Title: Review of CQC registration requirements **IA No:** 6104 **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 02/05/2014 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** John Culkin

Summary: Intervention and Options

RPC Opinion: GREEN

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**
£2.12m	£2.27m	-£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. This requirement makes it hard for CQC to prosecute providers in practice. 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. The registration requirements will be revised to make them clearer and easier to understand and the criminal offences will be made more specific and more targeted so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed. CQC will be able take stronger enforcement action via prosecutions where appropriate to better hold providers to account for their failings. These changes to the regulations will enable us to define what the fundamental standards of care are, in line with the recommendations of the Francis Inquiry.

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 (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: ..... ***Date:*** 2 July 2014

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:** £2.12m

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	£2.9m		£0.4m	**£6.21m**

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

Since there is no change in the requirements that providers will be execpted to meet, the main cost for providers will be the familiarsation costs of the new regulations. 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 effect.

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

The revised regulations may change the level of compliance, and hence enforcement action required by CQC either through greater deterrent effects from the increased risk of prosecution, or by making it easier for providers to understand compliance and/or CQC to identify non-compliance. It is not possible to predict what these changes might be

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	£0		£1m	**£8.33m**

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, which were confirmed by our work with providers during the consultation

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 likely to be effective. The quality of care could improve as simpler regulations mean that providers have a better understanding of what is required of them, whilst more effective enforcement might also lead to a deterrent effect for providers.

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: £0.17m	**Benefits:** £0.46m	**Net:** -£0.3m	Yes	OUT

Evidence Base

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);
    - inspecting and monitoring services against the registration requirements;
    - using enforcement powers (including prosecution) 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 have made a legal declaration that they meet the standards of quality and safety are allowed 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. On 9th February 2013 Robert Francis published his report on 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. This made a number of recommendations concerning the regulation of healthcare services, which were accepted by the Government in its initial response to the inquiry *"Patients First and Foremost",* and confirmed in its final response *"Hard Truths"*. The proposals to revise the CQC registration requirements and create a set of fundamental standards outlined in this Impact Assessment form one part of the package of changes being brought in as a result of these recommendations. Other measures include:
    - Introducing a new statutory duty of candour for providers via CQC registration requirements
    - Introducing a new fit and proper person tests for directors and other board level appointments to be enforced via CQC registration requirements

- Allowing CQC to issue performance ratings to providers
- Introduction of the three Chief Inspectors of Hospitals, General Practice and Adult Social Care

5. In addition to these, CQC are also making changes to their regulatory model in order to improve the effectiveness of regulation. This will include changes in their internal practice on how they register, monitor and inspect providers, and will help to shift the burden of regulation away from high performing providers towards those performing at the lower end of the scale in order to drive up quality.

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

6. CQC has a range of enforcement powers intended to be used where providers are found to be in breach of the registration requirements. These include issuing a warning notice that requires improvement within a specified time, placing a condition on the provider, 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.

7. There is currently a legal requirement for CQC to issue a warning notice to providers before they are able to prosecute a provider for a breach of the registration requirements. This 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 prosecute the provider.

8. 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. **Currently, no matter**

how serious the offence, prosecution cannot occur if the provider complies with the warning notice.

9. Although prosecution is not the only form of 'strong' enforcement action available to CQC, there are 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.

10. Our aim is to make the regulations sufficiently clear 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 where it is in the public interest to do so.

11. 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 them would also help to reduce the burden of regulation.

12. The proposed fundamental standards and their potential to reduce the burdens to business were discussed at the Healthy Living and Social Care Red Tape Challenge Star Chamber in October 2013. Ministers were supportive of the changes the fundamental standards would introduce and keen that these regulations should be brought in as soon as possible.

Relationship to the Francis recommendations:

13. 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 being unclear, 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.

14. The changes to the regulations discussed above will address these criticisms and enable the above recommendation to be met. The new registration requirements will increase clarity for providers in terms of 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. CQC have a statutory obligation to produce guidance about complying with the regulations, and this guidance will explain how the fundamental standards apply in each setting, and set out what enforcement CQC may take where they find a breach of these standards.

The case for government intervention:

15. Asymmetry of information between health and adult 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 adult 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 regulations and to improve the clarity of the regulations so that it is 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.

Alternatives to regulation and other options considered

16. Of the non-regulatory options listed in the government's online guide to reducing regulation[1] we consider this policy proposal to be a non-regulatory option in that it simplifies or clarifies the existing regulation rather than introduces new regulation. 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 associated offences.

Section B: Policy objectives and intended effects

17. 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 clearer and easier to understand and the criminal offences will be made more specific and more targeted so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed. CQC will be able take stronger enforcement action via prosecutions where appropriate to better hold providers to account for their failings. These changes to the regulations will enable us to define what the fundamental standards of care are, in line with the recommendations of the Francis Inquiry.
18. The intended effect of removing the requirement for CQC to issue a warning notice before bringing a prosecution is 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 in those cases where it is appropriate, the range of enforcement tools available to CQC will increase allowing enforcement to be more proportionate, better targeted and therefore more effective. It is possible that the threat of additional or stronger enforcement action could also create a stronger deterrent effect for providers against breaching the registration requirements, leading to an improvement in the quality of care.
19. Additionally, by making the registration requirements fewer and more precise and the regulatory intention clearer, the intended effect is to reduce the burden of regulation on providers by making it easier for them to understand what is required of them by the regulations and to judge whether or not they are compliant with the requirements. Responses from our consultation on the new regulations also suggested that better regulations and better understanding of these may also lead to an improvement in the quality of care for service users through improved compliance and innovations in service delivery.

[1] See https://www.gov.uk/government/policies/reducing-the-impact-of-regulation-on-business/supporting-pages/using-alternatives-to-regulation

Section C: Description of the options

Option 1: do nothing

20. 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.

21. Although prosecution is not the only form of enforcement action available to CQC, there are 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 breach of the requirements, a less appropriate form of enforcement must be used instead and as a result enforcement will be less effective. For example, there will be incidents 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. If we were to take this option, we would persist with a system that prevents CQC from being able to use the set of regulatory powers given to them by Parliament.

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

22. Under this option, the existing requirements will be revised to ensure that they are clear enough 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 the regulations and associated offences.

23. 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. We have redrafted the registration requirements and only attached criminal offences to those that are serious enough to warrant prosecution. This will create greater clarity for providers, in theory, of what constitutes an offence compared to the previous regulations that allowed for the possibility of prosecution for any potential breach of the requirements.

24. We have, via the consultation, tested and refined the clarity and precision of our new drafting. The consultation respondents generally agreed that the new draft regulations were simple to understand, and the intention behind them was clear. We have used the consultation responses to refine the wording of the regulations to remove as much ambiguity from them as possible. Many respondents picked out words or phrases that they thought were not as clear as they could be, and we have addressed these points rigorously, removing words that carry a subjective interpretation and clarifying clauses that had more than one potential reading. It should be noted that the version we consulted on were already considered simple to understand by the majority of respondents, and we have been able to further improve the clarity as a result of the consultation.

25. One of the key issues identified by the Francis Inquiry report 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.

26. For example, the intention of the current requirement to meet nutritional needs is that a provider should expect to be prosecuted if there is a clear risk that service users could be inadequately nourished. But the regulation also contains a number of additional specifications which would also result in a breach of the regulation, but do not reflect the intention of the requirement. For example, because the regulation states that there must be a choice of suitable food to meet service users' needs, this means that a provider may be committing an offence if they provide service users with adequate nutrition but do not offer a choice of food.

27. This issue is present in many of the current regulations and 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 – these will also be set out in the regulations so providers are clear as to what is required. In addition, the regulations will make clear what part of each regulation would be an offence if breached, so providers understand what they must do in order to comply with the law. The example below shows how two of the current regulations covering cleanliness, infection control, and safety of premises and equipment have been condensed into one much simpler regulation.

Current regulation(s)	Example revised regulation

Cleanliness and infection control (1) The registered person must, so far as reasonably practicable, ensure that— (a) service users; (b) persons employed for the purpose of the carrying on of the regulated activity; and (c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity, are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2). (2) The means referred to in paragraph (1) are— (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection; (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to— (i) premises occupied for the purpose of carrying on the regulated activity, (ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection. [(3) In this regulation, "medical device" has the same meaning as in regulation 2(interpretation) of the Medical Devices Regulations 2002.] **Safety and suitability of premises 15** (1) The registered person must ensure that service users and others having access to premises where a regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of— (a) suitable design and layout; (b) appropriate measures in relation to the security of the premises; and (c) adequate maintenance and, where applicable, the proper— (i) operation of the premises, and (ii) use of any surrounding grounds, which are owned or occupied by the service provider in connection with the carrying on of the regulated activity. (2) In paragraph (1), the term "premises where a regulated activity is carried on" does not include a service user's own home.	**Cleanliness, safety and suitability of premises and equipment** **1.**—(1) All premises and equipment used by the service provider must be safe for use for service users and properly used. (2) All premises and equipment used by the service provider must be— (a) clean and secure, (b) suitable for the purpose for which they are being used, (c) properly maintained, and (d) appropriately located. (3) The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used. (4) For the purposes of this regulation "premises" does not include the service user's own accommodation, where such accommodation is not provided as part of the service user's care or treatment. [NB, another section of the regulations will make clear that only paragraph one of the above regulation is an offence that can be prosecuted]

28. The changes we are making have allowed us to remove the legal requirement for CQC to issue a warning notice before they can bring about a prosecution. This will mean CQC can take stronger and more appropriate enforcement action where necessary.

29. Additionally, the regulations have been rationalised so that they are fewer in number and simpler to understand. There are now 11 fundamental standards (the fit and proper persons test and duty of candour will make 13 – these are subject to separate Impact Assessments), as opposed to the 16 in the previous set of regulations. This will make it clearer to providers what the key requirements are that must be met. Although the scope of the outcomes that providers are expected to achieve is unchanged, providers will have more freedom in how they go about achieving these outcomes – the emphasis in each regulation is on the outcome rather than on the processes or steps that must be taken. It is expected that this will help to reduce the burden of regulation on providers. As discussed above, we have tested these regulations with providers at consultation and made changes were necessary to ensure that they are as clear and easy to understand as possible.

30. It should be noted that although we have combined and condensed the requirements (as shown in the example above) there is no change in the scope of the requirements – they cover the same subjects as the original requirements, albeit within a different structure. This re-working has helped us to bring out the overall outcomes we want to see, but has not changed the overall standards of care that providers must meet.

31. Overall, these changes to the regulations will allow us to better define what is fundamental to providing good care. The requirements are more precise, making it more likely that CQC will use their full range of enforcement powers when breaches occur. CQC will define in guidance the things they will look for when checking whether care 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 serious consequences for providers who fail to meet the standards.

32. In addition to this, CQC is also changing how they will monitor, inspect and enforce against these new registration requirements as part of their response to the recommendations of the Francis Inquiry. For example, CQC will issue ratings to providers which will in part be based on how well they meet these requirements. It will also 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 only considers the impact of the new 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 changes to its regulatory model.

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

Costs:

Number of providers affected

33. In terms of the number of providers affected by the policy, analysis of the directory of providers registered with CQC as at 4th April 2014 shows that CQC registers providers in the following sectors:

Location Type/Sector	Number of CQC registered providers
Adult Social Care	12,750

Independent Healthcare	1,500
Dentists	8,000
GP services	7,500
Independent Ambulance	250
NHS Trusts	250
Total	30,500

Figures rounded to nearest 250
Note that figures may not sum due to rounding

34. To estimate the number of providers in each category that should be considered to be part of the private or third sector, we use the following assumptions about the split of public and private organisations within each sector that CQC regulates:

Sector	**% public**	**% private**	**Rationale**
NHS Trusts	100%	0%	Entirely funded and operated by the NHS
Independent healthcare	0%	100%	In the absence of further information it is assumed that 100% of the independent healthcare and private ambulance market is privately run.
GPs	94%	6%	Laing and Buisson 2013/14 Healthcare Market Review[2] found 6% of GPs worked entirely outside of the NHS
Dentists	70%	30%	Analysis of Dental Contracts found that approximately 30% of dental practices did not contract with the NHS
Adult Social Care	10%	90%	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. Similarly the Laing and Buisson 2013/14 Healthcare Market Review estimated that between 6% and 13% of adult social care providers were Local Authority or NHS run organisations.

35. In the case of GPs and Dentists, we are aware that the definition of public and private businesses is currently being reviewed by the Regulatory Framework Group. In advance of any decision from this group we have made a best estimate of the potential number of private sector GPs and Dentists using the best available data to hand. Following any further direction on this issue, we will be happy to provide the RPC with further information on how the analysis in this Impact Assessment might be affected.

36. We apply these assumptions to the analysis above in order to estimate the number of private or third sector providers in each case:

Sector	**CQC Registered Private Sector Providers**
Adult Social Care Org	11,500

[2] See Laing and Buisson 2013/14 Healthcare Market Review, not available online

Independent Healthcare Org	1,500
Primary Dental Care	2,500
Independent Ambulance	250
Primary Medical Services	500
NHS Healthcare Organisation	0
Total	16,250

Figures rounded to nearest 250, figures may not sum due to rounding

37. Finally, an examination of the number of providers registered with CQC suggests that the overall number of registered providers is growing over time. This must be factored into our calculation of the costs and benefits to providers for future years of this Impact Assessment. Analysis from CQC's State of Care report 2013[3] found that over the financial year 2012/13 the numbers of adult social care providers increased by 2% (driven by a growth in at home care, which offset a decline in residential care homes), whilst the number of NHS providers declined 10% as the sector consolidated. The number of independent healthcare providers increased by 9%, and the number of dental providers fell slightly (less than 1%).

38. Overall it is difficult to predict what the long term trend in provider growth rates might be. As CQC was only established in 2009 and the timetable for roll out of the registration process for different provider groups was staggered, there has been limited evidence on steady state growth rates, especially for certain sectors. All NHS trusts had to be registered by 1 April 2010, whilst providers of adult social care and independent health care were to be registered by October 2010. Dentists and ambulance services were required to be registered by April 2011, whilst GPs did not need to register with CQC until April 2013. In addition, we are aware that CQC are exploring options to make the registration process more robust in the adult social care sector, which will likely have a downward pressure on the number of applications and the number of providers registering with CQC. This is balanced by CQC's work to ensure that innovative providers are not put off by this more robust registration process.

39. In spite of these caveats, we have estimated average growth rates for each sector registered with CQC based on information on the number of providers registered with CQC at the end of each of the past three financial years. These growth rates are used to uprate the estimated annual costs to providers for future years of this Impact Assessment to reflect the greater number of providers affected.

Sector	**2011/12**	**2012/13**	**2013/14**[4]	**Average growth rate**
Social Care Org	12,500	12,750	12750	2%
Independent Healthcare Org*	1,250	1,500	1500	10%
Primary Dental Care	8,000	8,000	8000	0%
Primary Medical Services	-	7,750	7500	0%
Independent Ambulance	250	250	250	0%
NHS Healthcare Organisation*	250	250	250	-8%

*Figures rounded to nearest 250

40. However, we do not judge the 8% reduction in NHS trusts to be a sustainable long term trend. Over the past 5 years there has been a trend in consolidation within the NHS, however we judge that this is unlikely to continue for the whole duration of the 10 year period of this Impact Assessment (not least because this would result in more than half

[3] CQC The state of health care and adult social care in England 2012/13
http://www.cqc.org.uk/sites/default/files/media/documents/cqc_soc_report_2013_lores2.pdf

[4] Data for 2011/12 and 2012/13 was obtained from CQC's Annual Reports. Data for 2013/14 was obtained from internal analysis of the directory of providers registered with CQC as at 4th April 2014.

of NHS Trusts disbanding in this period). Based on internal advice from the DH provider policy team, it is not possible to accurately predict the likely number of NHS trusts over the next ten years. In the absence of further information, we therefore make the assumption that the number of NHS trusts is likely to remain more or less constant over the period of this impact assessment.

Provider implementation costs:

41. The new fundamental standards will replace the previous CQC registration requirements and will require providers to meet the same standards of care as previously expected. The main two differences are expected to be that

    - The regulations will be simpler and easier to understand. Providers will be able to better understand what is required of them and the standard of care that they must deliver
    - It will be easier for CQC to bring prosecutions for breaches of the standards without first issuing a warning notice. All else being equal, we expect this to increase the number of prosecutions.

42. The main cost to providers of implementing the new fundamental standards is therefore expected to be the costs of familiarisation with the new requirements. There is no change in the standards of care that providers will be expected to meet under the new requirements and so we do not expect any increase in the costs associated with meeting the requirements compared to the do nothing option. By making the standards easier for providers to understand, this might serve to reduce the costs of implementation, as providers are able to make changes in their operating model to improve the way that they deliver the required standards of care. This is discussed further in the benefits section of this Impact Assessment.

43. It is difficult to predict the amount of time providers might require to familiarise themselves with the new requirements. In the consultation stage Impact Assessment we assumed that approximately half a day of manager time would be required for providers to read, absorb, discuss and communicate the revised requirements to staff but acknowledged that this could vary significantly between different organisations depending on the size and complexity of the organisation and scope of regulated activities covered. 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 the implications of the revised requirements 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. Providers might also choose to use the introduction of the new regulations as an opportunity to undertake a more detailed review of their services to assess whether the requirements are currently being met, and if there are opportunities for improvement.

44. The responses to consultation confirmed our initial assessment that there could be significant variation around our initial estimate of half a day of manager time. Although most respondents agreed that there would be some additional transitional costs, some respondents felt that the additional costs would be minimal, since the new regulations would continue to reflect what providers already did, whilst others expressed concern that the familiarisation costs could be much higher.

45. However, it was difficult for respondents to disentangle these additional costs from those that might be incurred in the do nothing scenario. Our discussions with providers during the consultation suggested that all providers would be constantly in the process of examining the regulations and making improvements to their service design. In some

large providers there might even be a dedicated compliance team who examine and review the regulations every day. As part of our call for evidence respondents were asked about the Fundamental Standards and registration requirements, and indicated that they already spent on average between 1.8 hours and 3.7 hours "reading or thinking about them". As a result, respondents tended to view such costs as part of 'business as usual' costs, and as a result, found it difficult to provide any further indication of what the familiarisation and review costs associated with revised regulations might be.

46. Finally, we note that the burden of familiarisation costs might not be equally spread between providers. For example, a number of umbrella organisations responded to our consultation and indicated that they would spend a significant amount of time examining and interpreting the revised regulations on behalf of their members. This might suggest that providers themselves would be able to spend less time familiarising themselves with the requirements as they would be able to seek further advice and guidance from their umbrella body.

47. Based on these complexities, we take the view that our initial assessment of there being an average of half a day (i.e. 4 hours) of additional manager time required per provider to familiarise and review the revised requirements remains the best available estimate. 61% of respondent to our call for evidence indicated that they felt the figures in the consultation Impact Assessment to be a fair and accurate reflection of the impacts of the policy. A handful of respondents challenged our estimate of the familiarisation costs but did not supply any alternative estimates. These respondents were mainly from umbrella body organisations, and as noted above, we felt that these was a strong likelihood that these additional time requirements could be offset by corresponding time savings for member organisations[5]. Other providers explicitly gave support to our initial estimates. Finally, compared to the above figures for the 'do nothing' scenario that providers already spend between 1.8 and 3.7 hours per month examining the regulations, our estimate of half a day of additional time on top of this for familiarisation does not appear to be unreasonable. Based on data from the Annual Survey of Hours and Earnings (ASHE) 2013, the median gross hourly wage for Corporate Managers and Directors was £24 (including 15.3% non-wage costs[6]). Across the 30,500 providers regulated by CQC, the total transitional cost of familiarisation with the revised requirements is estimated to be approximately £2.9m. **Across the 16,250 or so private or voluntary sector CQC registered providers, the cost would be £1.5m.**

48. As previously discussed, the revised regulations will not place any new requirements on providers in terms of the standards of care that they must deliver. However, it is possible that by making the regulations easier and clear to understand and more outcomes focused, this could enable or allow providers to make more fundamental changes in the way that they choose to deliver these outcomes or demonstrate compliance, which might have additional cost implications. For the purposes of OITO, we consider these costs to be indirect costs since they would be incurred at the discretion of the provider, and will be dependent on whether the revised regulations led to them identifying any changes to their systems that they would wish to make. Since the revised regulations will not change the scope of the requirements that providers must meet, it is reasonable to assume that where providers choose to change the way that they meet these requirements, they do so because they anticipate the benefit of any such changes would outweigh the costs of the changes.

Costs of monitoring and inspecting against the revised regulations:

[5] As reflected by some respondent's view that familiarisation costs could be relatively low

[6] See http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=Wages_and_labour_costs&stable=1

49. 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.

50. In fact, as the policy intention is to revise the registration requirements 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.

51. 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:

52. 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. Although the criminal offences will be better targeted so that not all parts of the regulation would be an offence if breached, the intention is that prosecution can occur for the most serious incidents where harm has been caused. Overall, the number of prosecutions is therefore expected to increase. It is possible that by making prosecution a more realistic prospect for providers, this creates a stronger deterrent effect against non-compliance, and so would reduce the amount of enforcement activity (including prosecutions) required. A common response to the consultation was that clarity about what the offences are will be helpful to providers, and we believe that by making the offences clearer, we will increase providers' understanding of what they must do to comply with the regulations. It has not been possible to model these potential long-term effects on compliance as the empirical evidence on the deterrent effect of stronger enforcement is not well understood. Whilst there is strong evidence of a general deterrent effect from having a regulatory or criminal justice system, the evidence that specific measures or sanctions have deterrent effects is more limited[7]. Our estimates of the potential costs of increased prosecutions are therefore based on current patterns of compliance and we make no further assumptions for how this might change over time.

53. Data on the total enforcement action undertaken by CQC in 2012 showed that there were approximately 1,100 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

[7] See Chapter 4 "Deterrence: Scaring Offenders Straight" in Cullen, F.T. and Jonson C.L. 2012 *Correctional Theory Context and Consequences, SAGE Publications*

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 prosecutions. This gives a total of 15 possible additional prosecutions that might have been brought had the warning notice requirement not been in place. This is likely to be an overestimate of the potential number of prosecutions as it is not clear if all of these cases of non-compliance would relate to the parts of the regulations that CQC will have the power to prosecute against. This figure of 15 additional prosecutions should therefore be taken as the upper bound of potential additional prosecutions.

54. 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).

55. 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 £340 in 2012/13 prices.

56. It is difficult to cost CQC enforcement activity it cuts across many CQC functions and requires input from various different departments and staff. As a result, the costs of enforcement activity to 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. We also obtained information from the Health and Safety Executive in relation to estimates of the costs incurred from prosecution against Health and Safety at Work Act offences in relation to health and adult social care providers. This showed that between 1st April 2007 and 31st March 2012 there were approximately 100 prosecutions of health and social care providers by the Health and Safety Executive, with an associated average cost per case of approximately £18,000. However, when the analysis is restricted to only cases in the Magistrates Courts, this figure falls to approximately £12,000. Similar analysis on the costs awarded to Local Authorities in Health and Safety cases suggested figures closer to £8,500 for all cases and £6,000 for cases in the Magistrates Courts. We therefore use the figure of £12,000 per case from the Health and Safety Executive as a mid-point best estimate between the CQC and Local Authority figures, since we are aware that the CQC estimate of £21,000 is likely to be an over-estimate.

57. In terms of the cost of defending a prosecution for providers, these costs are unknown. Due to the low number of cases of prosecution by CQC it has not been possible to carry out any work with providers to understand the potential costs of defending such a case. Whilst the cost of legal defence for additional prosecutions represents an additional cost on society compared to the do nothing, for the purposes of OITO, these costs are considered to be out of scope. This is because only non-compliant providers would face the increased risk of prosecution under the new policy. Instead of first receiving a warning notice, CQC would be able to move straight to prosecution for these providers. Prosecution would remain reserved for only the most serious offences and so would continue to only affect a small minority of providers where there are serious compliance issues.

58. In the absence of any direct information about the costs of defending a prosecution for providers facing prosecution by CQC, MoJ have advised that the best proxy for defence costs would be to use average legal aid costs. MoJ have estimated that for cases heard

in the Magistrates court, the average legal aid cost per case was approximately £400. However, as legal aid would generally not be available for companies, it is not clear how representative these costs might be for organisations facing prosecution. No other studies of the costs of defending a prosecution could be identified, and so in the absence of any other information, we use this figure of £400 as a lower bound estimate of the potential cost of defending a prosecution. We also consider the costs to providers of defending a prosecution based on the assumption that the costs of defence are similar to those incurred by CQC to bring about the prosecution to give an upper bound estimate, however, we note that as discussed in the preceding paragraph, these costs are considered out of scope for the purposes of OITO.

59. As previously discussed, since 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 the Legal Aid budget. 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.

60. Overall, we estimate that if current patterns of compliance continue, there would be approximately 15 additional prosecution cases per year, creating an additional cost for HMCTS of approximately £5,100, and of £180,000 for CQC. For providers our lower bound estimate of the costs would be £6,000 whilst the upper bound might be £180,000. Due to the large range in these potential estimates we do not feel it would be appropriate to take a mid-point as our best estimate. Instead, in the interests of prudency, we proceed with our cost benefit analysis based on the higher of the two cost estimates. However, as discussed previously, it is not known whether the increased use of prosecution powers by CQC might act as a deterrent effect for non-compliant providers, or otherwise affect the pattern of compliance in the longer run.

61. In terms of the long term trend, we assume that, in the absence of any other changes in the pattern of compliance and enforcement (as discussed below), the number of enforcement and hence prosecution cases will grow in line with the growth in the number of providers.

Other potential costs related to enforcement:

62. Secondly, we have previously discussed the potential for the increased prosecution power of CQC to create a deterrent effect amongst providers, which could have an effect on overall levels of enforcement activity. There could also be a cost implication for providers as it would result in additional activity to meet the standards. Clarifying the regulations to ensure that the overall focus and intent of the requirement is clearly stated could also have similar effects, as providers (and CQC) 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.

63. Where providers are currently not meeting the requirements, this increased activity is considered to be out of scope for OITO purposes 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 existing 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.

64. For providers who currently do already 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 and we have tested these extensively with providers and other stakeholders during the consultation process to ensure that the resultant set of proposed regulations are as clear and easy to understand as possible. This process has also allowed us to mitigate the risks of any other unintended consequences arising. This also does not account for the fact that there are lots of other factors that compel a provider to deliver a standards of care above and beyond the fundamental standard set out in the regulations.

65. In terms of the costs to providers of additional action to improve compliance against the required standards, it has not been possible to quantify these further. CQC recently commissioned some work to understand providers' attitudes towards regulation[8], which highlighted the difficulties associated with estimating the compliance costs (as opposed to the administrative costs) associated with regulation. All providers interviewed in the study viewed CQC regulation as an essential part of running a health or adult social care service, with an unregulated world being unimaginable. This suggests that providers do not tend to distinguish between the costs associated with normal service delivery, and the costs of meeting the regulated standards of care. As part of CQC's ongoing work to understand and reduce the burden of regulation on providers, CQC have commissioned a further study to explore how these costs could be estimated and collected in the future. As, for the purposes of this Impact Assessment, we consider the costs of improving compliance to be out of scope for the purposes of OITO, we do not consider them further.

66. Any change in compliance will also affect the level of enforcement activity (including but not limited to prosecutions) required by CQC. As discussed above, it is not possible to know what the changing pattern of enforcement activity might look like. It is possible that overall costs could increase, at least in the short run, as clearer and more outcomes focused regulations enable CQC to better recognise and identify non-compliance. In the long run however, the potential deterrent effects discussed above may come into play, and reduce the total level of enforcement activity required by CQC.

67. However, whilst it is not possible to predict what the potential change in enforcement activity might be, we provide some illustrative examples of the potential impacts based on the cost estimates below:

    - **Cost to CQC of enforcement activity not involving prosecution:** As previously discussed, it is very difficult to accurately 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.

    - **Cost to justice system of appeals against CQC enforcement:** Providers have the right to appeal to the First-tier-Tribunal Health, Education and Social Care Chamber against enforcement action using the civil enforcement procedures (there is no right of appeal to the Tribunal in relation to warning notices, penalty notices or conviction for offences). HMCTS advise that the average cost to the justice system per case brought is approximately £6,000, with some potential start-up costs in the region of £1,700.

    - **Costs to providers of bringing an appeal:** Evidence on these costs are limited due to the small number of providers bringing appeals against CQC to the tribunal. MoJ tribunal statistics show that in the financial years 2011/12 and 2012/13

[8] *Health and Social Care Regulation: A study of Provider Attitudes and Behaviours*, A report for CQC, November 2013, available at http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

approximately 70 cases were brought to the Care Standards Tribunal per year and only a proportion of these cases would relate to appeals against CQC. Whilst HMCTS may have some record of the costs awarded to providers in the case of successful appeals, they have advised that it would not be possible to obtain this information without revisiting the files for each individual case. We therefore use cost figures from employment tribunals as a proxy for the cost of bringing an appeal to the care standards tribunal, as these costs are much better understood.

Previous estimates from the Department of Business Innovation and Skills suggest that an employment tribunal case would post the following costs on the provider, claimant, and the exchequer:

Table 1.3: Summary of costs incurred throughout employment tribunal process, by outcome

	Employment Tribunal Hearing	Individual Conciliation	Average across ET claim outcome
Employer	£4,200	£3,300	£3,700
Claimant	£1,500	£1,100	£1,300
Exchequer	£4,450	£640	

Source: BIS estimates from Acas, HMCTS, SETA and ASHE data in 2011 prices. Figures are rounded.

The costs to the employer include the time costs of managers and directors spent on the case, as well as legal costs, whilst the cost to the claimant includes loss of earnings, legal costs and communication and travel costs. Although the direct read across to the care standards tribunal would be for provider appeal costs to map to the claimant costs above, we will instead take the higher employer costs associated with employment tribunal hearings as an estimate of the provider costs of CQC appeals. This is because the use of legal advice may differ significantly between organisations and individuals, and the loss of earnings category of costs for claimants is unlikely to be applicable for providers appealing CQC enforcement action. Uprated to 2012/13 prices, we therefore estimate that the cost of appeal to be £4,260 for providers.

In terms of the burden on private or voluntary sector organisations, where the tribunal finds in favour of CQC, the costs of enforcement are considered to be out of scope of OITO since the costs will relate to action by non-compliant providers in connection with enforcement. CQC advise that of the 116 appeal cases since 2009, less than 10% found against CQC. Where the tribunal finds in favour of the provider, the tribunal will have the power to award the provider costs in relation to the appeal. This means that at least part of the legal costs of the provider would be paid by CQC. The overall cost impact on private providers is therefore likely to be very small. HMCTS advised that it would not be possible to provide further information about the average cost awards without revising the specifics of each case involved. We therefore do not further consider these costs in relation to OITO.

- **Costs to CQC associated with defending an appeal**: As discussed above, it is difficult to estimate accurate unit costs for different types of enforcement action due to the integrated approach that CQC take towards enforcement activity. Based on details from a recent case that resulted 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 by the tribunal and CQC instructed 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. CQC are carrying out further work to better understand their costs; however the timing of this work has meant that it has not been possible to make a more accurate estimate of the costs to CQC to inform this Impact Assessment. We therefore also use the employment tribunal costs as a proxy for the potential costs to CQC of appeals.

- **Current enforcement activity:** Data from CQC showed that in 2012 there were approximately 1,100 cases of enforcement activity, of which approximately 10% involved action beyond a warning notice.

  In the consultation stage Impact Assessment we estimated an appeal rate of 75% based on a comparison of the total number of cases in 2012 where CQC took enforcement action beyond issuing a warning notice (110) against the total number of receipts and disposals in the Health, Education and Social Care Chamber of the First-Tier Tribunal (but we note that this will also cover cases other than appeals against CQC enforcement). However, we were aware that this figure would be an overestimate of the potential appeal rate as the data on the number of receipts and disposals to the Tribunal will include non-CQC related appeals as well. CQC have now advised that since April 2009 they have been involved in a total of 116 appeals to the First-Tier Tribunal. This suggests an average of 23.2 cases per year, which, when compared to the annual number of enforcement cases, suggests a much lower appeal rate of 20%.

68. Based on these cost estimates, we present some illustrations of the potential cost implications for different changes in patterns of compliance and enforcement. The implication of these scenarios on the overall cost benefit analysis is further explored within the sensitivity analysis presented later in this Impact Assessment.

    - If enforcement activity were to increase by 10% compared to current levels, the total number of enforcement cases would increase by approximately 110 cases per year. This would create an additional cost to CQC of £60,500 for this enforcement. The number of cases progressing beyond a warning notice would increase by approximately 10 cases, which at a 20% appeal rate would suggest that there could be an additional 2 appeal cases per year, at a cost of £12,000 to HMCTS, and £8,500 for CQC and providers.
    - If enforcement activity were to reduce by 10% compared to current levels, there would be a reduction in the number of enforcement cases by approximately 110. The cost saving to CQC would be approximately £60,500. The number of appeals would fall by approximately 2 cases a year, generating a saving of £12,000 to HMCTS and £8,500 for CQC and providers.
    - If enforcement activity were to halve compared to current levels, the cost savings would be 5 times those described in the bullet above.

Costs - summary:

69. The costs are summarised in the table below:

			Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
			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**
Familiarisation costs			2,910,000	-	-	-	-	-	-	-	-	-	2,910,000
Total			**2,910,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**2,910,000**
Prosecution costs	HMCTS		5,100	5,160	5,220	5,280	5,340	5,420	5,490	5,570	5,660	5,750	54,000
	CQC		180,000	182,000	184,000	186,000	189,000	191,000	194,000	197,000	200,000	203,000	1,910,000
	Providers		180,000	182,000	184,000	186,000	189,000	191,000	194,000	197,000	200,000	203,000	1,910,000
Total			**365,000**	**369,000**	**373,000**	**378,000**	**383,000**	**388,000**	**393,000**	**399,000**	**405,000**	**412,000**	**3,870,000**
Enforcement costs	Enforcement	CQC	-	-	-	-	-	-	-	-	-	-	-
	Total		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	Appeals	CQC	-	-	-	-	-	-	-	-	-	-	-
		Provider	-	-	-	-	-	-	-	-	-	-	-
		HMCTS	-	-	-	-	-	-	-	-	-	-	-
	Total		-	-	-	-	-	-	-	-	-	-	-
Total			**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total cost (undiscounted)			**3,270,000**	**369,000**	**373,000**	**378,000**	**383,000**	**388,000**	**393,000**	**399,000**	**405,000**	**412,000**	**6,770,000**
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)			**3,270,000**	**356,000**	**348,000**	**340,000**	**332,000**	**324,000**	**318,000**	**311,000**	**305,000**	**299,000**	**6,210,000**

NB: figures may not sum due to rounding

Benefits:

70. 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.

71. More effective regulation is expected to improve the quality of care for service users. Better enforcement action CQC may act as a deterrent to non-compliance with the required standards, whilst by making the regulations outcomes based and clearer, this is expected to improve the ability of providers to deliver against the expected standards.

72. Finally, 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.

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

Increased accountability:

74. 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 they commit serious breaches of the requirements. Although prosecution is not the only form of enforcement action available to CQC, there are instances where prosecution would be the most appropriate form of action for CQC to take. For example, there will be incidents 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

75. 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.

76. 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, although we provide some illustrative examples below.

77. For those affected by poor care, the on-going effects of the damage caused and sense of injustice can be substantial and will often lead individuals to expend considerable time and effort in seeking justice. For example, in the case of Mid-Staffordshire NHS Foundation Trust, campaigning by families for justice has been on-going since 2007. In the case of the Hillsborough disaster, campaigning has lasted over 20 years since the incident. While it is not possible to quantify the exact value affected individuals place on achieving justice, these examples give an indication of the magnitude of feeling that might be involved where there has been unacceptable care and no one is appropriately held to account.

78. For the general public and those not directly affected by the failings, there may still be a feeling of injustice associated with the perception that those guilty of inflicting harm on patients or service users are not appropriately punished. While it would be difficult to derive a total value for this benefit and it would be likely to represent a relatively modest amount per individual, the cumulative effect across society as a whole could potentially

be very large. As there are approximately 44m adults in England and Wales, this suggests that for the societal benefits of improved accountability to outweigh potential costs of the proposal, the average willingness to pay for increased accountability would only need to be £0.02p to generate a total annual gain to society of £880,000, which would outweigh the estimated average annual cost of the proposal.

Increased quality of care:

79. By making the registration requirements fewer and more precise and the regulatory intention clearer, the intended effect is to reduce the burden of regulation on providers by making 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. Responses from our consultation on the new regulations suggested that better regulations and better understanding of these may lead to an improvement in the quality of care for service users through improved compliance and innovations in service delivery. In addition, by making prosecution a more realistic prospect for providers, this might create a stronger deterrent effect for providers against breaching the registration requirements, and thus increase the overall level of compliance with the regulations across providers.

80. It is difficult to quantify the size of the potential health gain to service users that could arise from improved quality of care. The size of any health gain would depend on what changes providers might be able to make in the way that they deliver services in response to the revised regulations and potentially stronger enforcement action from CQC. 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[9]. This framework asks individuals to rate their health from 1 to 5 in five different domains, including the experience of pain, mobility and anxiety. These ratings can then be converted into QALY values using standard mapping tools based on surveys of the general population that rank all possible health states against one another. Based on this methodology, any reduction in quality of life away from perfect health for one year equates to a QALY loss of at least 0.094 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 at least a 0.008 QALY gain. Based on a societal willingness to pay of £60,000 per QALY, this would equate to a societal benefit of at least £470.

81. Tackling the problem the other way, if the total annual QALY gain resulting from the proposed fit and proper requirement was at least 12, the annual societal benefits of the policy would exceed the estimated average annual costs above. Using the above figure of a 0.008 QALY gain that would arise if one service user is able to avoid one month's worth of less than perfect health due to poor quality care, this suggests that there could be a gain of 12 QALYs if 1,500 service users were to benefit in this way.

The benefit of regulation on providers:

82. 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 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, providers could find it unclear what actions or requirements would put the provider at risk of prosecution and so spend additional time trying to clarify or determine this. The

[9] 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

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.

83. It is difficult to quantify what this cost saving will be as it is not possible to predict exactly how the revised regulations will cause or allow providers to change their behaviour. In the consultation stage IA we identified three scenarios where the majority of providers will be able to make some staff time savings: less time spent understanding and interpreting the regulations, less time taken training staff and less time taken to demonstrate that the regulations have been met. The results of the consultation provide evidence to support our original modest assumptions. These scenarios are outlined below. Although it is not possible to determine the exact size of the benefits, these investigations suggest that, even under very modest assumptions, the cost savings arising to businesses are likely to outweigh the costs 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 cannot be fully determined.

84. We issued a call for evidence as part of our consultation which asked respondents specific questions about how they currently use the regulations, and what the benefits might be of simpler regulation. We received about 170 responses to this, the majority from healthcare providers, although some were also from Umbrella organisations representing the views of provider organisations. Respondents agreed with us that there would be benefits to their businesses if the regulations were easier to understand; of those who answered the question, 80% agreed that simpler regulations would be beneficial, 18% said there would be no change and only 2% felt that there would be no benefits. Respondents also agreed that the new draft regulations were easier to understand. Of those who responded, 77% agreed that they were simpler (and we have since made further refinements to the regulations based on providers' comments). Many commenters were able to identify positive impacts, and many made the distinction between the quantifiable short-term transitional costs and the less quantifiable benefits. Some expressed reservations about the extent of the benefits, while others supported the original IA. Significantly, many respondents pointed out that it is in reality very difficult to quantify the impact in an accurate way. Whilst a large number of respondents provided further information and suggestions on what the potential benefits of the revised regulations would be for them, they were unable to further quantify these benefits. However, overall the majority of providers agreed with our original assessment of the costs and benefits in the consultation stage Impact Assessment.

85. Of those who gave an opinion, 61% thought the IA accurately calculated the impact, 25% expressed reservations, and 14% had mixed views. The main reservations were that the Impact Assessment did not consider the costs to providers arising from other parts of the regulatory system. We have added an assessment of the wider context and changes to the regulatory system as a separate section to this IA, but note that for the purposes of OITO the additional changes CQC are making to their regulatory system are out of scope and to be considered separately in CQC's Accounting for Regulator Impact (ARI). We have worked closely with CQC on the drafting of the fundamental standards to ensure that they are aligned with and support CQC's other changes to the regulatory framework to mitigate the risk of any negative unintended consequences.

86. We have used the results of the consultation to confirm our previous estimates of the impacts as follows:

87. **Benefit 1:** Since the revised regulations make it clearer for providers to understand the intention of each regulation (and 77% of consultation respondents agreed that the

revised regulations are easier to understand), we expect that many providers are likely to need to spend less time interpreting what the regulations mean. When respondents were asked about the Fundamental Standards and registration requirements, the average time spent "reading or thinking about them" was between 1.8 hours and 3.7 hours per month, and about 55% of providers expected to "save time" if they were easier to understand. A number of respondents also commented that the current regulations were too open to interpretation, and so it was time consuming to try to understand what the regulations actually required.

88. It is likely that the majority of the time will relate to providers considering how they could meet the regulations for their organisation, rather than time reading and understanding the regulations, we therefore assume that only 10% of the reported time relates to the latter. We expect that the time providers will still need to spend thinking about how to meet the regulations will not change as result of these changes. However we expect the amount of time spent reading and interpreting the regulations will reduce proportionately to the length of the regulations. Based on a count of characters, words and number of regulations, the new regulations are about 25% shorter than the original. Taking all of this into account, we estimate that the revised regulations could reduce the amount of time providers will have to spend reading and interpreting the regulation by between about 20 and 35 minutes per year. This supports our previous assessment made in the consultation stage Impact Assessment that existing providers could save up to 20 minutes per year from simpler to understand regulations.

89. We previously estimated that the time saving for new providers could be more significant as new entrants, who would be looking at the regulations for the first time, would be less familiar with the regulations and thus spend longer reading and understanding them. For example, a recent survey for GPs preparing for CQC registration found that on average they spend 7.4 staff days preparing for registration. This compares to our above estimate that existing providers spend an average of approximately 2.7 staff days a year reading and thinking about the regulations. This supports our assumption from the consultation stage Impact Assessment that newly registering providers might take approximately three times as long to read and understand the regulations. We therefore continue to make the estimate that newly registering providers could save an average of an hour of time in reading and understanding the regulations.

90. Thus we continue to estimate that a newly registering provider could save one hour of a manager's time from having simpler regulations, and an existing provider could save 20 minutes. We estimate that of 30,500 providers currently registered with CQC, approximately 3,000 were newly registered organisations in 2012 (excluding GPs, as these providers were newly brought into scope around this time), which also suggests a figure of 27,500 for the number of existing providers. Costing this based on the gross hourly wage for Corporate Managers and Directors of £24 (including 15.3% non-wage costs) from ASHE, this implies a total cost saving of approximately £225,000 per year. **Focusing only on private and third sector providers only, approximately 2,200 of the 16,250 CQC registered providers were newly registered in 2012, which implies the remaining 14,050 or so would be existing providers. This gives a total cost saving of £125,000 per year under the same assumptions.**

91. **Benefit 2:** From our consultation, we know that providers refer to CQC regulations or guidance when inducting new staff (when asked about the benefits of simpler regulations, 44% of respondents listed this as a potential benefit), with one respondent additionally commenting that these changes would 'make induction of staff much easier' whilst others also commented that the revised regulations would improve staff understanding of what is required. These findings support the second source of cost savings resulting from simpler regulations we quantified in the consultation stage Impact assessment – that there 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.

92. Rough estimates based on the 2012 NHS Staff Census and the 2012 Skills for Care report indicate that there are approximately 1.4m NHS staff and 1.6m people working in adult social care respectively. While no such comprehensive survey is available for the independent healthcare sector, a 2011 report by Skills for Health on the labour market for healthcare in England[1] estimated that the public sector healthcare workforce is approximately three times as large as in the private sector. We assume a 11% rate of labour turnover (from a 2013 survey of recruitment and retention carried out by the Chartered Institute of Personnel and Development), and that on average 5 minutes of time might be saved per new member of staff with an associated average cost saving of £14 per hour based on the median gross hourly wage for Human Health and Social Care Activities under the Standard Industrial Classification (SIC2007) in ASHE (15.3% non-wage costs). This implies a total cost saving of roughly £430,000 per year. **Based on our assumption that 90% of adult social care providers and 100% of independent healthcare providers are in the private or voluntary sector, and assuming the same distribution of staff numbers between the public and private sectors, this suggests a benefit of £240,000 for private or third sector businesses.**

93. **Benefit 3**: A number of respondents commented in the consultation that having simpler and more precise regulations would benefit them in helping them to understand compliance with 72% of those responding to the question saying that they would expect to benefit from better compliance if the regulations were easier to understand. In the consultation stage Impact Assessment we proposed that this could lead to a time saving for providers in terms of monitoring compliance and preparing and facilitating an inspection. For example, providers would find it easier to assess their own compliance and gather the relevant evidence for CQC if they have a better understanding of what is required of them. This view was confirmed at consultation, with respondents also suggesting similar benefits of simpler regulations. For example, one provider commented that greater clarity would enable easier and less complex governance and monitoring, whilst another suggested that simpler regulations would allow them to be used as an operational tool rather than a complex set of rules.

94. Previous estimates of the time required for providers to prepare for an inspection for the Department of Health's Strategic Audit of Regulation, suggested that providers might be spending up to 20 hours to prepare for and facilitate an inspection. It is not known how much time providers might spend monitoring compliance. As discussed above, from the consultation responses and the recent survey by CQC of provider attitudes to regulation, providers tended to view such costs as an integral part of delivering a service and so were unable to separately identify the costs. As in the consultation stage Impact Assessment, if the proposed policy were to lead to a reduction in manager time required to prepare for an inspection of half an hour[10], then based on the gross hourly wage for Corporate Managers and Directors of £24 (including 15.3% non-wage costs) from ASHE, this implies a total cost saving of £240,000 per year, **or £130,000 for private and third sector providers only.**

95. In addition to these savings, respondents to our consultation also identified other mechanisms by which simpler regulations might benefit their business. Many highlighted the benefits for front line staff, saying there would be "better understanding […] and therefore consistency in application" and that it would be "easier for staff, who are perhaps not as well educated or for whom English is a second language, to understand". They highlighted benefits in the day to day work of managers saying "Practice Managers would maybe have greater control over their individual locations and

[10] As previously discussed, 61% of respondents agreed with the impacts identified in the consultation stage Impact Assessment and we received no challenge on this figure in particular

feel more comfortable with their registered manager responsibilities" with an "improved relationship with CQC". Other, unquantifiable benefits include those to the public and patients with "a wider range of people […] able to gain understanding, […] people will not feel scared / daunted by them" as well as it being "easier to involve the people who use our service and make it more meaningful to them." Other respondents also had more concrete suggestions such as one provider who suggested that by having a fewer requirements, they would be able to easily display the requirements on the wall of their establishment to facilitate staff understanding. The current number and complexity of the existing requirements meant that this had not been possible.

96. These additional benefits support our overall assessment that the benefits of simpler regulations are likely to be realised through the revised regulations, and will outweigh the potential familiarisation costs of revising the regulations.

97. As previously discussed in the costs section of this Impact Assessment, a key benefit of the revised standards could be that by making the regulations clearer and easier to understand and more outcomes focused, this could enable or allow providers to make more fundamental changes in the way that they choose to deliver these outcomes or demonstrate compliance. During the consultation, providers agreed that this could be an important benefit associated with the revised regulations (for example, some expressly commented that it would allow them to improve service delivery), however were unable to provide any quantification of these benefits, as they would be likely to depend significantly on the actual nature of the changes that made[11]. In addition, the majority of providers tended to view these benefits in terms of their improved ability to provide a quality service for patients, rather than in terms of potential cost savings or increases in business revenue. This was also reflected in a recent study commissioned by CQC on provider attitudes to regulation[12], which found that all providers surveyed demonstrated a clear commitment to improving standards and the quality of care offered to service users regardless of the regulations. As a result, this benefit remains unquantified.

Wider indirect benefits for providers

98. We also anticipate that there will be other indirect benefits to providers associated with improvements in the quality of care. These improvements are expected to arise out of the whole package of changes to CQC regulation as discussed in the introduction to this Impact Assessment and below. Thus these benefits are difficult to quantify or to attribute specifically to any one policy, however they are briefly discussed as follows:

    - Improved quality might have reputational benefits for providers. Improved quality and reputation for the sector as a whole may serve to increase overall demand for services, which benefits all providers in the market. Although the demand for health and adult social care will be in part limited by need for the service, some scope for market growth is expected to remain. For example, in the adult social care sector, there is evidence to suggest that individuals substitute between the formal and informal care sectors. Kemper (1992)[13] finds that amongst disabled elderly people, the use of formal home care increases and the use of informal care decreases with income. Similarly, the availability of immediate family increases reliance on informal care and reduces reliance on formal care. Although this study did not directly consider whether the perceived quality of care in the formal care market would

[11] For example, the revised regulations could enable a relatively minor change, such as in the way that providers monitor against compliance or collect data, or might result in a much wider scale change in the way that they deliver services

[12] *Health and Social Care Regulation: A study of Provider Attitudes and Behaviours*, A report for CQC, November 2013, available at http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

[13] *The use of formal and informal home care by the disabled elderly;* P Kemper; Health Serv Res. Oct 1992; 27(4): 421–451

similarly induce a substitution effect, other studies have estimated that the elasticity of demand with respect to quality in care homes may be as high as 0.44[14]

- Although the general view is that higher quality is associated with higher costs, this may not necessarily always be the case. Weech-Maldonado et al (2003) found that nursing homes that produce better outcomes of care were able to achieve lower patient care costs and report better financial performance. They cite a number of studies that demonstrate a positive link between quality of care and efficiency. Improvements in safety will reduce the need for costly remedial action (e.g. further surgery or care needs) and the potential number of medical malpractice claims. This could potentially also feed through into lower insurance premiums for providers if insurers judge that the overall risk of litigation has fallen.
- Improved patient satisfaction through better quality of care and improved patient relations is also likely to reduce the volume of costly patient complaints and medical malpractice claims.

The wider policy context

99. The proposals discussed in this Impact Assessment are part of a package of measures coming out of Francis to improve the quality and effectiveness of regulation. In addition to the legislative changes described in this and other related Impact Assessments, CQC are currently introducing changes in their inspection regime designed to coincide and work alongside these legislative changes. The aim of CQC's new inspection regime is to create a more effective and proportionate regulatory system. They will make better use of the data they already collect to develop an intelligent monitoring system to allow them to better target their inspection activity in areas of greatest risk. As a result high quality and compliant providers should face fewer inspections. The burden of regulation should as a result shift from high quality and well performing providers on to the poor quality and potentially non-compliant providers. CQC also anticipate that providing a more robust and broader assessment of provider performance will benefit providers by giving them a clearer view of the quality of their services and their strengths and weaknesses, which assists providers in designing their services[15]. The overall impact of these changes will be discussed in more detail within CQC's Accounting for Regulator Impact (ARI) process.

100. In addition to the direct impacts on business that these changes might have, overall improvements to the effectiveness of CQC regulation may also have benefits for business. For example, CQC state in their interim Impact Assessment for Adult Social Care Services[16] "*Better performing providers may also find reduced levels of scrutiny from commissioners. In addition it is likely that providers will benefit from not having to facilitate multiple inspections by different organisations or provide the same information twice as local authorities have more confidence in the way CQC assesses care provided through our inspections and ratings*." In evidence supplied to the Red Tape Challenge and the Focus on Enforcement it has been estimated that Local Authority duplication of CQC activity resulted in approximately £30 million of additional burdens just in the Care Homes sector, so the potential impact on this sector from any reduction in duplication could be significant. However, this is considered to be an indirect benefit to business as it is dependent on additional action being taken by local authorities in response to the changes being made in the regulation of health and adult

[14] *Quality Change and the Demand for Hospital Care*; Feldstein, M. Econometrica, Vol. 45, No. 7 (Oct., 1977), pp. 1681-1702 estimates the long run elasticity of hospital admissions with respect to quality is 0.44

[15] This is a key benefit of CQC as identified by providers in a recent report on provider attitudes to CQC regulation, as carried out by Research Works Ltd on behalf of CQC. See http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

[16] CQC "Changes to the way we regulate and inspect adult social care - Interim regulatory impact assessment". Available at: http://www.cqc.org.uk/sites/default/files/media/documents/20140409_asc_ria_for_april_2014_consultations_-_final.pdf

social care. In addition, it is not possible to attribute this effect to any one particular measure within the package of legislative and operational changes to CQC as described above.

Value for money:

101. 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:

Overall NPV:

			Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 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**
Familiarisation costs			2,910,000	-	-	-	-	-	-	-	-	-	2,910,000
Total			**2,910,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**2,910,000**
Prosecution costs	HMCTS		5,100	5,160	5,220	5,280	5,340	5,420	5,490	5,570	5,660	5,750	54,000
	CQC		180,000	182,000	184,000	186,000	189,000	191,000	194,000	197,000	200,000	203,000	1,910,000
	Providers		180,000	182,000	184,000	186,000	189,000	191,000	194,000	197,000	200,000	203,000	1,910,000
Total			**365,000**	**369,000**	**373,000**	**378,000**	**383,000**	**388,000**	**393,000**	**399,000**	**405,000**	**412,000**	**3,870,000**
Enforcement costs	Enforcement	CQC	-	-	-	-	-	-	-	-	-	-	-
	Total		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	Appeals	CQC	-	-	-	-	-	-	-	-	-	-	-
		Provider	-	-	-	-	-	-	-	-	-	-	-
		HMCTS	-	-	-	-	-	-	-	-	-	-	-
	Total		-	-	-	-	-	-	-	-	-	-	-
Total			**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total cost (undiscounted)			**3,270,000**	**369,000**	**373,000**	**378,000**	**383,000**	**388,000**	**393,000**	**399,000**	**405,000**	**412,000**	**6,770,000**
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)			**3,270,000**	**356,000**	**348,000**	**340,000**	**332,000**	**324,000**	**318,000**	**311,000**	**305,000**	**299,000**	**6,210,000**
Description of Benefits													
Societal benefits	Improved quality of care		Unquantified										
	Improved accountability		Unquantified										
Provider benefits	Time saved reading and interpreting regulations		223,000	226,000	229,000	232,000	235,000	239,000	243,000	247,000	252,000	256,000	2,380,000
	Time saved inducting staff		431,000	441,000	451,000	462,000	474,000	486,000	500,000	514,000	530,000	547,000	4,840,000
	Compliance savings		242,000	245,000	248,000	251,000	254,000	257,000	261,000	265,000	269,000	273,000	2,570,000
	Other benefits		Unquantified										
Total Benefit (undiscounted)			**897,000**	**912,000**	**927,000**	**945,000**	**963,000**	**982,000**	**1,000,000**	**1,030,000**	**1,050,000**	**1,080,000**	**9,780,000**
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)			**897,000**	**880,000**	**864,000**	**849,000**	**835,000**	**822,000**	**810,000**	**800,000**	**790,000**	**782,000**	**8,330,000**
Net Present Value			**- 2,380,000**	**523,000**	**516,000**	**509,000**	**503,000**	**498,000**	**493,000**	**489,000**	**485,000**	**483,000**	**2,120,000**

NB: figures may not sum due to rounding

Business NPV

			Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 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**
Familiarisation costs			1,540,000	-	-	-	-	-	-	-	-	-	1,540,000
Total			**1,540,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,540,000**
Prosecution costs	Providers		95,500	97,500	99,700	102,000	104,000	107,000	110,000	113,000	116,000	119,000	1,060,000
Total			**95,500**	**97,500**	**99,700**	**102,000**	**104,000**	**107,000**	**110,000**	**113,000**	**116,000**	**119,000**	**1,060,000**
Enforcement costs	Appeals	Provider	-	-	-	-	-	-	-	-	-	-	-
Total			**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total cost (undiscounted)			**1,640,000**	**97,500**	**99,700**	**102,000**	**104,000**	**107,000**	**110,000**	**113,000**	**116,000**	**119,000**	**2,610,000**
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)			**1,640,000**	**94,100**	**92,800**	**91,600**	**90,500**	**89,500**	**88,600**	**87,800**	**87,100**	**86,500**	**2,450,000**
Description of Benefits													
Provider benefits	Time saved reading and interpreting regulations		126,000	129,000	132,000	135,000	138,000	142,000	146,000	150,000	155,000	160,000	1,410,000
	Time saved inducting staff		240,000	250,000	259,000	270,000	281,000	293,000	306,000	321,000	336,000	353,000	2,910,000
	Compliance savings		129,000	131,000	134,000	137,000	141,000	144,000	148,000	152,000	156,000	160,000	1,430,000
	Other benefits		Unquantified										
Total Benefit (undiscounted)			**495,000**	**509,000**	**525,000**	**542,000**	**560,000**	**580,000**	**600,000**	**623,000**	**647,000**	**673,000**	**5,750,000**
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)			**495,000**	**492,000**	**489,000**	**487,000**	**486,000**	**485,000**	**485,000**	**485,000**	**487,000**	**489,000**	**4,880,000**
Net Present Value			**- 1,140,000**	**394,000**	**389,000**	**385,000**	**381,000**	**378,000**	**375,000**	**373,000**	**371,000**	**369,000**	**2,270,000**

NB: figures may not sum due to rounding

Equivalent Annual Net Cost for Business

			Year 0	Year 1	Year 2	Year 3	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9		
Description of Costs			**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**
Familiarisation costs							1,540,000	-	-	-	-	-	-	-	-	-	1,540,000	
Total							**1,540,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,540,000**	
Prosecution costs	Providers						Out of scope											
Total							**Out of scope**											
Enforcement costs	Appeals	Provider					Out of scope											
Total							**Out of scope**											
Total cost (undiscounted)							**1,540,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,540,000**	
Deflated to 2009 Prices							**1,440,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,440,000**	
Discount adjustment			1	0.97	0.93	0.90	1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73		
Total Present Cost (discounted)							**1,440,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,440,000**	
Description of Benefits																		
Provider benefits	Time saved reading and interpreting regulations						126,000	129,000	132,000	135,000	138,000	142,000	146,000	150,000	155,000	160,000	1,410,000	
	Time saved inducting staff						240,000	250,000	259,000	270,000	281,000	293,000	306,000	321,000	336,000	353,000	2,910,000	
	Compliance savings						129,000	131,000	134,000	137,000	141,000	144,000	148,000	152,000	156,000	160,000	1,430,000	
	Other benefits						Unquantified											
Total Benefit (undiscounted)							**495,000**	**509,000**	**525,000**	**542,000**	**560,000**	**580,000**	**600,000**	**623,000**	**647,000**	**673,000**	**5,750,000**	
Deflated to 2009 Prices							**462,000**	**476,000**	**491,000**	**506,000**	**523,000**	**541,000**	**561,000**	**582,000.00**	**604,000**	**629,000**	**5,380,000**	
Discount adjustment			1	0.97	0.93	0.90	0.87	0.84	0.81	0.79	0.76	0.73	0.71	0.68	0.66	0.64		
Total Present Benefit (discounted)							**402,606**	**400,779**	**399,429**	**397,711**	**397,172**	**396,948**	**397,703**	**398,638**	**399,717**	**402,185**	**3,992,891**	
Net Present Value							**- 1,040,000**	**401,000**	**399,000**	**398,000**	**397,000**	**397,000**	**398,000**	**399,000**	**400,000**	**402,000**	**2,550,000**	**297,000**

NB: figures may not sum due to rounding

102. The main costs of the proposed policy are the costs associated with familiarisation with the revised regulations and the potential increase in the number of prosecutions. This cost is expected to remain low as prosecutions will be targeted on a relatively small number of serious breaches. Although we expect that the proposed policy is likely to have additional impacts on the patterns of compliance, and hence enforcement activity, it has not been possible to model and quantify these impacts, although they are outlined above and examined further in the sensitivity analysis below.

103. 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 by £1m to a £1.02m net benefit. The business NPV would reduce by £350,000 to a net benefit of £1.9m, but the EANCB is predicted not to change as we consider the business cost of defending a prosecution to be out of scope of OITO.
- If enforcement activity were to increase by 10% a year, then as calculated previously, there would be an additional cost per year of approximately £90,000. The overall net present value for society would fall by £780,000 to £1.3m net benefit. The business NPV would fall by £50,000 to a net benefit of £2.2m. The EANCB is predicted not to change as we consider the business cost of responding to enforcement activity to be out of scope of OITO.
- If enforcement activity were to reduce by 10% a year, then as calculated previously, there would be a cost saving per year of approximately £90,000. The overall net present value for society would increase by approximately £790,000 to £2.9m net benefit. The business NPV would rise by £50,000 to a net benefit of £2.3m. The EANCB is predicted not to change as we consider the business cost of responding to enforcement activity to be out of scope of OITO.
- 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 by £430,000 to £2.55m net benefit. The business NPV would rise by £30,000 to £2.3m net benefit. The EANCB is predicted not to change as we consider the business cost of responding to enforcement activity to be out of scope of OITO.
- If the transitional costs of the policy are double the current estimates, the overall net present value to society would decrease to £785,000 net cost and the EANCB would be approximately £130,000 net benefit.

104. 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.

105. 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. Our work with providers during the consultation stage has confirmed this view with the large majority of providers agreeing that simpler regulations would benefit their business. We also provide some sensitivity analysis on the benefits below:

- If the provider time savings were half those currently estimated, the overall NPV would fall to £1.1m net benefit and the EANCB would fall by £58,000 to approximately £240,000 net benefit.
- If the time saving in inducting new staff were half of that currently estimated, the overall NPV would fall to £68,000 net benefit and the EANCB to £180,000 net benefit.
- If the savings associated with better understanding of compliance were half of those currently estimated, the overall NPV would fall to £1m net benefit and the EANCB to £240,000 net benefit.

106. 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

107. This policy proposal impacts all CQC registered health and adult 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 adult 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

108. In any affected market, would the proposal:

- Directly limit the number or range of suppliers?

109. 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?

110. 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?

111. The requirements are not expected to have any impact on suppliers. It will impact all CQC registered providers of health and adult social care equally.

112. The registration requirements do 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?

113. 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.

Small and Micro Business Assessment

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

114. Although CQC do not collect information about the size of the organisations it regulates, it has been possible to gain a sense of the size distribution of providers it regulates from other sources. The 2013 Skills of Care report on the size and structure of the adult social care workforce[17] used ONS data to estimate that there were a total of 17,100 adult social care providers, of which 86% would be considered small or micro businesses.

	Size group (employees)							
Service type	Total	0 - 4	5 - 9	10 - 19	20 - 49	50 - 99	100 - 249	250 +
Residential services (SIC2007 87)	7,900	1,600	900	1,600	2,300	1,000	400	200
Non-residential (SIC2007 88)	9,200	4,000	2,000	1,300	1,100	500	200	100
Total adult social care	**17,100**	**5,600**	**2,800**	**2,900**	**3,400**	**1,400**	**700**	**300**

Individual rows may not sum to totals due to rounding

115. This estimate is similar to that obtained from the BIS Annual Business Population Survey, which found that in 2013, there were approximately 50,000 employers in England with the Standard Industrial Classification (SIC2007) Human Health and Social Work Activities, of which 94% would be considered a small or micro business.

Count of number of private businesses within SIC2007 Q - Human Health and Social Work Activities in England

All employers	50,295
1	5,285
2-4	14,305
5-9	10,025
10-19	9,505
20-49	8,115
50-99	1,975
100-199	650
200-249	110
250-499	175
500 or more	150

Source 2013 BIS Business Population Survey

116. Thus, it is likely that the majority of private providers registered with CQC will be small or micro businesses, although it is possible that there might be significant variation between sectors. Under the previous Care Standards Act 2000, CQC's predecessor collected some information for Agency Social Care which suggested that 64% of these organisations were recorded as being 'large' whilst the remaining 36% were considered 'small'.[18]

[17] Skills for Care, *The size and structure of the adult social care sector and workforce in England,* 2013

[18] No further information was available however on the types of organisations covered or the classification of small versus large. As this data is likely to be relatively out of date now, no further conclusions are drawn from it.

117. The revised registration requirements will apply equally to providers of all sizes. The rationale for this approach is because the risks associated with health and adult social care that CQC regulation is designed to mitigate is unlikely to vary significantly with the size of the organisation. For example, it is likely that the potential risks to a service user from a residential care home owned by a large national chain will be much the same as from a much smaller local provider. This is because the key determinants of risk in health or adult social care are the type of service provided and the potential for patient harm or adverse consequences associated with this, and the vulnerability of people using the service rather than the size of the organisation providing the service. In the example of residential care homes, the potential consequences for service users from poor quality care might include pressure ulcers and the potential for abuse, whilst the vulnerability of service users will be determined by factors such as disability status and whether they have mental capacity. These factors are likely to remain the same across the care home sector, and as a result, it is important that there is the same assurance of levels of safety and quality wherever people access services.

118. However, this is not to say that CQC does not take into account regulatory burden. Under the 2008 Health and Social Care Act, CQC has a duty to ensure that any action it takes is proportionate to the risks to which it is addressed and is targeted only where it is needed. As a result, CQC takes into account and makes adjustments in how it monitors and inspects providers in order to minimise regulatory burden.

119. As discussed above, CQC expect all providers to meet the same set of standards, as set out by the regulations, and will judge compliance and rate providers based on this same set of criteria. However, what this means in terms of inspection length and/or frequency, and the amount of evidence providers will be expected to provide will vary as follows:

    - The methodology by which CQC inspect compliance is likely to vary by sector and in accordance with the nature and the complexity of the service provided. For example, a large NHS hospital is likely to undertake a wider range of regulated activities involving a greater number of staff and patients compared to a small care home, which might provide a single regulated activity with a handful of staff. It is clearly the case that CQC would need to spend longer inspecting and considering the available evidence where providers provide a more complex and larger range of services. As an illustration of this, CQC anticipate that, under their new regulatory model, a typical inspection at an Acute Hospital might take up to 22 days whilst the typical inspection at a care home would more likely take between 3 to 5 days. In terms of the impact on small and micro businesses, it is likely that, subject to the factors below, they would face shorter and less intensive inspections due to the nature of the services that they would be providing.
    - CQC operate a regulatory model that is proportionate to risk. Where CQC have existing concerns about a provider, they will focus more regulatory activity here for example by conducting a more intensive and lengthy inspection, asking to see more evidence from the provider, or inspecting on a much more frequent basis. On the other hand, where providers have a good history of compliance, they would face less scrutiny from CQC. Under CQC's new regulatory model, it is proposed that inspection frequency will be linked to provider ratings, so that providers who are found to be high performing will be inspected less frequently than is currently the case. This approach suggests that a provider of any size will face a lower regulatory burden associated with monitoring and enforcement against the regulations, provided that they maintain a high quality and compliant service.
    - Finally, in terms of how CQC will judge compliance against any requirement, CQC are not prescriptive in terms of the evidence that providers would need to supply.

Rather than CQC specifying what providers must provide, it is the duty of the provider to demonstrate to CQC how it is meeting the standards. For example, whilst a large provider might be able to demonstrate how it is meeting the registration requirement on complaints with reference to the work being carried out by the dedicated complaints manager, CQC would not expect a smaller provider to also have such a person in place. Instead, a small provider might demonstrate compliance by being able to provide written records of the complaints it received and what subsequent action was taken.

120. CQC recently commissioned some work to understand providers' attitudes towards regulation.[19] This involved interviews with 59 providers of a variety of different sizes, including large NHS hospitals, single-location care homes and private dental practices. Although providers did identify some burdens associated with managing the regulatory requirements, all providers viewed such regulation as an essential part of running a health or adult social care service, with an unregulated world being unimaginable. Overall, whilst this suggests that providers of all sizes are supportive of regulation, it is important to ensure that this regulation is carried out in a way to minimise the potential burdens. On the back of this work, CQC are committed to doing more to understand the burden of regulation on providers, and to work continually to reduce the burdens of regulation on providers as part of the duty for non-economic regulators to have regard for growth.

Legal Aid/ Justice Impact

121. 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? **Yes**
- Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? **Unknown but potentially 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

122. 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

[19] *Health and Social Care Regulation: A study of Provider Attitudes and Behaviours*, A report for CQC, November 2013, available at http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

- 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)

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

124. 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.

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

Wider impacts

126. The main purpose of the proposed policy is ensure that the regulation of health and adult 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

127. 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

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

Social impacts

129. No other social impacts of the policy have been identified

Section F: Summary and Conclusions

130. 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 registration requirements will be revised to make them clearer and easier to understand and the criminal offences will be made more specific and more targeted so that the requirement for CQC to issue a warning notice before bringing a prosecution can be removed. CQC will be able take stronger enforcement action via prosecutions where appropriate to better hold providers to account for their failings. These changes to the regulations will enable us to define what the fundamentals standards of care are, in line with the recommendations of the Francis Inquiry.

131. The main costs of the proposed policy for providers will be the costs of familiarisation with the revised regulations since the new regulations will clarify and not change the required standards that providers will have to meet. There will be costs to society associated with increased prosecutions that CQC will be able to bring stemming from the removal of the warning notice requirement, and we also consider that there could be other resultant changes in the pattern of compliance and enforcement. The changes in prosecution and enforcement are considered out of scope for the purposes of OITO since they would only affect non-compliant providers.

132. The main societal 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 will reduce the burden of regulation on providers. Our work with providers during the consultation has confirmed our initial estimates of these potential benefits, with the majority of providers agreeing with the estimates made in the consultation stage Impact Assessment, and agreeing that the revised regulations would benefit their business. We note also that providers were able to point to additional benefits of simpler regulations that we have been unable to quantify. We are therefore confident that this preferred option would not only create a net benefit for society, but will also represent a net benefit for business.