Title: Review of CQC registration requirements **IA No:** **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 20/09/2013 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** John Culkin/Tongtong Qian

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£2.35m	£2.65m	-£0.3m	Yes	OUT

What is the problem under consideration? Why is government intervention necessary?

There is currently a legal requirement for CQC to issue a warning notice before bringing a prosecution, necessitated by the complexity of the existing regulations. This requirement makes it hard for CQC to prosecute providers in practice and as a result, CQC may be prevented from taking the most appropriate course of action to reflect the seriousness of a breach and providers may not always be fully held to account for their actions. Government intervention is required to revise these requirements to make them clearer so that the warning notice requirement can be removed. The results of the Francis Inquiry also recommended that the regulations be clearer and stronger enforcement action available where necessary.

What are the policy objectives and the intended effects?

The objective of the policy is to ensure that CQC regulation is as effective as possible, so that risks to service users are better managed and the quality of care is improved, whilst minimising the burden on providers. The registration requirements will be revised to make them clear enough so that CQC will no longer need to issue a warning notice before prosecuting. CQC will be able take stronger enforcement action via prosecutions where appropriate, whilst clearer regulation will also reduce the burden of regulation on providers. Overall there will be better safeguards against poor quality care and increased accountability where providers fail to meet the standards of care required

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing: The current 16 registration requirements would remain as they are. The regulations would continue to remain unspecific and unclear so that the requirement for CQC to issue a warning notice before prosecution cannot be removed. As a result CQC would continue to find it difficult to use their prosecution powers in practice.

Option 2 (preferred option):Revise the registration requirements so that the warning notice requirement can be removed: The existing requirements will be revised and rationalised to ensure that they are sufficiently precise so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed. CQC will be able to use their full suite of enforcement powers and so better match the type of action taken against the seriousness of the breach. The revisions to the regulations are also intended to make them simpler and easier for providers to understand, which will reduce the burden of regulation.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Other key non-monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Other key non-monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline. Under the do nothing option, there is a risk that health and social care regulation is not as effective as it could be, and that in the case of serious failings providers cannot be fully held to account for their actions.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Review and recast the registration requirements so that they are clearer and easier to understand

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** £2.35m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	£3.15m		£0.6m	**£8.6m**

Description and scale of key monetised costs by 'main affected groups'

There will be costs to CQC, providers and the justice system arising from any increase in the number of prosecutions brought. Although this is likely to be higher in the short term, in the long run it may be the case that the increased risk of prosecutions create a stronger deterrent for providers against non-compliance, which might reduce the need for enforcement action and result in a cost saving. It has not been possible to quantify this latter effect at this stage.

Other key non-monetised costs by 'main affected groups'

Revising the regulations could lead to additional transitional costs for providers associated with familiarising themselves with and interpreting the new regulations. There is also a risk that there are further unintended consequences, for example if the revised regulations unintentionally introduce new complexities or otherwise create additional burdens for providers. An increase in the deterrent effect could lead to even compliant providers taking unnecessary action beyond what is required.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	unquantified		£1.1m	**£9.35m**

Description and scale of key monetised benefits by 'main affected groups'

Clearer regulations may help to reduce the burden of regulation on providers, for example by making it easier to understand and interpret what the regulations mean. Although it is difficult to quantify the exact scale of the benefits, we have identified a number of mechanisms through which these benefits are likely to flow, and analysis indicates that even under modest assumptions, the reduction in burdens are likely to outweigh the additional costs to business of the proposals.

Other key non-monetised benefits by 'main affected groups'

CQC will be able to better reflect the severity of breaches of the registration requirements and better hold providers to account for serious failings. Enforcement will be more proportionate, better targeted and therefore more effective. The threat of additional or stronger enforcement action will create a stronger deterrent effect against non-compliance and so improve the overall quality of care provided.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

CQC's planned changes to their regulatory model will also impact on the costs of regulation. It has not been possible to take these changes into account as the policies are still under development.
The impacts on compliance are uncertain and likely to vary between the short and long run depending on the strength of the deterrent effect. There is also a risk that there are unintended consequences from revising the regulations that introduce new burdens or complexities for providers.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0.1m	**Benefits:** £0.4m	**Net:** -£0.3m	Yes	OUT

Evidence Base (for summary sheets)

Policy Background

1. The Care Quality Commission (CQC) is the independent regulator of health and adult social care providers in England and has a key responsibility in the overall assurance of safety and quality of health and adult social care services. Under the Health and Social Care Act 2008 all providers of regulated activities, including NHS and independent providers, have to register with CQC and meet a set of requirements of safety and quality.
2. CQC forms part of the wider quality framework, having responsibility for:
    - providing independent assurance and publishing information on the safety and quality of services;
    - registering providers of regulated activities (including NHS, adult social care and independent sector healthcare providers), ensuring the care they provide is of a sufficient standard to allow them to enter the market safely;
    - monitoring compliance against a set of registration requirements;
    - using enforcement powers (where appropriate) to ensure service providers meet requirements or, where appropriate, to suspend or cancel registrations;
    - undertaking special reviews and investigations of particular services, looking across providers and commissioners of health and adult social care;
    - monitoring the use of the Mental Health Act; and
    - operating a proportionate regulatory system that avoids imposing unnecessary burdens on providers and on the regulator itself, and helping to manage the impact of regulation more generally on health and adult social care service providers and commissioners.
3. CQC's purpose is to improve care by regulating and monitoring services. CQC ensures that only providers who meet the standards of quality and safety are registered to provide care. Once services are registered, CQC continues to monitor and inspect them against these standards. It acts quickly in response to any concerns and takes swift enforcement action where services are failing people. This can include issuing a warning notice that requires improvement within a specified time, prosecution, or cancelling a provider's registration and removing its ability to provide regulated activities, or, for the NHS, triggering the quality failure regime.
4. The 16 registration requirements set the essential levels of safety and quality of care that people should be able to expect, and are built around the main risks inherent in the provision of health and adult social care services. They cover a wide range of inputs and outputs related to the delivery of care, from ensuring that service users are protected from abuse, to ensuring that accurate records are kept. In order to remain applicable and relevant to all health and social care activities that CQC regulate, these requirements are defined at a high level. CQC also produce more detailed guidance to help providers interpret these requirements.

The evidence base of this impact assessment is structured as follows:

Section A: Definition of the underlying problem and rationale for government intervention

Section B: Policy objectives and intended effects

Section C: Description of the options

Section D: Costs and benefits assessment of the options (including specific impacts)

Section E: Summary of specific impact tests

Section F: Summary and conclusion

Section A: Definition of the underlying problem and rationale for government intervention

5. CQC uses a range of possible enforcement action where providers are found to be in breach of the registration requirements. This can include issuing a warning notice that requires improvement within a specified time, prosecution, or cancelling a provider's registration and removing its ability to provide regulated activities. The level of enforcement action taken is chosen to be proportionate to the seriousness of the breach, which is determined by the level of risk posed to service users as a result of the breach. The aims of CQC's enforcement action are to first protect service users from harm, second to ensure compliance with the requirements and third to make providers accountable for their failings.

6. There is currently a legal requirement for CQC to issue a warning notice to providers before they are able to take any action to prosecute the provider. This requirement is necessitated by the way that the registration requirements are currently drafted. The Third Report of Session 2009-10 by the Joint Committee on Statutory Instruments (JCSI) examined the draft regulations at the time and came to the opinion that the registration requirements were too unspecific to attach criminal sanctions to. They found the regulations to be "insufficiently precise to enable a person to decide what must be done to avoid committing an offence". As a result, a requirement was brought in for CQC to issue a warning notice to the relevant person to specify how the relevant provision is being contravened and what is required to ensure compliance. Only if compliance is not secured in the specified time, can CQC take further again to bring a prosecution against the provider.

7. This requirement has created an unintended consequence. As CQC are only able to bring a prosecution if they first issue a warning notice and if the conditions set out in the warning notice are not complied with, this makes the possibility of prosecution for a provider a relatively remote prospect. Thus CQC are unable in practice to use the full range of enforcement tools available to them and as a result it is not always possible for CQC to reflect the seriousness of a breach of the registration requirements and providers may not always be fully held to account for their actions. No matter how serious the offence, prosecution cannot occur if the provider complies with the warning notice.

8. Although prosecution is not the only form of 'strong' enforcement action available to CQC, there are many instances where prosecution would be the most appropriate form of action for CQC to take. By making it difficult in practice for CQC to prosecute, a less appropriate form of enforcement must be used instead and as a result enforcement will be less effective. For example, there will be incidences where the breach is not sufficiently serious to warrant closing the provider down, but strong enforcement action is still required to hold the provider to account and create a deterrent for others. In other cases, the breach may be so serious that it is felt appropriate to both close the provider down and to prosecute them, so that they are publically held to account for their actions. For CQC regulation to be effective, CQC must have available its full suite of enforcement and regulatory powers.

9. As a result, we wish to make the regulations sufficiently precise to enable a person to judge what must be done to avoid committing an offence so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed, allowing CQC to prosecute quickly and effectively whenever it is necessary.

10. In addition unclear regulations may also have an impact on providers, as they will require additional time to understand and interpret the intention of the requirements and to determine what must be done to avoid prosecution. Revisions to the requirements that make it easier for providers to understand and interpret would also help to reduce the burden of regulation.

Relationship to the Francis recommendations:

11. The report of the Public Inquiry into the role of the commissioning, supervisory and regulatory bodies in the monitoring of the Mid-Staffordshire NHS Foundation Trust from January 2005 to March 2009 criticised the CQC registration requirements for lacking in clarity for providers, being overly bureaucratic and failing to reflect the seriousness of breaches and separate out the essential from the desirable requirements. The report recommended there should be a set of fundamental standards of care that clearly set out the standards below which it would be unacceptable to fall, where providers could expect stronger and swifter enforcement action.

12. The changes to the regulations discussed above are expected to also help to address these criticisms and enable the above recommendation to be met. The more precise registration requirements, when combined with the guidance CQC will issue, will increase clarity for providers on what they must do to comply with the regulations, and CQC will be able to take stronger enforcement action via increased prosecutions where appropriate to better reflect the seriousness of breaches. These changes will enable us to define through a combination of regulations and guidance, what the fundamental standards of care are in each setting, and what enforcement will result from a breach of these standards.

The case for government intervention:

13. Asymmetry of information between health and social care providers and consumers, and the potential incentives for providers to provide sub-optimal care means that there may be market failure that could be addressed by independent regulation. Regulation of health and social care is a public good, and as such the market does not always naturally provide it. Government intervention was thus necessary in this area to ensure that all providers meet the essential standards of care and safety. Further intervention is required to address the unintended consequences of the previous regulation and to improve the clarity of the regulations so that it easier for providers to understand what is required of them. This will enable CQC to take stronger enforcement action where appropriate and better reflect the seriousness of the requirements, which will increase the effectiveness of regulation and allow providers to be better held to account for their failings.

Section B: Policy objectives and intended effects

14. The objective of the policy is to ensure that CQC regulation is as effective as possible, so that risks to service users are better managed and the quality of care is improved. The registration requirements will be revised to make them sufficiently precise, removing the requirement for CQC to issue a warning notice before bringing a prosecution. CQC will be able take stronger enforcement action via prosecutions to better hold providers to account for their failings where appropriate. These changes to the regulations will enable us to define, through a combination of regulations and guidance, what the fundamentals standards of care are in each setting, in line with the recommendations of the Francis Inquiry.

15. Removing the requirement for CQC to issue a warning notice before bringing a prosecution is intended to make it possible for CQC to take stronger and more appropriate enforcement action where necessary. CQC will be able to better reflect the relative severity of different types of breaches of the registration requirements and better hold providers to account for serious failings. By making prosecution a more realistic prospect for providers, the range of enforcement tools available to CQC will increase allowing enforcement to be more proportionate, better targeted and therefore more effective. The threat of additional or stronger enforcement action will create a stronger deterrent effect for providers against breaching the registration requirements, and thus the overall level of compliance would be expected to increase, leading to overall improvements in the quality of care and levels of safety for users of health and adult social care services.

16. Additionally, by making the registration requirements fewer and more precise and the regulatory intention clearer, this could also make it easier for providers to understand what is required of them by the regulations and to judge whether or not they are compliant with the requirements. This would reduce the burden of regulation on providers. Improvements in providers' understanding of what is required may also improve their ability to deliver, leading to an improvement in the quality of care for service users.

17. Once the requirements are more precise, CQC will be able to use their full range of enforcement powers when breaches occur. CQC can define in guidance the things they will look for when checking whether care has fallen too low, what constitutes a breach of the fundamental standards and the regulatory consequences providers should expect. Taken together, these changes will meet the Francis recommendation that there should be a set of fundamental standards of care below which care should never fall, with the law allowing for a zero tolerance approach to be taken for non-compliance against these standards. As described above, the intended effect is to increase the effectiveness of regulation and provide better safeguards against poor quality care for service users by making it clearer to provider the standards they must achieve, and increasing the deterrents against not meeting these standards.

Section C: Description of the options

Option 1: do nothing

18. The current 16 registration requirements would remain as they are and CQC would still be required to first issue warning notices for any breach of the registration requirements before a prosecution can be brought.

19. Although prosecution is not the only form of enforcement action available to CQC, there are many instances where prosecution would be the most appropriate form of action for CQC to take. By making it difficult in practice for CQC to prosecute, a less appropriate form of enforcement must be used instead and as a result enforcement will be less effective. For example, there will be incidences where the breach is not sufficiently serious to warrant closing the provider down, but strong enforcement action is still required to hold the provider to account and create a deterrent for others. For some types of providers, the impact on service users of closing the provider down would be too great for this to be a viable action for CQC to take even in the case of serious failings (for example a large hospital), and it is important that in these cases CQC has an alternative avenue of strong enforcement action available. In other cases, the breach may be so serious that it is felt appropriate to both close the provider down and to prosecute them, so that they are publically held to account for their actions.

Option 2: Revise and simplify the registration requirements so that the warning notice requirement can be removed

20. Under this option, the existing requirements will be revised to ensure that they are sufficiently precise to enable a person to understand what is required of them and to judge what must be done to avoid committing an offence so that the requirement for CQC to issue a warning notice before bringing a prosecution is removed. No other options have been considered, as it is not possible to remove the warning notice requirement other than by making changes to clarify the regulations and satisfy the JCSI's criticisms.

21. In practical terms, this means redrafting the regulations so that the outcome we want to achieve or avoid is clearly stated in simple language, and the intention is clear. The consultation to which this impact assessment relates will allow us to test and refine the clarity and precision of our new drafting.

22. The key issue that the JCSI identified was that, although the intention of the regulations was to allow for providers to be prosecuted where there is a clear failure to protect service users from the risk that is the focus of each registration requirement, the drafting of the registration requirements did not always fully reflect this and the overall intention and focus of the requirement was not always clear. Thus it was not clear to a service provider whether their actions would mean that they were in breach of the registration requirements and at risk of prosecution or not.

23. For example, the example that the JCSI gave was for the requirement to meet nutritional needs. Here, although the intention of the requirement is such that a provider should expect to be prosecuted for failing to comply with the regulation if there is a clear risk that service users could be inadequately nourished, the regulations also contained a number of additional specifications which would technically also result in a breach of the regulation, but do not reflect the intention of the requirement. For example, as the regulation states that there must be a choice of suitable food to meet service users' needs, this means that a provider would appear to be committing an offence when the provider ensures that all service users are adequately nourished without proving a choice of food.

24. This issue is addressed as follows. The registration requirements will be revised to ensure that the overall focus and intent of the requirement is clearly stated in simple language. For most requirements, there will be a number of things that providers may need to consider when delivering that requirement. But since these additional things would not in themselves be things a legal duty to carry out, there is no advantage to specifying them in the regulations. However, as it is also important for CQC to be able to take action where care is slipping, but where standard is not yet breached, we intend that each requirement is accompanied by a simple clause that requires providers to take appropriate steps relating to meeting the outcome (i.e. so they don't just meet the requirement through accident or luck). It will be for CQC's Guidance about Compliance to provide that additional level of detail of what steps they consider to be suitable.

25. In the nutrition example shown below, the proposed draft revision will make it immediately obvious to providers that the intention of the requirement is to ensure that the nutritional needs of service users are met. The important actions providers should have regard for in order to meet this requirement would be covered in CQC guidance (which will itself be subject to consultation once developed). This makes it clear that a breach of the requirement occurs when the overall intention of the regulation is breached, rather than any specific action.

<table>
<tr><th>Current regulation</th><th>Example revised regulation</th></tr>
<tr><td rowspan="2">Meeting nutritional needs
(1) Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of—
(a) a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
(b) food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
(c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
(2) For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.</td><td>Meeting nutritional needs
(1) The nutritional needs of service users must be met.
(2) The provider must take steps to ensure that users' nutritional needs are understood and can be met [or similar wording]</td></tr>
<tr><td>Example associated CQC guidance
In so meeting service users nutritional needs, the registered person must have particular regard to the need to—
(a) provide suitable and nutritious food and hydration in sufficient quantity,
(b) meet any reasonable requirements arising from a service user's religious or cultural background, and
(c) where necessary, support service users to eat and drink.</td></tr>
</table>

26. These changes should enable us to make a strong case to remove the legal requirement for CQC to issue a warning notice before they can bring about a prosecution, which would allow CQC to take stronger and more appropriate enforcement action where necessary.

27. Additionally, the regulations will be rationalised so that there are fewer in number and simpler to understand. This will make it clearer to providers what the key requirements are that must be met. Removing the specification of any specific actions that providers need to achieve will make the regulations less prescriptive. Although the scope of the outcomes that providers are expected to achieve is unchanged, providers may have more freedom in how they go about achieving these outcomes and it will no longer be necessary for providers to provide evidence that they are meeting each of the specific actions. It is expected that this will help to reduce the burden of regulation on providers and we will test this at consultation.

28. Although there will be no change in the scope of the requirements on providers, the revision and rationalisation of the existing regulations may lead to the creation of new requirements in legislation in order to better bring out the most important concepts that providers must take account of. For example, although the current regulations include the need to ensure that care is person-centred, this is covered within the body of a number of regulations, rather than as an important requirement in its own right. There is a risk that the new, simplified approach as outlined above would mean that this requirement would be lost if further rationalisations to the requirements are not made.

29. Overall, these changes to the regulations will allow us to better define what is fundamental to providing good care. Once the requirements are more precise, CQC will be able to use their full range of enforcement powers when breaches occur. CQC can define in guidance the things they will look for when checking whether care has fallen too low, what constitutes a breach of the fundamental standards and the regulatory consequences providers should expect. Taken together,

these changes will meet the Francis recommendation that there should be a set of fundamental standards of care below which care should never fall, with the law allowing for a zero tolerance approach to be taken for non-compliance against these standards.

30. In addition to this, CQC will also be making separate changes to how they will monitor, inspect and enforce against these newly cast registration requirements as part of their response to the recommendations of the Francis Inquiry. For example, CQC intend to issue ratings to providers which will in part be based on how well they meet these requirements, and also to adopt a more proportionate approach to inspections, meaning that providers who receive a higher rating are inspected less frequently. These changes will also impact upon the regulatory burden on providers from the regulations, and the level of enforcement activity taken against the new standards. This impact assessment will only consider the impacts of the proposed review of registration requirements, but it should be noted that the changes also underpin the wider regulatory model CQC are developing. CQC will undertake separate impact assessments of its own planned changes to its regulatory model.

Section D: Costs and benefits assessment of the options (including specific impacts)

Costs:

Costs of compliance with revised regulations:

31. Removing the requirement for CQC to issue a warning notice before bringing a prosecution is intended to make it easier for CQC to prosecute providers where appropriate. By making prosecution a more realistic prospect for providers, this is likely to create a stronger deterrent effect against non-compliance with the regulations, thus incentivising providers to take further action to ensure that they are compliant with the regulations and improve the quality of care provided. Clarifying the regulations to ensure that the overall focus and intent of the requirement is clearly stated could also have similar effects, as providers will be better able to recognise whether they are compliant with the regulations, enabling them to take further action if this is not the case.

32. Where providers are currently not meeting the requirements, this increased activity does not constitute an additional burden on providers as there is already an expectation on providers to take the necessary action to meet the requirements. Enabling CQC to take stronger enforcement action is only intended to strengthen the incentives on providers to meet the standards. Although we will rationalise and reduce the number of registration requirements, we do not expect that this will change the scope of the requirements that providers are expected to meet.

33. For providers who currently do meet the required standards, there is a risk that by strengthening the deterrent effect on providers there are unintended consequences, with providers going above and beyond and taking unnecessary additional action to ensure that they are compliant with the regulations. This risk will be mitigated by the fact that registration requirements will be revised and rationalised to make them clearer and more precise so that providers are better able to judge what must be done to avoid prosecution.

34. Additionally, there is a risk that, by revising the regulations, this could unintentionally introduce additional burdens or complexities into the requirements for providers, thus increasing the costs of complying with the regulations for providers. These risks will be mitigated via the consultation process by allowing providers to give feedback on the draft regulations to ensure that they are easy for providers to understand and that all potential for unintended consequences is properly considered and mitigated against.

35. Finally, there may be some transitional costs associated with providers taking time to read and familiarise themselves with the revised set of regulations. We assume that approximately half a day of manager time would be required for providers to read, absorb, discuss and communicate the revised requirements to staff. Depending on the size and complexity of the organisation and scope of regulated activities covered, the time requirement could be significantly higher, for example at a large hospital trust with large numbers of staff and complex management systems covering a wide variety of regulated activities, the time required to absorb and understand what the implications of the revised requirements might be for the organisation could alone take a couple of days and require input from multiple individuals. On the other hand, a small dental surgery with only a handful of staff might only require a couple of hours to read, understand and discuss with staff the implications of

the revised requirements and introduction of the fundamental standards. Our half day assumption might therefore mask considerable variation between different providers. Based on data from the Annual Survey of Hours and Earnings (ASHE) 2012, the median gross hourly wage for Corporate Managers and Directors was £26 (including 30% on costs). Across the 30,000 providers regulated by CQC, the total transitional cost of familiarisation with the revised requirements is estimated to be approximately £3.15m.

36. There is also an expectation that providers would take the opportunity to review their activities and actions to assess whether the requirements are still being met in the best way and what can be done to improve. Responses from CQC's consultation on the principles of the Fundamental Standards suggested that some providers would also wish to change their systems to be better aligned to proving compliance against the revised regulations (e.g. changes to the data they collect). It has not been possible to quantify these costs due to the large degree of variation that is likely to exist between what different providers choose to do, and the costs arising.

37. CQC categorise providers under the following six broad sectors: NHS trusts, GPs, Dentists, independent healthcare organisations, independent ambulance providers, and adult social care providers. Following BIS convention, we consider NHS trusts, GPs and dentists as public sector organisations. Data from 31st March 2010 (under CSA care sector) on providers by ownership type in the adult social suggests that approximately 90% of adult social care providers are voluntary or private organisations. For independent healthcare and independent ambulance service providers, we assume that all providers are private or voluntary sector organisations since the other major ownership type identified for social care services was local authorities, which is not likely to be applicable for these remaining organisation types. This suggests that of the 30,000 providers registered by CQC approximately 13,000 are private or voluntary organisations, whilst the remaining 17,000 are public. Thus the total transitional cost of familiarisation with the revised requirements falling on private or voluntary organisations is estimated to be roughly £1.35m.

Costs of monitoring and inspecting against the revised regulations:

38. CQC monitor and inspect providers against the registration requirements set out in the regulations. Overall, it is felt that it is unlikely that the revised regulations will have a significant effect on CQC's costs, independent of the other changes that CQC is planning to make to its regulatory model. For example, the cost of inspecting a provider will be determined by the frequency, duration and staff involved in the inspection. As the revised registration requirements make no changes to the scope of the requirements placed on providers, there should be no impact for CQC in terms of what is examined during an inspection, and thus no cost implication.

39. In fact, as the policy intention is to revise the registration requirements is to make them clearer, it could be argued that this will make it easier for CQC to determine whether a provider is compliant with the regulations, and thus there would be a reduction in the costs of monitoring and inspecting providers. However, these effects are likely to be small because the process of coming to a judgement about compliance is likely to be a very small part of the whole inspection and it will be difficult to unravel these aspects from the other inspection activities.

40. CQC will experience transitional costs associated with producing new guidance to inform and explain to providers how the registration requirements have been revised, and how CQC's enforcement action might change as a result. CQC estimate that the average cost of producing additional guidance is approximately £4,000 based on an assumption that, on average, guidance requires 3 days to prepare, 2 days to review, 2 days for quality assurance, 2 days for sign-off and 5 days to publish, with a daily staff rate of £277, which includes on-costs and absorbed overheads. This estimate is an average across all types of guidance CQC produce, and does not take into account the differing time requirements that there might be for producing guidance of different lengths or complexity.

Cost of additional prosecutions:

41. Removing the requirement for CQC to issue a warning notice before bringing a prosecution is intended to make it easier for CQC to prosecute providers where appropriate. This is expected to increase the number of prosecutions that CQC will bring against providers. In the long run, it is possible that by making prosecution a more realistic prospect for providers, this is creates a stronger deterrent effect against non-compliance, and so less actual enforcement activity (including prosecutions) is necessary. It has not been possible at this stage to model these potential long run

effects on compliance and so our estimates of the potential costs of increased prosecutions based on current patterns of compliance only.

42. Data on the total enforcement action undertaken by CQC in 2012 showed that there were approximately 1100 cases of enforcement action in total, of which 94% did not progress beyond a warning notice and only 1 case led to CQC bringing about a prosecution against a provider. As CQC would only decide to bring about a prosecution in the case of a serious breach of the registration requirements where there are significant risks to the health and safety of service users, we use the number of cases of enforcement action where an urgent condition was placed on the provider, or the provider's registration was suspended or cancelled as a proxy for the possible number of cases of additional prosecution action. This gives a total of 15 possible additional prosecution cases that might have been brought had the warning notice requirement not been in place.

43. Additional prosecutions will have cost implications for CQC, providers and the Justice system. CQC has the power to prosecute providers for a breach of the registration requirements under regulation 27 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. This is a summary offence liable for prosecution in the Magistrates Courts only, with a maximum penalty of a fine of £50,000 (which is set to become unlimited with the powers granted in the Legal Aid, Sentencing and Punishment of Offenders Act 2012).

44. Ministry of Justice (MOJ) data suggests that the average cost to the HM Courts and Tribunals Service (HMCTS) of a summary non motoring offence is £380 in 2011/12 prices. Uprating this to 2012/13 prices using the latest GDP deflator figures as at June 2013 gives an estimate of £386 in 2012/13 prices.

45. It is difficult to cost CQC enforcement activity as enforcement activity cuts across many CQC functions and requires input from various different departments and staff. As a result, the costs of enforcement activity by CQC are difficult to disentangle. Based on details from a recent case that ended in a tribunal, CQC estimate that the costs of prosecuting a provider could be as high as £21,000, although it is not clear how representative this particular case might be of a 'typical' case.

46. In the absence of any information on the costs of defending a prosecution on the provider, we assume that they will incur similar costs to CQC.

47. As legal aid would generally not be available for companies, it is not expected that an increase in prosecutions of providers by CQC would have any cost implications for this. Similarly there are not expected to be any custodial or probation costs, as the penalty for the offence is a fine only. As a fine would be a transfer payment, it is not considered an economic cost, and so we do not take these costs into account.

48. Overall, we estimate that if the patterns of compliance continue as they are currently, there would be approximately 15 additional prosecution cases per year, creating an additional cost for HMCTS of approximately £6,000, and of £315,000 on CQC and providers. However, in reality the patterns of compliance are likely to change in both the short and long run, as outlined below, so that the number of additional prosecutions, and hence costs, could be both lower or higher than currently estimated. It is not possible at this stage to model what these changes in compliance might look like.

Costs associated with other changes to enforcement:

49. As discussed above, revising the regulations to make them clearer might also mean that it becomes easier for both providers and CQC to recognise whether a provider is compliant with the requirements. Consequently, it could be the case that more instances of non-compliance are identified and so more enforcement action is taken by CQC as a result. However, in the longer run, this increased risk of detection coupled with the increased risk of prosecution might better incentivise providers to be compliant with the regulations and so reduce the need for enforcement action. At this stage it has not been possible to model what this change in the patterns of compliance and enforcement action might look like and so the total costs associated with these changes cannot be quantified.

50. Any change in compliance will affect the level of enforcement activity required by CQC. While it is not possible to know the nature of the enforcement activity that is likely to be affected, we can get a sense of the potential scale of the impact by examining current patterns of CQC enforcement activity. As discussed above, it is very difficult to accurate cost enforcement action. CQC advise that the budget for legal fees is £800,000 per annum and that approximately 75% of this might be related

to enforcement activity. Based on this fairly basic measure of total enforcement costs, and using the fact that there were approximately 1100 cases involving some enforcement activity by CQC in 2012, we estimate that the average cost of an additional case of enforcement activity could be in the region of £550.

51. Additionally, as providers have the right to appeal against any conditions CQC places on its registration to the Health and Social Chamber of the First-Tier Tribunal, changes in the patterns of compliance might also have additional cost implications for society. For example, if it is the case that a constant proportion of enforcement cases are appealed against, any increase in the number of enforcement cases would also lead to an increase in the number of appeals. Additional appeals will have cost implications for CQC, providers and the Justice system.

52. In terms of the costs to the justice system, the HMCTS 2012/13 Annual Report suggests average staff and judicial costs per sitting day are £1060 (£722 judiciary, £338 staff). This is an average for all tribunals not specific to Care Standards. Based on information from the Annual Tribunal Statistics published by the Ministry of Justice for 2012-13 on the number of sitting days for the Care Standards Tribunal (209) and the number of receipts and disposals (75 and 82 respectively) the average number of sitting days per case was calculated to be between 2.5 and 2.8. Overall, this suggests that the costs to HMCTS are approximately £3,000 per Care Standards Tribunal.

53. Based on details from a recent case that ended in a tribunal, CQC estimate that the costs of responding to an appeal could be as high as £45,000, although it is not clear how representative this particular case might be of a 'typical' case. This particular case was heard twice in court and CQC had to instruct a barrister rather than a solicitor so the day rates are likely to have been higher. Consequently, these costs should be treated as an estimate of the worst case scenario tribunal costs rather than a representation of the average costs. It has not been possible to provide a more accurate estimate of the costs to CQC of a tribunal at this stage, although work is on-going with CQC to better understand their costs.

54. In the absence of other information, we assume that the provider would face similar costs in bringing about their appeal.

55. While these costs give an indication of the potential impacts of changing patterns of compliance and enforcement, they cannot be quantified any further as we do not know how compliance might change as a result of the proposed policy.

Costs - summary:

56. The costs are summarised in the table below:

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
£('000)s	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	
Description of Costs	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**
Transitional costs: Provider	3,150	-	-	-	-	-	-	-	-	-	3,150
Additional costs: Provider	UNQUANTIFIED										
Monitoring and inspection costs: CQC	Low										Low
Transitional costs: CQC	4	-	-	-	-	-	-	-	-	-	4
Additional prosecutions: CQC	315	315	315	315	315	315	315	315	315	315	3,150
Additional prosecutions: Provider	315	315	315	315	315	315	315	315	315	315	3,150
Additional prosecutions: HMCTS	6	6	6	6	6	6	6	6	6	6	58
Other changes in enforcement action	UNQUANTIFIED										
Total cost (undiscounted)	3,750	635	635	635	635	635	635	635	635	635	9,500
Discount adjustment	1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)	3,750	615	590	570	550	530	515	495	480	460	8,600

NB: figures may not sum due to rounding

Benefits:

57. The objective of the policy is to ensure that CQC regulation is as effective as possible, so that risks to service users are clearly identified and the quality of care is improved. Removing the requirement for CQC to issue a warning notice before bringing a prosecution will make it easier for CQC to prosecute providers where necessary, so that CQC will be able to better reflect the relative severity of different types of breaches of the registration requirements and better hold providers to account for serious failings. By making prosecution a more realistic prospect for providers, this will create a

stronger deterrent effect for providers against breaching the registration requirements, and thus increasing the level compliance and leading to overall improvements in the quality of care.

58. Additionally, by making the registration requirements more precise, the regulatory intention clearer, and rationalising and reducing the number of regulations, this may also make it easier for providers to understand what is required of them by the regulations and to judge whether or not they are compliant with the requirements. This would reduce the burden of regulation on providers. Improvements in providers' understanding of what is required may also improve their ability to deliver, leading to an improvement in the quality of care for service users.

59. Although it has not been possible to quantify these benefits, the qualitative basis of them is set out below.

Increased accountability:

60. By enabling CQC to take stronger enforcement action where they feel it is appropriate via increased prosecutions, providers can be better held to account for their actions where the commit serious breaches of the requirements. Although prosecution is not the only form of enforcement action available to CQC, there are many instances where prosecution would be the most appropriate form of action for CQC to take. For example, there will be incidences where the breach is not sufficiently serious to warrant closing the provider down, but strong enforcement action is still required to hold the provider to account and create a deterrent for others. Enabling CQC to bring a prosecution against the provider will ensure that the most appropriate enforcement action is taken to reflect the seriousness of the breach and sufficiently hold providers to account for their actions

61. In other cases, breaches may be so serious that it is felt appropriate to both close the provider down and to prosecute them, so that they are publically held to account for their actions.

62. This increase in accountability is a benefit to society as it ensures that providers face the full consequences of their actions. It is not possible to quantify this benefit.

Increased quality of care:

63. By making prosecution a more realistic prospect for providers, we expect that this will create a stronger deterrent effect for providers against breaching the registration requirements, and thus increase the overall level compliance with the regulations across providers. Clarifying the regulations to ensure that the overall focus and intent of the requirement is clearly stated could also have similar effects, as providers will be better able to recognise whether they are compliant with the regulations, enabling them to take further action if this is not the case. Overall this is expected to increase the quality of care so that users of health and social care services are better protected against the risks of poor quality or unsafe care. It is not possible to quantify the impact of this as it is not possible to predict what the level of increased compliance might be. The resultant impact on health outcomes would depend greatly on the size and the level of risk associated with the regulated activities carried out by the organisation.

64. To provide an illustrative guide on the potential size of these benefits, we can calculate the impact of a small change in health outcomes using the EQ-5D framework for calculating health states[1]. This framework asks individuals to rate their health from 1 to 3 in five different domains, including the experience of pain, mobility and anxiety. A score of 1 means the individual has no problems whereas a response of 3 indicates serious or severe problems. These scores can then be turned into a health state by assigning values to each of the possible combination of scores and converted into a Quality Adjusted Life Year (QALY) [2] by also considering the duration of the health state. Based on this methodology, any move away from perfect health in any of the five domains leads to a reduction in an individual's health state of at least 0.155 points. Thus if one service user is able to avoid one month's worth of less than perfect health due to poor quality care, there would be a 0.013 QALY gain.

[1] As developed by the EuroQol Group. Please see Appendix 4 of the supplementary Green Book guidance for more information. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/191503/policy_appraisal_and_health.pdf

[2] The QALY approach weights life years (saved or lost) by the quality of life experienced in those years. Years of good health are more desirable than years of poor health. A value of 1 is equivalent to one additional year of perfect health. Please see Appendix 4 of the supplementary Green Book guidance for more information.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/191503/policy_appraisal_and_health.pdf

65. Based on data on the enforcement action CQC took in 2012, 4% of the 28,414 providers inspected were found to be non-compliant and required enforcement action. Assuming that half of these would make some minimal changes leading to the modest improvements described above in response to the threat of stronger enforcement action being taken against them, this would lead to a total QALY gain of 7.3. Based on a societal willingness to pay of £60,000 per QALY, the total societal value of this modest change in health outcomes would be just under £0.5m. If an additional 5% of compliant providers also made changes to their systems to better achieve the outcomes intended by the requirements, resulting in the same modest health improvements at each provider as described above, there would be a further £1.2m worth of benefits for society. The more dramatic the change in the quality and safety of care, and the more providers who exhibit this behaviour change, the higher the societal benefits will be.

The burden of regulation on providers:

66. The revised regulations will clearly set out in law what outcome providers must achieve so that the intention of each regulation is clearer. This might mean that providers do not need to spend as much time to understand and interpret what the regulations mean. For example, in some cases the existing regulations can contain a list of specific actions that are only applicable for certain providers and situations. Providers might spend significant time determining which specific actions would be applicable to them. Additionally, as criticised by the JCSI, providers could find it unclear what actions or requirements would put the provider at risk prosecution and so spend additional time to try to clarify or determine this. The removal of the specification of any specific actions that providers need to achieve will make the regulations less prescriptive. Although the scope of the outcomes that providers are expected to achieve is unchanged, providers may have more freedom in how they go about achieving these outcomes and it will no longer be necessary for providers to provide evidence that they are meeting each of the specific actions.

67. However, it is difficult to quantify what this cost saving might be as it is not possible to predict exactly how the revised regulations might cause or allow providers to change their behaviour. For example it is not clear how much time providers currently spend understanding the regulations and thus what the size of the burden placed by the current drafting is. The potential scope for a reduction in this burden is likely to depend on the final drafting of the regulations and this is something that can only be tested at consultation. Similarly, removing the requirements for specific actions to be taken in the regulations could lead to a varied response amongst providers. Some providers may be able to identify fundamentally different ways that they meet the standard, whilst others may not make any changes at all. The consultation process will allow us to test whether the revised regulations meet the policy aims and gather evidence on the likely size of the impacts.

68. In addition, further work is underway which will help to provide more evidence on the impacts of regulation on providers. CQC have already begun a project to establish the effect the current regulations have on private and third sector providers in terms of costs/benefits. This work will provide a benchmark against which the changes discussed in this impact assessment can be measured. The work is scheduled to finish in Q1 of 2014/15. We intend to reassess and evaluate the impact of this policy change in future, once the changes are embedded in the system, and with the benefit of this additional source of evidence.

69. Although it is not possible to determine the likely size of the benefits at this stage, initial investigations suggest that, even under very modest assumptions, the cost savings arising to businesses are likely to outweigh the costs to businesses associated with the policy. It is for this reason that we can be confident that the proposed policy is likely to lead to an overall reduction in the burden of regulation for businesses, even if the true size of the benefit is yet to be determined. Below we provide three possible illustrations for how this might come about.

70. As the revised regulations are intended to make it clearer for providers to understand the intention of each regulation, we expect that providers are likely to need to spend less time to understand and interpret what the regulations mean (although we expect that providers will still need to spend time thinking about *how* to meet the regulations). The most significant cost saving would be to new entrants who would be looking at the regulations for the first time, but it is likely that all providers will need to revisit the regulations over time as the scope and nature of their services change, and to continually assess their compliance against the regulations. Of the 30,000 providers currently registered with CQC, approximately 1,750 were newly registered organisations in 2012 (excluding GPs and dentists, as these providers were newly brought into scope around this time). Assuming

that a newly registering provider could saving one hour of a manager's time from having simpler regulations, and an existing provider might saving 20 minutes, and costing this based on the gross hourly wage for Corporate Managers and Directors of £26 (including 30% on costs) from ASHE, this implies a total cost saving of approximately £290,000 per year. Focusing only on private and third sector providers only, approximately 1,600 of the 13,000 CQC registered providers were newly registered in 2012, giving a total cost saving of £140,000 per year under the same assumptions. Evaluated over the ten year appraisal period, this figure is just shy of balancing the one off familiarisation costs to business we have identified, so that the equivalent annual net cost to business is calculated to be is only £14,000.

71. An alternative source of cost savings resulting from simpler regulations might be a saving in the time required to train new staff members about the regulations and what they must do if the regulations are easier to understand and explain. Rough estimates based on the 2012 NHS Staff Census and the 2012 Skills for Care report indicate that there are approximately 1.2m NHS staff and 1.5m people working in adult social care respectively. We assume a 12% rate of labour turnover (from a 2013 survey of recruitment and retention carried out by the Chartered Institute of Personnel and Development), and that 5 minutes of time might be saved per new member of staff with an associated average cost saving of £15 per hour based on the median gross hourly wage for Human Health and Social Care Activities under the Standard Industrial Classification (SIC2007) in ASHE (30% on costs). This implies a total cost saving of roughly £410,000 per year or £230,000 for private or third sector businesses only (making the rough assumption that the social care sector represents the private sector as a whole, as workforce estimates for the independent healthcare sector do not readily exist). Evaluated over the ten year appraisal period, this figure balances the one off familiarisation costs to business we have identified, so that the equivalent annual net cost to business is calculated to be a £55,000 cost saving.

72. Finally, for the purposes of complying with the regulations, providers now would only need to demonstrate that they have taken effective steps to achieve the outcome. They will no longer need to provide evidence for each of the specific actions currently listed under the regulations to avoid prosecution. This might lead to a cost saving in terms of the time required to prepare for and facilitate an inspection by CQC. Previous estimates made by the Department of the time required for providers to prepare for an inspection for the Department's Strategic Audit of Regulation, suggested that providers might be spending up to 20 hours to prepare for and facilitate an inspection. If the proposed policy were to lead to a reduction in manager time required to prepare for an inspection of half an hour, then based on the gross hourly wage for Corporate Managers and Directors of £26 (including 30% on costs) from ASHE, this implies a total cost saving of £390,000 per year, or £170,000 for private and third sector providers only. Evaluated over the ten year appraisal period, this figure balances the one off familiarisation costs to business we have identified, so that the equivalent annual net cost to business is calculated to be a £9,000 cost saving.

73. Overall, as it is possible to identify various scenarios resulting in cost savings that at least outweigh the costs to business under very conservative assumptions, we can be confident that the cost savings of the proposal are likely to outweigh the costs imposed on business by the proposal, even if we are less confident on the actual size of the cost savings. As our best estimate of the potential cost saving at this stage, we assume that, as the three scenarios identified above are not mutually exclusive, they could all occur, giving a total cost saving of £0.5m per year. However there is a large degree of uncertainty attached to this estimate at this stage, and we will seek more evidence from the consultation to provide a more robust estimate of the potential cost savings for the next stage.

74. Another potential benefit which may indirectly derive from this change to regulation is that it may help to reduce the burden on providers caused by the fact that local authorities sometimes duplicate CQC inspections and information requests. In evidence supplied to the Red Tape Challenge and the Focus on Enforcements it has been estimated that Local Authority duplication CQC activity resulted in approximately £30 million of additional burdens just in the Care Homes sector- the main reason for this duplication is that Local Authorities lack confidence in CQCs judgements, so seek to make their own.

75. There are a number of steps CQC are taking to ensure that local authorities have confidence in their model. The additional clarity provided by these regulations will also contribute by allowing CQC to make clearer judgements about quality of care, which should reduce the need for local authorities to duplicate CQCs work. However, it is not possible to quantify the amount by which these changes will contribute to that reduction in duplication.

Other steps to reduce the burden of regulation:

76. In addition to the changes above, we are constantly making further efforts to refine the regulations and to reduce the burden of CQC regulation for providers. We carried out an initial review of these regulations in 2010 and following this made a number of amendments in 2012.These amendments led to a equivalent annual net reduction in regulatory burden for private providers of around £0.42m.

77. We have identified further changes that we wish to make to the regulations, which are likely to further reduce the overall burden on providers. These changes include the possibility of removing some kinds of provider from the scope of the regulation, and making other changes to strengthen the regulations. Following the changes we are making to the regulations in response to the Francis Inquiry recommendations, we will consult of these proposals in due course.

Value for money:

78. The table below shows the profile of the net present value of identified impacts over a 10 year period. All figures are based on assumptions and should be treated as such, however this represents our best understanding of the likely impacts:

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
£('000)s	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	
Description of Costs	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**
Transitional costs: Provider	3,150	-	-	-	-	-	-	-	-	-	3,150
Additional costs: Provider	UNQUANTIFIED										
Monitoring and inspection costs: CQC	Low										Low
Transitional costs: CQC	4	-	-	-	-	-	-	-	-	-	4
Additional prosecutions: CQC	315	315	315	315	315	315	315	315	315	315	3,150
Additional prosecutions: Provider	315	315	315	315	315	315	315	315	315	315	3,150
Additional prosecutions: HMCTS	6	6	6	6	6	6	6	6	6	6	58
Other changes in enforcement action	UNQUANTIFIED										
Total cost (undiscounted)	3,750	635	635	635	635	635	635	635	635	635	9,500
Discount adjustment	1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)	3,750	615	590	570	550	530	515	495	480	460	8,600
Description of Benefits											
Increased accountability of providers	UNQUANTIFIED										
Improvements in care quality	UNQUANTIFIED										
Reduced regulatory burden	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	10,950
Total benefit (undiscounted)	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	1,100	10,950
Discount adjustment	1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Benefit (discounted)	1,100	1,050	1,000	980	950	915	880	850	820	795	9,350
Net Present Value	- 2,681	480	500	520	540	560	580	595	615	630	2,350

NB: figures may not sum due to rounding

79. The table below reflects the direct impacts to businesses only. The figures are presented in 2009 prices and the present value base year is 2010/11 as required for the One In Two Out initiative. Similarly the costs associated with non-compliance with the regulation are excluded.

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year		
£('000)s	0	1	2	3	4	5	6	7	8	9	10	11	12	13		
Description of Costs/Benefits	**2010/11**	**2011/12**	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**	**EANCB**
Transitional costs: Provider					1,350	-	-	-	-	-	-	-	-	-	1,350	
Deflated to 2009 prices					1,250	-	-	-	-	-	-	-	-	-	1,250	
Additional costs: Provider					UNQUANTIFIED											
Additional prosecutions: Provider					Zero as assume 100% compliance											
Total cost (undiscounted)					1,250	-	-	-	-	-	-	-	-	-	1,250	
Reduced regulatory burden					540	540	540	540	540	540	540	540	540	540	5,400	
Deflated to 2009 prices					505	505	505	505	505	505	505	505	505	505	5,050	
Total benefit (undiscounted)					505	505	505	505	505	505	505	505	505	505	5,050	
Discount adjustment	1	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	0.70	0.68	0.65	0.63		
Total Present Cost (discounted)					665	- 420	- 405	- 390	- 380	- 365	- 350	- 340	- 330	- 315	- 2,650	- 305

NB: figures may not sum due to rounding

80. The main costs of the proposed policy are the costs associated with the potential increase in the number of prosecutions. This cost is expected to remain low due to the relatively small number of serious breaches that we would expect to occur based on current patterns of compliance. Although we expect that the proposed policy are likely to have additional impacts on the patterns of compliance, and hence enforcement activity, it has not been able to model and quantify these impacts, although they are outlined above. Our expectation is that the clearer regulations would make it easier for CQC to identify where a breach occurs, which could lead to increased

enforcement action. In the long run the deterrent effect on providers of an increased risk of prosecutions might lead to increased compliance and so a reduction in enforcement action.

81. There may also be some transitional costs on providers, which it has not been possible to quantify and there also remains the risk that there could be additional cost burdens on providers due to any unintended consequences arising from the revised regulations.

82. We provide some additional sensitivity testing on the cost estimates based on different scenarios as follows:

    - If the number of prosecutions required increases by a further 5 per year, the overall net present value for society would fall to £0.5m, although there would be no effect on the EANCB.
    - If enforcement activity were to increase by 10% a year, the overall net present value for society would fall to £1.8m, although there would be no effect on the EANCB. These cost estimates do not include any impact on HMCTS as it is not possible to determine how changing enforcement activity might affect the number of appeals made.
    - If enforcement activity were to reduce by 10% a year, the overall net present value for society would increase to £2.9m, although there would be no effect on the EANCB. These cost estimates do not include any impact on HMCTS as it is not possible to determine how changing enforcement activity might affect the number of appeals made.
    - If enforcement activity is 10% higher for the first 2 years and then 10% lower for the remaining 8 years, the overall net present value for society would increase to £2.6m, although there would be no effect on the EANCB. These cost estimates do not include any impact on HMCTS as it is not possible to determine how changing enforcement activity might affect the number of appeals made.
    - If unintended consequences that required 1 extra hour of a mangers time per year (costed at £26 per hour) occurred, the overall net present value to society would decrease to £4.4m net cost and the EANCB to £32,000 net benefit.
    - If the transitional costs of the policy are double the current estimates, the overall net present value to society would decrease to £0.75m net cost and the EANCB would be £175,000 net benefit.

83. There will also be additional impacts on compliance and enforcement due to the changes that CQC will be making to their regulatory model, which will affect the costs of monitoring, inspecting and enforcing the registration requirements. It has not been possible to incorporate these new cost implications into the analysis above, as CQC are still in the process of developing and testing these proposals.

84. The net present value is positive as we estimate that the cost savings to providers of having simpler and easier to understand regulation will outweigh the costs of familiarisation and increased enforcement activity associated with the policy. Overall there is a positive benefit to business, as the total cost saving for private and third sector providers is expected to outweigh the costs of familiarisation for these providers. As the intention of the policy is to recast regulation in order to reduce burdens on business, we consider the policy proposal to be deregulatory (as discussed in the Better Regulation Framework Manual), and as we calculate that the direct incremental economic benefit to business exceeds the direct incremental economic cost to business, we classify this proposal as an OUT for the purposes of the One In Two Out framework.

Section E: Summary of specific impact tests:

Equality Impact Assessment

85. This policy proposal impacts all CQC registered health and social care providers. The costs will not impact service users or any specific groups. The benefits of improved quality of care through more effective regulation will be realised by users of health and social care services equally. This policy will not disproportionately affect any one demographic or social group. In general, the users of healthcare services tend to be people from older age groups, lower income distribution and those with disabilities or long term conditions.

Competition

86. In any affected market, would the proposal:

- Directly limit the number or range of suppliers?

87. No. The proposals do not involve the award of exclusive rights to supply services, procurement will not be from a single supplier or restricted group of suppliers.

- Indirectly limit the number or range of suppliers?

88. CQC ensures that only providers who have made a legal declaration that they meet the standards of quality and safety are allowed to provide care. The proposed policy is not intended to change the standards that providers must meet before they are able to enter the market, although it will make the standards clearer and easier to understand. This may reduce the costs on potential entrants of meeting these standards and gaining entry into the market.

- Limit the ability of suppliers to compete?

89. This duty is not expected to have any impact on suppliers. It will impact all CQC registered providers of health and social care equally.

90. This duty does not limit the scope for innovation for the introduction of new products or supply existing products in new ways. It does not limit the sales channels a supplier can use, or the geographic area in which a supplier can operate. It does not limit the suppliers' freedoms to organise their own production processes or their choice of organisational form. It does not substantially restrict the ability of suppliers to advertise their products.

- Reduce suppliers' incentives to compete vigorously?

91. The proposal does not exempt the suppliers from general competition law. They do not require or encourage the exchange between suppliers, or publication, of information on prices, costs, sales or outputs.

<u>Small and Micro Business Assessment</u>

- How does the proposal affect small businesses, their customers or competitors?

92. The duty would apply to all CQC registered providers of health and social care of all sizes and the impacts are as described above. Overall the proposed changes are not intended to change the scope of requirements on providers and so would not lead to any additional burdens. In the short run there would be transitional costs associated with understanding and familiarisation with the revised requirements. In the long run, by making the regulations simpler and easier to understand, there could be a reduction in the burden on regulation on providers of all sizes.

93. Overall, we note that regulation tends to have a disproportionate impact on smaller firms. The impact of this regulation on small businesses by allowing providers discretion in how they meet the new requirements and through CQC's proportionate and risk based regulatory approach, which seeks to minimise the burdens of regulation on providers.

<u>Legal Aid/ Justice Impact</u>

94. The following have been considered in the main impact assessment above and in the Ministry of Justice impact test provided alongside this document:

- Will the proposals create new civil sanctions, fixed penalties or civil orders with criminal sanctions or creating or amending criminal offences? **No**
- Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? **Yes**
- Create a new right of appeal or route to judicial review? **No**
- Enforcement mechanisms for civil debts, civil sanctions or criminal penalties? **No**
- Amendment of Court and/or tribunal rules? **No**
- Amendment of sentencing or penalty guidelines? **No**
- Any impact (increase or reduction on costs) on Legal Aid fund? (criminal, civil and family, asylum) **No**

- Any increase in the number of offenders being committed to custody (including on remand) or probation? **No**
- Any increase in the length of custodial sentences? Will proposals create a new custodial sentence? **No**
- Any impact of the proposals on probation services? **No**

Sustainable Development

95. The proposals are not expected to have a wider impact on sustainable development. There will be no impact on climate change, waste management, air quality, landscape appearance, habitat, wildlife, levels of noise exposure or water pollution, abstraction or exposure to flood.

Health Impact

- Do the proposals have a significant effect on human health by virtue of their affects on certain determinants of health, or a significant demand on health service? (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)

96. The potential impacts on health have been considered above in the cost benefit analysis of this impact assessment, see Section D above

97. There are no expected health risks in association with, diet, lifestyle, tobacco and alcohol consumption, psycho-social environment, housing conditions, accidents and safety, pollution, exposure to chemicals, infection, geophysical and economic factors, as a result of the proposals

Rural Proofing

- Rural proofing is a commitment by Government to ensure domestic policies take account of rural circumstances and needs. It is a mandatory part of the policy process, which means as policies are developed, policy makers should: consider whether their policy is likely to have a different impact in rural areas because of particular circumstances or needs, make proper assessment of those impacts, if they're likely to be significant, adjust the policy where appropriate, with solutions to meet rural needs and circumstances.

98. The proposals will not lead to potentially different impacts for rural areas or people.

Wider impacts

99. The main purpose of the proposed policy is ensure that the regulation of health and social care providers is as effective as possible in mitigating the risks to service users, minimising the regulatory burdens on providers and ensuring that the requirements placed on providers are clear and easy to understand. Enforcement activity will also be strengthened to ensure that providers can be properly held to account in the event of serious breaches of the requirements.

Economic impacts

100. The costs and benefits of the proposals on businesses have been considered in the main cost benefit analysis of this impact assessments, see Section D above.

Environmental impacts and sustainable development

101. The proposals have not identified any wider effects on environmental issues including on carbon and greenhouse gas emissions.

Social impacts

102. No impact has been identified in relation to rural issues or the justice system

Section F: Summary and Conclusions

103. Based on the above impact assessment, the preferred option is Option 2: Revise the registration requirements so that the warning notice requirement can be removed: The existing requirements will be revised to ensure that they are sufficiently precise so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed. As a result CQC will be able take stronger enforcement action via prosecutions to better hold providers to account for their failings

where appropriate. CQC will be able to use their full suite of enforcement powers and so better match the type of action taken against the seriousness of the breach.

104. The main costs of the proposed policy are the costs associated with additional prosecutions, although there may be some transitional costs for providers and CQC associated with revising the regulations. The policy is likely to also have other impacts on compliance and hence on enforcement, which it has not been possible to quantify. It is likely that in the short run enforcement activity might be expected to increase as the revised regulations might make breaches easier to identify, whilst in the long run, enforcement action (and hence costs) may fall as the overall level of compliance is expected to increase.

105. The main benefits of the proposed policy are to increase the ability of CQC to hold providers to account and to increase incentives for providers to comply with the regulations so that the risks to patients of poor quality care is reduced. Additionally, by making the regulations simpler, this could also reduce the burden of regulation on providers. Although it has been difficult at this stage to determine the likely size of the benefits, initial calculations suggest that, even under very modest assumptions, the cost savings arising to businesses are likely to outweigh the costs to businesses associated with the policy. Thus we are confident that the proposed policy is likely to lead to an overall reduction in the burden of regulation for businesses. We will test these assumptions and seek further evidence on the true size of the benefit during the consultation process.