have published three Impact assessments on these new regulations which cover the consultation on regulations guidance.
these standards\textsuperscript{2}. We will also make wider changes to ensure we take the most appropriate enforcement action to help tackle poor quality care or non-compliance.

3. This impact assessment provides an assessment of the likely impacts of the proposed changes to how we will use our enforcement powers outlined in our consultation that is published alongside this document. A final impact assessment will be published in autumn 2014, before we introduce our proposed changes.

**Background to proposed changes**

4. The proposed changes outlined in this document are part of a wider system of changes concerned with how CQC will regulate health and social care providers in future. In our provider handbook consultations we outlined changes to how we will regulate and inspect providers, which also included plans for providing ratings to all providers.

5. Our approach to enforcement will also need to be modified so that it is fully integrated within the new approach. Similarly future changes to the regulations that will underpin fundamental standards of quality and safety will ensure that how we use our enforcement powers mirrors those new standards laid out in the Care Act 2014. These changes will ensure we have a clear route to enforcement action, and that we also take the most appropriate action in order to remedy breaches or quality of care concerns.

6. It is our specific intention that the proposed changes encourage providers to continually improve their provision of health and social care services. As we move to becoming a performance-based regulator, the use of our enforcement powers will become a key tool to achieve this objective. Enforcement must relate to breaches of legislation, but our decision to use enforcement powers will also be influenced by whether a provider has ratings of ‘requires improvement’ or ‘inadequate’ and in particular whether there is a history of repeated ratings of ‘inadequate’. This will incentivise the provider to make improvements so as to improve their rating in future.

7. Finally, the proposed changes will help to close regulatory gaps associated with confusion over roles and responsibilities for enforcement action. CQC’s powers of prosecution will align more closely with those of the Health and Safety Executive, and the two regulators will set out an agreement giving more clarity about how their prosecution roles join up. This will help to ensure events such as Mid-Staffordshire and Winterbourne View are dealt with appropriately and in a timely manner to help protect users and their families from adverse effects of poor quality care.

\textsuperscript{2}Six of these fundamental standards have prosecutable clauses.
Summary of proposed changes to CQC’s enforcement guidance

8. Our consultation document provides detailed information to stakeholders of the proposed changes. A summary of these are included below:

**Summary of proposed changes**
These changes will affect all health service bodies from October 2014 and for all other providers from April 2015.

**Requirements**
Formally known as “compliance actions”, these act as a precursor to enforcement and notify providers where they are failing. If providers do not improve then we can move to formal enforcement action under any of the below.

**Use of conditions**
The use of conditions will now be a key enforcement tool that CQC can utilise to secure compliance. We will continue to either impose, vary or remove conditions of registration as is deemed appropriate.

**Warning notices**
There are two types of warning notice. One will be used to encourage improvement and is used to help secure compliance with the relevant regulations. The other is a special warning notice used only for NHS trusts and foundation trusts and act as a precursor for “special measures”.

**Prosecution**
CQC will use a range of civil and criminal sanctions to prosecute providers. They are now the principle prosecuting authority and this now closes a regulatory gap with the Health and Safety Executive. Fines can now be unlimited. The new fundamental standards have a number of prosecutable clauses.

**Non-linear approach to enforcement**
We will use any of the proposed enforcement tools to secure compliance, remedy breaches and hold providers to account. In practice this means we will no longer use an enforcement escalator.
CQC assessment of impacts

Overview of current enforcement policy

9. We will take enforcement against registered persons who breach conditions of registration and/or relevant sections of the Act, the Care Quality Commission (Registration) Regulations 2000, the Health and Social care Act 2008 (Regulated Activities) 2014, and other legislation that is relevant to achieving registration requirements. We also take enforcement action against unregistered providers providing regulated activities.

10. We have a number of tools that we can use to secure compliance with the current list of 16 essential standards of quality and safety. We first identify whether a provider is non-compliant with any of these essential standards and then identify the appropriate response based on whether the impact is (or has the potential to be) minor, moderate or a major impact on people’s health and safety. For example, those providers found to have been non-compliant and having a minor impact on people’s health will normally have been issued with a compliance action. For those found to be non-compliant and have a major impact on people’s health, we could use a range of civil and criminal sanctions, i.e. fines, etc. to help secure compliance.

11. Use of our enforcement powers has traditionally consisted of using an escalator approach to help secure compliance with the relevant regulations. For example, we would normally start with simple compliance actions, and move through to warning notices (for multiple breaches) through to prosecution for the most serious offences. This has meant we have not always been able to act more swiftly and use the most appropriate tools in situations where users have been at risk or receiving poor quality care and experience adverse effects as a result thereof.

Policy objectives

12. In making changes to our enforcement policy and use of our powers we feel we will be better able to fulfil the following two objectives:

- To protect people who use regulated services from harm and the risk of harm.
- To hold providers and individuals to account for failures in how the service is provided.

13. As the use of enforcement powers is central to our emerging regulatory approach, we are keen to ensure we secure both an improvement in service while also being proportionate and minimising any unintended consequences of action taken on the provider in question. Our enforcement principles outlined in the consultation document provide more of an overview for how we plan to achieve these aims.
14. Finally we believe the proposed changes will allow us to take swifter action to help remedy breaches. This removes the need for the “enforcement escalator” which should allow us to use the most appropriate tools to target poor performing providers.

Proposed changes to our enforcement policy

15. All enforcement action will now be taken with the aim of securing any of the following three outcomes:

   i. Requiring improvement
   ii. Forcing improvement
   iii. Holding providers to account

16. The outcome of a provider rating will particularly have significance for the type of enforcement action required. For example, providers who are rated as “inadequate” may experience action that forces a provider to improve on the quality of care services provided. This would be the case if we have concerns that the level of care provided would have serious implications for the longer-term health of users. Similarly those providers who have been rated as ‘Requires improvement’ may experience action that encourages the provider to improve on their provision of care.

17. Depending on the severity of the breach, we may choose to pursue a combination of any of the three outcomes listed above. For example, we can hold providers to account if we feel the provision of care has resulted in serious long-term adverse effects or death. At the same time we can also force that same provider to improve on their provision of care services if found to be sub-optimal.

18. The following is a summary of proposed changes to our enforcement policy and how we will use our enforcement powers to help secure any of the three outcomes as listed above. Stakeholders should refer to the consultation document published alongside this impact assessment for a fuller description of these changes.

Requirements

19. Requirements aren’t specifically enforcement action but act as a precursor to enforcement action. Formerly known as ‘compliance actions’ we would serve these on providers if we feel their provision of care had (or has the potential to) inflict minor or moderate adverse impacts on service users.

20. We would typically require a report from a provider which must include plans and actions for how they intend to improve on the provision of the regulated activity that we have concerns on. This requirement would be time-bound and we would re-inspect a provider to assess if there have been improvements made between the time the requirement was served on the provider, and the subsequent re-inspection. If the improvement requested by us has not been met, then we can move to formal enforcement action to help secure improvement in the service.
Costs
21. Providers are likely to incur the costs of producing a report and putting in place actions that will help bring the provision of care up to standard. The costs incurred are likely to differ but will typically stem from two factors:
   
   i. Type of action required within the report
   ii. Provider resources used to secure the required improvement in service

22. It is difficult to be precise as to the size and magnitude of what the costs are likely to be, however we know that this is likely to be influenced by these two factors as outlined above. For example, in a scenario where we feel the provision of a regulated activity is heavily understaffed and is likely to pose a risk to the outcome service users if continued as is, the costs to the provider will simply include the costs of recruiting and training additional staff and maintaining the payroll of these additional staff.

23. It is important to note that we would always ensure that the requirement served on the provider would be proportionate and would be used in a way that both minimises the burden to the provider while also helping to secure the required improvement in the provision of the service.

Benefits
24. In serving a requirement on a provider, both the provider itself and service users are likely to benefit. For the provider they will be aware of where they are going wrong and how to improve. This could also help facilitate an improvement in the rating if the requirement is fully met by the providers. For commercial sectors i.e. care homes, etc. an increase in the rating could aid increases in business. Similarly for hospitals this could lead to better reputational effects stemming from an improvement in the rating.

25. For service users they will benefit from greater assurance that the provider will put in place plans to improve. Should these plans and actions be fully met, then service users will benefit from the improvement in the provision of care provided.

Conditions
26. Use of conditions will now be a key enforcement tool with which we will be able to secure compliance with the registration requirements. We will retain the legal powers to impose, vary or remove conditions of registration; however we will be more proactive in using these to secure compliance.

27. In the case of the registration requirements that do not relate directly to harm to patients and service users, CQC would be able to make use of its civil enforcement powers, such as issuing a warning notice, imposing a condition on a provider’s registration and cancelling registration in order to hold providers to account.

28. CQC’s power to place conditions on providers will become a key enforcement tool, to be used in cases where a provider is breaching, or is close to breaching a regulation. CQC can prosecute providers for breaching a condition.
Costs
29. As with requirements, it is difficult to assess costs associated with conditions because they can relate to major, substantive issues, or relatively straightforward ones. However, increased use of conditions will involve restricting risky activity, so they are likely to cause a reduction in providers’ ability to earn income in some cases. Increased use of conditions may also involve requiring providers to undertake additional activity in order to improve, and this may increase their costs.

Benefits
30. The key benefit of increasing our use of conditions is that it will enable us to stop risky services or force improvement, and thereby protect service users from the risk of harm. Whereas prosecutions are often lengthy, and warning notices inherently involve a delay before intervening, conditions particularly enable swift protection from harm.

Warning notices
31. 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 breach of regulations.

32. The proposed changes now separate out the warning notice into two types:
   i. Warning notice where significant improvement is required in an NHS trust of NHS foundation trust (as outlined in the Care Act 2014).
   ii. Warning notice for all providers – pure warning function.

33. The first category of warning notice is more severe and can be used as a basis for which we can put a trust into ‘special measures’. This would occur if the trust had not made significant improvements within a specific timeframe. In this case we would appoint a special administrator and would work with the relevant authorities i.e. Monitor, Trust Development Authority, etc. to help identify an appropriate course of action for the trust going forward.

34. The second category of warning notice will act as a pure warning function and will no longer be required before a prosecution.

Costs
35. In the case of warning notices issued to an NHS trust or foundation trust, it is likely that the trust will experience significant costs to be able to significantly improve their provision of services. (Although these costs relate to complying with legal requirements, which they ought to be doing already.) It is difficult to be precise as to the size and magnitude of these costs as these will depend specifically on the scale of significant improvements required to be able to bring the trust up to the required level of service quality.
36. We also know that as we will undertake another comprehensive inspection to ensure improvements have been made, the trust is likely to incur additional administrative costs i.e. costs of facilitating the CQC inspection and providing information to CQC to help judge service improvements.

37. For providers that are issued the second category of warning notice listed above, costs incurred are also likely to stem directly from the service improvements that are required of the provider. We know that the costs to provider are likely to be more severe should they have not made the required improvements at the end of a set period, as further regulatory action is likely to follow.

**Benefits**

38. Service users are likely to be the main beneficiaries of both these changes to use of warning notices issued to providers. We know service users will likely see a decrease in the risk of harm as the use of the warning notice will likely mitigate such risks to service users. If improvements are made as a consequence of issuing the warning notice, then service users and their families will experience greater assurance that the quality of care provided is of an acceptable level. For warning notices issued to NHS trusts and foundation trusts, we know that CQC is likely to benefit as we will have time to put in place appropriate contingency plans to help plan for appropriate courses of action that help mitigate the risks to service users in the event of provider failure.

39. Where service users are not at immediate risk of harm, and providers are judged to have capability to improve, allowing a further, time-limited period in which they must improve is more proportionate than going straight to more severe regulatory action. It is also more in line with CQC’s purpose of encouraging improvement. However, its value in this regard is to a large extent interdependent on our other proposals to increase the use of conditions and prosecutions: a warning that is an empty threat is unlikely to create sufficient pressure for improvement to result in much benefit. Our experience with NHS bodies placed into special measures supports this hypothesis that a final, time-limited period can be effective in ensuring improvement.

**Prosecution**

40. We will prosecute providers with the aim of holding them to account for serious failing which has led to, or if left unchanged is likely to lead to harm or significant risk of harm for service users. We currently have a range of civil and criminal sanctions we can use to prosecute providers; however the main changes are proposed as follows:

   i. No enforcement escalator – if we feel care has fallen below an acceptable level we can move straight forward to prosecution without the need for a warning notice.

   ii. Breaches of fundamental standards – six of which have prosecutable clauses (including the new Duty of Candour and Fit & Proper Person).

41. We will tend to use this power if the concern is serious, multiple or persistent, and meets criteria (set out in the consultation document) and to do so is in the public interest.
Costs
42. There are likely to be a range of financial and non-financial costs that are likely to be incurred by the provider in the event of prosecution. The likely costs could include those reputational damage costs as a result of being prosecuted by CQC – this could be further compounded if we decide to publish the outcome of prosecution. For a full list of the offences and maximum court fines please refer to Appendix A that is published within the main consultation document.

Benefits
43. Experience from Winterbourne View and Mid Staffordshire NHS Foundation Trust indicates that the public expect providers who are responsible for serious failures to be held to account. Being able and willing to prosecute providers in order to ensure their accountability is a key value of independent regulation; conversely, failure to prosecute serious failures is likely to be perceived as weak regulation. Providers ultimately benefit from ‘tough but fair’ regulation as service users will recognise that providers are held to account, and be more likely to trust their services.