Title:	Impact Assessment (IA)
Registration of primary medical services providers with the Care Quality Commission – a final impact assessment on a proposed change to the date of registration	**IA No:** 6019
	Date: 11/08/2011
	Stage: Final
	Source of intervention: Domestic
Lead department or agency: Department of Health	**Type of measure:** Secondary legislation
Other departments or agencies:	**Contact for enquiries:** Mark Bennett 0113 254 6501

Summary: Intervention and Options

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

All health and social care involves risks to the health of service users as well as asymmetric information and potential incentives to provide sub-optimal care. Given this, a previous IA found regulation of primary care providers by the Care Quality Commission to be socially beneficial. This conclusion is still valid.

However, the original timetable of bringing primary care providers into regulation by April 2012 may impose an unnecessary burden on the CQC and providers as it would add to an existing backlog of registration and impact negatively on the service received by providers and constrain the CQC's ability to review and refine its approach. Any change to the registration timetable requires government intervention in the form of secondary legislation.

What are the policy objectives and the intended effects?

The proposed policy aims to ensure that the CQC

1) can effectively monitor and enforce compliance of registered providers' with regulation requirements - and thus ultimately improve patient experience, safety and health outcomes.

2) can do so without imposing unwarranted burden on providers.

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

Option 1: Based on current legislation, the 'do nothing'-option is to bring primary care providers into CQC regulation from April 2012 as originally planned.
Option 2: To register providers of NHS out-of-hours services to patients who are not registered from April 2012, but defer the registration of all other providers of NHS primary care services until April 2013.
This is the preferred option, as the benefits of regulation will be achieved from 2012 for those providers identified as being of a higher risk, while the extra year before registering the majority of providers gives CQC time to incorporate lessons from recent experience and improve the system for all.

Option 3: To defer the registration of all NHS primary medical care providers until April 2013 - considered in evidence base only.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 9/2013	
What is the basis for this review? PIR. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister: ***Simon Burns*** Date: ***14 September 2011***

Summary: Analysis and Evidence

Policy Option 2

Description:

To register providers of NHS out-of-hours services in April 2012 and all other providers of NHS primary medical care in April 2013.

Price Base Year 2010	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £44.28m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	3	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£1.34m		£0.00m	**£0.59m**

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

Development of streamlined and improved registration process (the CQC). Small increase in total initial compliance costs due to churn in market (providers). Small increase in costs to transitory fee costs (CQC).
** Due to the costs being net effect of reprofiled costs and cost savings overall discounting reduces the value

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

None have been identified.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	3	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£42.91		£0.06m	**£44.87m****

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

Net benefits of increased effectiveness of regulation in 2012/13 and 2013/14; reduced adverse health events (patients), saved NHS treatments costs (NHS), and safety net effect (patients & public).Cost saving from streamlining processes (NHS primary medical care providers & the CQC). Costs savings from forgoing fees and review costs (providers).Cost savings from forgoing tribunal costs in 2012/13 (tribunal service).
** Due to some benefits being net effect of reprofiled costs overall discounting slightly increases the value.

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

No costs of distraction i.e. CQC being unable to maintain its regulatory oversight of registered providers as registration of the majority of NHS primary medical care providers in April 2013 gives the CQC time to learn from recent experience and improve its systems for all. (Patients; who could otherwise receive poor care, Providers; who could otherwise receive a poor service & the CQC; who could otherwise suffer loss of public confidence in its capacity as a regulator).

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

The marginal impacts of this timing option compared to "do-nothing" (bring all NHS primary medical care providers into regulation in April 2012) are based on the assumptions and analysis underpinning the "do nothing" as outlined in Annex 2 of the evidence base of this impact assessment.
Sensitivity testing shows that the value for money of this option is robust. There is a risk that the current capacity issues could still be an issue for CQC in April 2013.
The analysis quantifies opportunity costs by applying the standard DH 2.4 multiplier to impacts on the NHS, DH and/or exchequer budget. Sensitivity analysis has shown that the positive NPV is not sensitive to this, and this option would remain value for money even if opportunity costs were not reflected.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/04/2012		
Which organisation(s) will enforce the policy?			DH, CQC		
What is the annual change in enforcement cost (£m)?			£0		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** /	**Non-traded:** /	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** /	**Benefits:** /	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	19
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	19-20
Small firms Small Firms Impact Test guidance	No	20
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	20
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	20
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	20
Human rights Human Rights Impact Test guidance	No	20
Justice system Justice Impact Test guidance	No	20-21
Rural proofing Rural Proofing Impact Test guidance	No	21
Sustainable development Sustainable Development Impact Test guidance	No	21

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	*Impact Assessment of Health and Social Care Bill provisions for future regulation of health and adult social care* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080460
2	*Impact Assessment of the scope of registration of primary medical and dental care* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_083683.pdf
3	*Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008* *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_097143.pdf*
4	*Impact assessment of registration regulations made under the health and Social Care Act 2008* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_0115544.pdf
5	*Registration of primary medical services providers with the Care Quality Commission - A consultation on a proposed change to the date of registration* http://www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm

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Evidence Base (for summary sheets)

1. In October 2009, a final *impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008*[1] was published which informed the decision to require NHS primary medical care providers to register with the Care Quality Comission (CQC) from April 2012. This decision was implemented through regulations which set an exemption from registration for NHS primary medical care providers until 1 April 2012.[2] This impact assessment considers whether, in light of the experience of registering other providers, this date for NHS primary medical care registration is still appropriate.
2. We have reflected on the orginal decision to require providers of NHS primary medical services to register with CQC and have concluded that that decision is still valid. In light of new information since 2009, Annex 2 of this impact assessment updates the estimated costs and benefits from the original October 2009 impact assessment and concludes that the registration of these providers with CQC is still expected to yield value for money.
3. This impact assessment considers the timing of CQC registration of primary medical care providers and draws on the information in Annex 2. This impact assessment is being published alongside a response to consultation and a set of draft regulations to amend the date of registration or providers of NHS primary medical services.

Policy Background

4. Users of health and social care services have a right to know that the care that they receive is safe and of a suitable quality. System regulation focuses on the organisations that provide health and adult social care services and provides assurance that systems for safety and quality are in place and working well. System regulation complements professional regulation of health and social care professionals which focuses on the skills and competence of individual practitioners. The regulation of health and adult social care providers in England is carried out through a registration system operated by CQC.
5. CQC carries out the registration of providers of health and adult social care services under the terms of the Health and Social Care Act 2008. Under this legislation, all providers of 'regulated activities' are required to register with CQC. Regulated activities cover most health and adult social care services. Providing a regulated activity without being registered with CQC is an offence which can result in an unlimited fine and/or imprisonment of up to 12 months.
6. In order to be registered with CQC, and to remain registered, providers of regulated activities are required to comply with a set of registration requirements that establish the essential levels of safety and quality. These cover a range of outcomes including, for example, the care and welfare of service users, cleanliness and infection control, the safety and suitability of premises, safeguarding service users and staffing.
7. Where a registered provider fails to meet the registration requirements CQC has a range of enforcement powers that it can use to bring about improvements. These range from issuing a warning notice or placing a condition on a provider's registration through to cancelling registration or bringing a prosecution.
8. The Department of Health consulted extensively during the development of the registration system in 2008 and 2009. Responses to a number of consultations revealed strong support for the new regulatory framework and for the move to regulating specific activities rather than establishments and agencies. There was overwhelming support for registration to include providers of primary medical services, and for the proposal to introduce registration in a number of waves set out in regulations.
9. Regulations have set out a staged approach for CQC to bring providers of health and adult social care into the new registration system.

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115559
[2] The Health and Social Care Act 2008 (regulated activities) regulations 2010 http://www.legislation.gov.uk/uksi/2010/781/contents/made

- In April 2009, NHS providers of health care were registered against a single registration requirement relating to cleanliness and infection control, before being registered against the full set of registration requirements in April 2010.
- In October 2010, providers of adult social care services and independent sector providers of health care were registered under the new system.
- In April 2011, primary dental service providers and independent ambulance services were registered by CQC.
- In April 2012, NHS primary medical care providers are due to be registered with the CQC.

Since April 2010, the CQC has registered around 22,000 health and adult social care providers. It is expected that CQC will register around 9,000 further providers when the current exemption for NHS primary medical care lapses.

10. There have been a number of previous impact assessments looking at this area of policy:
    a. The impact assessment for the Health and Social Care Act 2008 included the costs of merging the three former regulators into CQC. It also set out the expected costs of regulating the same providers that the Commission for Social Care Inspection, the Mental Health Act Commission and the Healthcare Commission previously regulated[3];
    b. A partial impact assessment of bringing primary care providers into regulation was published with the consultation paper *The future regulation of health and adult social care providers* in March 2008[4];
    c. The assumptions in this partial impact assessment were revised as a result of consultation and new information supplied by the Healthcare Commission and, subsequently, CQC. This revised impact assessment, which considered the costs and benefits of bringing providers of primary dental care and providers of NHS primary medical care into registration was published in October 2009[5].
    d. Finally an impact assessment was published with the document *Response to consultation on the framework for registration of health and adult social care providers and consultation on draft Regulations* in March 2009. This covered the costs and benefits of the regulated activities that were expected to be brought into scope from April 2010. A revised version of this impact assessment was published in October 2009, *Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008.*[6]
11. The impact assessment, at c) and then d) above, found that registration of providers of NHS primary medical services with the CQC is the most effective way of mitigating system-related risks in primary care. Annex 2 updates this impact assessment and shows that registration of providers of NHS primary medical services with the CQC still represents value for money, and that continuing to exempt these providers from registration indefinitely would not be a valid alternative option.
12. Benefits of system regulation include
    a. Reduction in adverse patient health events leading to patient and saving NHS treatment costs;
    b. Increase in the overall quality of primary medical care;
    c. Improved consistency; a level playing field for all providers;
13. Costs of system regulation include
    a. Transition costs: initial registration and compliance costs;
    b. Annual costs of regulation: fees, costs of CQC reviews for providers and CQC; ongoing compliance costs; assisting ongoing regulation;

[3] Impact Assessment of Health and Social Care Bill provisions for future regulation of health and adult social care http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080460

[4] Impact Assessment of the scope of registration of primary medical and dental care http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_083683.pdf

[5] Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_097143.pdf

[6] Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115559

14. Given the findings of Annex 2, this impact assessment considers timing options for the registration of providers of NHS primary care with the CQC. It is structured as follows:

    A. The underlying rationale for government intervention;

    B. Policy objectives and intended effects;

    C. Description of the options;

    D. Costs and benefits assessment of the options (including specific impact tests);

    E. Summary of specific impact tests;

    F. Summary and conclusion.

Annex 1: Post Implementation Review

Annex 2: Updated analysis of CQC registration of NHS primary medical care providers

A. The underlying problem

15. Annex 2 outlines the continuing rationale for CQC to register providers of NHS primary medical services. Given that it demonstrates that the registration of NHS primary medical care providers still represents value for money, the underlying problem for consideration in this impact assessment is the start date for registration of these providers.

16. From April 2012, providers of NHS primary medical services are due to enter the new registration system. This timescale is set out in the Health and Social Care Act 2008 (Regulated Activities) 2010. This wave of registration includes all providers of NHS primary medical services under sections 3, 83(2)(b), 84 or 92 of the NHS Act 2006. This includes providers of GP practices, out of hours primary medical services, and others. This is the final wave of registration of health and social care providers and comprises of approximately 9,000 providers.

17. The Government is committed to bringing these providers into the registration system operated by CQC. However, it is also committed to keeping all regulatory requirements under review and to keep the burden of regulation to the minimum required to give assurance about the safety of services.

18. Registration of these providers will give valuable assurance to patients that NHS primary medical services are meeting essential levels of safety and quality and will provide a mechanism to address poorly performing service providers. However, in light of the experience of previous rounds of initial registration, it has become apparent that there may be an opportunity to improve CQC's ability to enforce compliance effectively, and reduce the burden of registration, by reconsidering the timing of the registration of primary medical services providers that was originally set out in regulations in 2010.

Compliance monitoring

19. The experience to date of registering more than 20,000 health and adult social care providers has been challenging both for providers and for CQC itself. The demands placed on CQC by a succession of new registration rounds have led to a backlog of routine registration work, which has had a detrimental impact on the service received by some providers and has constrained CQC's capacity to monitor and enforce compliance with essential levels of safety and quality of registered providers effectively. Rates of assessment of compliance are steadily increasing but need to be consolidated.

20. Going ahead with the registration of providers of NHS primary medical services in April 2012 would not allow CQC time and space to deal with its backlog before registering an additional 9000 providers. As a result, effective registration, compliance monitoring and enforcement of providers would be undermined and thus the benefits of regulation in 2012/13, and beyond, limited. It would also constrain CQC's ability to review and refine its approach.

21. Deferring the bulk of this registration round would provide time for the CQC to clear its backlog and release capacity and provide an opportunity to review and modernise its systems sooner rather than later. This would result in more responsive regulation, and more effective registration and compliance monitoring of registered providers.

Burden of registration

22. Going ahead with the registration of providers of NHS primary medical services in April 2012 would not allow CQC time and space to learn from experience and develop a more streamlined application process with a reduced burden for primary medical services providers (and in the future, new providers from all sectors). It would also not provide time for the further development of quality and accreditation schemes for primary medical services providers, which can be used as evidence of their compliance with the registration requirements, and for providers to participate in such schemes.

23. Deferring the date of registration would give CQC time to review and modernise its systems. This would streamline the application process and reduce the burden for CQC, primary medical services providers and future providers for all sectors when they enter the new registration system.

Proposal

24. For these reasons, the Department launched a six-week consultation on 17 June 2011 which proposed that the registration of most primary medical services providers for the NHS (due to take place in April 2012) should be deferred until April 2013. As set out in the consultation response published alongside this document, this was supported by those who responded.

25. The preferred option (as demonstrated in subsequent sections of this impact assessment) is that the majority of providers that are due to enter the registration system in April 2012 will not now be registered until April 2013. However, in view of concerns about the nature of the risks associated with some NHS out of hours services, those providers of NHS primary medical services in the out of hours period to patients who are not registered with them should still be registered in April 2012. GP practices that continue to provide out of hours care to their own registered patients should register alongside other GP practices in April 2013.

26. Without the change to the timing of the registration of NHS primary medical care providers may;

- undermine effective compliance monitoring and;
- impose an unnecessary burden on both providers and the CQC.

27. This change to the timing would require amendments to secondary legislation hence government intervention is required.

28. Some of the issues identified above may impact more heavily on certain groups. For example, children and elderly people utilise primary medical care more than other groups and therefore the proposal may have a disproportionate effect on these groups. These issues are discussed further in the equality impact assessment, see section E below.

B. Policy objectives and intended effects

29. Given the underlying problem set out above, there are two key policy objectives in considering the timing of registering providers of NHS primary medical services. These are:

- To enable effective compliance monitoring of providers;
- To ensure that registration does not impose unnecessary burdens on providers or CQC

Compliance monitoring: To enable effective compliance monitoring of registered providers

30. The timing of CQC's registration of NHS primary medical care providers must enable effective registration and effective compliance monitoring in order for the benefits of regulation to be fully realised. To achieve this the timing of the registration must allow for: the backlog of routine work to be dealt with; CQC to have the capacity to run a fully effective registration round and effectively monitor compliance of all registered providers; and, for CQC to review and refine its approach.

Burden of registration: To ensure that registration does not impose unnecessary burdens

31. The timing of CQC's registration of NHS primary medical care providers must ensure that registration and regulation does not impose any unnecessary burdens. To achieve this the timing of the registration must allow for: an opportunity to learn from and build on the experience of previous registration rounds; and, time for CQC to streamline its systems, tools and processes including drawing on the evidence of quality and accreditation schemes, such as the Royal College of General Practitioners' Practice Accreditation Scheme.

Intended Effects

32. In meeting the above policy objectives, appropriately timed registration of NHS primary medical care providers contributes to the prevention of poor quality service provision through a regulatory system that identifies sub-standard providers while imposing minimal burden on the vast majority of providers that provide care that is both safe and of a good quality.

C. The Options

33. Given that regulation of NHS primary medical care providers still represents value for money (as set out in Annex 2), this impact assessment considers three options for the timing of the registration of these providers.

    - Option one – do nothing – under this option all providers of NHS primary medical services that are currently exempt from registration would be required to register from 1 April 2012;
    - Option two – preferred option - register providers of NHS out of hours services to patients who are not registered with them in April 2012, while deferring the registration of providers of other NHS primary medical services until April 2013. Under this option the majority of providers of NHS primary care services, including GP practices, would continue to be exempt from registration until April 2013. However, providers of NHS out of hours primary medical services to unregistered patients, would be registered in April 2012 for all of their NHS primary medical services. Providers of these services would be registered earlier than providers of other primary medical services because the inherent risks in the service that they provide are different to those providing NHS primary medical care to registered patients. These services routinely treat patients who they do not hold records for and who they will not have an ongoing relationship with. In addition, they are likely to have a higher proportion of vulnerable patients with urgent care needs that are more complex than those generally found in traditional general practice in core hours.
    - Option three - delay the implementation of registration for all providers of NHS primary medical services until April 2013;

34. A further option of delaying registration of providers of NHS primary medical services for longer than 12 months was considered. However, given that we believe the issues of going ahead with registration in April 2012 can be overcome in 12 months, and that the impact of implementing registration is positive (as demonstrated in Annex 2), it is apparent that there would be limited additional benefit arising from a longer delay, and more likely, there would be additional costs. This option was therefore dismissed and has not been considered in detail in this impact assessment.

35. The benefits and costs of the above options are considered in Section D below.

D. Benefits and Costs

36. Given that Annex 2 demonstrates that the original decision to regulate NHS primary medical care providers is still valid, this section considers the costs and benefits of the options for the timing of registration as described in Section C above.

37. In line with impact assessment guidance, the marginal costs and benefits of each timing option relative to the do nothing option, Option 1, are assessed below. They reflect the full economic opportunity costs.[7]

38. The costs and benefits in this section are based on information contained within Annex 2, please refer to this annex.

[7] The benefits and costs reflect the full opportunity cost of NHS, DH and Exchequer resources, see Annex 2 para 161.

Option 1

39. Option 1, which is the do nothing option, is to require all NHS primary medical care providers to register with CQC from April 2012, as set in legislation. There are no marginal impacts to this option compared to the position as set out in Annex 2.

Option 2

40. Option 2 is to register all providers of NHS out of hours services to unregistered patients in April 2012, while deferring the registration of providers of other NHS primary medical services until April 2013.

Benefits

41. This option ensures effective compliance monitoring and reduces unnecessary burdens.

Effective compliance monitoring

- Benefits from increased effectiveness of regulation in 2012/13 and 2013/14
- No costs of distraction

42. It is through the initial registration process that most non-compliant providers will be made compliant.[8] From then on, it is CQC's review process that ensures compliance is maintained.

43. It is anticipated that only 150 providers of NHS out of hours services to patients who are not registered with them would be required to register in April 2012. The remaining 8,850 providers would register with CQC in 2013.[9]

44. Note that this compares to a do nothing option under which CQC would need to register 9,000 providers in April 2012 and it is now assumed, in light of recent experience, not to be in a position to do this effectively and tackle non-compliance properly. As a result, only a proportion of the potential annual net benefit of regulation would be realised in 2012/13 and in 2013/14 (See para 152 – 159 Annex 2 for details).

45. Under Option 2, on the other hand, CQC is expected to carry out effective registration and initial compliance monitoring of the small group of providers registered in 2012/13. By 2013/14, it is then expected to be in a position to register and monitor the remaining 8,850 providers effectively. The table below shows the expected profile of CQC compliance enforcement assumed under this option and the do nothing, Option 1.

Table D1: Assumed CQC enforcement of compliance over time under updated do nothing Option1 (as set out in Annex 2) and Option 2.

	2012/13	2013/14	2014/15 to 2021/22
Option 1 CQC compliance enforcement	20%	60%	100%
Option 2 CQC compliance enforcement	100%	100%	100%
Option 1 providers	9000	9000	9000
Option 2 providers	150	9000	9000
Option 1 consultations (m)	367	377	387-468
Option 2 consultations (m)	10	377	387-468
Option 1 consultations covered	73.4	226.2	387-468
Option 2 consultations covered	10	377	387-468

[8] See Para 152-159 in Annex 2 for details

[9] Cf. Annex 2 for a derivation of these figures.

46. Annex 2 estimates that, under the do nothing option, CQC regulation of primary care providers will generate (quantifiable) benefits[10] of £12.58m in 2012/13[11]. As table D1 shows, CQC is expected to generate these benefits by registering 9,000 providers and thus covering the risks associated with all 367m consultations in 2012/13, but only being able to enforce compliance in 20% of cases. This is equivalent to CQC mitigating the risks associated with 73m consultations with 100% effective enforcement (367m*20% = 73.4m).

47. Under option 2, on other hand, CQC is expected to register 150 providers and mitigate the risks associated with their 10m consultations[12] with 100% enforcement. This suggests that, in 2012/13, option 2 will generate about 13.6% of the benefits generated by the do nothing (10m/73.4m = 13.6%). Thus, benefits from option 2 are expected to amount to £1.72m (£12.58m *13.6% = £1.72m) in 2012/13. In that year, relative to the do-nothing, implementing option 2 is expected to lead to a reduction in the benefits of regulation of £10.86m (£12.58m-£1.72m). In addition, a proportion of the unquantifed benefits[13] such as the safety net effect and increased overall quality may be also be reduced in 2012/13 in line with the above.

48. However, this is more than compensated in 2013/14 as CQC is expected to have used the delay to clear their backlog of work and thus have the capacity to register effectively the remaining bulk of providers.

49. Annex 2 estimates that, under the do nothing option, CQC regulation of NHS primary medical care providers will generate (quantifiable) benefits of £38.77m[14] in 2013/14. As table D1 shows, CQC is expected to generate these benefits by registering 9,000 providers and covering the risks associated with 377m consultations in 2013/14, but only being able to enforce compliance in 60% of cases. This is equivalent to CQC mitigating the risks associated with 226.2m consultations with 100% effective enforcement (377m* 60% = 226.2m).

50. Under option 2, on the other hand, CQC is expected to be able to run a fully effective registration round in 2013/14 thus be able to fully enforce compliance for all 9,000 registered providers, and mitigate the risks associated with all 377m consultations with 100% effective enforcement.

51. This suggests that in 2013/14 the benefits under option 2 would be around 167% of the benefits under the do nothing option (377m/226.2=166.66%). Thus the benefits are expected to amount to £64.62m (£38.77m *166.66% = £64.62m) in 2013/14. Relative to the do-nothing, implementing option 2 is expected to increase benefits in 2013/14 by £25.85m. In addition, there will be an increase in the unquantified benefits[15] such as the safety net effect and increased quality in 2013/14.

52. This gives an overall net benefit due to increased effectiveness of compliance monitoring of **£14.98m** over 2012/13 and 2013/14 (£25.85m-£10.86m; figures may not sum due to rounding).

Table D2: Summary of marginal increase in health benefits

Total benefits:	2012/13	2013/14	2014/15
Option 1	£12,578	£38,771	£66,396
Option 2	£1,715	£64,619	£66,396
Option 2 marginal to Option 1	-£10,863	£25,848	£0
TOTAL difference	£14,985		

53. In addition, as noted in Annex 2 registering all 9,000 providers in 2012/13 will distract CQC from compliance monitoring of its other 20,000 registered providers (see Annex 2). This distraction cost will be much lower under this option, if CQC only registers the majority of providers in 2013/14 after

[10] Benefits are generated through CQC registration and regulation mitigating health risks associated with primary medical care consultations. See Para 205-252 in Annex 2 for details.

[11] See Table A2.12 and A2.14 and Para 205-244 in Annex 2 for details

[12] It is estimated that there will be around 10m NHS out-of-hours consultations by providers treating a unregistered list of patients. See Para 212 and table A2.5 for details.

[13] See annex 2 for details

[14] See Table A2.12 and A2.14 and Para 205-244 in Annex 2 for details

[15] See Para 244-252 in Annex 2 for details

adapting its processes in response to the experience of previous registration rounds and clearing its backlog of work. This benefit of deferral is unquantifiable but could be significant[16].

Reduction in the burden of registration and regulation

- Cost saving from streamlining processes
- Costs savings from forgoing fees to providers
- Cost savings from forgoing review costs to providers
- Costs savings from forgoing tribunal costs in 2012/13

Streamlining

54. Registering a small number of providers in April 2012 whilst deferring the majority of providers until April 2013 will give CQC an opportunity to streamline its registration process and increase its capability before registering the majority of providers of NHS primary medical services. As a result, the burden of initial registration from 2013/14 onwards may be reduced. Although this is difficult to quantify, as the work is yet to be done, CQC have suggested twelve months to streamline their own process could reduce their burden by up to 15%.

55. Annex 2 sets out that under the do nothing the cost to CQC of initial registration are estimated to be around £14.4m[17]. As 150 NHS out of hours providers are coming into registration in 2012/13, 1.67% (150/9000) of the initial registration cost to CQC is incurred in that year giving an overall cost saving of £14.16m (£14.4 *(100%-1.67%)) in 2012/13. In 2013/14, the initial registration cost for the remaining 98.33% of providers is incurred, but is assumed 15% lower. So compared to the do nothing option, there is cost increase in 2013/14 of £12.04m (£14.16m*(100%-15%)).

56. Therefore, as the delay allows the process to be streamlined before the main bulk of providers register, there are cost savings to CQC of **£2.12m** (£14.16m-£12.04m).

Table D3: Summary of marginal cost saving to CQC due to streamlining

Initial registration costs:	2012/13	2013/14	2014/15
Option 1	£14,400	£0	£0
Option 2	£240	£12,036	£0
Option 2 marginal to Option 1	-£14,160	£12,036	£0
TOTAL difference	-£2,124		

57. It is also expected that any improvement to the registration process will also reduce the burden of initial registration on providers. Again, this is difficult to quantify as the development work is yet to be done and evidence on the burden on providers is limited. However, a reduction by 5% is thought to be a prudent assumption.

58. Annex 2 sets out that under the do nothing the costs to providers of initial registration over years 2012/13 is estimated to be around £64.80m[18]. As above, under option 2, only 1.67% of this initial registration cost to providers is incurred in that year giving an overall cost saving of £63.72m (£64.8m*(100%-1.67%)) in 2012/13. In 2013/14, the initial registration cost for the remaining 98.33% of providers is incurred, but is assumed to be 5% lower. So, compared to the do nothing option, costs in 2013/14 increase by £60.53m (98.33%*£64.8m*(100%-5%)). In addition, under the do nothing, due to assumed churn in the market, there would be providers that register in 2012/13 only to leave the market in 2013/14and be are replaced by new providers who must also register for the first time. Under option 2, this would not occur due to the delay, those providers who leave the market would not have had to register, and as a result there is a cost saving of £1.15m[19], making the total marginal cost increase in 2013/14 £59.38m (£60.53-£1.15m).

59. In addition, under this option, the 5% streamlining reduction will apply to the initial registration costs of new providers from 2014/15 onwards. As set out in Annex 2, initial registration costs for new

[16] See Para 169 in Annex 2

[17] See table A2.14 and Para 167 in Annex 2

[18] See table A2.14 and Para 173 in Annex 2

[19] See Para 174 in Annex 2. £1.15m based on churn of 160 providers each year.

providers are assumed to be £1.15m[20] pa, therefore the cost saving under this options is £58k pa, (5%*£1.15m).

60. The above gives an overall estimated cost saving to providers of **£4.80m** (£63.72m-£59.38m+ (£58k*8years)) due to streamlining of the registration process.

Table D4: Summary of marginal cost saving to providers due to streamlining

Initial registration costs:	2012/13	2013/14	2014/15 onwards
Option 1	£64,800	£1,152	£1,152
Option 2	£1,080	£60,534	£1,094
Option 2 marginal to Option 1	-£63,720	£59,382	-£58
TOTAL difference	-£4,799		

Forgoing fees to providers

61. In 2012/13, the annual costs of regulation to CQC will only be incurred for the 150 out of hours providers registering in that year. As outlined in Annex 2, the annual cost is assumed to be around £1600 and, in the first year, this will be split 50:50 between provider fees and cost to CQC[21]. Therefore, the cost to providers in 2012/13 is £120k (£800*150). This is a cost saving of £7.08m compared to the do nothing option where all providers incur a fee (£800*9000=£7.2m).

62. Under option 2, it is assumed that CQC will still prudently set fees at the initial year cost recovery level of 50% in 2013/14 when the bulk of providers come into registration for the first time. As a result, the provider cost in 2013/14 is £7.2m (£800*9000). This is a cost saving of £3.6m compared the do nothing option where the fee is assumed to be around 75% cost recovery and thus the cost is £10.8m (£1600*75%=£1400, £1400*9000 is £10.8m). Following from this, under this option fee recovery is assumed to be 75% in 2014/15 giving a provider cost of £10.8m, which is a cost saving of £3.6m compared to the do nothing where fee recovery is 100% and the cost to providers is £14.4m (£1600*9000=£14.4m).

63. Overall, this gives a net cost saving to providers of **£14.28m** (£7.08m+£3.6m+£3.6m). This saving is a year's annual cost foregone minus the £120k cost that is still incurred for the out of hour providers whose registration is not delayed. Over time this is a full saving to providers, as CQC is assumed to provide the same transitory assistance, regardless of the date of registration. As discussed in Annex 2, as it is not known how provider fees will be recovered no assumptions about opportunity costs or tax implications are made.

Forgoing review costs to providers

64. In 2012/13, under this option only out of hours providers would be subject to review. As set out in Annex 2, reviews are assumed to cost on average £3.06k[22], and 50% of providers are reviewed in any one year. Therefore, in 2012/13, the cost to providers is £230k (£3.06k*150*50%). This is a cost saving of **£6.67m** compared to the do nothing option where it is assumed reviews take place for half of all registered providers with a cost of £6.89m (£3.06k*50%*9000*50%).

Forgoing tribunal costs

65. As set out in Annex 2, it is assumed that due to providers having the right to appeal CQC decisions, there may be a cost to the tribunal service. This is estimated to be around £480k when all providers are subject to registration. As under this option, only 150 providers are required to register, only 1.67% (150/9000) of this cost will be incurred in 2012/13, which is around £8k (1.67%*£480k). This represents a cost saving of **£472k** in 2012/13 compared to the do nothing option where all these costs would be incurred.

Benefits summary

[20] See Para 174 in Annex 2. £1.15m based on churn of 160 providers each year.

[21] See Para 184-189 in Annex 2

[22] See A2.14 and Para 195 in Annex 2, £13.77m/4500 as 50% of providers reviewed each year =£3,060

Table D5: Summary of marginal benefits (health benefits and cost savings)

	Costs in £m
Increased effectiveness of compliance monitoring	14.98
CQC cost savings through streamlining	2.12
Provider cost saving through streamlining	4.80
Provider savings (fee payments)	14.28
Provider savings (costs of CQC reviews)	6.67
Tribunal cost savings	0.47
TOTAL	**43.32**

66. From the above, the total marginal benefits of this option are estimated to be around **£43.32m** (undiscounted). Table D.8 below brings the costs and benefits together and calculates the marginal NPV of this option.

Costs

- Development costs of streamlined approach
- Small increase in initial compliance costs due to churn of providers
- Small increase in costs to transitory fee costs to CQC

Development costs

67. In order to improve the registration process over 2012/13, CQC will need to invest its resources. As this work is yet to fully begin, it is difficult to estimate the associated costs. However, based on discussions with CQC, costs are thought to be in the region of **£0.72m**[23] in 2012/13. These costs would not occur under the do nothing where there would be no time to streamline CQC processes.

Small increase in initial compliance costs to providers

68. As noted in Annex 2, table A2.13, under the do nothing option, it is assumed it will take CQC until 2014/15 to enforce compliance with all providers whereas this is expected to be achieved within two years under this option. Thus, under option 2, initial compliance costs to existing providers are spread out over two years (out of hours in 2012/13, majority of providers in 2013/14) rather than three years as under option 1 (due to CQC capacity issues).

69. As a result, some providers who leave the market due to natural churn will face initial compliance costs under this option, where as under the do-nothing they would leave before the compliance would be enforced. Based on churn of 160 providers, the cost increase is **£0.34m**[24].

Small increase in the fee costs to CQC

70. As explained above (Para 61-63) CQC is assumed to provide the same transitory assistance in terms of the prudent setting of fees to recover costs regardless of date. Therefore, the difference between this option and the do nothing option is the profile of costs. However, it is assumed that CQC will set a fee at 50% cost recovery in 2012/13 for the out of hours providers, and in 2013/14. This means that for the out of hours providers CQC will meet 50% of the annual costs in two years, rather than just one as under the do nothing. This gives rise to a cost of £120k (£800*150) in 2013/14, but as set out in Annex 2, CQC cost does represent DH grant in aid not saved, thus the opportunity cost is **£0.28m** (£120k*2.4)[25].

[23] Reflects total opportunity costs, based on a monetary cost of £300k. (£720k= £300k*2.4). See para 161 in Annex 2 for details on 2.4 multiplier.

[24] See Para 180 in Annex 2 for details

[25] See Para 161 in Annex 2 for explanation of 2.4 multiplier.

Costs summary

Table D6: Summary of marginal costs

	Costs in £m
Development costs of new registration process	0.72
Initial compliance costs to providers leaving the market in 2013/14	0.34
CQC costs of regulating out-of-hours providers in 2013/14	0.28
TOTAL	**1.34**

71. It can be seen from above that the total marginal costs of this option are around £1.34m (undiscounted). It is assumed that there are no further marginal costs of this options. In the consultation, the majority of respondents welcomed the proposed change in date of registration indicating that the marginal costs are likely to be insignificant. Table D.8 below brings the costs and benefits together and calculates the marginal NPV of this option.

Summary

72. Table D.7 below sets out the overall costs and benefits of registration of NHS primary medical care providers under the proposed timetable of option 2. Table D.8 reflects the above discussed marginal costs and benefits of option 2 compared to the do nothing option. These figures are equivalent to Table A2.14 in Annex 2 minus Table D.7.

73. It can be seen from Table D.8 that Option 2 is expected to yield value for money and have a net present value of **£44.28m**. In addition to this, there is the marginal unquantified benefit that CQC will not be distracted from its compliance monitoring of other sectors by registering a large number of providers when it does not have sufficient capacity.

Table D.7 Overall costs and benefits of CQC registration of NHS primary medical care providers as under the timetable of Option 2. NPV calculations, figures in £'000s, 2010/11 price base and general discount rate of 3.5% and a QALY discount rate of 1.5%. Opportunity cost multiplier used.

***With** OP costs 2.4 multiplier)*	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs and Benefits (£'000s)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Benefits											
QALYs	£1,573	£59,262	£60,891	£62,566	£64,286	£66,054	£67,871	£69,737	£71,655	£73,626	£597,521
Saved NHS Treatment Costs	£142	£5,357	£5,504	£5,656	£5,811	£5,971	£6,135	£6,304	£6,477	£6,656	£54,014
Increase in Quality of Care	UNQUANTIFIED										
Safety Net	UNQUANTIFIED										
Level Playing Field	UNQUANTIFIED										
Avoided Reporting Burden	UNQUANTIFIED										
Avoided Litigation Costs	UNQUANTIFIED										
Costs											
Initial registration costs to providers	£1,080	£60,534	£1,094	£1,094	£1,094	£1,094	£1,094	£1,094	£1,094	£1,094	£70,369
Initial compliance costs to providers	£315	£18,585	£336	£336	£336	£336	£336	£336	£336	£336	£21,588
Initial registration costs to CQC	£240	£12,036	£0	£0	£0	£0	£0	£0	£0	£0	£12,276
Development costs of new registration process	£720	£0	£0	£0	£0	£0	£0	£0	£0	£0	£720
Distraction costs	NONE										
Initial registration cost to commisioners	UNQUANTIFIED										£0
Annual cost to regulator; provider fees	£120	£7,200	£10,800	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£118,920
Annual cost to regulator; the CQC	£288	£17,280	£8,640	£0	£0	£0	£0	£0	£0	£0	£26,208
Provider cost of review	£230	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£124,160
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	£8	£480	£480	£480	£480	£480	£480	£480	£480	£480	£4,328
QALY Discount Rate	*0.000*	*0.015*	*0.030*	*0.046*	*0.061*	*0.077*	*0.093*	*0.110*	*0.126*	*0.143*	
General Discount Rate	*0.000*	*0.035*	*0.071*	*0.109*	*0.148*	*0.188*	*0.229*	*0.272*	*0.317*	*0.363*	
Total Benefits (undiscounted)	£1,715	£64,619	£66,396	£68,222	£70,098	£72,025	£74,006	£76,041	£78,132	£80,281	£651,536
Total Benefits (discounted)	£1,715	£63,562	£64,243	£64,934	£65,634	£66,343	£67,062	£67,790	£68,528	£69,276	£599,087
Total Costs (undiscounted)	£3,001	£129,885	£35,120	£30,080	£30,080	£30,080	£30,080	£30,080	£30,080	£30,080	£378,569
Total Costs (discounted)	£3,001	£125,493	£32,785	£27,131	£26,213	£25,327	£24,470	£23,643	£22,843	£22,071	£332,977
Net Present Value (net benefit)	-£1,286	-£61,931	£31,458	£37,803	£39,421	£41,016	£42,591	£44,147	£45,685	£47,205	£266,110

With OP costs 2.4 multiplier

Year	0	1	2	3	4	5	6	7	8	9	
Costs and Benefits (£'000s)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Benefits											
QALYs	-£9,962	£23,705	£0	£0	£0	£0	£0	£0	£0	£0	£13,742
Saved NHS Treatment Costs	-£901	£2,143	£0	£0	£0	£0	£0	£0	£0	£0	£1,242
Increase in Quality of Care	UNQUANTIFIED										
Safety Net	UNQUANTIFIED										
Level Playing Field	UNQUANTIFIED										
Avoided Reporting Burden	UNQUANTIFIED										
Avoided Litigation Costs	UNQUANTIFIED										
					720						
Costs/Cost Savings											
Initial registration costs to providers	-£63,720	£59,382	-£58	-£58	-£58	-£58	-£58	-£58	-£58	-£58	-£4,799
Initial compliance costs to providers	-£3,465	£11,025	-£7,224	£0	£0	£0	£0	£0	£0	£0	£336
Initial registration costs to CQC	-£14,160	£12,036	£0	£0	£0	£0	£0	£0	£0	£0	-£2,124
Development costs of new registration process	£720	£0	£0	£0	£0	£0	£0	£0	£0	£0	£720
Distraction costs	NONE										
Initial registration cost to commisioners	UNQUANTIFIED										
Annual cost to regulator; provider fees	-£7,080	-£3,600	-£3,600	£0	£0	£0	£0	£0	£0	£0	-£14,280
Annual cost to regulator; the CQC	-£16,992	£8,640	£8,640	£0	£0	£0	£0	£0	£0	£0	£288
Provider cost of review	-£6,656	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£6,656
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	-£472	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£472
QALY Discount Rate	*0.000*	*0.015*	*0.030*	*0.046*	*0.061*	*0.077*	*0.093*	*0.110*	*0.126*	*0.143*	
General Discount Rate	*0.000*	*0.035*	*0.071*	*0.109*	*0.148*	*0.188*	*0.229*	*0.272*	*0.317*	*0.363*	
Total Benefits (net benefits, undiscounted)	-£10,863	£25,848	£0	£0	£0	£0	£0	£0	£0	£0	£14,985
Total Benefits (net benefits, discounted)	-£10,863	£25,425	£0	£0	£0	£0	£0	£0	£0	£0	£14,562
Total Costs (net cost savings, undiscounted)	-£92,088	£67,818	-£3,658	-£58	-£58	-£58	-£58	-£58	-£58	-£58	-£28,330
Total Costs (net cost savings, discounted)	-£92,088	£65,525	-£3,414	-£52	-£50	-£48	-£47	-£45	-£44	-£42	-£30,306
Total Costs (net costs, undiscounted)	-£19,737	£19,665	£1,416	£0	£0	£0	£0	£0	£0	£0	£1,344
Total Costs (net costs, discounted)	-£19,737	£19,000	£1,322	£0	£0	£0	£0	£0	£0	£0	£585
Net Present Value (net benefit)	£100,962	-£59,100	£2,093	£52	£50	£48	£47	£45	£44	£42	£44,283

Table D.8: Marginal costs and benefits of Option 2 compared to do nothing Option 1. NPV calculations, figures in £'000s, 2010/11 price base and general discount rate of 3.5% and a QALY discount rate of 1.5%. Opportunity cost multiplier used.

74. From the above table, any increase in benefits and cost savings relative to the do nothing option constitute marginal benefits of this option as discussed in Para 41-66. Forgone benefits and increased cost relative to the do nothing option constitutes marginal costs of this option as discussed in Para 67-71.

75. The lines that relate to marginal costs are shaded in grey in the total collum, all other lines relate to marginal benefits.

76. The main assumptions underpinning the analysis, as outlined above, are thought to be prudent. Based on the above, it is concluded that this Option 2 generates a marginal benefit over the do-nothing (Option 1). Sensitivity testing shows this result to be robust:

- The present option would continue to yield a higher net present value than the do-nothing even if CQC could not streamline its processes.
- What is more, the current option is preferred to Option 1 even if CQC's ability to enforce compliance in 2012/13 was much greater than currently assumed. Note that the above analysis assumes that, under the do-nothing option, CQC regulation would lead to compliance of 20% of providers in 2012/13 and then 60% and 100% in 2013/14 and 2014/15 respectively. However, even at enforcement rates of 40% in 2012/13 and 100% thereafter, the present option would still yield a higher net benefit than the do-nothing.
- Option 2 assumes that CQC will lead to 100% compliance, from 2012/13 for out of hours providers and from 2013/14 for all other NHS primary medical care providers. There is a risk that CQC may not have dealt with its backlog, or that the current capacity issues will still be a problem; this would have an impact on the value for money of this option to delay. However, we believe the issues of going ahead with full registration in April 2012 can be overcome in 12 months, and therefore this risk should not be realised. Initial calculations suggest that even if CQC could only enforce 50% of compliance in 2013/14, Option 2 would still be preferred to Option 1.
- The results are not sensitive to the use of 2.4 multiplier. Even without this measure of opportunity cost, Option 2 would have an NPV of £34.38m, marginal to Option 1.

77. The above suggests that the policy recommendation is relatively insensitive to the main assumptions underpinning the analysis: the present option is preferable to the do-nothing.

Option 3

78. Option 3 is to defer the implementation of registration for all providers of NHS primary medical services until April 2013. It can be seen that this option would be less beneficial than option 2 and thus is not the preferred option.

79. The only difference between option 2 and option 3 is that 150 providers of NHS out-of-hours care to patients who are not registered with them would not be registered in 2012/13, but 2013/14. As a result,

- one-off costs of registering 150 providers of NHS out-of-hours care to unregistered patients as well as initial compliance costs for those providers will occur in 2013/14 rather than in 2012/13;
- benefits of regulating 150 providers of NHS out-of-hours care to unregistered patients in 2012/13 will be forgone while annual costs of regulation (including tribunal costs) will be saved.

Postponing one-off costs of registration

80. As table D2 shows, under option 2, initial costs to providers in 2012/13 amount to £1.40m (= £1.08m registration costs + £0.32m compliance costs). Costs of registration to CQC are £240k. Thus, the initial registration and compliance costs of option 3 in 2012/13 are lower than under option 2 by **£1.64m**.

81. As the providers in question will instead be registered in 2013/14, registration and compliance costs will be borne in that year. However, as explained under option 2, it is assumed that CQC will have streamlined its processes by 2013/14 so that CQC registration costs will be 15% lower and provider registration costs will be 5% lower than they would have been in 2012/13. Consequently, under option 3, the costs of registering 150 providers of NHS out-of-hours care to unregistered patients in 2013/14 are lower than they would have been in 2012/13: **£1.55m** (=£240k*(100%-15%) + £1.08k*(100%-5%)+ £315k).

82. Thus, not registering out-of-hours providers until 2013/14 would reduce costs by **£0.09m** relative to option 2.

Less net benefits of registration

83. However, the above savings do not outweigh the foregone net benefit of bringing NHS out-of-hours providers to unregistered patients into regulation in 2012/13. As table D2 shows, the benefits of regulating NHS out-of-hours providers to patients who are not registered with them in 2012/13

would amount to at least £1.72m (= £1.57m+ £0.14m; figures may not sum due to rounding).[26] In that year, the annual costs of regulation – excluding one-off costs considered above – amount to £646k (= £120k costs of regulation borne by providers + £288k costs borne by CQC + £230k provider costs of review + £8k tribunal costs).

84. Thus, the annual net benefits of regulating NHS out-of-hours providers to patients who are not registered with them in 2012/13 amount to **£1.07m** (=£1.72m - £646k). These potential benefits are foregone under option three.

85. In addition, there may be a benefit to registering provider of NHS out of hours before the majority in terms of process development of processes and learning. This benefit would be foregone under Option 3.

86. Overall, the benefits of bringing into regulation providers of out-of-hours care in 2012/13 outweigh the costs of doing so. Thus, option 3 – to defer registration of all providers including out-of-hours providers - is not the preferred option.

Summary

87. Based on the above analysis, **Option 2 is the preferred option**. Section E considers specific impact tests, and then Section F gives a full summary and conclusion, of this impact assessment.

E. Summary of specific impact tests

88. The analysis below summarises the results of the specific impact tests for Option 1 and then considers these impacts for Options 2 and 3, marginal to Option 1 (the impacts are assumed to be identical on the margin, unless indicated otherwise). No significant impacts in any of these areas have been identified.

Equality

89. A separate equality impact assessment has been completed and is published alongside this document on the Department of Health website at http://www.dh.gov.uk/publications

Competition

90. In any affected market, would the proposal:

91. Directly or indirectly limit the number or range of suppliers?

92. CQC regulation will restrict the ability of poorly performing providers to stay in the market without achieving full compliance with registration requirements. In extreme cases, CQC may refuse to register providers, or cancel an existing registration, resulting in their removal from the market. In addition, some providers might voluntarily leave the market rather than make the changes to comply with the essential levels of safety and quality.

93. On the margin, Options 2 and 3 propose to defer the registration of some primary medical care providers with the Care Quality Commission in order to streamline the registration process. This is not expected to result in substantial numbers of providers leaving the market. To the contrary, by delaying the registration process and developing a more streamlined approach, CQC regulation may become less burdensome and cause fewer providers to leave the market voluntarily.

94. Limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously?

95. Bringing NHS primary medical care providers into CQC regulation will provide assurance of essential levels of safety and quality. This is expected to increase quality-driven competition over and beyond these essential levels. Moreover, registration with the CQC will provide patients with additional information, allowing them to exercise more informed choice over providers.

96. Registration of NHS primary medical service providers with CQC also means that, in terms of registration, NHS and private sector providers are treated in the same way. This is expected to lead to greater focus on quality-driven competition.

[26] These benefits could indeed be higher if it had been possible to reflect the difference in risks between NHS out of hours care and other NHS primary medical care services.

Small firms

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

98. This policy only affects providers of NHS primary medical care. In line with the One-In, One-Out (OIOO) Methodology guidance[27], contractual obligations, such as the ones that primary medical care providers enter into with the NHS, are out-of-scope of OIOO, and thus not regarded as small firms. Finally, as agreed with the Cabinet Office, General Practitioners are regarded as part of the Public Sector family, and not as a business. Any regulation affecting public service delivery organizations as out of scope of the exemption.

Environmental impacts and sustainable development

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

Health Impact

100. 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)

101. The proposals are expected to have a positive impact on patients' health arising from the reduction in patient safety incidents (as explained in the main IA). No other impacts have been identified.

102. Marginal to Option 1, Options 2 and 3 are expected to result in greater patient health benefits. This is caused by efficiency gains realised through streamlining of provider registration and compliance monitoring. These improvements allow CQC to ensure higher provider compliance, resulting in a positive impact on patient's health arising from fewer patient safety incidents.

Human rights issues; covered within the separate equality impact assessment.

Legal Aid/ Justice Impact

103. Will the proposals create new civil sanctions, fixed penalties or civil orders with criminal sanctions or creating or amending criminal offences?

104. The CQC registration system involves civil sanctions, fixed penalties and criminal offences, although these provisions are already in place.

105. Marginal to Option 1, Options 2 and 3 will delay when some primary medical care providers enter the registration system.

106. Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases?

107. Yes - there is a right of appeal to the Health, Education and Social Care Chamber of the First Tier Tribunal against a decision taken by CQC. It is not possible to estimate the number of any such appeals. Based on other provider types we estimate that the annual cost to the Tribunal of considering these cases will be in the range of £100,000 to £200,000.

108. Marginal to Option 1, Options 2 and 3 will delay most such appeals being made to the Tribunal by at least one year.

109. The following questions have been cosidered as well. It has been found that the answer to each of these questions is "no":

- Create a new right of appeal or route to judicial review?
- Enforcement mechanisms for civil debts, civil sanctions or criminal penalties?
- Amendment of Court and/or tribunal rules?
- Amendment of sentencing or penalty guidelines?
- Any impact (increase or reduction on costs) on Legal Aid fund? (criminal, civil and family, asylum)

[27] http://www.bis.gov.uk/policies/better-regulation/better-regulation-executive/reducing-regulation-made-simple/one-in-one-out

- Any increase in the number of offenders being committed to custody (including on remand) or probation?
- Any increase in the length of custodial sentences?
- Will proposals create a new custodial sentence?
- Any impact of the proposals on probation services?

110. No significant risks were identified.

Rural Proofing

111. 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.

112. The proposals are not expected to lead to potentially different impacts for rural areas or people.

Sustainable Development

113. Are there significant environmental impacts of policy proposal? Significant environmental impacts relevant to any of the legal and regulatory standards identified? Significant impacts which may disproportionately fall on future generations?

114. 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.

F. Summary and Conclusion

115. Annex 2 reaffirms a previous impact assessment[28] in the conclusion that it is value for money for CQC to regulate providers of NHS primary medical care. The above sections have assessed the proposal to postpone the registration of these providers until 2013/14 except for where NHS out-of-hours care to unregistered patients is provided (Option 2).

116. By giving CQC time to adapt its processes in response to previous registration rounds, Option 2 ensures effective compliance monitoring and reduces the burden of registration to CQC and providers. This is found to justify foregoing some benefits of regulation by not regulating most providers until 2013/14.

117. Option 2 is found to generate a higher social net benefit than both the do-nothing Option 1 and Option 3 under which registration of all providers of NHS primary medical care (including providers of NHS out-of-hours services to patients who are not registered with them) would be postponed until 2013/14.

118. Thus, Option 2 is the preferred option. This impact assessment supports the recommendation to postpone regulation of NHS primary medical care providers until 2013/14 with the exception of providers of out-of-hours services who will still to be brought into regulation in 2012/13.

119. This policy is out of scope of the One-In, One-Out (OIOO) rules. In line with OIOO Methodology guidance[29], contractual obligations, such as the ones that primary medical care providers enter into with the NHS, are out-of-scope of OIOO and public service delivery organisations, such as these are not within the micro-businesses and start-ups exemption.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

[28] *Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_097143.pdf*

[29] http://www.bis.gov.uk/policies/better-regulation/better-regulation-executive/reducing-regulation-made-simple/one-in-one-out

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)]; Political commitment to review.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] The regulations governing the registration system are kept under constant review and are expected to be updated regularly in the light of experience. The Department of Health will also carry out a comprehensive review of how the registration of health and adult social care providers is functioning in 2014. This will include reviewing the regulation of primary care providers by the Care Quality Commission
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] The review will take the form of an in-depth evaluation of the effectiveness of the registration of providers of health and adult social care, including taking the views of stakeholders. This approach will enable us to consider the experience of providers in being registered as well as the effectiveness of registration in mitigating risks to patients and service users.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] Change will be measured against the current situation in which providers of NHS primary medical services are not registered by CQC.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] We will measure the success of the policy against the number of providers complying with registration requirements and the satisfaction or otherwise of providers with the registration process.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Ongoing contact with CQC about numbers of providers compliant with registration requirements and with primary medical providers to monitor the experience of registration.
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here] Not relevant

Annex 2

Updated analysis of CQC registration of NHS primary medical care providers in April 2012

Rationale

120. The provision of any health and social care services involves risks to the health of service users. In addition, there is asymmetric information between health and social care providers and consumers, and thus there are potential incentives for providers to provide sub optimal care. As a result, in some respects there may be market failure that could be addressed by independent regulation. Regulation of health and social care is a public good, and as such, the market does not always naturally provide it, and has not done so sufficiently in this area, hence government intervention may be required.

121. This annex updates previous work and re-establishes the case for continuing the policy for statutory regulation of NHS primary medical care services.

122. The original *impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008*[1] published in October 2009 considered whether the registration of providers of NHS primary medical services with CQC was the most effective way of mitigating risks in the provision of care by this group of providers. This original impact assessment considered a range of options for addressing risk posed in this sector. These included:

- supporting PCT commissioning and contract monitoring;
- promoting choice and competition;
- promoting practice accreditation;
- strengthening professional regulation;
- system regulation for the riskiest services; and
- system regulation for all providers

123. It concluded that a number of policy initiatives were in train that would contribute to addressing poor performance in providers of NHS primary medical services. For example, support for the collection, analysis and publication of a range of data to measure and compare service quality and recognise and reward excellence and support patient choice; and work to promote accreditation schemes to encourage improvement in quality and safety and to identify best practice. It also concluded that there must be a mechanism for assuring that providers meet the essential system requirements and that persistently poor performance can be addressed through a range of enforcement measures. Registration with CQC was identified as the most effective way to mitigate risks in the provision of care by these providers. We have reconsidered this proposition and concluded that it continues to hold good. CQC is the body with the appropriate enforcement powers to tackle poor performance, and this role complements and promotes the future NHS Commissioning Board's role of improving quality above and beyond the essential levels of safety and quality.

124. Prior to the introduction of the new regulatory framework in 2010, under which CQC operates, the previous regulatory framework was becoming fragmented and inconsistent with a variety of different sanctions and enforcement procedures in place. Regulation was based on the type of provider, on establishments and agencies, rather than on the kind of care being delivered. This made the system inflexible to accommodating changes in service delivery and to the development of new forms of care. This in turn led to inconsistencies whereby a particular kind of care might be regulated in some settings but not others.

125. In March 2008, the Department of Health consulted on the framework for a new registration system. The new system aimed to:

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115559

- be based on risk, taking account of protections offered by other regulatory, management and governance systems, and how much CQC regulation would effectively reduce those risks;
- be consistent across providers of health and adult social care, from both the independent and public sectors;
- treat all providers similarly, regardless of whether they are in the public or independent sector, or whether services are delivered in secondary, community, primary, residential or domiciliary settings; and
- avoid unnecessary burdens on providers and CQC.

126. CQC has been implementing a new registration system that fulfils these aims since NHS providers were registered against a single registration requirement relating to cleanliness and infection control in April 2009. At present, there remains in place a single exemption from registration with CQC. This exemption relates to the provision of primary medical services under the terms of an NHS contract. Under current legislation, this exemption will cease to apply on 1 April 2012. Provision of regulated activities by providers of NHS primary medical services.

127. In developing the proposal on the timing of the registration of these providers, we have taken the opportunity to reflect on whether providers of NHS primary medical services should be brought into the registration system. We have concluded that a permanent exemption of providers of NHS primary medical services would not be in line with the registration framework for a number of reasons:

- Scope for CQC risk mitigation; other regulation of primary medical care does not take a whole system approach, leaving some risks unaddressed.
- Adverse patient health events; the sheer volume of primary medical services means that even a small risk could have a relatively large impact.
- Adverse patient health events; primary medical services are changing rapidly with a wider range of NHS care being provided in primary settings, new ways of delivering care and new provider models; this increases the potential risks to patients from primary medical services.
- Consistency; wholly private primary medical care services are registered with CQC, thus the approach to regulating the same activities varies according to different provider types; this means there is no level playing field for providers and potential variation in minimum standards of service for patients .

Scope for CQC risk mitigation; other regulation

128. In the provision of care there are health risks, which may give rise to adverse patient health events. Some of these risks are system related. Current regulatory frameworks for primary medical services focus on the competency of the individual healthcare professional. Registration with the General Medical Council (GMC) requires the individual medical practitioners to comply with standards of practice. There is also a requirement for GPs working in the NHS to be included on a Primary Care Trust (PCT) Performers List, which confirms the competency and suitability of the individual. This means that no action can be taken where systems have failed but an individual has acted in a professionally competent way. Professional revalidation will ensure that healthcare professionals keep their skills up to date and are able to deliver services, but does not fully consider the organisations or the systems that they work within in the same way. Thus, there is scope for CQC to mitigate system related risks.

129. As a wider range of organisations are now delivering primary medical care services, increasing numbers of doctors are salaried and do not have control over the systems and premises that they work within. In addition, a report by the National Primary Care Research and Development Centre demonstrated that new NHS contracts have led to greater reliance on nurses and on co-operative working among general practices and between general practice and hospitals. These altered patterns of provision have reduced the power of GPs to act alone in determining how a service is operated. This increases the importance of ensuring that the systems and premises they work within are checked.

130. At present, in NHS primary medical care, there is not a consistent set of standards in place for all settings providing similar services. In the absence of nationally agreed requirements, it is unclear what patients have a right to expect. In addition, it has traditionally proved difficult for commissioners to take action under the primary care contracts. The enforcement options available under primary

care contracts are limited to either a 'notice to improve' or termination of contract. This makes it difficult to enforce essential safety and quality requirements.

131. CQC have a range of enforcement powers to assure compliance and tackle persistent poor performance. Registration of NHS primary medical care providers with CQC would ensure systems, as well as individual professional competencies, are monitored, and would be proportionate to risk given other safeguards in place.

Adverse patient health events; volume of consultations and changing care delivery

132. Primary medical services are at the forefront of the interaction between the NHS and patients – indeed, primary medical providers control much of the access to other areas of the NHS in its role of gatekeeper. Each year, over 300 million consultations take place in GP practices alone. Over 90 per cent of all contact with the NHS takes place outside of hospital. As a result, even relatively low risks can have a large impact in terms of adverse patient health events.

133. Given the numbers of people that receive primary medical services every day it is important that providers operate safely, that patients can be assured of the quality of care they receive and that the general public is given enough information to make informed choices on where to seek treatment.

134. Primary medical services are changing rapidly. The type of care provided in by primary medical services are increasingly wide, and many are offering more complex care. For example, over recent years, as knowledge of chronic conditions has improved and new drug therapies have been developed, the management of patients with chronic diseases has moved from secondary care settings to primary care settings. Where once patients with diabetes were routinely under the care of a hospital physician, a national survey of GPs in 1997[2] showed that 75 per cent of patients with diabetes are now managed outside of hospital. This increases potential risks to patients in primary medical services.

135. In addition, as noted by the National Patient Safety Agency (NPSA)[3][4], there have been a range of other changes which increase the complexity of primary medical services and the risks to patients. For example:

- Advances in technology allowing more treatments to be provided in GP practices;
- Changes to workforce roles (such as nurses being able to prescribe and triage);
- Increasing health needs of patients;
- Earlier discharge from hospital resulting in patients requiring more support in the community; and
- Primary care led prescribing and monitoring of potentially high risk drugs (including those for rheumatoid arthritis and infertility).

136. At the same time, there is increasing diversity in the types of providers delivering primary medical services under a number of different contract types. Where once primary care was delivered almost exclusively by organisations owned and run by GPs, there is now an evolving range of organisations providing primary medical services. Providers of primary medical services for the NHS now include single-handed practices, partnerships of GPs, partnerships involving GPs, dentists and other healthcare professionals and/or practice managers, nurse-led services, federations (groupings of practices), independent providers and third sector providers and social enterprises. The Government's Any Qualified Provider programme[5] will continue this process of extending the range of providers of NHS primary medical services.

137. From the above, it is clear that there are potential risks in primary medical care delivery, now and in the future, and that some of these risks will be system related. Registration of NHS primary medical care with CQC would require providers to comply with essential standards of safety and quality, and CQC have a range of enforcement powers to assure compliance and tackle persistent

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[2] Audit Commission 2004, "A Focus on General Practice in England" page 44 (available at http://www.audit-commission.gov.uk/SiteCollectionDocuments/AuditCommissionReports/NationalStudies/genprac.pdf)

[3] National Patient Safety Agency (2009) "Seven Steps to Patient Safety for Primary Care" (available at www.nlrs.npsa.nhs.uk)

[4] Wilson T, Pringle M and Sheikh A. "Promoting Patient Safety in Primary Care: research, action and leadership are required" *British Medical Journal* 2001; 323: 583-4.

[5] http://healthandcare.dh.gov.uk/any-qualified-provider/

poor performance. This would mitigate system related health risks and therefore reduce adverse patient health events, leading to improved health outcomes and reduced NHS treatment costs.

Consistency: non-NHS primary medical care providers

138. Most providers of primary medical services are not currently required to register with the Care Quality Commission. GP practices with an NHS contract are not required to register for any medical services that they provide, including any private services that they may provide. However, medical services provided by NHS organisations and by independent healthcare providers are registered with CQC. As a result, the same types of treatment offered by different types of provider are subject to different regulatory requirements.

139. Firstly, this means that there is an un-level playing field for providers. The overall objective for the regulatory framework is to ensure a level playing field is in place for all providers. Activities deemed to pose a risk to patients should be subject to the same checks regardless of the setting in which the activity is provided and the type of provider they are provided by. At present different providers are treated in different ways even when providing the same services. For example:

- Wholly private GP practices are required to register with CQC;
- GP practices providing NHS or mixed NHS and private services are not required to register;
- All services provided in hospital settings are required to register with CQC although the same services provided in primary medical settings are not;
- All services provided directly by PCTs are required to register but those commissioned by PCTs in similar settings are not.

140. This can encourage providers to configure themselves in a way that will avoid registration, even though this may not be the best way to provide services for patients. It can also be confusing for providers, commissioners and patients as it is not clear what can be expected from provider or why various provider types are treated differently.

141. Secondly, this means that there may be potential variation in minimum standards of service for patients. Patients want to know that all services at the least meet essential levels of safety and quality and they want to have enough information to make a real choice about the services they use.

142. Patients are currently unable to compare GP practices in order to determine which practice to register with, as there is not an easily accessible set of information available. The availability of information on compliance with essential requirements for safety and quality would assist with this and provide assurance that essential requirements are being met. Being confident that the essential requirements are being met by all providers would allow patients to take account of quality measures (such as accreditation and Quality Accounts) and therefore differentiate further.

143. Finally, the approach cannot be justified based on risk; increasingly services traditionally provided in hospital settings are being provided in primary care settings, where it could be argued that for some services poses a higher risk[6], yet there are no equivalent checks that essential levels of quality and safety are being met. This may affect issues beyond risks to health, such as service variability and patient choice.

144. Registration of NHS primary medical care providers with CQC would ensure the same requirements apply to all activities identified as posing a risk to patients, regardless of the setting that they are provided in or the type of organisation by which they are provided. It would level the playing field for providers and provide public assurance that all providers were meeting the same essential levels of safety and quality. This would also support patient choice.

Summary

145. The CQC's registration of NHS primary medical care providers would address the above issues. It will be proportionate to risk given other safeguards in place, it has the potential to reduce adverse patient health events, will ensure consistency for patients and provide a fairer approach to regulation of different types of providers. Providers of NHS primary medical services will be brought into regulation, and therefore, for the first time, have to demonstrate that they meet the essential requirements of safety and quality.

[6] For example, the facilities available in primary care settings are more limited and patients could therefore need to be transferred to a hospital if they were taken ill while being treated.

146. The above has outlined that there is still a clear rationale for requiring NHS primary medical care providers to register with CQC. The section below considers the likely benefits and costs of this policy.

Costs and Benefits

147. This section outlines the costs and benefits associated with CQC registering NHS primary medical care providers. This updates previous work for new information.

148. This annex outlines the do nothing option for the timing policy decision of this impact assessment.

General Assumptions and Information

149. There is some key general information and there are some general assumptions that are applied throughout this section, these are outlined below:

CQC registration regulations

150. When a provider is required to register with CQC, they must comply with the 16 registration regulations as set out in paragraphs 8 to 24 of The Health and Social Care Act 2008 (Regulated Activities) Regulation 2010. These are summarised in the below table.

Table A2.1: CQC registration regulations[7]

Req.9	Req. 10	Req. 11	Req. 12	Req. 13	Req. 14
Care and welfare of service users	Assessing and monitoring the quality of provision	Safeguarding vulnerable users	Cleanliness and infection control	Management of medicines and medical devices	Meeting nutritional needs
Req. 15	Req. 16	Req. 17	Req. 18	Req. 19	Req. 20
Safety and suitability of premises	Safety, availability and suitability of equipment	Respecting and involving service users	Consent to care and treatment	Complaints	Record keeping
Req. 21	Req. 22	Req. 23	Req. 24		
Competence and suitability of workers	Staffing	Effective management of workers	Co-operating with other providers		

151. It is through providers complying with these registration regulations that the costs and benefits considered in detail below are generated.

CQC methodology for registering providers of NHS primary medical services

152. CQC is an independent body that is responsible for its own strategy including when and how to monitor provider compliance. CQC's processes for the regulation of primary care providers are still evolving and subject to change. As a result, it is not possible to say with certainty exactly how CQC will register and review NHS primary medical providers. The below uses a hypothetical example based on current CQC practice in other sectors to estimate the benefits and costs as far as possible given the present level of uncertainty.

153. Under current legislation, the exemption of primary medical care from CQC registration expires in April 2012. Therefore, CQC will register all existing providers of NHS primary medical care in April 2012, and, from then on, all new providers going forward. It is expected that most non-compliant providers will be made compliant through the initial registration process while CQC's review process will ensure compliance is maintained.

154. CQC will review every provider's compliance with the essential requirements (see Table A2.1 above) within a two-year period. Providers are expected to gather evidence and information to demonstrate compliance and share it with CQC. For a majority of providers, the review will also involve an observational visit by CQC. In addition, CQC may also review compliance on a responsive basis, triggered by whistle blowing, patient or clinician concerns, or other warning flags

[7] Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, Part 3, available at http://www.cqc.org.uk/_db/_documents/HSCA2008RegulatedActivitiesRegulations2010.pdf

such as clinical indicators. Given the nature of the responsive review, it is not possible to predict how many providers would be affected each year.

155. In light of recent information, it appears likely that CQC does not have the capacity to carry out the above registration and review processes fully and effectively from April 2012. The demands placed on CQC by a succession of new registration rounds – registering more than 20,000 health and adult social care providers to date - have led to a backlog of work. This has constrained CQC's capacity to effectively monitor and enforce compliance of registered providers. This is a change in position from the original impact assessment, which assumed CQC would have the available capacity to deliver an April 2012 registration round. This change in assumption reflects an additional two years of experience and information.

156. Given this, registering all existing NHS primary medical care providers in April 2012 is going to be a difficult task. As a result, it is assumed that the initial registration of existing providers will not be effective at addressing non-compliance. However, some providers are expected to voluntarily adapt their behaviour in response to being formally registered with CQC.

157. CQC's next opportunity to address non-compliance of existing providers will be through the review process. However, it is assumed that this would be delayed until the latter half of 2012/13 and would then be less effective given the issues at initial registration.

158. As a result, it is assumed that CQC will only have dealt with all initial non-compliance by the end of 2014/15. CQC are expected to maintain full compliance through a fully effective review process from then on. Given this, the table below shows the assumed profile of successful compliance monitoring and enforcement:

Table A2.2: CQC effectiveness at increasing compliance

	2012/13	2013/14	2014/15	2015/16 to 2021/22
% of non-compliant made initally compliant	20%	40%	40%	0%
% benefits from increased compliance	20%	60%	100%	100%

159. In addition, given capacity constraints, this registration round is expected to distract CQC from its compliance monitoring of other sectors.

Main affected groups

160. It is assumed that there are seven main groups that will be affected by regulation of providers of NHS primary medical services; the providers, CQC, the Department of Health, commissioners, the tribunal service, patients, and the wider NHS. The following sections consider the relevant costs and benefits to these groups.

Accounting for distribution of impacts, opportunity and marginal costs

161. In line with standard practice, adjustments to the economic cost are made where there is enough information about those affected by the impacts of the options:

- Given the fixed budget of the NHS, DH and the Exchequer, it is important to account for the value forgone when reallocating resources away from alternative uses, i.e. the "opportunity cost". For instance, where practice time is spent on completing the application for registration, this time is not spent on activities that directly or indirectly generate health benefits to patients. It has been estimated that, at the margin, £1 of NHS resources can yield £2.4[8] worth of health benefit. Thus, where appropriate, impacts on NHS or DH resources are multiplied by 2.4 to reflect the opportunity cost of foregone NHS spending. Given the allocation of exchequer funding between departments, this opportunity cost multiplier is also used as reasonable proxy to reflect the opportunity cost of exchequer funding in general.
- There are no assumptions about tax implications or opportunity costs of provider fees, as it is not known how the cost of the fee will be recovered.

[8] These marginal treatments have been estimated to provide health benefits - measured in Quality Adjusted Life Years (QALYs) - at a *cost* of £25,000 per QALY. Importantly, however, society is currently estimated to *value* these QALYs more than twice as highly - at £60,000. This means that any policy which involves spending £1 from the NHS budget will deprive society of benefits worth £2.40.

Costs of Regulation

162. In order to assess the costs of this policy it is necessary to estimate the number of providers affected. Providers of NHS primary medical services include GP practices, NHS out of hours providers and others including providers of offender healthcare services in prisons. It is difficult to estimate the number of providers as there is limited information. However, the best estimate for the number of providers required to register with CQC under this policy is **9000**; of which, 8000 are GPs, 150 are NHS out of hours services, and 850 are others including prison health service. This estimate is based on figures on data for the numbers of NHS primary medical services[9], the fact that providers may provide more than one service, and that some providers will already be registered with CQC for other activities.

163. It is difficult to predict how many providers of NHS primary medical services there will be in the future. The best estimate is that the number of providers remains steady and constant at 9000[10]. However, there will still be some fluctuation with new providers joining the market and others leaving. It is assumed that there will be around 2% turbulence for GP providers and 0% for non-GP providers, giving around 160 new GP providers each year (offset by a similar number of providers leaving the market).

164. Requiring providers of NHS primary medical services to register with CQC gives rise to a number of costs to different groups, the main costs can be summarised as:

- Transition costs; initial registration and compliance costs;
- Annual costs of regulation: fees;
- Annual costs of regulation: CQC reviews;
- Annual costs of regulation: ongoing compliance;
- Annual costs of regulation: assisting ongoing regulation;

165. These costs are considered below.

Transition Costs; initial registration and compliance costs

The CQC

166. Initially registering all providers of NHS primary medical services requires CQC to develop criteria and guidance and to train analysts and inspectors for the regulation of primary medical services. These costs have now been incurred for registration starting in April 2012, and are sunk.

167. In addition, for first time registration, CQC will need to carry out a number of additional activities including: processing all the initial applications, collecting data for analysis and risk profiling. Although it is assumed that first time registration will not be fully effective, these activities will still occur in one way of another and thus costs of going through the process for CQC will still be incurred. These costs are covered through DH transition funding which is already absorbed into CQC's current budget and capacity. However, this has an opportunity cost as it represents capacity that could be spent on other tasks. CQC advises that there are initial costs of registering existing providers of NHS primary medical services of around **£6.00m in 2012/13**, and as it is assumed that this is funded through previous DH transition money, thus has an opportunity cost of **£14.4m** (£6m*2.4).

168. CQC will incur similar initial costs for new providers that enter the market after April 2013. However, the relatively small number of providers involved means that this cost is recovered through the annual fee charged to all providers (see below).

169. As previously discussed, given the backlog of work, registering 9,000 providers of NHS primary medical services in 2012/13 would put a significant strain on CQC and its capability to effectively enforce compliance in these providers in 2012/13 and the two years following (see Table A2.2). In addition, it is possible that there could be impacts into other areas of regulation and on other already

[9] 8300 GP practices in Sept 2010 according to IC (http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-2000--2010-general-practic). ODS data (http://www.connectingforhealth.nhs.uk/systemsandservices/data/ods/genmedpracs) 8250 GP practices, 265 out of hours services and around 4000 "other" prescribing cost centres in May 2011. CQC estimates that only 2000 of the other cost centres (including 70 providing healthcare in prisons) provide a regulated activity that would require registration.

[10] There has been a declining trend in primary medical services providers over the last ten years, with the increase in demand (consultations) being met by fewer but larger practices (http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/general-practice/trends-in-consultation-rates-in-general-practice--1995-2009). CQC and the BMA expect this trend to continue over the next ten years. However, the GP workforce is growing and more care is being delivered in primary care settings. Two opposing pressures, assumed to balance.

registered providers, as the CQC has to focus a disproportionate amount of resource on registering providers of NHS primary medical services. It is not possible to quantify these costs in 2012/13 and following years, as it is difficult to know what the effect would be, but it is expected that these **distraction costs** could be significant.

Providers of NHS primary medical services

170. First time registration with CQC will require providers of NHS primary medical services to complete an initial application and to demonstrate compliance with registration requirements and/or to put in place an action plan to achieve compliance. As a result, providers of NHS primary medical services may incur some transition costs because of initial registration with CQC.

171. CQC is an independent body that is responsible for its own strategy including when and how to monitor provider compliance and these processes are still evolving and subject to change. As a result, it is not possible to definitively say exactly what the registration process NHS primary medical care providers will be. Therefore is it necessary to make assumptions based on CQC previous processes and pilots. The below is an example of what the registration process may involve, and the assumptions consider feedback from pilot sites, a dental practice and conversations with CQC.

172. The initial application process requires providers to complete an application form and provide evidence that they comply with the registration requirements. There is already a great deal of information that provider can draw on for their application, for example, Quality Outcome Framework (GPs), National Quality Requirements (out of hours) and data collected by commissioners. As a result, much of the information required to complete an application for registration should already be available and the task for providers will be in assembling the existing evidence. It is assumed that this could take 22.5 hours (3 days) of a practice manager's time at an hourly cost of £35[11] and 22.5 hours of a general practioner/clinician's time at an hourly cost of around £100[12], this gives an initial registration cost of around £3000 ((22.5*35)+(22.5*100)) per provider.

173. This gives total one-off initial registration cost of **£27m** (£3000 * 9000 total providers) in **2012/13** as all existing providers are brought into registration for the first time. These staff costs do represent NHS resources forgone, and therefore are multiplied by 2.4 (see Para 142), given a total opportunity cost of **£64.8m** (£27m*2.4) **in 2012/13**.

174. There will also be ongoing annual costs as new providers joining the market each year are also subject to these initial costs of registration. Based on the assumption of 160 new providers each year, these are estimated at **£0.48m pa** from **2013/14**, (£3000*160 new providers). Again these staff costs represent NHS resource foregone and are therefore multiplied by 2.4, to give total opportunity cost of **£1.15m pa** (£0.48m*2.4) **from 2013/14** onwards.

175. For some providers initial registration may not just be case of demonstrating compliance, as there may be some areas of initial non-compliance. This may require the provider to change behaviour and/or to invest resources in order to become compliant. Based on experience CQC estimates that potentially around 25% of all providers will have some areas of initial non-compliance.

176. CQC has suggested that areas of initial non-compliance could be around quality monitoring and service user involvement (requirements 10 and 17 in table A2.1 above). For NHS out of hours providers, it is suggested that the areas are likely to be similar to those for GP practices, but that there was potential for non-compliance with requirements on staffing and record keeping (requirements 20 and 22 in table A2.1 above). In general, it is considered unlikely that many providers will have issues of non-compliance with areas such as suitability of premises and cleanliness and infection control. As a result, the main change to ensure compliance is likely to involve providers spending time and effort thinking about how they can utilise their existing information and systems to maximum value. It is difficult to estimate what these costs would be as it will vary case by case. However, if it took a week (37.5 hours)of a practice manager's time at £35 hourly cost it would cost £1300 (37.5*£35). If it took a 3 hour workshop involving an entire 7 person practice at an average hourly cost of around £73[13] it would cost around £1500 (3hours*7

[11] £35 a hour is in (2010/11 prices) based on average earnings of £37k*1.2(standard DH uplift for average employer costs such as NI and pensions)*1.3(overheads assumption based on BRE guidance) divided by 1650 hrs (~220 working days*7.5 hours). Earnings data from http://www.firstpracticemanagement.co.uk/PM_salary_survey/survey_summary_intro.htm

[12] £104 hourly costs based on PSSRU data for an average hour of GMS activity, used as a proxy. http://www.pssru.ac.uk/pdf/uc/uc2010/uc2010_s10.pdf

[13] Assumes 4 GPs at a hourly cost of £104, one practice manager at hourly cost of £35 , a nurse practioner/other clinican at £38 per hour (based on PSSRU data uplifted to 2010/11 prices http://www.pssru.ac.uk/pdf/uc/uc2010/uc2010_s10.pdf) and an admin staff at £23 per hour

people*£73). Therefore, it is estimated that changing behaviour from initial non-compliance to compliance involves a one-off staff cost of around £1500 per provider.

177. In addition, again based on previous experience, CQC estimates that potentially a further 5% of providers may have more significant issues of non-compliance. As a result, they may have significant changes to make to meet the registration requirements, and would thus incur higher costs. Again it is difficult to estimate these costs as they will vary case by case. However, assuming that some these providers could have more issues relating to premises (which may be more costly to correct), it is estimated that an average cost could be around £10,000 per provider.

178. The total initial compliance costs to providers are therefore estimated at £7.88m ((£1500*25%*9000) + (£10,000*5%*9000)). As discussed above it is assumed that not all initial non-compliance will be tackled straight away at initial registration and instead some will be tackled with reviews. The profile for addressing initial non-compliance is outlined in table A2.2, and thus this cost is profiled as **£1.58m in 2012/13** (20%*£7.88m), and **£3.15m in 2013/14** and **2014/15** (40%*£7.88m).

179. Again, these costs represent NHS resources forgone and as a result, the true opportunity cost is £18.9m; **£3.78m** (£1.58m*2.4) **in 2012/13** and **£7.56m** (£3.15m*2.4) **in 2013/14 and 2014/15**.

180. There will also be ongoing annual costs as new providers joining the market each year are also subject to these initial compliance costs. Based on the above and the assumption that around 160 new providers join each year, these are estimated as **£0.14m pa from 2015/16** onwards, ((£1500*25%*160 new providers) + (£10,000*5%*160 new providers)). Again, the true opportunity cost is **£0.34m** (£0.14m*2.4) **pa from 2015/16** onwards.

181. Providers struggling to demonstrate compliance are likely to be required to identify the changes they need to make to achieve compliance, and may also have conditions attached to their registration. CQC does not envisage refusing the application for registration of many, if any, providers. However, some providers that struggle with initial compliance may themselves decide to leave the market if they do not have the capability or inclination to invest the time and effort to achieve compliance with registration requirements. This would represent a loss of income to the provider, a loss of provision to patients, and a need for commissioner to identify alternative services. It is not possible to know how many providers this could apply to or the extent of the impact, but is not expected to be significant.

Commissioners

182. During initial registration, the CQC and providers may require assistance from commissioners. CQC may require commissioners to assist highlighting potential issues with certain providers for initial registration and/or providing information to support the risk profiling of providers of NHS primary medical services. In addition, providers of NHS primary medical services may require assistance from commissioners to prepare for initial registration.

183. The previous impact assessment assumed these costs would be significant. However, the experience of previous registration rounds suggests that the level of support provided by commissioners has been lower than expected. This is likely to be even lower for registration of primary medical care providers since PCTs will be in the process of being wound down, and the NHS Commissioning Board will not be fully functioning. It is expected that commissioners role will be to identify and alert CQC to those providers which may struggle to meet the registration requirements. These costs are unquantifiable but are expected to be insignificant.

<u>Annual costs of regulation; fees</u>

184. In regulating providers, CQC incurs costs associated with inspections, processing self-assessments, data collection and risk profiling, enforcement such as investigation actions and processing registration of new providers. CQC has the power to recover these costs through the payment of registration fees by providers.

185. CQC is responsible for setting these registration fees, and is required to consult with providers before it sets fees. Therefore, for the purpose of this impact assessment it is necessary to make a number of assumptions based on the approach that CQC has taken in setting fees for providers that have entered registration in previous registration rounds. It is assumed that CQC will take a prudent approach to setting registration fees initially and that the registration fee may be in the region of

(based DH analysis of Information Centre average earnings data: average HCHS admin and clerical 10/11 **paybill** (inc employer costs) per FTE £29.5k*1.3(overheads) divided by 1650 hrs(~220 working days*7.5 hours))

around half of the total cost of registering providers of NHS primary medical services. Once these providers are registered, CQC will be in a position to develop a fuller understanding of the costs of regulating this sector. It is assumed that once CQC has experience of regulating these provider it will seek to move towards full cost recovery through fees over a relatively short period.

186. On the basis that the cost to CQC of registering providers of NHS primary medical services is estimated to be around £1,600 per provider a year, it is assumed that the average registration fee in the first year of registration will be in the region of £800 to £900. The level of fee will move towards full cost recovery over time. This is shown in the table below:

Table A2.3: Assumed cost recovery provider fee profile

	2012/13	**2013/14**	**2014/15 to 2021/22**
Cost Recovery	50%	75%	100%
Provider Fee	£800	£1,200	£1,600
Cost to CQC	£800	£400	£0

187. The above is based on an assumption of the approach that may be taken and the proposed fees will be developed by CQC and will be subject to consultation.

Care Quality Commission

188. From the above tables, total costs to the CQC can be estimated to be **£10.8m; £7.2m in 2012/13** (£800*9000 providers) and **£3.6m in 2014/15** (£400*9000 providers). There is link between fee income and DH grant in aid; as CQC costs are increasingly met by fees, DH grant in aid reduces. Therefore, the proportion of annual costs not recovered through provider fees represents DH grant in aid not saved. Therefore, it is a cost to the NHS budget, and the opportunity cost is **£25.92m** (£10.8m*2.4); **£17.28m** (£7.2m*2.4) **in 2012/13** and **£8.64m** (£3.6m*2.4) **in 2014/15**.

Provider of NHS primary medical services

189. From the above table the total cost of fees to providers is **£7.2m** (£800*9000 providers) **in 2012/13** increasing as cost recovery increases to **£10.8m** (£1200*9000 providers) **in 2013/14** and **£14.4m pa** (£1600*9000 providers) **from 2014/15** onwards. It is no known how these costs of these fees to providers will be recovered, therefore tax implications are not considered nor is any opportunity cost multiplier.

Annual costs of regulation; CQC reviews

Care Quality Commission

190. The costs to CQC of carrying out reviews are covered through the registration fees paid by providers as discussed in para 186 above.

Providers of NHS primary medical services

191. As discussed above it is therefore only possible to propose a hypothetical example based on current practice for other sectors of what CQC reviews might involve. For the purpose of this impact assessment, it is assumed that all providers will be reviewed once in a two-year period, this is assumed equivalent to 50% of providers being reviewed in any one year. It is assumed that for all providers the review will involve gathering evidence and information to demonstrate compliance and sharing it with CQC. It is further assumed that for a majority of providers it will also involve an observational visit by CQC; in order to estimate potential costs a majority is assumed to be 75%.

192. It is difficult to estimate the burden on providers and it will vary case by case, but the costs of information sharing are assumed to be less than under initial registration above as providers will draw on the same available data sources but should be more aware of what is required and where to get it. Therefore, it is assumed that it could involve a day (7.5 hours) of practice manager's time at an hourly cost of £35, and half a day (3.5 hours) of a clinician's time at an hourly cost of around £100. This gives a total cost of around £600 per provider ((7.5hours*£35) + (3.5hours* £100)). This gives a total annual cost to providers of around £2.7m (£600*9000*50%).

193. Again it is difficult to estimate the burden on providers, but if an observational visit by CQC takes up one day (7.5 hours) preparation by a practice manager and an administrative staff and half a day of a practice manager and clinician's time to facilitate the visit, then cost could be around £900 per provider. This is based on 1.5 days (11 hours) of practice managers time at £35 an hour, one day of

admin staff time at £25[14] per hour and half a day (3.5 hours) of clinician time at around £100 an hour ((11*£35)+(7.5*£25)+(3.5*£100)). This cost only applies to 75% of providers, so the total annual cost of visits is £3.04m (£900*75%*9000*50%).

194. This gives an estimated annual cost to providers of reviews of £5.74m (£2.7m+£3.04m). These staff costs represent NHS resources forgone so the opportunity cost is £13.77m (£5.74m*2.4).

195. As discussed above it is assumed that the due to a lack of capacity and the scale of initial registration of existing NHS primary medical care providers CQC will only be able to start their review process half way through the year in 2012/13. Therefore, the total costs will be **£2.87m in 2012/13** and **£5.74m pa from 2013/14**, and total opportunity costs will be **£6.88m in 2012/13** and **£13.77m pa from 2013/14** onwards.

196. Due to the backlog of work and a less effective registration round in April 2012, it is assumed that the reviews in 2012/13 to 2014/15 will be less effective as addressing non-compliance. This is reflected in the assumed profile of compliance in Table A2.2, and affects the profile of compliance costs and benefits. Despite being less effective these reviews, the full costs to providers are still assumed to be incurred, as they have to go through the same process.

197. In addition to the above planned reviews, CQC will also carry out responsive reviews, which could be triggered by a number of factors. Given their responsive nature, it is not possible to estimate how many responsive reviews there would be, if these would replace planned reviews for those providers or what a responsive review would involve. Therefore, it has not been possible to estimate these costs.

Annual costs of regulation; ongoing compliance

Providers of NHS primary medical services

198. As discussed previously, it is estimated that around 25% of providers may struggle in some areas of compliance and an additional 5% of providers may have significant issues. It was discussed above that at the time of initial registration this may require a change in behaviour and an investment of time and effort. It may be that this requires an ongoing change in behaviour or investment to maintain compliance. It is not possible to estimate what these on going costs may be. The current regulatory framework has not been in place long enough for there to even be any anecdotal evidence of what providers need to do to maintain ongoing compliance. Therefore, these costs have not been quantified.

Annual costs of regulation; assisting on-going regulation

Commissioners

199. As with initial registration, CQC and providers may require assistance from commissioners to support ongoing regulation.

200. CQC may require commissioners to provide information and support on an on-going basis and vice versa. This will be supported by the proposed duty for CQC and the NHS Commissioning Board to co-operate contained in the Health and Social Care Bill that is currently before Parliament. The role of CQC in providing assurance of essential levels of safety and quality could free up capacity for commissioners to focus on driving up quality beyond these levels.

201. Providers may also require support from commissioners to complete forms to prove on going compliance and deal with CQC reviews.

202. The overall impact on commissioners is mixed and difficult to quantify. However, if there is an overall cost on commissioners it is not expected to be significant. In the light of previous registration rounds we now expect the involvement of commissioners in most cases to be restricted to alerting CQC to those providers about which there are concerns

Tribunal Service

203. Providers have a right of appeal to the Health, Education and Social Care Chamber of the First Tier Tribunal. It is not possible to estimate with any degree of certainty the likely number of appeals to Tribunal from providers of NHS primary medical services. Based on previous experience of social care regulation the cost is estimated to be around **£0.20m pa** from **2012/13** onwards (as appeals could be made against CQC decision at initial registration as well as throughout on-going

[14] ref hourly cost calc

regulation). As this is a cost to the exchequer the full opportunity cost is **£0.48m pa** from **2012/13** onwards (£200k*2.4).

Costs Summary

204. Table A2.4 brings the costs discussed above together, shown with and without opportunity cost adjustments. Costs are shown in £'000s and are in 2010/11 prices.

Without OP costs 2.4 multiplier

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Initial registration costs to providers	£27,000	£480	£480	£480	£480	£480	£480	£480	£480	£480	£31,320
Initial compliance costs to providers	£1,575	£3,150	£3,150	£140	£140	£140	£140	£140	£140	£140	£8,855
Initial registration costs to CQC	£6,000	£0	£0	£0	£0	£0	£0	£0	£0	£0	£6,000
Development costs of registration process	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
Distraction costs	UNQUANTIFIED										
Initial registration cost to commisioners	UNQUANTIFIED										
Annual cost to regulator; provider fees	£7,200	£10,800	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£133,200
Annual cost to regulator; the CQC	£7,200	£3,600	£0	£0	£0	£0	£0	£0	£0	£0	£10,800
Provider cost of review	£2,869	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£54,506
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	£200	£200	£200	£200	£200	£200	£200	£200	£200	£200	£2,000
Total Costs (undiscounted)	£52,044	£23,968	£23,968	£20,958	£20,958	£20,958	£20,958	£20,958	£20,958	£20,958	£246,681

***With** OP costs 2.4 multiplier)*

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Initial registration costs to providers	£64,800	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£75,168
Initial compliance costs to providers	£3,780	£7,560	£7,560	£336	£336	£336	£336	£336	£336	£336	£21,252
Initial registration costs to CQC	£14,400	£0	£0	£0	£0	£0	£0	£0	£0	£0	£14,400
Development costs	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
Distraction costs	UNQUANTIFIED										
Initial registration cost to commisioners	UNQUANTIFIED										
Annual cost to regulator; provider fees	£7,200	£10,800	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£133,200
Annual cost to regulator; the CQC	£17,280	£8,640	£0	£0	£0	£0	£0	£0	£0	£0	£25,920
Provider cost of review	£6,885	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£130,815
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	£480	£480	£480	£480	£480	£480	£480	£480	£480	£480	£4,800
Total Costs (undiscounted)	£114,825	£42,402	£37,362	£30,138	£30,138	£30,138	£30,138	£30,138	£30,138	£30,138	£405,555

Benefits of regulation

205. The main benefits of CQC regulation of primary medical care providers originate from the CQC's role as the enforcement authority of essential levels of safety and quality. In addition, bringing providers of NHS primary medical services into registration also puts in place a fairer regulatory structure for all providers of regulated activities. This encourages competition, patient choice, and reduces service variability (Chipty and White, 2007) [15]. Therefore, the main benefits of CQC regulation can be summarised as:

- Reduction in adverse patient health events; patient health gains and saved NHS treatment costs;
- Increase in the overall quality of primary medical care;
- Improved consistency; a level playing field for all providers.

Reduction in adverse patient health events; patient health gains and saved NHS treatment costs

206. In the provision of NHS primary medical services there are potential patient harm incidents, each of which has an associated health loss that can be measured in terms of its likelihood, severity, and duration. Some of these events are unavoidable, whereas the risk of others can be influenced by the care provider and therefore can be mitigated. It is expected that system regulation by CQC could bring about reductions in all three aspects of these hazards.

207. In order to quantify both the patient health gains, as well as the reduction in NHS treatment costs, a risk-based approach is used. This approach considers the risks that occur in primary care and the extent to which CQC can mitigate them. The health gains and treatment cost savings resulting from risk mitigation are then monetised. As a result, the above approach requires the following

[15] Chipty, T and White, A (1998) 'Effects of Information Provision in an Vertically Differentiated Market,' NBER Working Paper No W6493)

information: number of consultations, likelihood, severity and duration of adverse health outcomes, valuation of the patient health losses, CQC's capacity to mitigate risks and NHS treatment costs,.

Consultations

208. Based on NHS Information Centre data, in 2008/9 there were approximately 304m consultations in general practice setting.[16] It is difficult to predict how many consultations there will be in the future. However, it should be noted that the number of consultations in general practice increased by 42% between 1999/2000 and 2008/9.[17]

209. This is partly driven by demographic pressure – older people tend to have a greater demand for healthcare. Thus, as the average age of the population rises, there is a greater demand for GP consultations. This pressure is set to remain over the coming decade, particularly as the "baby boomer" generation grows older. Given current GP consultation rates by demographic cohort and Office of National Statistics population predictions[18], it is estimated that future demographic pressure alone will cause an average annual increase in consultation rates of 1% pa. This would be a low growth scenario.

210. In addition, over the past decade, consultation rates have risen above demographic pressure. For instance, according to IC data, the average rate of GP consultations per male person aged 70 to 74 rose by 50% between 1999/2000 and 2008/09. This increase may be due to changes in policy, funding, technology and/or epidemiology. It is not possible to predict future development of such factors. However, it should be noted that consultation rates would increase by 4.5%pa if future trends were to reflect the growth in consultation rates for persons of a given demographic cohort exhibited between 1999/2000 and 2008/09. This would be a high growth scenario.

211. It may be argued that growth rates might drop off following years of high growth. However, future policy is expected to move more care into the community. In the absence of better information, the midpoint between the low and high growth scenarios is taken as the best estimate: 2.75%pa. This gives an estimate of about 339m GP consultations in 2012/13.

212. In addition, consultations in out-of-hours services need to be considered. National Audit Office data suggests about 9m patients received out-of-hours care in 2006. [19] However, some of these patients will have had more than one out-of-hours consultation in that year, but some of these will have be with a patient's registered GP. Therefore, it is assumed that as a best estimate there will be about 10m consultations with specific out of hours providers in 2012/13.

213. Finally, there are about 850 other providers of NHS primary care. These are expected to provide specialised services and be smaller than the average GP practice. Thus, the rate of consultations per provider in this group as a best estimate is expected to be 50% lower than that in GP practices. For 2012/13, this suggests about 18m consultations.

214. Thus, as a best estimate, it is expected that there will be a total of **367m** primary medical consultations in 2012/13. In the absence of better information, the best estimate growth rate for GP consultations is applied to all consultations. Therefore the 367m total consultations in 2012/13 will then rise at **2.75%pa** to **468m** in 2021/22. Table A3.1 shows the best estimate time profile of consultations.

Table A2.5: Profile of consultations (in millions)

	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Best estimate	367	377	387	398	409	420	432	443	456	468
o/w out of hours services	10	10	11	11	11	11	12	12	12	13

[16] NHS IC 2009: Trends in Consultation Rates in General Practice 1995/96 to 2008/09. http://www.ic.nhs.uk/webfiles/publications/gp/Trends_in_Consultation_Rates_in_General_Practice_1995_96_to_2008_09.pdf

[17] NHS Information Centre 2009, Trends in consultation rates in General Practice - 1995-2009, http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/general-practice/trends-in-consultation-rates-in-general-practice--1995-2009 insert ref/link

[18] NHS IC 2009: Trends in Consultation Rates in General Practice 1995/96 to 2008/09. http://www.ic.nhs.uk/webfiles/publications/gp/Trends_in_Consultation_Rates_in_General_Practice_1995_96_to_2008_09.pdf and ONS population projections at http://www.statistics.gov.uk/statbase/Product.asp?vlnk=997

[19] NAO 2006, The provision of out-of-hours care in England, http://www.nao.org.uk/publications/0506/out-of-hours_care_in_england.aspx

Likelihood of adverse health events

215. There is insufficient data to disaggregate reliably adverse events by cause or type. However, it is expected that the impact of adverse events will vary, which is reflected through categorising adverse events by their expected level of patient harm[20]:

- no harm - no treatment required,
- low harm - requiring only first-aid level treatment; example: rash resulting from an adverse reaction to medication,
- moderate harm - can range from an extra consultation to several weeks in intensive care; example: a patient being given an out-of-date vaccine,
- severe harm - resulting in permanent disability; example: a trip hazard in provider premises leading a fall and fractured hip, or a late referral leading to a disabling stroke
- death – a potentially curable cancer leading to death due to missed or delayed diagnosis.

216. Assumptions on the likelihood of the above categories of adverse events are based on relevant literature and sources, including input from the National Patient Safety Agency (NPSA).

217. Data on primary medical services patient safety incidents is limited. In 2003, a review of older literature found reported rates of incidents ranging from 5 to 80 errors per 100,000 consultations[21], whereas newer studies report much higher incidence rates – of up to 7,000 errors per 100,000 consultations[22].

218. It should be noted that different studies use different definitions of what constitutes an incident. This restricts the comparability of results. In addition, most of the reviewed literature relies on reporting by a potentially biased and usually small sample of practitioners. Only one study (from Australia) uses anonymous incident reports by a representative sample of 84 GPs.[23] This study reports an incidence rate of 78 incidents per 100,000 consultations.

219. Recent literature has taken to reviewing patient records rather than relying on reports by practitioners. These studies have found much higher incident rates, concluding that there may be up to 7,000 incidents per 100,000 consultations. However, as these studies rely on findings from small samples of GP practices, results cannot be generalised. Therefore, as a prudent best estimate, it is assumed that there are 80 incidents per 100,000 consultations with a range of 40 to 200.

220. Note that most of the incidents are expected to result in no patient harm. The exact split of incidents by severity of patient harm varies across the literature, depending on the definitions used. Thus, data on patient incidents in acute hospitals (as reported to the National Patient Safety Agency[24]) are used as a proxy. Due to limited data in this area, it is assumed that the categories of adverse events and the share of incidents below is representative of the overall distribution of adverse events in all NHS primary medical services.

[20] These categories are based on those developed by the National Patient Safety Agency (NPSA)

[21] Sandars, J & Esamail A 2003: The frequency and nature of medical errors in primary care: understanding the diversity across studies, Family Practice 20, 231 – 236.

[22] De Wet, C. and Bowie, P 2009: The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records, Postgrad Med J 85, 176 – 180.
Gaal, Sander et al 2011: Prevalence and consequences of patient safety incidents in general practice in the Netherlands: a retrospective medical record review.
Rubin, G. et al 2003: Errors in general practice: development of an error classification and pilot study of a method for detecting errors, Qual Saf Health Care 12, 443-447

[23] Makeham, Meredith Anne Blatt 2007: The measurement of threats to patient safety in Australian general practice, University of Sydney, http://ses.library.usyd.edu.au/bitstream/2123/3899/1/makeham-thesis-2008.pdf

[24] Note that Makenham 2007 only reports the share of no harm events and that this is roughly consistent with the NPSA figures.

Table A2.6: National Patient Safety Agency adverse event severity categories

Hazard Severity	Category Description	Representative Condition	Likelihood (per 100,000 consultations)	Share of Incidents
No Harm	No treatment or follow-up required;	Lack of signature on a prescription;	57.8	72.2%
Low Harm	Requires only first-aid level treatment;	Examination, reassurance, disinfection;	17.2	21.5%
Moderate Harm	Harm that requires extra healthcare investigation, observation or treatment, but does not lead to permanent disability; can have a wide range of outcomes ranging from extra GP visit to a long stay in hospital;	Application of wrong vaccine, delayed diagnosis leading to emergency admissions;	4.4	5.6%
Severe Harm	Event that causes permanent disability;	Fractured hip due to trip hazard, disabling stroke following an undetected mini-stroke;	0.4	0.5%
Death	Harm leading to patient death;	Missed diagnosis of cancer;	0.1	0.2%

Severity and duration of adverse health outcomes

221. The NPSA classification of adverse health outcomes allows for aggregation of severity levels across various causes of health loss. Here, it is assumed that the hazard categories reported by NPSA are representative of the distribution of all adverse events in NHS primary medical care. The data does not allow a more granular approach. As a result, a single heading, such as low harm events, incorporates more than just one possible health outcome, as per the descriptions in Para 217 above.

222. The EQ-5D framework developed by EuroQol is used to measure the severity of the hazards outlined in table A2.7. The model is designed to give an estimate of how individuals rate their quality of life using a questionnaire with five independent domains: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each of these domains is rated using a discrete scale between 1 (representing no problems) and 3 (representing severe problems). Scores are then translated into a quality-of-life score using regression analysis, in order to give a continuous value between 1 (representing someone in perfect health) and -0.594 (representing someone with considerable and severe problems). Death is associated with a health state of zero.

223. To derive the severity of adverse incidents, representative health states and corresponding answers to the EQ-5D questionnaire have been developed, taking into account input from the NPSA. These are assumed to be illustrative of an individual experiencing each of the hazards identified in table A2.6. For instance, a severe health loss (such as a medication error) may be described by an EQ-5D score of 11231 (indicating some problems with usual activity and severe pain/discomfort), which translates into a 40% reduction in one's quality of life. Table A3.3 summarises the EQ-5D severity assumptions, together with examples of health states in each category.

224. The average primary medical care patient is estimated to be 50 years old, as indicated by data from the Information Centre[25]. Therefore, initial patient health state should reflect the average quality of life score for the representative age group. Using figures derived in the Illness Atlas for EQ-5D (Macran and Kind, 2005), it is estimated that the average patient's health state corresponds to a Quality of Life (QoL) score of 0.845 (as opposed to a score of 1 for a perfectly healthy person). Moreover, because elder patients are more likely to suffer harm through incidents (e.g. because

[25] NHS IC 2008: Trends in consultation rates in General Practice - 1995-2009, http://www.ic.nhs.uk/pubs/gpcons95-09

they are more frail or suffer from co-morbidities),[26] it is assumed that patients suffering harm are aged 55, corresponding to an average QoL score of 0.805.

225. Accounting for the above considerations, the absolute health loss derived from the EQ-5D model is lower than for a perfectly healthy person suffering from the same adverse event. For example, an incident bringing down a patient's QoL to 0.705 is not treated as bringing it down by 0.295, but rather by 0.1 (= 0.805 - 0.705). However, it is acknowledged that such a reduction in one's QoL is proportionately more severe for individuals starting out from a lower health state. Thus, the severity of the above health loss is taken to be 0.124 (= 0.1 / 0.805). The assumptions used to develop the ratings are compiled in table A2.7.

226. The above argument extends to assumptions regarding duration of various health outcomes. The aggregation of health states into the NPSA severity categories leads to development of an average duration approach, i.e. on average how long an adverse event is expected to last.

227. More severe adverse events are expected to result in life-long health loss, as defined by the NPSA severity categories[27]. The discussion above points out that older patients are more likely to experience these events. According to 2010 ONS data, life expectancy of a 55 year-old is 27.17 years, which is equivalent to a quality-adjusted life expectancy of 19.89, after accounting for quality of life decreasing with age.

228. The representative hazard severity and duration assumptions, which were developed taking into account input from the NPSA, can be found in Table A2.7 below.

Table A2.7: EQ-5D assumptions by severity of patient harm

Hazard Severity	**EQ-5D Scoring Assumptions**	**Average QALY Loss**	**Average Duration**
No Harm	21211	0	N/A
Low Harm	21212	0.087	1 week
Moderate Harm	Midpoint between: 21212 and 22222	0.2115	1 month
Severe Harm	Midpoint between: 22222 and 33311	0.6505	19.89[28]
Death	N/A	1[29]	19.89[30]

CQC risk mitigation

229. The extent to which CQC can reduce the overall impact of the adverse events depends on three factors: (1) the nature of the risks that are being mitigated, (2) how CQC adds to existing regulatory mechanisms, and (3) the extent to which providers are already meeting CQC registration requirements.

230. Existing literature (Dovey et al., 2002[31]) suggests that a significant proportion of risks in primary medical services are avoidable and concentrated in areas of care delivery systems (such as administrative errors, record keeping, screening and monitoring) where compliance with CQC registration requirements is likely to have a mitigating effect. However, certain groups of adverse events will be either unavoidable or have causes that do not fall within CQC's scope of risk mitigation. These can be classified into the following categories: patient self-harming, clinical assessment, and treatment procedure (together accounting for approximately 21% of all patient

[26] In Makeham 2007, the average age of patients involved in errors with harm was 58 years while the average age of patients involved in errors with no harm was 50 years. (Makeham, Meredith Anne Blatt 2007: The measurement of threats to patient safety in Australian general practice, University of Sydney, http://ses.library.usyd.edu.au/bitstream/2123/3899/1/makeham-thesis-2008.pdf)

[27] http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/ and http://its-services.org.uk/silo/files/npsa-guide-to-root-cause-analysis-glossary.doc

[28] Quality-adjusted life expectancy at 55 years of age

[29] Reflects a fall of QoL to zero. Note, that shorter duration adjusts for lower initial QoL, reflecting the correct health loss resulting from death

[30] Quality-adjusted life expectancy at 55 years of age

[31] Dovey SM, Meyers DS, Phillips Jr RL, Green LA, Fryer GE, Galliher JM, Kappus J, Grob P. (2002) "A preliminary taxonomy of medical errors in family practice." *Quality and Safety in Health Care,* 11: 3, 233–8, cited in National Patient Safety Agency (2009) "Seven Steps to Patient Safety for Primary Care")

incidents[32]). This reduces CQC's regulatory impact by decreasing the number of incidents that can be mitigated by system regulation. At the same time, it is important to note that these adverse events may have multiple underlying causes, some of which may be concentrated around delivery systems. Given the above, it is assumed that 10% of adverse events take place in areas where compliance with CQC registration requirements does not have a mitigating effect.

231. A significant proportion of providers will already meet CQC standards in all areas of care. For these providers, being required to comply with CQC requirements is expected to have a limited impact. Based on experience CQC estimates that around 25% of providers may have some difficulty in initially proving compliance and additional 5% may have significant difficulties. It is through targeting these providers than CQC will have most effect on reducing the overall impact of adverse events.

232. The evidence presented above has to be considered in light of existing regulation that may already cover certain aspects of CQC requirements. In particular, recent developments in professional regulation (such as the Good Medical Practice Framework for Appraisal and Revalidation[33]) point to an increasing emphasis on the suitability of systems that are used in primary medical care settings. This in turn creates overlaps with CQC regulatory requirements and contributes to a decrease in the extent of CQC risk-mitigation, as it has to be viewed in terms of a marginal addition to existing regulation.

233. Primary medical practitioners are subject to legally binding regulation by the General Medical Council (GMC)[34], and Nursery and Midwifery Council (NMC)[35]. Registration and ongoing appraisals by these bodies have a positive impact on provider compliance with minimum quality standards and thus with CQC registration requirements. 70% of providers are assumed to currently meet CQC standards. However, there are regulatory gaps, given that 30% of providers are expected to not meet CQC essential requirements. These providers are expected to expose their patients to higher level of avoidable risk, when compared to their compliant counterparts. Thus, significant improvements can be achieved through CQC registration, as enforcement of compliance is expected to bring those 30% of providers to the "natural" unavoidable level of risk, which is exhibited by compliant providers and is inherent in the provision of primary medical care.

234. Based on the above, as a prudent estimate, CQC is expected to be able to mitigate 3% of patient risks in primary care, which can be broken down as approximately 0% for the already-compliant providers and average of 15% across all the providers that would have problems meeting CQC requirements.

235. The likelihood and severity of patient incidents found in out-of-hours care are assumed to be comparable to those in traditional general practice setting[36]. However, the urgency and nature of consultations in out-of-hours care lead to specific sources of risk that are largely absent in GP practices. A study by the Medical Protection Society shows that some of the most common areas of risk in out-of-hours care had a relevant system aspect: inappropriate prioritisation of callers, inadequate recruitment of staff, failure to document home-visits, lack of knowledge about procedures and failure to provide effective risk management strategies.[37] Therefore, the nature of risk in out-of-hours care suggests that system regulation by CQC can play a particularly important role in mitigating patient risks. These arguments presented above are reinforced by the findings of the Department of Health report on out-of-hours care[38]. In particular, the authors concluded that when evaluating the out-of-hours setting, the following circumstances should be considered: unfamiliar patients, initial assessment often being completed on the phone, colleagues who may not be well-known to the clinician prior to the shift, unfamiliar surroundings/equipment, and a higher proportion of vulnerable patients with urgent care needs often more complex than those generally found in daytime general practice as these patients are not known to the clinician.

236. Given the above, registration with CQC is expected to have greater potential for risk mitigation in out-of-hours setting. However due to insufficient data this effect has not been quantified and given

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[32] http://www.nrls.npsa.nhs.uk/resources/?EntryId45=131059

[33] http://www.gmc-uk.org/GMP_framework_for_appraisal_and_revalidation.pdf_41326960.pdf

[34] http://www.gmc-uk.org/

[35] http://www.nmc-uk.org/

[36] Smits, Marleen et al 2010: Patient safety in out-of-hours care: a review of patient records, BMC Health Services Research 10:335 ff. http://www.biomedcentral.com/content/pdf/1472-6963-10-335.pdf

[37] Wilson, Julie and Taylor, Kate 2011: Clinical risk management in out-of-hours services, Nursing Management 17 (10), 26 – 30

[38] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111892

the relatively small number of providers involved (150/9000=1.67%), a 3% average effectiveness is assumed across all primary medical settings.

Table A2.8: Likelihood, severity, duration and potential CQC risk mitigation of adverse patient health events in NHS primary medical care.

	(B) Likelihood (per 100,000 consultations)	(C) Severity (Quality of Life score)	(D) Duration (in years)	(E) Risk mitigation
No harm	57.8	0	0.00	3.00%
Low harm	17.2	0.09	0.02	3.00%
Moderate harm	4.4	0.21	0.08	3.00%
Severe harm	0.4	0.65	19.89[39]	3.00%
Death	0.1	1[40]	19.89[41]	3.00%

237. It is assumed that one person-year in full health (a QALY) is worth £63,000[42] (in 2010/11 prices) to society. Based on the above, it is possible to quantify the expected avoided health loss from CQC regulation using the following calculation: Benefits = A x B x C x D x E x £63,000, where: A = Number of consultations, B = likelihood of adverse event, C = severity of adverse event, D = duration of adverse event, E = reduction through system regulation.

238. As discussed in Para 152-159, in light of recent experience, it has become apparent that CQC's systems require further development. As a result, it is assumed that only 20% of benefits of reduction in adverse patient health events would be realised in 2012/13. This is mainly due to incomplete registration process leading to insufficient monitoring and enforcement, which causes delayed compliance with registration requirements. The remaining 80% of benefits are assumed to be realised in two equal stages: 40% in 2013/14 and 40% in 2014/15, when ongoing monitoring and assessment identify the remaining non-compliant providers. Based on the above, the annual patient health benefits are estimated to be **£11.5m** in **2012/13**, **£35.6m** in **2013/14**, and **£60.9m** in **2014/15** recurring annually, but increasing in line with the estimated growth in the number of consultations to **£73.6m** in **2021/22**, as shown in the table below.

Table A2.9: Patient health benefits (undiscounted, £ millions)

Patient Health Benefits:	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**
TOTAL	£11.5m	£35.6m	£60.9m	£62.6m	£64.3m	£66.1m	£67.9m	£69.7m	£71.7m	£73.6m
o/w out of hours services	£0.3m	£1.0m	£1.7m	£1.7m	£1.8m	£1.8m	£1.9m	£1.9m	£2.0m	£2.0m

239. In addition to the discussion above, an adverse event may also lead to a range of negative impacts on the provider-patient relationship. Even no- or low-harm incidents may cause a loss of trust and unwillingness to cooperate with recommended treatment, leading to further negative health outcomes. Primary care outcomes often translate directly into secondary care, which may lead to one error resulting in an entire chain of adverse events (e.g. a loss of patient records leading to misdiagnosis and further unwillingness of patient to cooperate, resulting in emergency hospital admission). It is not possible to reliably quantify this effect.

Reduction in adverse patient health events; saved NHS treatment costs

[39] Quality-adjusted life expectancy at 55 years of age]

[40] Reflects a fall of QoL to zero. Note, that shorter duration adjusts for lower initial QoL, reflecting the correct health loss resulting from death

[41] Quality-adjusted life expectancy at 55 years of age]

[42] Based Department for Transport research showing a QALY being worth £60,000 in 2008/09 prices, uplifted to 10/11 prices using HMT's GDP deflators

240. Most adverse events are directly associated with NHS treatment costs. Therefore, in addition to the health (QALY) benefits identified above, mitigation of adverse events can result in avoided NHS treatment costs. Even in the case of events that caused no lasting harm (such as low harm health outcomes), there is a likelihood of further consultations and additional costs on the NHS that could be avoided.

241. Average treatment costs for each severity category are developed using data from the Unit Cost of Health and Social Care 2010[43]. Figures from both data sources are then uplifted to reflect 2010/11 prices. The treatment costs are then assumed to increase in line with the GDP deflator, resulting in no change in the real price of NHS treatment over the appraisal period. The representative treatment assumptions are outlined in table A2.10 below. These proxy treatments for individual severity categories were developed taking into account input from the NPSA.

Table A2.10: NHS treatment cost by severity of patient harm

Hazard Severity	**Representative Treatment**	**Reference Cost Look-up**	**Average Cost**
No Harm	No treatment or follow-up required;	N/A	£0
Low Harm	Additional consultation with a General Practitioner.	N/A	£40
Moderate Harm	Non-elective short hospital stay, averaged across 1200 various conditions.	TPCTNEI_S	£1,300
Severe Harm	Average of two representative conditions: Major Hip Procedure and Non-transient Stroke with annual follow-up aggregated over the course of remaining life years (27 years is the life expectancy of an average PMC patient).	Hip Procedure – HA11A Stroke – AA04Z Follow-up – PA57Z	£34,000
Death	Approximately corresponding to the average of an emergency hospital admission and non-elective long hospital stay.	TPCTNEI_L	£3,000

242. It is possible to quantify the expected benefits of avoided NHS treatments costs from CQC regulation using the following calculation: Cost savings= A x B x E x F, where: A = Number of consultations, B = likelihood of adverse event, E = reduction through system regulation, F = Saved treatment cost on NHS. These cost savings free up the resources for other activities, which improves the overall quality of health outcomes in the NHS. These cost savings free up resources for other activities, which improves the overall quality of health outcomes in the NHS. To reflect this, NHS costs need to be multiplied by 2.4 to reflect the opportunity cost savings of saved NHS resources. This results from the assumption that any £1 of freed up resources can contribute to creating £2.4 of patient health benefits. For more details, see paragraph 161.

243. As explained in paragraph 238, it is assumed that not all benefits of reduction in NHS treatment costs would be realised in 2012/13 and 2013/14. Based on these assumptions, the annual benefit is estimated to be **£1m** in **2012/13**, **£3.2m** in **2013/14**, and **£5.5m** in **2014/15** recurring annually, but increasing in line with the estimated growth in the number of consultations to **£6.7m** in **2021/22**, as shown in table A2.11 below.

Table A2.11: NHS treatment cost savings (£, millions)

NHS treatment cost savings:	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**
TOTAL	£1.0m	£3.2m	£5.5m	£5.7m	£5.8m	£6.0m	£6.1m	£6.3m	£6.5m	£6.7m
o/w out of hours services	£0.03m	£0.09m	£0.15m	£0.15m	£0.16m	£0.16m	£0.17m	£0.17m	£0.18m	£0.18m

[43] http://www.pssru.ac.uk/pdf/uc/uc2010/uc2010.pdf] and the 2009/10 NHS reference cost data http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_123459

244. In addition to the treatment costs identified above, every adverse outcome leads to patient time-effort costs, which are assumed to be proportionate to the severity of the incident and reflect how much patient's time and effort is necessary to mitigate the consequences of an adverse event. This may range from having to visit a GP again in order to get the correct prescription to a life-long commitment to rehabilitation and on-going treatment. It is not possible to reliably quantify these costs.

Increase in overall quality of primary medical services and the 'safety net' effect

245. As discussed in paragraph 231, most providers of NHS primary medical services already comply with the essential levels of safety and quality. Although this may limit the effect that CQC registration will have on reduction of adverse events, there is still scope for improvement of care beyond essential levels. A number of studies [Gravelle and Misiero, 2000[44], Dranove et al., 2003[45], Carslile, 2007[46]] show how the implementation of minimum quality standards can lead to quality improvements. This is achieved though providers that are already compliant making additional improvements to the quality of their services to differentiate themselves from their competitors (Chipty and White, 1997[47]). This mechanism is particularly relevant in the NHS environment, where prices are fixed (based on a tariff) and competition between providers is driven by improvements in quality.

246. CQC can further improve this mechanism by providing patients with additional information about primary medical service providers, which may enhance the patient choice drive behind quality improvement [Dranove et al., 2003[48]]. Moreover, enforceability of minimum standards is often directly linked to overall quality, as pointed out by [Shaw, 2001[49]]. The robust enforcement mechanisms that form a key part of the CQC regulatory model are particularly likely to achieve this outcome.

247. In addition to improving overall quality, CQC registration also provides a 'safety net', which ensures that already-compliant providers maintain their good practice standards. This effect may lead to mitigation of future risks resulting from the evolutionary nature of primary medical services. In particular, the development of care in new settings and the increasing range of treatment in primary care settings (for example minor surgery) may lead to a lack of compliance with essential levels of safety and quality and negative patient outcomes. The 'safety net' also ensures that new market entrants are compliant with essential levels of safety and quality before they begin providing care.

248. Although registration of providers of NHS primary medical services would be carried out in 2012/13, the annual benefits identified are unlikely to be realised until 2013/14. It is not possible to reliably quantify these benefits, yet they are expected to be significant.

Improved consistency; a level playing field for all providers

249. The above effect may be reinforced by CQC providing a fair playing field for all providers. In requiring providers of NHS primary medical care to register, CQC will provide assurance of the same requirements on safety and quality across both public and private providers and across all settings. Such 'fair treatment' of all providers may lead to a focus on quality-driven competition, as all providers would have to meet the same essential levels.

250. Compliance with registration requirements across all providers may decrease local variability of service quality. Viewed in light of a greater consistency of enforcement actions, this may allow patients to make better informed and more flexible choices, as they can be reassured of a minimal level of service that they can expect from every provider of NHS primary medical services.

251. These benefits, as with the other benefits discussed, are assumed to accrue in line with the profile of compliance enforcement as outlined above. For example, the safety effect would be realised in line with CQC ability to enforce compliance, as would the level playing field for providers, as until compliance is fully enforce for all the playing field will not be level.

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[44] Gravelle, H. and Masiero, G (2000) 'Quality incentives in a regulated market with imperfect information and switching costs: capitation in general practice,' Discussion Papers 00/18, Department of Economics, University of York

[45] Dranove, Kessler, McClellan, Satterthwaite (2003): 'Is More information better? The effects of "Report Cards" on health care providers'. Journal of Political Economy, vol 111, no.3

[46] Carslile (2007): 'Internet report cards on quality: What exists and the evidence on impact'. West Virginia Medical Journal, vol 103

[47] Chipty, T and White, A (1998) 'Effects of Information Provision in an Vertically Differentiated Market,' NBER Working Paper No W6493

[48] Dranove, Kessler, McClellan, Satterthwaite (2003): 'Is More information better? The effects of "Report Cards" on health care providers'. Journal of Political Economy, vol 111, no.3

[49] Shaw C. External assessment of health care. BMJ 2001;322:851e4

Other benefits

252. Currently reporting adverse events places an additional burden on providers of NHS primary medical services, as well as on the agencies supporting the reporting structures (NPSA, PCTs, GMC, etc.). The National Audit Office has reported that only 4% of GPs report to the NPSA regularly[50]. Under CQC regulation, there will be a statutory requirement on providers to report certain adverse events to CQC. It is assumed that there would be no significant additional burden beyond the burden of CQC regulation already discussed in the previous section. Therefore, there should be an overall increase in incident reporting rates resulting from better accountability structures and thus an improvement in the quality and quantity of error reporting and transparency of the system.

Summary of Benefits

Table A2.12: Summary of benefits

Benefits:	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**
Patient Health	£11.5	£35.6	£60.9	£62.6	£64.3	£66.1	£67.9	£69.7	£71.7	£73.6
Treatment Cost Savings	£1.0	£3.2	£5.5	£5.7	£5.8	£6.0	£6.1	£6.3	£6.5	£6.7
Increase in Quality of Care	UNQUANTIFIED									
Safety Net	UNQUANTIFIED									
Level Playing Field	UNQUANTIFIED									
Better Reporting	UNQUANTIFIED									
TOTAL	£12.6	£38.8	£66.4	£68.2	£70.1	£72.0	£74.0	£76.0	£78.1	£80.3

Summary of Costs and Benefits

253. The above cost and benefits are summarised below in Table A2.13 without opportunity cost adjustments and A2.14 with opportunity cost adjustments. This is then followed by a sensitivity analysis that shows the overall result to be robust.

[50] National Audit Office (2007), Improving Quality and Safety, Progress in Implementing Clinical Governance in Primary Care: Lessons for the New Primary Care Trusts

Table A2.13: NPV calculations, figures in £'000s, 2010/11 price base and general discount rate of 3.5% and a QALY discount rate of 1.5%. No opportunity cost multiplier used.

Without OP costs 2.4 multiplier)

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs and Benefits (£'000s)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Benefits											
QALYs	£11,535	£35,557	£60,891	£62,566	£64,286	£66,054	£67,871	£69,737	£71,655	£73,626	£583,779
Saved NHS Treatment Costs	£434	£1,339	£2,294	£2,357	£2,421	£2,488	£2,556	£2,627	£2,699	£2,773	£21,988
Increase in Quality of Care	UNQUANTIFIED										
Safety Net	UNQUANTIFIED										
Level Playing Field	UNQUANTIFIED										
Avoided Reporting Burden	UNQUANTIFIED										
Avoided Litigation Costs	UNQUANTIFIED										
Costs											
Initial registration costs to providers	£27,000	£480	£480	£480	£480	£480	£480	£480	£480	£480	£31,320
Initial compliance costs to providers	£1,575	£3,150	£3,150	£140	£140	£140	£140	£140	£140	£140	£8,855
Initial registration costs to CQC	£6,000	£0	£0	£0	£0	£0	£0	£0	£0	£0	£6,000
Development costs of registration process	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
Distraction costs	UNQUANTIFIED										
Initial registration cost to commisioners	UNQUANTIFIED										
Annual cost to regulator; provider fees	£7,200	£10,800	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£133,200
Annual cost to regulator; the CQC	£7,200	£3,600	£0	£0	£0	£0	£0	£0	£0	£0	£10,800
Provider cost of review	£2,869	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£5,738	£54,506
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	£200	£200	£200	£200	£200	£200	£200	£200	£200	£200	£2,000
QALY Discount Rate	*0.000*	*0.015*	*0.030*	*0.046*	*0.061*	*0.077*	*0.093*	*0.110*	*0.126*	*0.143*	
General Discount Rate	*0.000*	*0.035*	*0.071*	*0.109*	*0.148*	*0.188*	*0.229*	*0.272*	*0.317*	*0.363*	
Total Benefits (undiscounted)	£11,970	£36,896	£63,185	£64,922	£66,708	£68,542	£70,427	£72,364	£74,354	£76,399	£605,767
Total Benefits (discounted)	£11,970	£36,326	£61,246	£61,958	£62,680	£63,410	£64,150	£64,900	£65,659	£66,427	£558,725
Total Costs (undiscounted)	£52,044	£23,968	£23,968	£20,958	£20,958	£20,958	£20,958	£20,958	£20,958	£20,958	£246,681
Total Costs (discounted)	£52,044	£23,157	£22,374	£18,902	£18,263	£17,646	£17,049	£16,472	£15,915	£15,377	£217,200
Net Present Value (net benefit)	-£40,074	£13,169	£38,872	£43,056	£44,417	£45,765	£47,101	£48,427	£49,743	£51,050	£341,526

Table A2.14: NPV calculations, figures in £'000s, 2010/11 price base and general discount rate of 3.5% and a QALY discount rate of 1.5%. No opportunity cost multiplier used.

***With** OP costs 2.4 multiplier)*	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs and Benefits (£'000s)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**TOTAL**
Benefits											
QALYs	£11,535	£35,557	£60,891	£62,566	£64,286	£66,054	£67,871	£69,737	£71,655	£73,626	£583,779
Saved NHS Treatment Costs	£1,043	£3,214	£5,504	£5,656	£5,811	£5,971	£6,135	£6,304	£6,477	£6,656	£52,772
Increase in Quality of Care	UNQUANTIFIED										
Safety Net	UNQUANTIFIED										
Level Playing Field	UNQUANTIFIED										
Avoided Reporting Burden	UNQUANTIFIED										
Avoided Litigation Costs	UNQUANTIFIED										
Costs											
Initial registration costs to providers	£64,800	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£1,152	£75,168
Initial compliance costs to providers	£3,780	£7,560	£7,560	£336	£336	£336	£336	£336	£336	£336	£21,252
Initial registration costs to CQC	£14,400	£0	£0	£0	£0	£0	£0	£0	£0	£0	£14,400
Development costs	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
Distraction costs	UNQUANTIFIED										
Initial registration cost to commisioners	UNQUANTIFIED										
Annual cost to regulator; provider fees	£7,200	£10,800	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£14,400	£133,200
Annual cost to regulator; the CQC	£17,280	£8,640	£0	£0	£0	£0	£0	£0	£0	£0	£25,920
Provider cost of review	£6,885	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£13,770	£130,815
Provider cost of ongoing compliance	UNQUANTIFIED										
Annual cost to commisioners; support	UNQUANTIFIED										
Tribunal Costs; covered by DH	£480	£480	£480	£480	£480	£480	£480	£480	£480	£480	£4,800
QALY Discount Rate	*0.000*	*0.015*	*0.030*	*0.046*	*0.061*	*0.077*	*0.093*	*0.110*	*0.126*	*0.143*	
General Discount Rate	*0.000*	*0.035*	*0.071*	*0.109*	*0.148*	*0.188*	*0.229*	*0.272*	*0.317*	*0.363*	
Total Benefits (undiscounted)	£12,578	£38,771	£66,396	£68,222	£70,098	£72,025	£74,006	£76,041	£78,132	£80,281	£636,551
Total Benefits (discounted)	£12,578	£38,137	£64,243	£64,934	£65,634	£66,343	£67,062	£67,790	£68,528	£69,276	£584,525
Total Costs (undiscounted)	£114,825	£42,402	£37,362	£30,138	£30,138	£30,138	£30,138	£30,138	£30,138	£30,138	£405,555
Total Costs (discounted)	£114,825	£40,968	£34,878	£27,183	£26,264	£25,375	£24,517	£23,688	£22,887	£22,113	£362,698
Net Present Value (net benefit)	-£102,247	-£2,831	£29,366	£37,751	£39,370	£40,968	£42,545	£44,102	£45,641	£47,163	£221,827

254. The main assumptions underpinning the analysis, as outlined in this annex, are thought to be prudent. Sensitivity testing presented below reaffirms the robustness of the above positive NPV results:

- The benefits of regulation would outweigh the costs even if CQC was able to mitigate only 2% of primary medical care risks, rather than 3% as has been assumed in the above analysis.
- The proposal would be value for money even if adverse events were 37.5% less likely to occur than it has been assumed (50 adverse events per 100,000 consultations rather than 80).
- The proposal remains value for money even if annual compliance and review cost estimates are increased two-fold.
- The benefits of regulation continue to outweigh the costs even if providers are made compliant with CQC regulation at an annual rate of 10%, arriving at full compliance of all providers after the 10th year of regulation.
- As evident in Table A2.13, the results are not sensitive to the use of 2.4 multiplier. Even without this measure of opportunity cost, the proposal remains value for money with a positive net present value.

255. The above suggests that the policy recommendation is relatively insensitive to the main assumptions underpinning the analysis. Each of the main assumptions has an error margin of at least a 30% in which the proposal continues to yield a positive net present value.

Table A2.15 Thresholds for a positive NPV

Assumption Tested	**Value-for-money Threshold**
CQC risk mitigation	1.86%
Likelihood of adverse events	50 / 100,000
Annual provider costs	199% increase

256. It is clear from the above NPV calculation and sensitivity analysis that registration of providers of NHS primary medical services still represents value for money overall and a permanent exemption for these providers from registration would not be a valid alternative option.