EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) REGULATIONS 2010

2010 No. [DRAFT]

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Regulations set out the health and social care activities that are to be "regulated activities" for the purposes of the Health and Social Care Act 2008 ("the Act"). These regulated activities will be subject to regulation by the Care Quality Commission ("the Commission"); a new body set up by the Act, which, amongst its other functions, is responsible for regulating providers of regulated activities.

2.2. The Regulations also contain the registration requirements relating to safety and quality that providers of regulated activities must meet. Failure to do so will be an offence. Other registration requirements (which are subject to a lower maximum fine in the event of prosecution) are set out in the Care Quality Commission (Registration) Regulations 2009 (SI 2009/3112).

2.3 For certain offences, a fixed penalty is payable as an alternative to prosecution. The instrument prescribes these offences and specifies the monetary amount of the penalty in each case.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Annex to this memorandum sets out further information about the way in which these Regulations have been drafted and, in particular, the nature of the character and specification of the obligations in Part 4 and our approach to the creation of offences in the Regulations.

3.2 These Regulations replace a previous set of draft Regulations (the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009) which were laid in draft on 29th October 2009) and were considered by the Joint Committee on Statutory Instruments (JCSI) at their meeting on 16th December 2009 (see Third Report of Session 2009/10). JCSI reported this previous draft of the Regulations for unusual or unexpected use of powers, doubtful vires and requiring elucidation in certain respects.

3.3 The Department has taken careful account of the Committee's concerns and, as a result, has decided to withdraw the previous draft Regulations and lay this amended set of Regulations, which seeks to address all the points raised by the Committee. This will be issued free of charge to all known recipients of the previous draft instrument.

3.4 The first criticism was that, in the Committee's view, the failure of the Secretary of State to give in regulations 9, 10, 11, 14, 15, 16, 17, 23 and 24 a more adequate indication of exactly what conduct will constitute an offence, or at least provide a compulsory mechanism whereby that conduct can be established in advance in individual cases, was an unusual and unexpected use of the power conferred by the 2008 Act.

3.5 The "outcome focus" of the requirements in regulations 9-24 sets out for providers the requirements relating to the essential levels of safety and quality that must be met by a registered person. Those requirements are not expressed in overly prescriptive terms because they are intended to reflect the outcomes that people who use services should be able to expect, and leave to the provider how compliance is to be achieved. However, we have considered the Committee's comments very carefully and have decided, as a result of those comments, to amend regulation 27. The amendment limits the circumstances in which a prosecution can be brought to cases of continuing failure where a registered provider has been issued with a warning notice in respect of the alleged failure and has failed to comply with the requirement within the time specified in the notice. The warning notice will thus specify the conduct, which appears to the Commission to constitute a failure to comply with the relevant requirements and will give the registered person an opportunity to remedy the breach within a specified time before a prosecution can be brought. This compulsory procedure will ensure that a registered person is informed by the Commission of details of the conduct that constitutes a failure to comply with the relevant requirement. In addition, it gives the registered person the opportunity to take action to comply with the requirement and thereby avoid prosecution.

3.6 The Committee reported regulations 11(3), 13(2), 16(1)(b) and 18(b) as requiring elucidation which was provided by the Department in its memorandum. The Committee asked who the "expert bodies" referred to in these regulations were and the Department explained that these references were intended to refer to bodies generally recognised to have expertise on the subject-matter dealt with by the relevant regulation such as the National Institute for Clinical Excellence. Since, for the reasons set out below, we have now removed the regulations in question, this issue no longer arises.

3.7 The Committee reported regulations 11(3), 13(2), 16(1)(b) and 18(b) as of doubtful vires because they gave unidentified persons the power to set matters to which those affected must have regard, or which they must follow, whereas the Act requires this to be done by Regulations subject to parliamentary procedure. Having reflected on this point, we recognise the concerns of the Committee. We have therefore removed regulations 11(3), 13(2), 16(1)(b) and 18(b). We are of the view that the Commission will still be able to take into account relevant guidance in assessing whether registered persons are complying with the Regulations themselves and this will be set out in its Guidance about Compliance.

3.8 The Committee reported regulation 27, so far as it relates to regulations 11(3), 13(2), 16(1)(b) and 18(b) as of doubtful vires given that it backs unidentified, non-statutory guidance with a criminal sanction. The removal of the references to guidance referred to in paragraph 3.7 above addresses the Committee's concern.

4. Legislative Context

4.1 The Act establishes the Care Quality Commission and gives it the function of setting up and maintaining a registration system for providers of health and adult social care who carry out regulated activities (Section 8 of the Act). Those providers are then required to meet the registration requirements (Section 20 of the Act). Failure to meet the requirements will be an offence.

4.2 Earlier Regulations, which came into force on 1st April 2009, (the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009, (SI 2009/660), "the 2009 Regulations") prescribed certain regulated activities for NHS bodies, relating to the prevention, detection, control and treatment of health care associated infections.

4.3 These Regulations supersede (and revoke) those earlier Regulations and put in place an expanded registration system to cover a wider range of regulated activities and impose an increased number of registration requirements. NHS providers of these regulated activities will be

brought into regulation from 1st April 2010, except for any social care activities for which they are presently registered in pursuance of the Care Standards Act 2000 ("CSA").

4.4 Providers who are currently regulated by the Commission as an establishment or agency under the CSA (including NHS providers), and who carry on a regulated activity (or activities), will be brought into the new system, in respect of that regulated activity (or activities), on 1st October 2010 (subject to certain exceptions set out in the Regulations) along with any new providers of regulated activities.

4.5 In addition to these Regulations, the Care Quality Commission (Registration) Regulations 2009 (SI 2009/3112) set out further registration requirements made under section 20 of the Act, where the offence for failure to comply is punishable with a fine of level 4 or lower on the standard scale. The Care Quality Commission (Registration) Regulations also make provisions in respect of systems and processes around registration.

4.6 Subject to parliamentary approval, the draft Health and Social Care Act 2008 (Consequential Amendments No. 2) Order 2010 will make consequential amendments to other primary legislation, which will be required on repeal of certain provisions in the CSA. Transitional provisions to bring NHS providers into the new system on 1st April 2010 have been put in place (SI 2009/3023). It is intended that there will be further statutory instruments, which will contain further consequential amendments and make transitional provisions in relation to providers currently registered under the CSA.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Minister of State for Health Services has made the following statement regarding Human Rights:
In my view, the provisions of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 are compatible with the Convention rights.

7. Policy background

- What is being done and why

7.1 The Act creates a new system of registration for providers of health and adult social care and establishes the Commission as the new single regulator responsible for regulating health care and adult social care and for monitoring the operation of the Mental Health Act 1983. On 1st April 2009, the new Commission began to carry out its functions and replaced the existing regulatory bodies: the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission), the Commission for Social Care Inspection and the Mental Health Act Commission.

7.2 The policy objective behind the reorganisation was to achieve the integration and alignment of health and adult social care regulation across all types of providers, whether public, private or third sector. This will ensure, for example, that the NHS and private and voluntary healthcare are subject to common regulatory procedures and standards. In addition, for many individuals, care outcomes depend on health and social care services working well together. Having a single regulatory framework across these sectors is intended to help achieve this.

7.3 In accordance with the ministerial commitment in our *Response to the consultation on the future regulation of health and adult social care in England*[1], published in October 2007, the new registration system was introduced for NHS providers of prescribed health care services on 1st April 2009. These providers must meet requirements relating to the prevention, detection, control and treatment of health care associated infections as set out in the 2009 Regulations.

7.4 These Regulations will replace the 2009 Regulations. In Part 2 and Schedule 1 they set out the regulated activities (a provider of which will need to register with the Commission). In Parts 3 and 4, they list the registration requirements (the requirements relating to persons carrying on or managing a regulated activity, and what a provider will need to do in relation to the quality and safety of services provided in order to register and stay registered with the Commission) under the full registration system.

7.5 Decisions on which activities were to be regulated activities were based on the level of risk to the service user and whether full system regulation with the Commission would be the most sensible way to address that risk. This approach aims to avoid placing an unnecessary burden on the providers or the regulator by not registering activities for which the registration requirements would be largely irrelevant. The underlying intention was that the scope of the new system was to be broadly similar to that which applied under the CSA, but would bring in the NHS so that there is a fair playing field for providers from all sectors.

7.6 The most significant addition to the scope of registration, in terms of number of providers, will be primary dental care and primary medical care services. These services will come into regulation under the new system in April 2011 and 2012 respectively, once the time-limited exceptions in the Regulations expire. There was strong support from consultation respondents for the inclusion of primary medical and dental services within the registration framework. However, providers of such services will need time to prepare for regulation, and the Commission needs to have the necessary capacity to register and regulate the new providers. It is for these reasons that we have included the time-limited exclusions.

7.7 The registration requirements, set out in Parts 3 and 4 of the Regulations, must be met by all providers carrying on a regulated activity in order to register and remain registered with the Commission. The intention behind these requirements is that service users will have the same level of assurance of the quality and safety of their care and treatment, whether the NHS, local authorities, the independent sector or voluntary sector is providing it. The requirements have been framed to focus on the outcomes a provider is expected to achieve so that they address the concerns of service users and cover the matters on which they seek assurance in relation to their care and treatment. They are intended to provide clarity about the essential levels of safety and quality that must be met by a provider without being overly prescriptive about how compliance with the requirement is to be achieved.

7.8 Part 5 of the Regulations details the Codes of Practice and guidance that registered persons must have regard to for the purposes of compliance with the Regulations. Regulation 27 creates the offence of failing to comply with the registration requirements in Part 4 of the Regulations. It provides that no prosecution may be brought except in cases of continuing breach where the registered person has been issued with a warning notice under section 29 of the Act in respect of the breach, and has failed to secure compliance within the time period specified in the notice. This provides a compulsory mechanism whereby the conduct, which has resulted in an offence being committed, is made clear to the registered person in advance of any prosecution proceedings and the registered person is given an opportunity to secure compliance. The policy behind setting this offence is detailed in the Annex to this Memorandum. Regulation 27 also states that if a service provider or registered manager can demonstrate that he has taken all reasonable steps or exercised all due diligence in relation to ensuring that the provisions in question have been complied with then that is a valid defence to any proceedings for an offence.

[1] http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227

7.9 Part 6 of the Regulations makes provision for the Commission to issue fixed penalty notices (pursuant to sections 86 and 87 of the Act), instead of prosecuting for the offences set out in the instrument. It will enable the Commission to take a more proportionate approach to enforcement and to take action without the delay and costs associated with legal proceedings. The monetary amount of the penalty for each fixed penalty offence is set out in Schedule 4. These have been set in order to be proportionate to the seriousness of the offence. The monetary amount reflects the fact that, in most cases, the notice will have a greater financial impact on registered managers, who will be individuals, than on registered providers who are likely to be organisations. Therefore, the most serious offences of not being registered (section 10 of the Act), failing to comply with conditions in relation to registration (section 33 of the Act), carrying on a regulated activity while registration is cancelled or suspended (section 34 of the Act) and failing to comply with registration requirements (Regulation 27 of the Regulations) will attract penalty notices of £4,000 in cases where the offence is committed by a service provider and £2,000, where the offence is committed, where applicable, by a registered manager.

7.10 The Regulations also allow the Commission to issue penalty notices in lieu of prosecution for offences that are focused on a failure to co-operate, rather than registration functions. These offences are obstructing entry and inspection (section 63 of the Act), failure to provide documents and information (section 64 of the Act) and failure to provide an explanation (section 65 of the Act). The amount of the penalty for these offences will be set at £300 for any person who commits the offence.

8. Consultation outcome

8.1 The Department has previously held a full 12-week consultation and a number of stakeholder events on both the broad principles of the new system and the detailed policy considerations behind these Regulations. There was strong support for the proposals across a wide range of stakeholders.

8.2 It has since consulted publicly on whether the draft Regulations (specifying the regulated activities and the registration requirements) matched the stated policy position, over a 9-week period during spring 2009.

8.3 There were 72 responses to that consultation, from respondents covering both health and social care, public, private and third sectors. The majority of respondents were of the view that the draft Regulations, as then drafted, accurately reflected the policy set out in the consultation document.

8.4 Those responses have informed the drafting of these Regulations and the Department's *Response to the consultation on draft Regulations for the framework for the registration of health and adult social care providers* can be found on its website[2].

9. Guidance

9.1 The Care Quality Commission has carried out a full 12-week consultation on the guidance it will use to assess compliance with the new registration requirements, in accordance with section 23 of the Act. The Commission published its draft Guidance about Compliance in December 2009[3].

[2] http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

[3] http://www.cqc.org.uk/publications.cfm?widCall1=customDocManager.search_do_2&tcl_id=1&search_string=&top_parent=4512

9.2 The Department of Health has consulted on the Code of Practice relating to health care associated infections, in accordance with section 21 of the Act and the Department published the revised Code of Practice on 16th December 2009[4].

9.3 The Commission has also carried out a series of consultation stakeholder events and is committed to keeping stakeholders informed about development of the new registration system.

10. Impact

10.1 The impact on business, charities or voluntary bodies is detailed in the attached Impact Assessment.

10.2 The impact on the public sector is detailed in the attached Impact Assessment.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

12. Monitoring and review

12.1 The Regulations aim to ensure that health and adult social care providers carrying on a regulated activity are all registered with the Commission in relation to such an activity and that they all meet the same requirements relating to safety and quality of care. The Department will keep the registration system under review with a view to keeping it up-to-date and relevant**.**

13. Contact

Lisa Smedley at the Department of Health, tel: 0113 2545715 or email: lisa.smedley@dh.gsi.gov.uk can answer any queries regarding the instrument.

4

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110288

ANNEX:

Policy behind setting the offence of failing to comply with the Part 4 Regulations

1. As previously indicated, the Care Quality Commission will issue guidance about compliance with the registration requirements set out in Part 4 of the Regulations. This will explain in more detail how providers can comply with the new registration requirements, (with the exception of 'Cleanliness and infection control' which will be the subject of guidance issued by the Secretary of State). The guidance will not itself be enforceable, but providers of regulated activities must have regard to it as set out in regulation 26. The Commission must also take it into account when making decisions about registration (see section 25 of the Act).

3. The relationship between the regulations and guidance flows largely from the statutory framework under which they are made. Section 23 of the Health and Social Care Act 2008 specifically allows the Care Quality Commission to issue guidance about compliance with the requirements of regulations under section 20 (other than in relation to health care associated infections, where the Secretary of State issues guidance under section 21). The legislation therefore sets out a system where the Regulations focus on outcomes to be achieved or steps that must be taken. The Commission's guidance will explain what tests the Commission will use to assess that the relevant outcomes have been achieved. This reflects the approach to the drafting of criminal offences recommended by the Macrory Review published in November 2006.

4. The approach taken in relation to these Regulations is very similar to the present system under the Care Standards Act 2000 that is being replaced. Under that Act, the Secretary of State publishes National Minimum Standards (NMS) (see section 23 of the Care Standards Act), which have the same function as the compliance guidance. The NMS had to be consulted upon and the Care Quality Commission is required to consult on its compliance guidance in much the same way.

5. Furthermore, the nature of these draft Regulations is very similar to those currently made under the Care Standards Act 2000.. For example:

- The Care Homes Regulations 2001 (2001/3965). In particular, see Regulations 12 (health and welfare of service users), 13 (further requirements as to health and welfare) and 16 (facilities and services);

- The Domiciliary Care Agencies Regulations 2002 (2002/3214). In particular, see Regulations 13 (conduct of agency) and 14 (arrangements for the provision of personal care);

- The Private and Voluntary Health Care (England) Regulations 2001 (2001/3968). In particular, see Regulations 9 (policies and procedures), 15 (quality of treatment and other service provision) and 16 (care and welfare of patients).

6. Regulations under the Care Standards Act have proved to be enforceable, with 31 successful prosecutions being brought by the regulators and 48 cautions issued in lieu of prosecution since 2004. Provision has now been included in these Regulations (which was not included in the original draft Regulations) to limit prosecution to continuing breaches where the Commission has given the registered person a warning notice under section 29 of the Act in respect of a breach of regulation before bringing a prosecution. The warning notice will set out the conduct that appears to the Commission to have resulted in the breach of a requirement and, will give the registered person time to rectify the breach. The Commission will only be able to prosecute, if at the end of the time period set in the notice for securing compliance, compliance has not been achieved. In the most serious cases of non-compliance (where for instance there is a clear and immediate risk of harm to the people using the services), the timescale for compliance in the warning notice is likely to be quite short, reflecting the seriousness of the breach or, alternatively the Commission may seek to urgently suspend registration or take other enforcement action rather than issue a warning notice.

7. In addition, the offence for failure to comply with the registration requirements includes provision for a "due diligence" defence. A person who can prove that they took all reasonable steps or exercised all due diligence in order to ensure that the provision in question was properly complied with will have a defence to any proceedings for a breach of the Regulations.

8. Prosecution is only one of a range of sanctions available to the Commission in relation to breach of any of the registration requirements in these Regulations. These sanctions are set out in the 2008 Act and include the issue of warning notices (section 29), penalty notices (administrative fines) (section 86), imposition of conditions (section 12(5)) and suspension or cancellation of registration (sections 17 and 18). The Commission will only use the sanction of prosecution in more serious and clear-cut cases. The Commission's guidance (to be issued under section 88 of the Act) will set out its intended use of sanctions (which the Commission is obliged to consult on).

9. In developing the new system, the Department of Health has considered the system under the Care Standards Act. It has also consulted extensively: between November 2006 and February 2007, it carried out a consultation, (*The Future Regulation of Health and Adult Social Care in England*[5]) on the implementation of the new regulatory framework. This consultation informed the drafting of the Health and Social Care Bill (now the Act) which set out the overall framework for the registration system. Since then, the Department has consulted on the registration framework[6] and then in responding to this also consulted on the content of the draft Regulations themselves[7]. The Department has taken into account the responses to these consultations in the drafting of these Regulations and has also worked closely with representative stakeholder groups on specific issues as well as the Care Quality Commission.

[5] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286
[6] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625
[7] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097141

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of Registration Regulations made under the Health and Social Care Act, 2008**	
Stage: Final	**Version:** 1	**Date:** 27 January 2010
Related Publications: Consultation document and regulations		

Available to view or download at:

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations

Contact for enquiries: Lisa Walder **Telephone:** 0113 254 5514

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

There is concern that the scope of registration for the Care Quality Commission currently does not match the extent of mitigatable risk in health and adult social care provision.

What are the policy objectives and the intended effects?

To bring coherence and proportionality to different regulatory arrangements within health and adult social care services and to ensure that the same requirements apply to providers whether in the public sector or independent sector (IS), thus facilitating entry and contestability and supporting choice policy. Also, to improve the cost effectiveness of regulation to support sustained reductions in the costs of regulation.

What policy options have been considered? Please justify any preferred option.

Option 1: Do nothing option

Option 2 (preferred): Define the scope of registration in terms of regulated activities based on the relative risk of the service and whether this risk can be mitigated by system regulation, so that only providers delivering these activities are required to register with the CQC;

Option 3: In addition to option 2, specifically include those providers of services currently registered under the CSA but out of the defined scope of the new registration system.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

DH intends to review the likelihood of risk in the activities listed, and will monitor how proportionate the burden of regulation is to the mitigation of those risks within the next three years.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

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

Signed by the responsible Minister:

Mike O'Brien .....Date: ***28th January 2010***

Summary: Analysis & Evidence

Policy Option: 2 (Preferred)	Description: Define the scope of registration in terms of regulated activities based on the relative risk of the service.

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ +2.0m to +3.3m	3
Average Annual Cost (excluding one-off)	
£ -21.9m to -2.0m	

Description and scale of **key monetised costs** by 'main affected groups' Exchequer costs (over ten years)

Annual costs to CQC: -£19.8m to -£1.3m

Annual cost to public providers: -£2.0m to -£0.7m

One off cost of registration to CQC: +£1.8m to +£2.5m

One off cost to public providers: +£0.2m to +£0.8m

Total Cost (PV) **£ -379m to -13.6m**

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

Compliance costs of providers will be influenced by the nature of compliance methodology and process the CQC introduces.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ -1.6m to +1.0m	2
Average Annual Benefit (excluding one-off)	
£ +75.6m to +84.3m	

Description and scale of **key monetised benefits** by 'main affected groups' Non-exchequer benefits (over ten years)

Annual benefit to private providers: +£8.2m to +£17.3m

Annual benefit to patients: +£67.0m

One off (dis)benefit to private providers: -£1.6m to +£1.0m

Total Benefit (PV) **£ +568m to +640m**

Other **key non-monetised benefits** by 'main affected groups' Reduced risk for users of newly registered services like prrison health services and immigration health services. The CQC will be more flexible as it can set the compliance criteria itself. Providers of Health and Social Care have to register only once not twice.

Key Assumptions/Sensitivities/Risks The compliance criteria will be devised by the CQC and these criteria will determine the scale of the costs and benefits associated with compliance.

Price Base Year 2008	Time Period Years 10	**Net Benefit Range** (NPV) **£ +581m to +1019m**	**NET BENEFIT** (NPV Best estimate) **£ +800.2m**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			2010/11	
Which organisation(s) will enforce the policy?			CQC	
What is the total annual cost of enforcement for these organisations?			£ NA	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ NA	
What is the value of changes in greenhouse gas emissions?			£ NA	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0.2m-0.9m Decrease of £ 6.5m-14.2m **Net Impact** **£** -5.4m to -14.0m

Key: **Annual costs and benefits:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 3	Description: Same as option 2. Additionally, include providers currently registered with CSA that will be out of

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ +2.3m to +3.2m	3
Average Annual Cost (excluding one-off)	
£ +1.0m to +9.2m	

Description and scale of **key monetised costs** by 'main affected groups' Exchequer costs (over ten years)

Annual cost to CQC: +£1.0m to +£9.2m

Annual cost to public providers: £0m to +£0.002m

One off cost of registration to CQC: +£2.3 to +£3.2m

One off cost of registration to public providers: +£0.4m to +£0.8m

Total Cost (PV) **£ +21.8m to +186m**

Other **key non-monetised costs** by 'main affected groups' Compliance costs of providers will be influenced by the nature of compliance methodology and process the CQC introduces.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ -5.7m to -3.8m	3
Average Annual Benefit (excluding one-off)	
£ +65.9m to +73.1m	

Description and scale of **key monetised benefits** by 'main affected groups' Non-exchequer benefits (over ten years)

Annual benefits to private providers: -£1.4m to +£6.1m

Annual benefit to patients: +£67m

One off (dis)benefit to private providers: -£5.3m to -£3.3m

Total Benefit (PV) **£ +488m to +547m**

Other **key non-monetised benefits** by 'main affected groups' Reduced risk for users of newly registered services like prison health services and immigration health services. The CQC will be more flexible as it can set the compliance criteria itself. Providers of Health and Social Care have to register only once not twice.

Key Assumptions/Sensitivities/Risks The compliance criteria will be devised by the CQC and these criteria will determine the scale of the costs and benefits associated with compliance.

Price Base Year 2008	Time Period Years 10	**Net Benefit Range** (NPV) **£ +302m to +525m**	**NET BENEFIT** (NPV Best estimate) **£ +414m**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			2010/11	
Which organisation(s) will enforce the policy?			CQC	
What is the total annual cost of enforcement for these organisations?			£ NA	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ NA	
What is the value of changes in greenhouse gas emissions?			£ NA	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 5.2m-8.6m Decrease of £ 4.2m-7.2m **Net Impact** **£** -2.1m to +4.5m

Kev: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Regulations made under the Health and Social Care Act 2008: Evidence Base for the Impact Assessment

Introduction

1. This impact assessment (IA) considers the impact of proposed regulations under the Health and Social Care Act 2008 (the 2008 Act). These regulations:

    - specify which activities are within the scope of registration by the Care Quality Commission (CQC) under the 2008 Act; and
    - specify the registration requirements for those who are required to register with the Care Quality Commission.

2. The Health and Social Care Act 2008 brings together the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission into a single new regulator for heath and adult social care, the Care Quality Commission (CQC). The Act also creates a framework for the registration of providers of health and social care, enabling much of the detail concerning the specification of the registration system to be set in secondary legislation, and how this is implemented in guidance about compliance and criteria to be set by the Care Quality Commission.

3. The impact assessment that accompanied the 2008 Act gave broad estimates of the costs and benefits arising from the introduction of the new registration system. The Department of Health has subsequently undergone a process of developing the underpinning regulations, which included running formal consultations (together with accompanying IAs), further evidence gathering, and stakeholder engagement and involvement. We have simultaneously developed our policy around the future regulation of primary medical and dental care provision. We are now able to provide greater refinement to the estimates set out in the Act IA. Therefore, the costs and benefits in this impact assessment (and the associated IA covering the regulation of primary care) supersede those in the 2008 Act impact assessment.

4. The impact assessment that accompanied the 2009/10 Regulations enabling the registration of NHS providers against HCAI requirements only set out the relevant costs and benefits for 2009/10, as the Care Quality Commission was undertaking a one-year process for this registration.

5. This impact assessment considers the costs and benefits of the regulations defining the full registration system, which commences from April 2010 for NHS providers of healthcare, and all other providers of health and adult social care from October 2010. It focuses on the changes to costs and benefits for the regulator, providers and patients/people using services, rather than the total costs.

6. The impact assessment covering the regulation of primary care is closely linked to this IA, as the regulations setting out the scope of registration also set a date from which primary care will be brought into registration. Once within scope, primary care providers will be expected to comply with the same registration regulations as other providers. However, because of the complexity around the inclusion of primary care in registration, and the timing for the inclusion, the costs and benefits of this area of the policy is dealt with in a separate, but linked, IA.

7. Cost estimates have been based on identifying similar activities in the current system of regulation and projecting how these might change in nature or magnitude in the new system. This assessment presents the incremental costs and benefits associated with implementing the policy. There is only an indirect relationship with budgets for the bodies concerned

because budgeting takes into account factors such as the timing of expenditure and the structure of the body.

Rationale for Intervention

8. The safety and quality of health and adult social care provision has been regulated for many years. The purpose of system regulation is to protect patients and people using services by providing assurance that essential levels of safety and quality of care are being met, and to increase the information on provider quality available publicly to help them make choices and to encourage providers to improve the quality of their care.

9. The existing regulatory framework for health and adult social care has become fragmented over time. In healthcare, there are different regulatory procedures and standards for NHS and independent sector (IS) providers, with a variety of sanctions and different enforcement procedures. Adult social care does have a unified regulatory framework across public and independent sector providers, but it lacks the flexibility to address changes and developments as health and social care services become more innovative and integrated.

10. The current legislation is not flexible enough to cope with the increasing pace of change in the delivery of services. This has led to inconsistencies, giving rise to a situation in which the same type of care may be registered in some settings but not in others. The lack of flexibility is also problematic because some new forms of care do not fit neatly into the existing legislative models, which specify the type of provider, and establishment or agency rather than the type of service or care offered. Additionally, the previous commissions did not have the same range of sanctions and enforcement powers to address problems in the NHS that they could use with independent health and adult social care providers.

11. The introduction of a new registration system also presents the opportunity to review whether the scope of registration is appropriate, and system regulation is targeted where it can most efficiently reduce risks to people receiving care.

Policy objectives

12. In March 2008, the Department of Health consulted on the framework for the new registration system[8], including the overall approach to defining scope and registration requirements and the areas each would cover. In March 2009, the Department published its formal response, and launched a further consultation[9] on the detailed content of these and other regulations (covering the registration process and enforcement) that will underpin the 2008 Act registration system, operated by the Care Quality Commission.

13. In these consultations, we set out our intention to create a system of registration that the Care Quality Commission will operate, which:

- is consistent across providers of health and adult social care, from both independent and public sectors (including NHS trusts and foundation trusts);
- requires providers to manage key risks to the safety, quality and governance of the care they provide;
- seeks to address the concerns of people using health and adult social care services, and cover the topics on which they want assurance;
- provides clarity about ***what*** is required to deliver essential levels of safety and quality and so achieve compliance, without being prescriptive about ***how*** compliance is achieved; and,
- allows the Care Quality Commission to judge compliance and if necessary, to take a range of enforcement actions against non-compliance.

[8] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625
[9] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991

14. To support these objectives, we proposed to define the scope of registration in a way that ensures that:

    - all providers are treated fairly regardless of whether they are public or independent sector, or whether services are delivered in secondary, community, primary, residential or domiciliary care settings;
    - the Care Quality Commission can operate a proportionate registration system, avoiding unnecessary burdens on providers and the Commission itself, and avoid unnecessary barriers to entry;
    - decisions on which services are to require registration are based on the risk of harm to people using them, after taking into account any other protections offered by other regulatory or management and governance systems, and how much system regulation would effectively reduce those risks;
    - there is flexibility to accommodate changes and innovations in models of care provision;
    - the definitions encompass the increasing integration between health and adult social care services;
    - it is clear to providers, the public and the new Commission when registration is required;
    - decisions on which activities require registration take into account inequalities, so that we do not inadvertently remove protective regulation from activities that will have an adverse effect on particular populations.

15. Respondents to the consultations were broadly supportive of the overall approach to the new framework. In particular, there was general support for the approach of having a single regulatory framework for health and adult social care, and including the NHS within the registration system.

16. The objectives were then translated into proposed draft regulations that will bring about two major changes to the registration system that is currently operated under the Care Standards Act (CSA) 2000, which covers adult social care providers and independent sector providers of health care.

17. The first change is to the requirements detailing what is expected of a provider, and to the way the compliance framework is set out. The existing registration system is based on prescriptive regulations made under the Care Standards Act, and detailed National Minimum Standards (NMS) set by the Department of Health. Although these NMS are not binding on the regulator or providers, they have to be taken into account when the regulator makes a decision about whether providers are meeting the regulations, significantly restricting their discretion. The previous regulators also developed methodology and guidance to support its decision-making process.

18. Under the framework for the new registration system set out in the 2008 Act, registration decisions will be judged against a set of high-level, outcome-focussed registration requirements for essential quality and safety, specified in secondary legislation. These requirements have been derived from the areas covered by existing regulations and standards, and focus on addressing key risks to patients and people using services. The areas which will be covered by the registration requirements for essential quality and safety are:

    - Care and welfare of service users;
    - Assessing and monitoring the quality of service provision;
    - Safeguarding service users from abuse;
    - Cleanliness and infection control;
    - Management of medicines;
    - Meeting nutritional needs;
    - Safety and suitability of premises;
    - Safety, availability and suitability of equipment;

- Respecting and involving service users;
- Consent to care and treatment;
- Complaints;
- Records;
- Requirements relating to workers;
- Staffing;
- Supporting workers;
- Cooperating with other providers.

19. As these requirements cover the same general areas as those for the current system, we do not consider the effect of the registration requirements in this impact assessment, over and above that of introducing the new system.

20. The secondary legislation also sets out requirements that support the operation of the registration system. As above, we do not expect these requirements to represent a significant new burden on service providers as they largely carry forward existing requirements for currently registered providers. In the case of NHS providers, some provisions will not apply, and others will make use of existing reporting mechanisms to avoid additional burden.

21. In general, respondents did not think there were any major omissions in the set of requirements we proposed, and there were no requirements included that were felt to be inappropriate. As these requirements cover the same general areas as those for the current system, we do not consider the effect of the registration requirements in this impact assessment, over and above that of introducing the new system. The Care Quality Commission will also be providing more detail on the specifics of each (high-level) requirement in its Guidance of Compliance. It would therefore be difficult to assess the impact of the registration requirements themselves, before the Guidance about Compliance has been agreed.

22. The Care Quality Commission has a statutory obligation to develop and consult on its Guidance about Compliance, and must take this guidance into account when it makes judgements about providers' compliance with the registration requirements. It is also required to take a proportionate approach. Removing some of the prescriptiveness of the existing system should reduce the burden to providers, and the Commission, of demonstrating and judging compliance.

23. The second change is to the scope of registration, both in terms of coverage and how scope is defined. To address issues such as inconsistencies in whether services are registered or not, and to provide flexibility for future innovations and change in service delivery, the regulations will define the scope of the new registration system in terms of what services ("regulated activities") providers deliver, rather than whether they are an establishment or an agency (eg a hospital, care home or nurses agency). This will ensure that those services that pose the most risk to those receiving the care are better reflected in the scope.

24. There was also broad support from respondents to the consultations for the list of regulated activities we proposed to define the scope of registration, which were developed through detailed discussion with stakeholders, and the application of a model to assess the degree of risk associated with each activity. These are:

    - Personal care;
    - Accommodation for persons who require nursing or personal care;
    - Accommodation for persons who require treatment for substance misuse;
    - Accommodation and nursing or personal care in the further education sector;
    - Treatment of disease, disorder or injury;
    - Assessment or medical treatment for persons detained under the 1983 Act;
    - Surgical procedures;
    - Diagnostic and screening procedures;

- Management of supply of blood and blood derived products;
- Transport services, triage and medical advice provided remotely;
- Maternity and midwifery services;
- Termination of pregnancies;
- Services in slimming clinics;
- Nursing care;
- Family planning services.

25. More detail on how this list was developed can be found in Annex A.

26. Some respondents made suggestions about how the list could be refined, or proposed other services that are not currently included in the scope of registration, to be included in future. These included:

- non-residential community substance misuse services;
- counselling where it is not provided by healthcare professionals;
- day care;
- services provided independently by allied health professions;
- transport services not using vehicles designed to carry patients;
- low-level diagnostics;
- telecare;
- doctors providing a mixture of NHS and privately-funded medical services;
- defence medical services;
- chiropractors;
- school nurses;
- psychologists;
- genetic testing.

27. We do not currently have sufficient evidence that this risk is sufficiently great and can be appropriately addressed by system regulation to bring these services into the scope of registration at this time. However, it is our intention to keep these services under review. Therefore, the effects of these services are not considered in this Impact Assessment.

Options

28. The majority of providers delivering the above regulated activities are already subject to some form of regulation by the Care Quality Commission; the Annual Healthcheck for NHS healthcare providers, or registration under the CSA for IS healthcare and adult social care providers. However, we now wish to regulate according to the activity being performed rather than the provider setting, as we believe risk is better determined in this way. Because the focus of registration is now based on the service provided rather than the type of establishment or agency, some providers of specific services not previously within the scope of registration now come within scope for the first time. Equally, there will be some IS healthcare and adult social care providers that currently provide CSA listed services that do not come under the scope of registration under the 2008 Act.

29. As many providers deliver a range of the above services, it is not possible to consider the impact of each regulated activity as a discrete component . Therefore, we consider the different types of providers affected by the specified list of activities, and establish the preferred option for whether registration with the Commission would be appropriate, or whether there is an alternative that would more effectively mitigate the risk associated with the activity.

30. For ease of description, we have considered providers grouped by their delivery of the following services:

a) Independent sector provided healthcare services;

b) Adult social care services;

c) NHS-provided healthcare services;

d) Private prison health services;

e) Immigration removal centre health services;

f) Transport services using vehicles designed to carry patients;

g) Accommodation with treatment for drug or alcohol misuse;

h) Non-surgical use of class 3B and 4 lasers and intense pulsed light equipment;

i) Nurses agencies solely providing staff to other registered providers;

j) Domiciliary care agencies solely providing staff to other registered providers.

Derivation of options

31. For the services delivered by these providers, we considered whether system regulation is the most appropriate way of mitigating the risk of providers delivering unsafe, low quality care, or whether it could be reasonably addressed by other forms of regulation such as professional regulation, self-regulatory systems or accreditation.

32. Many of the risks inherent in delivering health and adult social care are related to the system of which it is a part. For example, the risk of:

- unsafe, inappropriate care or treatment (including that arising from the improper management of information);
- abuse to vulnerable service users;
- abuse of the dignity, privacy and independence of those receiving care;
- unsafe use and management of medicines and medical devices;
- unsafe or unsuitable premises;
- inadequate nutrition and dehydration;
- unfit staff (including risks arising from employing staff with a lack of qualifications or skills, suitable character background, and sufficient levels of support and training).

33. Other regulatory mechanisms would only support aspects of regulation of the overall care delivery. For example, professional regulation would provide assurance that the staff had the correct qualifications for the task, but would not provide the governance to ensure they were appropriately engaged and supported in the task they were delivering in terms of the overall system, eg supervision, information flows and physical environment. In addition, although there are existing criminal sanctions that enable action against individuals committing specific offences, and provision for the professional regulator to take enforcement action against the professional (eg strike them off the professional register), this would not enable any retribution against the provider itself for any system failure (ie that they did not provide protection to the person receiving the care as part of the provider's management of the care delivery). Further, there would be potential for inconsistencies in the way regulation was implemented across the range of providers, as there is no single professional regulatory body with that jurisdiction.

34. A self-regulatory system would provide some assurances around the way that the system operates, particularly in terms of supporting the provider in developing its governance and improving its compliance with any guidance or industry-set standards (for example, ensuring that the equipment used is safe, and that staff are properly trained and supported in its use). However, this would not provide independent oversight of the provider, which is crucial to ensuring the delivery of safe, quality health or adult social care, particularly as those using the services are often in a vulnerable situation. Nor does this regulatory system have the power to take enforcement action or impose sanctions to address serious failures, over and above excluding the provider from the system or those available under existing legislative mechanisms (which can only be directed towards individuals, not organisations). Again,

there would be potential for inconsistencies in the way regulation was implemented for the same service delivered by a range of providers, as it is likely that there would be no overall self-regulatory body.

35. As we believe that the alternatives do not provide the necessary assurances for these types of providers of healthcare services, we conclude that system regulation is the most appropriate way to mitigate the risks posed in the delivery of health and adult social care. As the Care Quality Commission is the existing regulator of health and adult social care, we believe it would be inefficient to create an alternative, independent regulatory body for these providers.

36. The options considered in this Impact Assessment are:

- **Option 1**: Continue the Care Quality Commission's registration of IS healthcare providers and adult social care providers under the existing regulations and National Minimum Standards, and the Annual Health Check for NHS healthcare provision. For providers not currently regulated by the Care Quality Commission, continue to not regulate them through this route;
- **Option 2 (preferred)**: Define the scope of registration in terms of what is provided (regulated activities) based on the relative risk of the service and whether this risk can be mitigated by system regulation, so that only providers delivering these activities are required to register with the Care Quality Commission;
- **Option 3**: Define the scope of registration in terms of what is provided (regulated activities) based on the relative risk of the service and whether this risk can be mitigated by system regulation, so that providers delivering these activities are required to register with the Care Quality Commission. In addition, specifically include those providers of services currently registered under the CSA but out of the defined scope of the new registration system.

Mechanism of Impact

37. The registration requirements have been developed after extensive consultation and are intended to reduce the risks to patients undergoing the activities identified above. The methodology to be used by the Commission is yet to be finalised. However, the Commission is required by the Health and Social Care Act to act in a proportionate way that places the minimum burden possible on the system. It looks likely that the process will include:
    - A requirement for providers to carry out a self-assessment and declare that they are compliant with the registration requirements. This will ensure providers focus on meeting the essential requirements.
    - The triangulation of all the available information (including the self-assessment, contract monitoring information, patient surveys, QOF data, complaints data, prescribing data, and other intelligence from PCTs) to develop a risk profile.
    - Inspections of providers identified to need follow-up by the risk profiles
    - Random inspections of providers to check the quality of the self-declarations and the risk profiles

38. The Commission will have a range of enforcement powers available to it if providers do not comply with the registration requirements. For example, NHS trusts are not currently subject to registration, but are assessed by the Care Quality Commission through the Annual Health Check. Under the current system, poorly performing trusts do not currently lose their right to operate. Under the new registration system, trusts can be deregistered, fined or have conditions placed on their registration if they fail to meet the registration requirements. The threat of sanctions should therefore lead to improved performance by trusts, and other health and adult social care providers within the scope of registration.

Costs and benefits of the options

39. For the purposes of this IA, we distinguish between exchequer costs and non-exchequer costs. Exchequer costs (and benefits expressed as negative costs) include costs to the Care Quality Commission, the NHS and Local Authorities (LAs), as well as costs to businesses that will be passed on to their pubic sector commissioners, such as private prisons and immigration removal centres. Non-exchequer costs (expressed as negative benefits) include costs to independent sector providers. All costs (negative or positive) in the cost section therefore refer to the costs that would ultimately fall to the public sector. All benefits (negative or positive) in the benefits section therefore refer to all benefits to private providers, patients or the wider public.

40. For the Care Quality Commission, and for most types of provider, we will calculate the annual costs of the registration process by aggregating the costs of the three main parts of the compliance process, which are;

    - the cost of first time registration (as every year a certain number of providers will apply for registration for the first time);
    - the cost of the annual self assessments to existing providers; and
    - the cost of inspections (the proportion of providers inspected by Care Quality Commission varies according to provider type).

41. There are also transitional costs generated by the transfer to the new system. These comprise of;

    - the costs of transferring providers from their existing regulatory framework to the new system; this includes those existing providers requiring registration for the first time;
    - the costs of inspections (Care Quality Commission would expect to inspect a proportion of providers coming into the regulatory framework).

42. This section appraises the costs and benefits of each of the options for each type of provider in turn. Because of the limitations of the available data, it has not been possible to quantify every option, however the rationale is set out for each type of provider. An estimate of the costs of the preferred options are then conducted, to establish their potential impact. There are also other costs which cannot be divided between the different providers being registered. These are therefore considered in a later section.

43. It is our intention that the new registration system (which includes the changes described above) will come into effect from April 2010 for NHS providers, and from October 2010 for other providers of health and adult social care (mostly providers with existing registrations under the CSA 2000). Private ambulance services and primary dental care services will be brought in from April 2011, and primary medical care from April 2012. This incremental approach is to enable the Care Quality Commission to work with providers to build capability, so that the registration and ongoing compliance processes are implemented efficiently and effectively. The approach to primary care regulation and the associated costs and benefits are discussed further in the accompanying primary care impact assessment.

a) Independent sector provided healthcare services

44. Independent sector (IS) hospitals and healthcare providers of listed services require registration with the Care Quality Commission under the Care Standards Act.

45. Independent sector-provided healthcare services are delivered by a range of different types of IS providers, including private acute and mental health hospitals, hospices and private doctors. The majority of these providers will require registration in future, as they deliver across the range of regulated activities within the scope of the new registration system. As stated previously, the move from establishments and agencies to defining scope in terms of regulated activities, will bring some (predominantly single-service) providers newly within

scope, and not require other existing providers to register in future. The main example considered in this IA is private ambulance service providers. The costs and benefits for these specific groups of providers are considered in separate sections below.

46. The Care Quality Commission estimates that it currently registers approximately 1,400 providers under the CSA that it expects will require registration under the new scope definitions.

Option 1 – Do nothing

47. It would be possible to continue to register independent sector provided healthcare services under the current CSA requirements. The Care Quality Commission would still have the power to inspect independent sector healthcare providers and retain the same, limited enforcement powers to deal with poor practice. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

48. The Care Quality Commission already registers IS healthcare providers, giving people receiving care, the public and Parliament, an assurance of providers' ongoing compliance with their terms of registration.

49. For these providers, we considered the same issues and alternative regulatory options as set out above in the section on derivation of options, and came to the same conclusion.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£0.6 million	none
Transitional costs to CQC	£0.2 million	£0.2 million
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£0.6 million	£1.3 million
Transitional savings to providers	-£1.8 million	-£1.6 million

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner.

Costs

50. We estimate that the annual cost to the Care Quality Commission of registering these providers could be reduced by between 0% and 10% of current spend, because we expect the new system to be less burdensome than that currently in place.. Based on figures supplied by the Care Quality Commission we estimate that they currently spend £10 million per annum on the registration of IS healthcare providers, this would equate to a saving of up to £0.6 million per year. More detail on how these figures are calculated can be found in Annex B.

51. The Care Quality Commission will need to develop a process to transition these providers into the new registration system. Although we expect this process to be less costly than a first time registration, there will be some cost implications.

52. We estimate the combined costs of first time registration to the Care Quality Commission to be £200,000. More detail on how these costs have been calculated can be found in Annex B.

Benefits

53. For these providers, we estimate annual cost savings of between £0.6 million and £1.3 million, as a result of the change in the way that providers will be registered. Activity rather than establishment-based registrations enables a provider to register at company level for each activity rather than at individual sites, giving economies of scale for multi-site companies. Additional savings can be made if the registration requirements (and the way the Commission judges compliance with them) are less burdensome to prove compliance with. More detail of these calculations can be found in Annex C.

54. It is difficult to estimate what the transitional costs may be for providers moving into the new system, as this depends on the approach to transition adopted by the Care Quality Commission. Given the Care Quality Commission's commitment to be proportionate with its approach, we therefore assume that the cost to IS providers of transition will be similar to those they would face for an annual assessment. This leads to costs of between £1.6 million and £1.8 million in the transition year. More detail of the reasoning behind these assumptions can be found in Annex C.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

55. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

b) Adult social care services

56. Adult social care services are delivered by both publicly and privately owned providers. They mainly comprise of care homes, shared lives schemes, domiciliary care agencies and nurses' agencies. All these types of providers require registration with the Care Quality Commission under the CSA. The majority of these providers will require registration in future, as they deliver a range of regulated activities within the scope of the new registration system. As stated previously, the move from establishments and agencies to defining scope in terms of regulated activities, will bring some (predominantly single-service) providers newly within scope, and not require other existing providers to register in future. The adult social care providers affected in this way are domiciliary care agencies and nurses agencies. Therefore, the costs and benefits for these specific providers are considered in separate sections below.

57. The Care Quality Commission estimates that it currently registers approximately 18,500 providers under the CSA (excluding domiciliary care and nurses agencies) that it expects will require registration under the new scope definitions.

Option 1 – Do nothing

58. It would be possible to continue to register adult social care services under the current CSA requirements. The Care Quality Commission would still have the power to inspect independent sector providers and would still have some enforcement powers to deal with poor practice. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Move to the new system of registration with Care Quality Commission for all providers carrying out the specified activities

59. The Care Quality Commission already registers adult social care providers, giving people receiving care, the public and Parliament, an assurance of providers' ongoing compliance with their terms of registration.

60. For these providers, we considered the same issues and alternative regulatory options as set out above in the section on derivation of options, and came to the same conclusion.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£2.2 million	none
Transitional costs to CQC	none	none
Annual costs to LA providers	-£0.9 million	-£0.4 million
Transitional costs to LA providers	none	none
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£3.7 million	£6.0 million
Transitional savings to providers	none	none

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner.

Costs

61. We estimate the annual saving to be between 0% and 5% of current spend, as we believe that there is less scope for savings related to the registration of adult social care providers, because of the differences between the way the Healthcare Commission and CSCI operated the current registration systems, and the way CSCI had already begun to change the way they approached registration.

62. We therefore estimate that the Care Quality Commission will be able to make only small savings from the money currently spent on the registration and inspection of adult social care providers (around £60 million[10]). Therefore, a saving of 5% suggests a possible annual saving of up to £2.2 million. This saving relates to the registration of the 18,500 currently registered providers that we expect to continue to require registration. More detail on how these figures were derived can be found in Annex B.

63. LA-run providers would also be able to make annual savings due to the way compliance is judged and the move from location to activity-based registration. This could save such providers between £0.4 million and £0.9 million. More detail of these calculations can be found in Annex C.

64. There could also be some transitional costs to moving providers over to the new system of registration. However, in the transition year the Commission's current intention is to replace the annual self-assessment process with a simple process that can also be used for registration. Although there may be additional costs because providers will be unfamiliar with the new system, there should also be fewer information requirements than in the normal

[10] £60 million is the budget for all social care. As we are here excluding domiciliary care agencies and nurses agencies, we only consider approximately 75% of this budget.

annual self-assessment process. We assume these effects cancel one another out so that the transitional costs for adult social care providers and for the Care Quality Commission are neutral[11].

Benefits

65. The changes in the way compliance is judged and the move from location to activity-based registration could potentially save independent providers between £3.7 million and £6.0 million per year. More detail of these calculations can be found in Annex C.

66. There may also be some transitional costs but, using the same reasoning as for LA-run adult social care providers set out in the costs section above, we assume that these will be cost neutral.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

67. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

c) NHS provided healthcare services

68. NHS Trusts are currently registered with the Care Quality Commission for infection control procedures and have to demonstrate compliance against HCAI standards. Trusts are also subject to an Annual Health Check by the Care Quality Commission, which measures Trusts' performance against core Standards for Better Health, existing commitments and Vital Signs, and use of resources.

Option 1 – Do nothing

It would be possible to continue to register NHS providers solely against a single requirement relating to HCAIs, to carry out periodic reviews of the performance of NHS bodies and to carry out investigations into the provision of NHS care. The Care Quality Commission would still have the power to take a range of enforcement action in regard to breaches of the HCAI registration requirement and to give advice to the Secretary of State if a provider were found to have serious failings. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

69. The Care Quality Commission already registers NHS providers under the 2008 Act against a single requirement to manage healthcare associated infections (HCAI). Under the National Health Service (NHS) Act 2006, it also produces the Annual Health Check, a performance assessment of NHS organisations, based on the core Standards for Better Health, existing commitments and Vital Signs, and use of resources.

70. For the services delivered by NHS providers, we considered the same issues and alternative regulatory options as set out above in the section on derivation of options, and came to the same conclusion.

71. The Department of Health and Monitor (in respect of NHS foundation trusts) already have some enforcement powers to address significant issues in NHS trusts. However, neither is appropriate in terms of ability to identify and address dysfunctional system issues and take proportional enforcement action across the full range of provider types without significant legislative and functional changes. This potentially introduces an inconsistency that the new system of registration was set up to address.

[11] Other transition costs to CQC of the registration process such as developing the systems, and developing the guidance about compliance, are dealt with separately.

72. As we believe that the alternatives do not provide the necessary assurances, we conclude that system regulation, by a single, independent regulator is the most appropriate way to mitigate the risks posed in the delivery of health and adult social care, and provide consistency across the sector. As the Commission is the existing regulator of health and adult social care, we believe it would be inefficient to create an alternative, independent regulatory body for these providers.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£1.2m	none
Transitional costs to CQC	£0.2m	£0.3m
Annual costs to NHS providers	unquantified	unquantified
Transitional costs to NHS providers	£1.2m	£2.4m
Benefits		
Benefits to patients	£67m	£67m

Unquantifiable costs and benefits

COSTS	As CQC will have a wider range of enforcement powers, we expect an increase in enforcement action. However, the scale of individual actions should be smaller, as the CQC can use a more focussed and proportionate approach. We have not quantified annual costs to the NHS, but we would expect them to be small.
BENEFITS	Enforcement powers, and a focus on outcomes rather than process, should support the CQC and providers in identifying and tackling issues, leading to an improvement in essential levels of safety and quality. The new system of registration will allow the CQC more flexibility to develop a more targeted approach to regulation. This should lead to cost savings to NHS Trusts (apart for some transitional costs) due to a less burdensome system, as well as cost savings to CQC as they can focus inspections on Trusts they assess as being subject to more risk. Registering NHS Trusts will create a level playing field between the NHS and IS providers, reassuring patients that they will get essential levels of safety and quality, regardless of the care setting.

Costs

73. We estimate that it could cost the Care Quality Commission up to £30,000 to register each trust each year if Trusts were registered under the current system. We believe that the new system could be between 0% and 10% cheaper than this, giving estimated annual savings of up to £1.2 million. As these estimates are based on aggregate figures for the sector, it is assumed these include annual self-assessment, inspections and first time registrations. For further details of these calculations, see Annex B.

74. We expect some annual costs to NHS Trusts as, although we would not expect first time registrations, existing trusts may need to ask for changes to their registration if they want to open a new location or offer a new service. It is very difficult to estimate the likelihood of such an event, as it depends on how many trusts will provide new services, and the way the CQC specifies the trust's registration.

75. Using figures supplied by the Care Quality Commission, we estimate that the transitional costs to CQC of registering the 395 trusts (including PCTs and Foundation Trusts) will be between £171,000 and £344,000[12]. We estimate the transitional cost of bringing all NHS trusts into registration of between £1.2 million and £2.4 million. More detail of these calculations can be found in Annex C.

Benefits

76. If the introduction of the new system leads to an improvement in the quality of services, this could also translate into a better quality of care for patients. We estimate this improvement to be worth £67 million a year. An explanation of how this figure was derived can be found in Annex D.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

77. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

d) Prison health services in private prisons

78. Most prisons are publicly owned, and their healthcare is provided by local PCTs. However, there are 10 privately run prisons in England. Of these, 7 contract healthcare services from IS providers currently registered under the CSA. As healthcare services are subcontracted by these private contractors, it is unclear whether the remaining three prison healthcare services are delivered by either currently registered IS providers, or by the NHS. However, there is a possibility that these are directly provided and therefore not currently subject to either NHS or IS healthcare regulatory mechanisms.

Option 1 – Do nothing

79. It would be possible to continue with the current system, whereby prison healthcare services would be subject to differing (or no) regulation depending on the type of provider delivering the services. The Care Quality Commission would still have the power to inspect independent sector providers and would still have some enforcement powers to deal with poor practice, and would produce an Annual Health Check for PCT or trust-provided services. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

80. Prison healthcare services are predominantly provided by the NHS as the majority are publicly-owned. The majority of privately-run prisons contract their healthcare services from CSA-registered providers. Therefore, the pros and cons of the appropriateness of system regulation for NHS and IS provided healthcare services equally apply here. However, this

[12] Our estimates are based on figures supplied by CQC.

leaves the three private prison healthcare services, for which we cannot currently identify the provision type.

81. Private prison provided healthcare services cover primary and community care, with a strong emphasis on drug-related services. Under the proposed definitions of regulated activities, provision of these services would automatically come within scope of the new registration system. For the three remaining services, if they were not provided either by the NHS or currently registered providers, it would only be possible to keep these private prison services out of scope by setting a specific exemption for those providers in the regulations.

82. It is not viable to exclude these services from registration when identical services delivered by other providers are included, as this leaves people using these services exposed to a risk that is being addressed by regulation elsewhere. Further, there is no existing regulatory mechanism, and it would be inefficient to set up an alternative regulatory system for up to three providers (in terms of both resource implications and effectiveness/parity of regulatory action). Therefore, we conclude that system regulation by the Care Quality Commission is the most efficient form of regulation.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	none	£8,000
Transitional costs to CQC	none	£13,000
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	-£9,000	none
Transitional savings to providers	-£18,000	none

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner. Registering NHS Trusts will create a level playing field between the NHS and IS providers, reassuring patients that they will get essential levels of safety and quality, regardless of the care setting.

Costs

83. Given that these facilities will be primary and community care services with a strong emphasis on drug-related services, we assume they are as expensive to register as hospital-provided listed services. We therefore use figures provided by the Care Quality Commission for hospital-provided listed services to estimate the costs of first time registration, annual self-assessments and inspections. We estimate that the inclusion of prison services will therefore cost the Commission up to £8,000 annually to regulate these providers.

84. Using the cost information from hospital provided listed services we estimate the transitional cost of bringing these prisons into registration during 2010/11 would cost the Commission up to £13,000. This includes the cost of inspecting each provider in the first year.

Benefits

85. As we assumed for the costs to the regulator, we assume that the cost to prison services of regulation will be similar to that of a hospital providing listed services. This implies annual costs of up to £9,000 per year. We estimate that the transitional cost to the prisons of coming within the scope of registration will be up to £18,000. More detail of these calculations can be found in Annex C.

86. Publicly run prison health services are either provided by PCTs or are commissioned by PCTs. These will be therefore be captured either by the registration of PCT provision, or when primary care registration is brought in from April 2012. Therefore, there will not be a level playing field between privately run prisons and public prisons. Bringing private prisons into registration will therefore create a level playing field between the different types of providers.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

87. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

e) Immigration removal centres

88. There are currently nine immigration removal centres in England. Most offer general medical services, but two centres also offer some inpatient facilities. Of these, three centres (including those offering inpatient facilities) have healthcare services provided by IS healthcare providers currently registered with the Care Quality Commission under the CSA. Two others have their healthcare services provided by the local PCT. As healthcare services are subcontracted by these private contractors, it is unclear whether the remaining four centres' healthcare services are delivered either by currently registered IS providers, or by the NHS. However, there is a possibility that these remaining centres are not currently subject to either NHS or IS healthcare regulatory mechanisms.

Option 1 – Do nothing

89. It would be possible to continue with the current system, whereby immigration removal centre healthcare services would be subject to differing (or no) regulation depending on the type of provider delivering the services. The Care Quality Commission would still have the power to inspect independent sector providers and would still have some enforcement powers to deal with poor practice, and would produce an Annual Health Check for PCT or trust-provided services. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

90. Immigration removal centre (IRC) healthcare services are predominantly provided by the NHS or contracted from CSA-registered providers. Therefore, the pros and cons of the appropriateness of system regulation for NHS and IS provided healthcare services equally apply here. However, as with prison healthcare services, this leaves a potential anomaly of the four centres' healthcare services, for which the provider type is unclear.

91. The immigration removal centres in question deliver primary and community care. Under the proposed definitions of regulated activities, provision of these services would automatically come within scope of the new registration system. For the other four services, it would only be possible to keep these services out of scope by setting a specific exemption for those providers in the regulations.

92. It is not viable to exclude these services from registration when identical services delivered by other providers are included, as this leaves people using these services exposed to a risk that is being addressed by regulation elsewhere. Further, there is no existing regulatory mechanism, and it would be inefficient to set up an alternative regulatory system for up to four providers (in terms of both resource implications and effectiveness/parity of regulatory action). Therefore, we conclude that system regulation by the Care Quality Commission is the most efficient form of regulation.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	none	£10,000
Transitional costs to CQC	none	£10,000
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	-£9,000	none
Transitional savings to providers	-£17,000	none

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner.
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner. Registering immigration removal centres will create a level playing field between those IRCs already commissioning healthcare from registered providers, and those providing healthcare in-house.

Costs

93. Under these assumptions, the additional costs to the Care Quality Commission would be up to £10,000 per annum. Bringing immigration removal centres into registration in 2010/11 could cost the Commission up to £10,000 as a transitional cost.

Benefits

94. The additional costs to providers could be up to £9,000 per annum. In the transition year, it could cost providers up to £13,000. This depends on how many centres provide care directly, rather than commissioning services from another registered provider. More detail of these calculations can be found in Annex C.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

95. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

f) Transport services using vehicles designed to carry patients

96. Many transport services that use vehicles designed to carry patients (referred to below as "specialist" transport services for brevity) are provided by one of the 11 NHS ambulance trusts in England. However, there are also up to 300 independent sector "specialist"

transport services operating in England[13] (usually known as private ambulance services). Provision of private ambulance services does not require registration under the CSA, nor is it regulated under the current NHS system.

Option 1 – Do nothing

97. Continuing with the current system would mean that providers of "specialist" transport services would only be subject to regulation (ie the Annual Health Check) by the Care Quality Commission if they were NHS providers. Providers of equivalent services in the independent sector would continue without formal regulation. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

98. The "transport services, triage and medical advice provided remotely" regulated activity as currently drafted will bring "specialist" transport services (where they involve a vehicle designed for the primary purpose of carrying a person who requires treatment) into the scope of registration under the 2008 Act. However, it will not bring in provision of other, low risk transport services, such as those only conveying patients to/from hospital (ie taxi services that are not designed for the primary purpose of carrying a person who requires treatment). There is currently no regulatory system in place for transport services.

99. All NHS ambulance trusts provide this regulated activity. Therefore, the pros and cons of the appropriateness of system regulation in mitigating the risks related to this regulated activity (as set out in the section on IS and NHS providers above) are equally applicable here.

100. We anticipate that not all of the estimated 300 providers of private ambulance services would be brought into scope, as some may not use vehicles that are designed for the primary purpose of carrying a person who requires treatment (these will only be providing lower risk services). However, the proposed definitions would automatically bring the remaining private ambulance services into scope, unless a specific exemption was set in the regulations. At the moment, we do not have an estimate of the size of these two groups. We therefore use the range of 0 to 300 potential additional providers in our estimations.

101. It is not viable to exclude from scope these higher risk private ambulance services, when equivalent services delivered by NHS providers are included, as this leaves people using these services exposed to a risk that is being addressed by regulation elsewhere. Further, it would be inefficient to set up an alternative regulatory system for this small number of providers (in terms of both resource implications and effectiveness/parity of regulatory action). Therefore, we conclude that system regulation by the Care Quality Commission is the most efficient form of regulation.

102. As previously stated, it is our intention that private ambulance services will be brought into the new registration system from April 2011 rather than October 2010. This approach enables the Care Quality Commission to work with these providers to build capability, so that the registration and ongoing compliance processes are implemented efficiently and effectively.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	none	£0.7m
Transitional costs to CQC	none	£0.8m
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	-£0.7 million	none
Transitional savings to providers	-£1.3 million	none

[13] From Lang & Buisson, Independent Healthcare markets, 2007-12

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner. Registering private transport vehicles will create a level playing field between them and NHS ambulance services, reassuring patients that they will get essential levels of safety and quality, regardless of the care setting.

Costs

103. The Care Quality Commission does not register any services similar to the transport described here so we do not have reliable data on the potential costs. To get a best estimate, we assume that the cost of registering an independent sector ambulance service is similar to that of registering a hospital providing listed services. We therefore estimate the additional costs to the Commission to therefore be up to £0.7 million. Using the same assumptions, the one off costs for registration could be up to £0.8m for Commission. This includes the cost of inspecting every new provider in the transition year.

Benefits

104. Using the assumption that there will be up to 300 providers incurring costs similar to those incurred by hospitals providing listed services we estimate that the annual cost to providers will be up to £0.7 million per year. The transitional costs are estimated to be up to £1.3 million for providers. More detail of these calculations can be found in Annex C.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

105. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

g) Accommodation with treatment for drug and alcohol misuse

106. Most providers of accommodation together with treatment for drug or alcohol misuse are already registered as adult social care providers under the CSA, so are included with those costings above. However, 21 providers of these services are not currently registered under the CSA, but are part of the National Treatment Agency directory. It is possible there could be more than this, but we do not expect large numbers. We suspect that this anomaly has arisen as a result of the inflexibility of the establishment and agency definitions of scope in the CSA (ie accommodation with treatment that is not provided in a hospital setting, and is not a care home).

Option 1 – Do nothing

107. It would be possible to continue with the current system, whereby these services would be subject to differing (or no) regulation depending on the type of provider delivering the services. The Care Quality Commission would still have the power to inspect independent sector providers and would still have some enforcement powers to deal with poor practice,

and would produce an Annual Health Check for PCT or trust-provided services. The 21 (or so) providers of equivalent services in the independent sector and not registered under the CSA would continue without formal regulation. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

108. Accommodation together with treatment for drug or alcohol misuse healthcare is either provided by the NHS or by CSA-registered providers. Therefore, the pros and cons of the appropriateness of system regulation for NHS and IS provided healthcare services equally apply here. However, this leaves the potential anomaly of the 21 providers not currently registered under the CSA.

109. Under the proposed definitions of regulated activities, provision of accommodation together with treatment for drug or alcohol misuse would automatically come within scope of the new registration system. For the 21 anomalistic providers, it would only be possible to keep them of out of scope by setting a specific exemption in the regulations.

110. It is not viable to exclude these services from registration when identical services delivered by other providers are included, as this leaves people using these services exposed to a risk that is being addressed by regulation elsewhere. Further, there is no existing regulatory mechanism, and it would be inefficient to set up an alternative regulatory system for these 21 or so providers (in terms of both resource implications and effectiveness/parity of regulatory action). Therefore, we conclude that system regulation by the Care Quality Commission is the most efficient form of regulation.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	£50,000	£53,000
Transitional costs to CQC	£16,000	£17,000
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	-£22,000	-£24,000
Transitional savings to providers	-£27,000	-£29,000

Unquantifiable costs and benefits

COSTS	Potential for increase in number of enforcement actions, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Improvement in quality for those receiving care, driven by change in focus from processes to outcomes, and by wider range of enforcement powers being able to address issues in more targeted and proportionate manner. Registering these providers will create a level playing field between them and the majority of similar providers that are already registered, reassuring patients that they will get essential levels of safety and quality, regardless of the care setting.

Costs

111. Using the estimated annual cost to the Care Quality Commission of the ongoing compliance process (£2,500), the additional 21 providers brought in could cost CQC between £50,000 and £53,000 per year.

112. These providers are becoming registered for the first time. Therefore, the cost of first time registration of all 21 providers to the Commission, as well as inspecting each new provider, is estimated to be between £16,000 and £17,000.

Benefits

113. We estimate that the annual cost for the approximately 21 new providers[14] would be between £22,000 and £24,000 per year[15]. The transitional cost of registering for the first time, and being inspected in that transition year, is estimated to be between £27,000 and £29,000. More detail of these calculations can be found in Annex C.

Option 3 – Care Quality Commision to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

114. For this category of provider, Option 3 is identical to Option 2, and therefore has the same costs and benefits.

h) Non-surgical use of class 3B and 4 lasers and intense pulsed light equipment

115. There are approximately only 1,000 high-street providers registered with the Care Quality Commission under the CSA for the non-surgical use of class 3B and 4 lasers and intense pulsed light equipment. It is believed that there are up to 4,000 additional providers currently practicing without being registered.

Option 1 – Do nothing

116. It would be possible to continue with the current system, whereby high-street providers of these lasers and lights services would still be required to register with the Care Quality Commission under the CSA. The Commission would still have the power to inspect independent sector providers, and retain the same, limited enforcement powers to deal with poor practice or failure to register. There would probably still be the same high proportion of unregistered providers of lasers and lights services, as the Care Quality Commission would still not be able to easily identify and prosecute unregistered providers. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

117. Non-surgical lasers and lights services tend to be delivered by independent sector, high-street providers, the majority of whom are not currently registered with the Care Quality Commission under the Care Standards Act (despite being required by law to do so). The 2008 Act scope definitions do not include these high-street providers of non-surgical lasers and lights services. Therefore, it would only be possible to bring these providers into scope by setting a specific inclusion in the Regulations.

118. The 2008 Act scope definitions are constructed around the greatest risks to, and levels of vulnerability of, those receiving the care, that can most be most effectively addressed by system regulation. To determine whether this is the best approach for the regulation of lasers and lights providers, we have identified and analysed the available information. This included taking advice from other regulatory bodies, considering the risks posed by these services, and the extent to which system regulation by the Care Quality Commission could mitigate these risks (as per the description in the section on IS healthcare providers). This

[14] We assume that all such providers are privately owned, but this may not be correct.
[15] The same assumptions are made as for nursing agencies above, as accommodation for substance misuse is also a social care provider.

has enabled us to assess relative risks to people using these services against the costs of regulation, and to consider which type of regulation (if any) would bring most benefit.

119. Although these procedures pose some risks, based on the evidence available, this does not appear to be high. The people who use these procedures are less vulnerable than people accessing many of the other services considered, particularly in that they have more freedom to choose whether to undertake the risk or not. In addition, the main risks to people who choose to have non-surgical lasers and lights procedures arise principally from the ability of the provider to use the equipment appropriately. Although system regulation could reduce this risk to a degree by checking that appropriate training had been undertaken, most of the other registration requirements would be irrelevant, which makes system regulation a heavy-handed approach in this field.

120. Therefore, we concluded that system regulation by the Care Quality Commission is not the most appropriate approach to the regulation of non-surgical lasers and intense pulsed light services. However, DH has agreed to work with the sector and representative bodies to explore options for an alternative approach that better targets the specific risks associated with these procedures. These include both alternative statutory mechanisms, targeted at the specific risks to these services, and self-regulatory routes. This work is currently underway.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£2.3 million	-£2.3 million
Transitional costs to CQC	none	none
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£2.4 million	£2.4 million
Transitional savings to providers	none	none

Unquantifiable costs and benefits

COSTS	Reduced burden to CQC as these providers would be outside system regulation, enabling CQC to better focus on those services where system regulation is the most appropriate way of mitigating risks
BENEFITS	Reduced burden to providers as they would not be required to produce unnecessary amounts of information to conform with the aspects of system regulation that are not appropriate to these providers. Allows for an alternative approach to regulation of these services to be developed which better targets the specific risks associated with these services. Not including these providers in the future registration system will introduce a level playing field across high-street providers of services of similar risks.

Costs

121. The Care Quality Commission would save the costs of regulating this sector. These savings are estimated to be £2.3 million. More detail on how this was calculated can be found in Annex C.

Benefits

122. If the approximately 1,000 laser and lights establishments currently registered are no longer required to register, we estimate annual savings to providers of approximately £2.4 million per year.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

123. The 2008 Act scope definitions do not include high-street providers of non-surgical lasers and lights services. Therefore, a specific inclusion in the Regulations would be required to bring these providers into scope.

124. If this inclusion were in place, the Care Quality Commission would have the power to register these lasers and lights providers against the full range of registration requirements; and take enforcement action for breaches of compliance with these requirements, or failure of a provider to register. This approach has two potential problems: that system regulation is not the most appropriate regulatory mechanism for these providers; and the Commission would still have problems with identifying and taking action against unregistered providers of lasers and lights services.

125. Option 2 (above) sets out the arguments for not including these providers in system regulation by the Care Quality Commission. On the issue of unregistered providers, the 2008 Act puts the onus is on the provider to ensure it is registered, rather than for the Commission to be pro-active in identifying them. Therefore, the Care Quality Commission is not well-placed to identify these providers unless there are complaints made against them, as they tend to be single-service and high-street based. Further, the only enforcement action is the prosecutable offence of failure to register to provide a regulated activity, which is often a lengthy and costly process and would not necessarily achieve the sector's desired effect of driving out bad practice amongst providers. Sanctions and enforcement mechanisms available through other regulatory mechanisms are likely to be more effective, such as immediate fines or removal of a kite mark awarded through an accreditation scheme. These options are being considered as part of the Department's work with the sector and representative bodies on an alternative approach to lasers and light services regulation.

126. Therefore, we conclude that the available evidence does not support the inclusion of non-surgical lasers and light services in the scope of registration under the 2008 Act.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	£5.7 million	£8.8 million
Transitional costs to CQC	£1.5 million	£1.9 million
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	-£7.7 million	-£4.9 million
Transitional savings to providers	-£8.2 million	-£5.9 million

Unquantifiable costs and benefits

COSTS	Increase in number of enforcement actions against unregistered providers. Potential increase in enforcement actions for registered providers, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner
BENEFITS	Although system regulation is a heavy-handed approach, there is a potential for improvement in quality for those

accessing services. By proactively pursuing unregistered providers to get them to register, the CQC would then be able to use the wider range of enforcement powers to address compliance issues for relevant requirements in more targeted and proportionate manner for registered providers.

Costs

127. If lasers and lights were to be explicitly put within scope of registration, we would expect the Care Quality Commission to try to register all providers, not just those currently registered. If we therefore estimate that between 4,000 and 5,000 could become registered, this could lead to transitional costs to the Care Quality Commission of between £1.4 million and £1.9 million.

128. The annual costs to the Care Quality Commission of registering these providers are estimated to be between £5.7 million and £8.8 million. More detail of these calculations can be found in Annex B.

Benefits

129. With between 3,000 and 4,000 estimated additional providers, there could be transitional costs of between £5.9 million and £8.2 million for the sector. There could also be annual costs of between £4.9 million and £7.7 million. More detail of these calculations can be found in Annex C.

i) Nurses agencies solely providing staff to other registered providers

130. Nurses' agencies are agencies that either provide nurses directly to the person requiring the service, or to another registered provider (eg a care home). In the former situation, the agency is directly controlling the provision of the care. In the latter situation, the nurse is providing care on behalf of the registered provider, who has responsibility for ensuring the suitability of the nurse in the same way as any other member of their staff**.** The Care Quality Commission currently regulate 734 nurses' agencies, but is not currently able to distinguish between the two categories of agency provision set out above.

Option 1 – Do nothing

131. It would be possible to continue with the current system, whereby all nurses' agencies would still be required to register with the Care Quality Commission under the CSA. The Commission would still have the power to inspect these agencies, and retain the same, limited enforcement powers to deal with poor practice. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

132. The 2008 Act scope definitions do not include nurses' agencies where the agency solely provides staff to other registered providers, and is not directly engaged in the delivery of care. Therefore, it would only be possible to bring these providers into scope by setting a specific inclusion in the Regulations.

133. As described in the section on IS providers of healthcare, the 2008 Act scope definitions are constructed around the greatest risks to, and levels of vulnerability of, those receiving the care, that can be most effectively addressed by system regulation. The registration requirements focus on the concerns of people using health and adult social care services and cover topics on which they want assurance. For those nurses' agencies solely providing

staff to other registered providers rather than directly to people using services, most of the registration requirements would not be applicable. Further, it would be unnecessary duplication to apply those requirements around the suitability of staff to these agencies, because both the agency, and the registered provider to whom it supplied staff, would have responsibility for ensuring the relevant checks are carried out. The registered provider will be ultimately responsible for the safety of people using its services, and will be in a better position to determine that the worker has the appropriate skills etc. Compared to the benefits, this makes system regulation a bureaucratic and costly approach for both providers and regulators.

134. Including these providers in registration would involve further regulatory duplication because the nurses are professionally regulated.

135. The Care Quality Commission currently registers 734 nurses' agencies under the CSA, but does not hold information on how many of these only provide staff to other registered providers. Although we believe it to be relatively few, we use the range of 0 to 734 providers potentially outside the future scope of registration.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£1.8 million	none
Transitional costs to CQC	none	none
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£60,000	£0.8 million
Transitional savings to providers	none	none

Unquantifiable costs and benefits

COSTS	Remove duplication from system, as CQC will only need to register providers delivering care (and thus making judgement about requirements relating to suitability of staff), rather than also registering those agencies solely supplying staff. Reduced CQC burden as these providers would be outside system regulation, enabling CQC to better focus on those services where system regulation is the most appropriate way of mitigating risks
BENEFITS	Reduced burden to providers as they would not be required to produce unnecessary amounts of information to conform with the aspects of system regulation that are not appropriate to these providers. Not including these providers in future registration system will introduce a level playing field across providers of similar services.

Costs

136. Based on the current costs of registering social care providers, we estimate that the average saving to the Care Quality Commission would be £2,500 per provider per year.[16] A number of nurses' agencies are likely to provide other regulated activities, so will still require registration. This exclusion would therefore lead to annual savings of up to £1.8 million per year. As this estimate is based on aggregate figures, it is taken to include first time registrations, self-assessments and inspections.

137. There may be some transitional costs for the Commission with respect to those nurses agencies that would move to the new system of registration. However, using the same reasoning as for adult social care, we assume these costs would be neutral.

Benefits

138. Providers could save between £60,000 and £0.8 million per year, depending on how many nurses' agencies did not need to register. More detail of these calculations can be found in Annex C.

139. Again, we assume the transition costs to those nurses' agencies that did remain within scope of registration would be neutral.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

140. For this option we would include all nurses' agencies within the scope of the new system of registration, irrespective of whether they provider services directly, or solely provide staff to other registered providers. However, as the provider the member of staff is supplied to is also subject to the registration requirements, there is a risk that this system would be overly burdensome and lead to duplication.

141. The 2008 Act scope definitions do not include nurses' agencies that solely provide staff to other registered providers. Therefore, a specific inclusion in the Regulations would be required to bring these providers into scope.

142. If this inclusion were in place, the Care Quality Commission would have the power to register these providers against the full range of registration requirements; and consider enforcement action for breaches of compliance with these requirements. However, the registration requirements focus on the concerns of people using services, but these providers do not provide services directly to people, so it would not be possible to assess these providers against most of the requirements. Therefore, system regulation by the Care Quality Commission is not the most appropriate regulatory mechanism (as set out in Option 2 above).

143. Therefore, we conclude that the available evidence does not support the inclusion of nurses' agencies that solely provide staff to other registered providers in the scope of registration under the 2008 Act because the assurance of essential safety and quality is in place for people who use services through the regulation of registered providers.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£90,000	none
Transitional costs to CQC	none	none
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£60,000	£120,000
Transitional savings to providers	none	none

[16] This is based on CSCI currently spending £60 million per year on registration and assuming that the cost of maintaining the registration of a nursing agency is similar to that of other providers. As there are around 24,000 providers, this gives us a cost of £2,500 each.

Unquantifiable costs and benefits

COSTS	Potential increase in enforcement actions for registered providers, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner. Duplication of CQC activity as checking same staff as part of compliance checks on two different providers – those providing and those employing staff to provide care. Additionally, problematic for CQC as those agencies solely providing staff by definition do not provide care, so would be difficult to judge them against many of registration requirements
BENEFITS	Increased burden on providers compared to benefits, as a result of duplication introduced by registration of these providers in addition to registration of those providers to whom they provide staff, and difficulties in providing evidence about compliance with requirements that are not particularly applicable to the service they provide

Costs

144. As for other providers, we estimate the annual saving to the Care Quality Commission be between 0% and 5% of current spend. Using an average cost of £2,500 per provider per year, this leads to potential savings of up to £90,000 per year. As this estimate is based on aggregate figures, it is taken to include first time registrations, self-assessments and inspections.

Benefits

145. Using our estimate of 10-20% savings to providers in comparison to the current system, we estimate that nurses' agencies could save between £60,000 and £120,000 per year. We are assuming that all nurses' agencies are privately run. More detail of these calculations can be found in Annex C.

146. There may be some transitional negative benefits involved in moving over to the new system. However, using the same reasoning as above for adult social care, we assume these costs to be neutral.

j) Domiciliary care agencies solely providing staff to other registered providers

147. Domiciliary care agencies are agencies that either provide domiciliary care directly to the person requiring the service, or to another registered provider. In the former situation, the agency is directly controlling the provision of the care. In the latter situation, the employee is providing care on behalf of the registered provider, who has responsibility for ensuring the fitness of the employee in the same way as any other member of their staff. The Care Quality Commission currently regulate 5,100 domiciliary care agencies, but are not currently able to distinguish between the two categories of agency provision set out above.

Option 1 – Do nothing

148. It would be possible to continue with the current system, whereby all domiciliary care agencies would still be required to register with the Care Quality Commission under the CSA. The Commission would still have the power to inspect these agencies and retain the same, limited enforcement powers to deal with poor practice or failure to register. However, this option does not fulfil the policy objectives set out above, and is therefore not appropriate.

Option 2 (Preferred) – Care Quality Commission only to register providers carrying out regulated activities

149. The 2008 Act scope definitions do not include domiciliary care agencies where the agency solely provides staff to other registered providers, and is not directly engaged in the delivery of care. Therefore, it would only be possible to bring these providers into scope by setting a specific inclusion in the Regulations.

150. As described in the section on IS providers of healthcare, the 2008 Act scope definitions are constructed around the greatest risks to, and levels of vulnerability of, those receiving the care, that can be most effectively addressed by system regulation. The registration requirements focus on the concerns of people using health and adult social care services, and cover topics on which they want assurance. For those domiciliary care agencies solely providing staff to other registered providers rather than directly to people using services, most of the registration requirements would not be applicable. Further, it would be unnecessary duplication to apply those requirements around the suitability of staff to these agencies, because both the agency, and the registered provider to whom it supplied staff, would have responsibility for ensuring the relevant checks are carried out. The registered provider will be ultimately responsible for the safety of people using its services, and will be in a better position to determine that the worker has the appropriate skills etc. Compared to the benefits, this makes system regulation a bureaucratic and costly approach for both providers and regulators.

151. The Care Quality Commission currently registers 5,134 domiciliary care agencies under the CSA, but does not hold information on how many of these only provide staff to other registered providers. Although we believe it to be relatively few, we use the range of 0 to 5,134 providers potentially outside the future scope of registration.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£12.8 million	none
Transitional costs to CQC	none	none
Annual costs to LA providers	-£0.7 million	-£0.05 million
Transitional costs to LA providers		
Benefits	**Low estimate**	**High estimate**
Annual savings to IS providers	£0.4 million	£4.8 million
Transitional savings to IS providers	none	none

Unquantifiable costs and benefits

COSTS	Remove duplication from system, as CQC will only need to register providers delivering care (and thus making judgement about requirements relating to suitability of staff), rather than also registering those agencies solely supplying staff. Reduced CQC burden as these providers would be outside system regulation, enabling CQC to better focus on those services where system

	regulation is the most appropriate way of mitigating risks
BENEFITS	Reduced burden to providers as they would not be required to produce unnecessary amounts of information to conform with the aspects of system regulation that are not appropriate to these providers. Not including these providers in future registration system will introduce a level playing field across providers of similar services.

Costs

152. Based on an average saving of £2,500 per year per provider[17], we estimate this exclusion would therefore lead to annual savings of up to £12.8m. A number of domiciliary care agencies are likely to provide other regulated activities and so still require registration. This is therefore the upper estimate. As this estimate is based on aggregate figures, it is taken to include first time registrations, self-assessments and inspections.

153. Using similar assumptions, LA run providers could save between £50,000 and £0.7 million per year, depending on how many domiciliary care agencies do not need to register. More detail of these calculations can be found in Annex C.

Benefits

154. Privately run providers could also save due to moving outside the scope of registration. Using the same assumption as above, we estimate annual savings of between £0.4 million and £4.8 million a year. More detail of these calculations can be found in Annex C.

155. Again, there may be transitional costs (negative benefits) to providers but, using the same reasoning as for adult social care providers, we assume these will be cost neutral.

Option 3 – Care Quality Commission to register providers carrying out regulated activities, and those providers currently registered under the CSA 2000

156. For this option we would include all domiciliary care agencies within the scope of the new system of registration, irrespective of whether they provider services directly, or solely provide staff to other registered providers. However, as the provider the member of staff is supplied to is also subject to the registration requirements, there is a risk that this system would be overly burdensome and lead to duplication.

157. The 2008 Act scope definitions do not include domiciliary care agencies that solely provide staff to other registered providers. Therefore, a specific inclusion in the Regulations would be required to bring these providers into scope.

158. If this inclusion were in place, the Care Quality Commission would have the power to register these providers against the full range of registration requirements; and consider enforcement action for breaches of compliance with these requirements. However, the registration requirements focus on the concerns of people using services, but these providers do not provide services directly to people, so it would not be possible to assess these providers against most of the requirements. Therefore, system regulation by the Care Quality Commission is not the most appropriate regulatory mechanism (as set out in Option 2 above).

159. Therefore, we conclude that the available evidence does not support the inclusion of domiciliary care agencies that solely provide staff to other registered providers in the scope

[17] This is based on CSCI currently spending £60 million per year on registration and assuming that the cost of maintaining the registration of a nursing agency is similar to that of other providers. As there are around 24,000 providers, this gives us a cost of £2,500 each.

of registration under the 2008 Act because the assurance of essential safety and quality is in place for people who use services through the regulation of registered providers.

Quantifiable costs and benefits

Costs	**Low estimate**	**High estimate**
Annual costs to CQC	-£0.6 million	none
Transitional costs to CQC	none	none
Annual costs to CQC	-£0.1 million	-£0.1 million
Transitional costs to CQC	none	none
Benefits	**Low estimate**	**High estimate**
Annual savings to providers	£0.4 million	£0.7 million
Transitional savings to providers	none	none

Unquantifiable costs and benefits

COSTS	Potential increase in enforcement actions for registered providers, although these will probably be smaller in scale as CQC has wider range of enforcement powers than previously, so can utilise in more focussed manner. Duplication of CQC activity as checking same staff as part of compliance checks on two different providers – those providing and those employing staff to provide care. Additionally, problematic for CQC as those agencies solely providing staff by definition do not provide care, so would be difficult to judge them against many of registration requirements
BENEFITS	Increased burden on providers compared to benefits, as a result of duplication introduced by registration of these providers in addition to registration of those providers to whom they provide staff, and difficulties in providing evidence about compliance with requirements that are not particularly applicable to the service they provide

Costs

160. As for other providers, we estimate the saving to the Care Quality Commission be between 0% and 5% of current spend. Using an average cost of £2,500 per provider per year, this leads to potential annual savings of up to £0.6 million per year. As this estimate is based on aggregate figures, it is taken to include first time registrations, self-assessments and inspections.

161. Using our estimate of 10-20% annual savings to providers in comparison to the current system, we estimate that LA run domiciliary care agencies could save between £54,000 and £110,000 per year. More detail of these calculations can be found in Annex C.

162. There may be some transitional costs for the Care Quality Commission and for providers with respect to those nurses agencies that would move to the new system of registration. However, using the same reasoning as for adult social care, we assume these costs would be neutral.

Benefits

163. Using our estimate of 10-20% annual savings to providers in comparison to the current system, we estimate that privately run domiciliary care agencies could save between £0.4 million and £0.7 million per year.

164. Again, we assume the transition costs to those domiciliary care agencies that did remain within scope of registration would be neutral.

Other costs

Compliance costs

165. It is expected that there will be some further, as yet unquantifiable costs to registration due to providers improving their performance to meet the standards set for registration (compliance costs), or due to some indirect consequences of the registration on providers. These are discussed in Annex E. However, it should be noted that the Care Quality Commission will in due course be publishing their own IA on the compliance costs, which should consider the impact of their compliance procedure.

Enforcement

166. The new system also allows the Care Quality Commission a range of enhanced enforcement powers. More detail on these new enforcement powers can be found in Annex F. Whilst we cannot really appreciate how the Commission will use this enhanced range of enforcement powers until it has them at its disposal, the additional powers will enable a more proportionate response to non-compliance with registration requirements. This gives greater potential for providers to be brought back into compliance without having to use more extensive and costly sanctions such as cancellation of registration. Although it is possible that the greater range of enforcement options could increase the number of enforcement actions carried out by the Commission, we believe that costs associated with this would be offset by the ability to take a proportionate approach to each specific breach of the registration requirements.

167. **Enforcement costs for the Care Quality Commission:** The Commission is currently responsible for enforcing the CSA registration regulations against 24,000 adult social care providers (costing £2.1 million) and around 2400 IS healthcare providers (costing £1.3 million). We have estimated that around 1,000 fewer healthcare providers will be registered from October 2010 (as providers of non-surgical class 3B and 4 laser and intense pulsed light treatment will no longer be within the scope of regulation), but up to 300 more will be registered from April 2011 when independent sector ambulance services come into scope. Therefore, we estimate that the cost of healthcare enforcement should be 42% lower than current costs in 2010, but nearer to 29% lower in 2011[18].

168. In adult social care, the number of providers will fall by between zero and 5800, as both domiciliary care and nurses' agencies that only provide staff to other registered providers are no longer within scope. However, as we expect there to be relatively few of these providers, we assume the number of adult social care providers does not change very much, so assume that the enforcement costs to the Care Quality Commission relating to the registration of adult social care providers will not change significantly from the current level.

169. The above estimate of healthcare costs does not take into account the 395 NHS Trusts which will be registered in 2010. As the size and mix of activities delivered by these providers are so different from the IS healthcare providers, it is very difficult to quantify their impact on the cost of enforcement. Although there will be fewer healthcare providers registered under the new system (25% less in 2010, and 13% less in 2011), many are much

[18] Deducting 1000 providers and adding 300 means decrease in the number of health care providers by 35%.

larger, more complex, organisations that are not accustomed to the formal process of registration. Therefore, we assume that healthcare enforcement costs will not decrease as a result of bringing the NHS into registration. However, we do not expect a significant increase either, as NHS providers already have strong performance management and oversight mechanisms and are therefore less likely to require formal enforcement action by the Care Quality Commission.

170. **Enforcement Costs at the First Tier Tribunal:** A similar argument to that set out above applies here. There is the potential for the number of appeals (and with that costs) to rise as a result of bringing newly registered, more complex, organisations into a formal registration system. However, there are fewer providers overall. Additionally, under the new registrations system, the Care Quality Commission has a wider range of enforcement powers, enabling it to act in a more proportionate and targeted manner. Therefore, we assume that costs related to the First Tier Tribunal will not differ significantly from current levels.

171. **Enforcement costs for providers**: We do not estimate any significant changes to enforcement costs incurred by registered providers. The current level of enforcement against IS providers is low, due to high levels of compliance. We therefore do not expect the changes to affect costs significantly. In adult social care, providers may now be subject to more forms of enforcement, but these powers would also be used in a more flexible manner and so the increase in the number of enforcement actions is likely to be balanced against the burden of the individual enforcement action to a particular provider.

Overheads

172. The above costings attempt to quantify the variable costs which the Care Quality Commission will incur as it registers different sets of providers. However, they will also incur a certain degree of fixed costs, particularly during transition, associated with moving over to the new system of registration, training staff and developing the guidance about compliance. The Commission have provided initial estimates of what these costs may be[19].

	Low estimate		High estimate	
	2009/10	2010/11	2009/10	2010/11
Management and Administration	£600,000	£450,000	£730,000	£550,000
Developing new processes and training staff	£1,300,000	£1,150,000	£1,600,000	£1,400,000
Developing and testing guidance about compliance	£810,000	£750,000	£990,000	£910,000
Total	£2,700,000	£2,300,000	£3,300,000	£2,900,000

173. The Commission will also annually face general overheads concerned with the management of the additional workload. Following discussions with the Commission, we shall use an estimate of £180,000 p.a. for these costs.

Fees

174. The Care Quality Commission will continue to charge fees to providers for registration. We expect that the fees will relate to the Care Quality Commission's cost of operating the new registration system. Details of the fees structure and amount will be determined by the Commission, and formally consulted on in due course.

[19] Because of the uncertainly around these figures, we have subtracted 10% and added 10% to CQC's estimates, to present a range.

Administrative Burden

175. In this section, we consider what impact the different options will have on the administration costs of private and third sector organisations.

Option 2

176. We have calculated above that the new system will save about 10-20% of the administrative costs that IS health care providers and privately run social care providers have to bear due to first time registration and annual self-assessment. Some domiciliary care agencies and nurses agencies, as well as lasers and lights services, will also fall out of scope of registration, leading to further administrative savings.

177. However, the new system of registration will also bring new private providers within the scope of registration for the first time, such as private prisons and private transport services.

178. We summarise these impacts on the administrative burden on private providers in the table below. As already discussed, there is a larger burden in the transition year (remembering that private transport services do not come into scope until 2011/12).

Table 1: Summary of administrative burden imposed by Option 2

	2010		2011		2012 onwards (annually)	
	Low estimate	High Estimate	Low estimate	High Estimate	Low estimate	High Estimate
Private Prisons	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m
Private transport services	£0	£0	£0	£1.3m	£0	£0.7m
Accommodation for substance misuse	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m
IS healthcare providers	£2.0m	£3.0m	-£1.3m	-£0.6m	-£1.3m	-£0.6m
Private social care providers	-£0.2m	-£0.1m	-£6.0m	-£3.7m	-£6.0m	£-3.7m
Private domiciliary care agencies	-£3.3m	-£0.0m	-£4.8m	-£0.4m	-£4.8m	-£0.4m
Private nurses agencies	-£0.5m	-£0.0m	-£0.8m	-£0.0m	-£0.8m	-£0.0m
Lasers and lights providers	-£1.2m	-£1.2m	-£2.4m	-£2.4m	-£2.4m	-£2.4m

179. This leads to an average decrease in the administrative burden of between £5.4 million and £14.0 million per year, when considering all years up to 2018/19.

Option 3

180. Similarly, we can estimate the expected impact which Option 3 would have on the administrative burden of private providers. The main differences are that all domiciliary care agencies, nurses agencies and laser and light providers would remain within the scope of registration.

181. We summarise these impacts on the administrative burden on private providers in the table below. Again, there is a larger burden in the transition year (remembering that private transport services do not come into scope until 2011/12).

Table 2: Summary of administrative burden imposed by Option 3

	2010		2011		2012 onwards (annually)	
	Low estimate	High Estimate	Low estimate	High Estimate	Low estimate	High Estimate
Private Prisons	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m
Private transport services	£0	£0	£0	£1.3m	£0	£0.7m
Accommodation for substance misuse	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m	+£0.0m
IS healthcare providers	£2.0m	£3.0m	-£1.3m	-£0.6m	-£1.3m	-£0.6m
Private social care providers	-£0.2m	-£0.1m	-£6.0m	-£3.7m	-£6.0m	£-3.7m
Private domiciliary care agencies	-£0.0m	-£0.0m	-£0.7m	-£0.4m	-£0.7m	-£0.4m
Private nurses agencies	-£0.0m	-£0.0m	-£0.1m	-£0.0m	-£0.1m	-£0.0m
Lasers and lights providers	£7.6m	£13.0m	£4.9m	£7.9m	£4.9m	£7.9m

182. This leads to an average change in the administrative burden of between a £1.8m decrease and a £5.1m increase per year, when considering all years up to 2018/19.

Opportunity costs

183. The total Department of Health (DH) budget is fixed, in a given period and as such any funds committed to new policies must therefore be reallocated away from some other use, elsewhere in DH. To fully reflect the impact of a particular policy, it is therefore important to consider the effect of reallocating funds away from this alternative use. The impact of reallocation is the policy's true cost – or "opportunity cost" – and we must reflect this in Impact Assessments.

184. To calculate the impact of reallocating funds to a new policy, it is necessary to determine how much benefit would have been realised from the alternative use of these funds. This can be done using standard estimates of the amount of benefits generated by, for example, NHS treatments "at the margin" that may be withdrawn if the availability of funding is reduced. The benefits of these marginal treatments are estimated, by society, to be approximately 2.4 times more valuable than the cost of the treatments[20].

185. The ratio of 2.4:1 of benefits to costs implies that any policy that involves spending from the DH budget will deprive society of benefits worth 2.4 times as much (before the policy's own benefits are taken into account). Similarly, any cost saving measure that releases DH budget to be spent elsewhere is expected to provide benefits valued at 2.4 times the cost saving.

186. To correctly reflect the cost impacts of policies and programmes, we therefore must multiply any effects on the DH budget by 2.4 in order to calculate their true cost to society. This will produce the amount of benefits lost by diverting spending to the policy in question – and it follows that the policy should itself generate greater benefits, in order to provide an overall positive impact.

[20] These are Department of Health estimates, based on differing valuations of Quality Adjusted Life Years (QALYs).

187. For this proposal, we must therefore consider the costs to the Care Quality Commission, the NHS and to LA run social care providers as all being costs incurred by the DH budget. The opportunity cost is found by calculating the total costs to these different bodies and multiplying by 2.4.

188. For this policy, the total discounted opportunity cost for the preferred option is -£196 million. This means that it is actually a benefit. For option 3, the total discounted opportunity cost is +£104 million. Although these opportunity costs are not included in the values for the total costs and total benefits, the value of the opportunity costs is subtracted from the benefits (along with other costs) to obtain the net benefit.

Risks and unintended consequences

189. There are three main risks that would create significantly different costs to those described above:

- The compliance criteria developed by the Care Quality Commission are not proportionate;
- The compliance criteria developed by the Care Quality Commission are as prescriptive as the NMS; and
- The funding formula does not allow all equally efficient providers to achieve the same standards.

190. The Care Quality Commission is required by the Act to be proportionate in its actions and its manifesto states that it will be tough, fair and proportionate. This is understood to include a requirement that it ensures that the societal benefits of compliance with its standards and of its enforcement interventions exceed their opportunity costs. The Care Quality Commission will also use a balanced scorecard to review its progress and engage with the Department of Health. It is intended that Better Regulation is one of the elements of this scorecard.

191. The Care Quality Commission is an independent body and, as such, will be able to raise concerns if it thinks that the allocation under the funding formula does not permit some providers to achieve the same standards as others.

192. There are also three main risks to the defined scope of registration:

- There will be a withdrawal of provision
- It will lead to barriers to entry in some sectors, and stifle competition
- The scope of activities defined do not capture the riskiest activities, or capture activities that actually do not generate much risk

193. There is a risk that the imposition of registration may lead to a withdrawal of provision for smaller providers in certain sectors. However, we believe this risk to be low, as the majority of providers within scope of registration are already within scope under the Care Standards Act, and this system should actually be less burdensome to those providers.

194. For those providers entering registration for the first time, namely immigration removal centres, private prisons and accommodation for the treatment of alcohol and substance misuse, there is a risk that the costs of registration could create a barrier to entry to the market, or damage competition. However, we believe this risk to be low, as the majority of competitors in this sector are already subject to registration and therefore the new definition of scope is merely creating a level playing field. More detail of this can be found in the competition impact assessment and the small firm impact assessment.

195. Although we have made use of the best evidence available, and engaged heavily with stakeholders and experts, to compile the list of activities which will come within the scope of registration, we acknowledge that the evidence base is limited and will therefore continue to

monitor the activities to better understands the risks associated with the activities and ensure the burden of registration is proportionate to the risk involved.

Monitoring and evaluation

196. The costs and benefits in this impact assessment, and in particular the costs falling on the Care Quality Commission, will be monitored and evaluated through two methods:

- The Department will evaluate the appropriateness of the list of activities within the scope of the new system, through ongoing discussions with the Care Quality Commission and with representative bodies of the organisations affected
- The Department will ensure the regulatory burden is proportionate to the risk through its ongoing role as sponsor of the Care Quality Commission

197. For all sectors, the Department will continue to consider new evidence that comes to light on the risks of different activities, to build on the evidence base for these activities, and will keep the estimation of these risks under review.

198. For organisations coming within scope for the first time, the Department intends to review over the next 3 years what the administrative cost on organisations has been in practice, and ask the Care Quality Commission to review how standards have improved within the different sectors, to determine whether the imposition of regulation has been proportionate to the risk.

Limitations of the analysis

199. All estimates in this Impact Assessment are based on the best information available. The Care Quality Commission are currently developing the operational side of the new system. This will be based on different compliance criteria and methodology from the CSA 2000 system, using a proportionate and risk-based approach. Therefore, many features that will determine costs and benefits are not yet in place and these estimates should be treated with due caution.

200. We generally use the costs of the current regulatory systems (ie the CSA 2000 registration of Independent Sector (IS) healthcare and adult social care providers, and the Annual Health Check for NHS providers) to estimate the potential costs of the new system. As the new system will have some operational differences from these systems, using these proxies poses some challenges, which we tackle in the following ways:

- **Costs to the Care Quality Commission**: the Care Quality Commission have provided estimates of the cost of regulating certain types of independent sector providers and these are used as proxies for similarly sized providers. However, as the cost categories do not cover every size of provider, we may sometimes underestimate the costs and sometimes overestimate them. We assume that these approximations even themselves out in the total costs presented. Costs of registering NHS Trusts and social care providers are estimated using aggregate Annual Health Check information and overall expenditure on social care registration respectively.
- **Activity versus location based registration**: cost figures for IS providers and adult social care providers are based on the current registration system, which is location based. Therefore, to provide a sensible comparison between old and new systems, we have calculated the costs using numbers of locations of these providers rather than numbers of new organisations.
- **Inspections**: although the Healthcare Commission and the CSCI had become increasingly targeted in their inspection work in recent years, they felt that the minimum inspection frequencies of 3 years for social care and 5 years for IS healthcare providers (set in the regulations underpinning the CSA 2000) limited their discretion. The new legislation does not specify an inspection frequency, enabling the Care Quality Commission to develop and implement a more focussed, targeted way of inspecting providers, together with an ongoing surveillance model of each providers' compliance with registration. Therefore, the duration (and potentially the

frequency) of inspections for some providers are likely to reduce over time, as these processes are embedded. As this inspection model is still in the early stages of development, we have assumed there will not be any initial change to the number of inspections of IS healthcare and adult social care providers. In order that the Commission has robust evidence to support any enforcement action, they may need to carry out more inspections of NHS Trusts than they would under the Annual Health Check. However, because Commission will deal with specific incidents of non-compliance, these inspections can be more targeted. Therefore, the effects are likely to balance each other out in terms of costs. We intend that the annual programme of HCAI inspections will be unaffected by the changes.

- **Annual costs of providers**: each year, a number of new providers are registered whilst others leave the system as a result of enforcement action or by choice. Therefore, our estimate of annual costs uses the cost of maintaining registration compliance (including self-assessment), plus first time registration costs for the proportion of turnover of each type of provider. Those leaving the system do not generate any significant costs.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	No

Annexes

Contents of the Annexes

Annex A: Assessing the list of activities to be registered under the proposed new system

A1. The Care Quality Commission will be required to take a proportionate approach to regulation. It will focus on functions to reduce risks to patients and people using services, after taking into account any other protections offered by other regulatory or management and governance systems, such as professional regulation or the health and safety executive, and how much system regulation would effectively reduce those risks.

A2. We are proposing to base registration on the risk of harm inherent in activities, rather than on the setting in which they are carried out. This becomes even more important as health and social care services become more integrated. This will give the Care Quality Commission more flexibility to regulate new types of services, and to base regulation on risk of harm to those receiving the care or treatment, rather than inflexible organisational structures.

A3. The scope of registration under the new system will be broadly similar to that which currently applies to adult social care and independent health providers. A notable change is that NHS providers will have to register to deliver services that come within scope. Registering NHS providers in the same way as other providers will assure the general public that whichever provider they use, all services will be required to meet the same, consistent, national safety, quality and governance requirements, and will be subject to the same enforcement regime if they fail to do so.

A4. We looked at risk in terms of the likelihood of harm to people using the service. For the scope of registration, we looked at the risks to people's safety, health, well-being and dignity that are inherent in health and social care activities. No activity can be made entirely risk free, nor should we always seek to intervene to try to make it so. We prioritised for registration those that carry the greatest degree of risk and where there is potential to mitigate against this risk.

A5. We consulted on which activities health and adult social care providers will be required to register with the Care Quality Commission (the scope of registration). A majority of respondents said they agreed with the list of activities we proposed in the consultation document.

A6. One of the strongest points made in the consultation on the issue of scope was that we should develop a more rigorous evidence base for determining whether activities should be within scope.

A7. Following further research and discussions with existing regulators and other experts in the field, we looked at the following evidence, where available:

- the types of suffering people experience as a result of poor quality or inappropriate care;
- the likelihood that the people experience such care;
- the severity of suffering that people experience;
- the circumstances of patients or people using services and their vulnerability;
- the change in suffering that system regulation would deliver; and
- the cost of regulation, including administration costs, barriers to entry, and indirect costs arising from providers ceasing to provide certain services to avoid regulation.

A8. This information has been a useful indicator that has made it easier to compare activities that create different risks to patients and people who use services. However, we have not been able to find detailed data to make a calculation of the effect of system regulation for

every activity. For example, data on adverse incidents often does not separate avoidable incidents from unavoidable ones. We have therefore used this information, along with other information provided during the course of the consultation as an aid to decision making.

Regulated activities

A9. In March 2008 the Department consulted on the range of activities that should be regulated. The outcome of that consultation was that the proposed list of regulated activities will be as follows:

- Personal care
- Accommodation for persons who require nursing or personal care
- Accommodation for persons who require treatment for substance misuse
- Accommodation and nursing or personal care in the further education sector
- Treatment of disease, disorder or injury
- Assessment or medical treatment for persons detained under the Mental Health Act 1983
- Surgical procedures
- Diagnostic and screening procedures
- Management of supply of blood and blood derived products etc
- Transport services, triage and medical advice provided remotely
- Maternity and midwifery services
- Termination of pregnancies
- Services in slimming clinics
- Nursing care
- Family planning services

A10. We have considered the evidence described above to inform the range of services to be captured within each regulated activity. These are set in the draft regulations which are to be laid before Parliament.

<u>Personal care</u>

A11. We have defined personal care to be physical assistance, or prompting with supervision in connection with eating, drinking, toileting, washing, dressing, oral care, or care of the skin, hair or nails. Providers who carry out those activities for people in their own homes will be required to register under this activity heading. There was strong support for this activity being within the scope of registration in the responses to the consultation earlier this year.

A12. This will capture most providers that currently have to register under the Care Standards Act (CSA) for providing domiciliary care, where we consider the inherent risk of harm (from, for example, poor quality care or physical, mental or financial abuse) and the potential vulnerability of the people who use the service to be such that registration is justified. In order to meet the registration requirements, providers will need to demonstrate to the Care Quality Commission that they have enough properly qualified and safety checked staff, and that they are taking steps to avoid abuse.

<u>Accommodation for persons who require nursing or personal care</u>

A13. This will capture the providers that currently have to register under the CSA for providing care homes. We consider the inherent risk of harm to be such that registration is justified, in the same way as it is for domiciliary care. There was strong support for this activity being within the scope of registration in the responses to the consultation earlier this year.

Accommodation for persons who require treatment for substance misuse

A14. This activity will bring in drug and alcohol misuse services where treatment is provided together with accommodation, which would otherwise be outside of scope. The risks inherent in this kind of service include risks of poor quality treatment by untrained staff who are not aware of best practice, lack of proper supervision and management, and not being joined up with other agencies. Providers will need to demonstrate that staff are properly qualified and supported, and that the provider is cooperating with other providers. A small number of additional providers, not currently registered under the CSA, will be brought within regulation, to create a level playing field. We consider the inherent risk of harm to be such that registration is justified. There was support for this to be a regulated activity in the responses to the consultation earlier this year.

A15. The regulation does not bring non-residential alcohol and drug services into regulation. We have not found sufficient evidence to bring those services into regulation by the Care Quality Commission at this stage. However, there are other protections in place, as they are overseen by the National Treatment Agency and PCTs as part of their commissioning responsibilities.

Accommodation and nursing or personal care in the further education sector

A16. This will capture the providers that currently have to register with the Care Quality Commission under the CSA for providing personal or nursing care in further education settings, where more than 10% of the students require personal or nursing care. The inherent risk of harm is the same as it is for domiciliary care, and therefore regulation is justified in the same way. The responses to the consultation earlier this year were in favour of regulating this activity, but were divided over whether it would be more appropriate for Ofsted to have responsibility for regulating it. In the light of the comments we received, and further discussions we have had with stakeholders, we are continuing discussions with Ofsted and DCSF over whether to transfer the responsibility (and the resources) for regulating this sector at some point in the future.

Treatment of disease, disorder or injury

A17. This activity will capture healthcare carried out by, or in a multi-disciplinary team including, one of the following:

- medical practitioner,
- dental practitioner,
- dental hygienist,
- dental therapist,
- dental nurse,
- dental technician,
- orthodontic therapist,
- nurse,
- midwife,
- biomedical scientist,
- clinical scientist,
- operating department practitioner,
- paramedic, or
- radiographer.

A18. It will also capture mental health care, where the treatment is carried out by, or in a multi-disciplinary team including a social worker.

A19. This will bring the private and voluntary sector hospitals and community health services that are regulated under the CSA into regulation. It will also bring NHS providers into regulation. The risks inherent in these services include: poor quality treatment because proper governance systems are not in place, neglect of the patient, the premises or equipment, poor record keeping leading to mistakes in treatment, poor quality care (for example not ensuring people are able to eat and drink), physical abuse etc.

A20. Providers will need to demonstrate, for example, that proper governance is in place, premises and equipment are fit for purpose, people are properly cared for, adequate records are kept, hygiene standards are met etc. This will enable us to provide a level playing field across the public and independent sectors, so that patients will have the same level of assurance of essential safety and quality wherever they have their treatment. There was widespread support for including this activity in the scope of registration in the consultation responses earlier this year.

A20. Primary medical care and primary dental care are excluded initially, and are dealt with under their own impact assessment.

A21. We do not want to duplicate the professional regulation systems already in place for healthcare professionals. Where care or treatment is provided as a standalone service, we felt the risks were adequately mitigated by the professional regulation already in place than by system regulation, which would be a duplication. Therefore, the services provided by healthcare professionals outside those we have listed will only fall within scope where they are provided as part of a care package delivered by multidisciplinary team with certain other healthcare professionals.

<u>Assessment or medical treatment for persons detained under the Mental Health Act 1983</u>

A22. This will bring NHS psychiatric hospitals that detain mental health patients into registration. People detained under the Mental Health Act are particularly at risk of abuse or poor quality treatment in the same way as other hospitals or care homes, with the additional risks related to being detained. Providers will be required to demonstrate that proper governance is in place, premises and equipment are fit for purpose, people are properly cared for, that staff are properly qualified and supported, and that the provider is cooperating with other providers. etc. There was support for including this activity in the scope of registration in the consultation responses earlier this year.

<u>Surgical procedures</u>

A23. This will bring private and voluntary sector providers of surgical procedures (including cosmetic procedures), that are currently regulated under the CSA, into regulation. It will also bring NHS providers into regulation. The responses to the consultation earlier this year were in favour of including this as a regulated activity, but there was support for excluding minor surgery because it was felt to be less risky.

A24. Some simple surgical procedures, which are currently not regulated under the CSA, are specifically excluded. For example, we have excluded simple nail surgery, and treatment of verrucae and warts, where a healthcare professional carries them out, and only local anaesthesia is used. This is because we do not think that the risk inherent in those services is enough to justify inclusion in scope, bearing in mind the existing professional regulation

that is in place. That will avoid, for example, high street chiropodists being within the scope of registration.

A25. We have assessed the relative risk, and the costs of regulation of the non-surgical use of class 3B and 4 lasers and intense pulsed light equipment, which is currently regulated under the Care Standards Act. We found that:

- although these procedures do pose some risks, based on the evidence available this does not appear to be high; and
- people who use these procedures are less vulnerable than those accessing many other services, particularly in that they have more freedom to choose whether to undertake the risk or not.

A26. We have concluded, therefore, that regulation by the Care Quality Commission is not the most appropriate approach to regulation in this area. Instead we are working with the sector and representative bodies on an alternative approach that better targets the specific risks associated with these activities.

Diagnostic and screening procedures

A27. This will bring providers of diagnostic and screening procedures, that are regulated under the CSA, into regulation. It will also bring NHS providers into regulation. A small number of currently unregulated private providers will be brought into registration for the first time under this activity.

A28. In these procedures there are risks of harm (both inherent in the procedure and in the risk of misdiagnosis) through poor quality care as a result of staff being not properly trained, or equipment not properly maintained, poor quality governance and systems management, not being properly joined up with other services etc. Providers will need to demonstrate to the Commission that their staff are properly trained and equipment properly maintained, that they have effective governance and systems management in place and that they are working effectively with other services. Respondents to the consultation earlier this year supported the proposal to include this as an activity within scope, but agreed that low risk procedures should be excluded.

A29. The conclusion we came to under this activity was to include in the scope of regulation, providers of:

- pathology and cytology;
- x-rays and other kinds of radiation scanning;
- cameras or other equipment that is used to look inside the body or take samples for biopsy;
- the use of equipment to monitor the physiological functioning of the major organ systems; and
- analysis and interpretation of the results of these.

A30. We have excluded:

- national cancer screening programmes, because we believe there is already sufficient independent oversight and quality assurance of those services;
- x-rays when carried out by a chiropractor, because their professional body, the General Chiropractic Council, specifically oversees their training in the use of x-rays and they are

also subject to regulation by the Care Quality Commission under the Ionising Radiation (Medical Exposure) Regulations;
- ultrasound scanning when carried out by physiotherapists, because they will have a direct face to face relationship with their client during the procedure, which reduces the risk of scanning the wrong body part, or recording the results against the wrong patient etc;
- the use of an auroscope, which carries very little risk of causing harm to the patient.

A31. Each of these would have brought in large numbers of providers without the burden being justified.

A32. We have also excluded, because the inherent risk was not found to be enough to justify the burden of regulation,:

- pin prick blood tests, where the sample does not need to be sent away for analysis;
- the taking of samples for genetic testing, where the procedures are not part of the planning and delivery of care or treatment.

Management of supply of blood and blood derived products etc

A33. This will bring NHS Blood and Transplant, which is currently subject to the Care Quality Commission's Annual Health Check and the *Code of practice for the prevention and control of healthcare associated infections*, into the scope of registration. This was not part of the consultation earlier this year.

Transport services, triage and medical advice provided remotely

A34. This activity brings private and NHS ambulance providers into regulation (although private providers are excluded until April 2011). It also brings in providers of urgent telephone or internet based triage, such as that provided by NHS Direct and out-of-hours providers (although these will be brought into regulation along with the rest of primary care). The consultation responses supported the inclusion of these services in the scope of regulation.

A35. Bearing in mind that people travelling to and from hospital tend to be relatively vulnerable, we considered bringing all patient transport service providers into regulation, but we were concerned that this would mean taxi firms were required to register if they carried patients to and from hospital. We felt that this would be a disproportionate burden on providers of taxi services and volunteer drivers providing a relatively low risk service, and would potentially create access problems if they were unable to provide transport to and from hospital unless registered with CQC, and, therefore cause unnecessarily long waits for transport.

A36. We also felt that the main risks inherent in transport services for people not requiring medical treatment were addressed by other means. For example, all staff employed by an independent or NHS provider who have access to patients in the normal course of their duties should have Criminal Records Bureau checks prior to employment and the general roadworthiness or suitability of vehicles is overseen by the DVLA.

A37. We have therefore defined the services we want to capture as transport by means of a vehicle, which is designed for the primary purpose of carrying a person who requires medical treatment. Regulation by the Care Quality Commission will address the risks inherent in this activity, which, in addition to the vulnerability of the patients, include issues around the suitability and cleanliness of the vehicle and equipment, and the fitness of the staff.

A38. For remote urgent health advice and triage, we found that the greatest risk is from misdiagnosis, likely to be due to the diagnosis algorithm used. Our decision to include this as a regulated activity was informed by the volume of people that use this service.

Maternity and midwifery services

A39. This activity brings private and voluntary sector providers of maternity and midwifery services that are regulated under the CSA and NHS providers of these services into the scope of registration. They would not otherwise be captured by the treatment for disease, disorder or injury regulation.

A40. The risks in these services are similar to those in the services captured by the treatment for disease, disorder or injury activity. The respondents to the consultation earlier this year supported this being a regulated activity.

A41. We have excluded support services that we consider to have low risk, such as antenatal classes, and lay advisory services. We think a requirement to register would be disproportionate, and could put people off providing those services.

A42. We have also temporarily excluded midwifery services provided by independent midwives, where they only provide services at the home of the person who uses the service. This is because the sector is not yet sufficiently prepared for regulation. We do consider these services to be inherently risky but bringing them into regulation at this time would create a burden that would be likely to drive providers out of business, and would therefore be disproportionate. The Department is developing policy to support these providers in operating as part of third sector organisations, which will give a corporate umbrella under which to work. These organisations will provide systems of contracting and corporate governance that will support independent midwives in their provision. It is our intention to bring these organisations into regulation in the future.

Termination of pregnancies

A43. This activity brings private and voluntary sector providers of termination of pregnancy services that are regulated under the CSA and NHS providers of these services into the scope of registration.

A44. The risks in these services are similar those in the services captured by the treatment for disease, disorder or injury activity. The respondents to the consultation earlier this year supported this being a regulated activity.

Services in slimming clinics

A45. This activity covers medical services provided in slimming clinics, which include prescribing medicines for the purpose of weight loss, that are currently regulated under the CSA.

A46. The risks are similar to those inherent in treatment for disease, disorder or injury, for example, poor quality care because staff are not properly trained or supervised, but these services would not necessarily be captured within that activity. There are some additional specific risks linked to this activity, including the prescribing of very strong drugs, for example amphetamines, which may be prescribed outside of the use that they are recommended for. We also consider the people who use these services to be relatively vulnerable. They are often seeking quick results to a distressing condition, with high risks,

and may not receive appropriate advice or referrals onwards. System regulation would address both of these. This activity was not part of the consultation earlier this year.

Nursing care

A47. This activity will bring private and voluntary healthcare providers and nursing agencies, as well as NHS providers of nursing care into regulation.

A48. The risks are similar to those for personal care and the treatment for disease, disorder or injury activities.

Family planning services

A49. This activity will bring private and voluntary healthcare providers of the fitting of intrauterine devices, that are currently regulated under the Care Standards Act and NHS providers of these services, into the scope of registration.

A50. We do not expect any independent sector providers to be captured solely under this regulation. They are likely to have to register as providers of other regulated activities (eg nursing care, termination of pregnancy, maternity and midwifery services, or treatment for disease, disorder or injury). The regulation ensures that the Care Quality Commission is able to assess the service that those providers are providing against the registration requirements. Because it is not in itself treatment for disease, disorder or injury, where it is carried out by a healthcare professional (other than a nurse), it would not otherwise be subject to regulatory oversight.

A51. There may be a small number of NHS community clinics that are only captured by this regulation. We considered regulating a range of contraceptive service provision but decided that only the most risky, ie the fitting of intra uterine contraceptive devices, should be a regulated activity. These require additional training that is not required for other forms of contraception. Widening the scope to capture other forms of contraception would be likely to bring otherwise unregulated providers into the scope of registration, and be disproportionate.

A52. The risks are similar to those inherent in treatment for disease, disorder or injury, for example, poor quality care because staff are not properly trained or supervised, but these services would not be captured within that activity. We did not specifically include this activity in the consultation earlier this year, but respondents suggested that it should be added to the scope of registration because it would not be captured elsewhere.

Annex B: Calculating potential costs and savings to the regulator of moving to the new system of registration.

B1. We try to calculate the potential impact of the new regulatory framework by comparing it to the frameworks already in place, namely the Annual Health Check for NHS trusts and the Care Standards Act for adult social care providers and independent sector (IS) health providers.

Healthcare

B2. Considering the regulation for healthcare first, the new system is in some ways similar to the Annual Health Check because the regulator can set out the compliance criteria that need to be met and hence can be more targeted and flexible to the provider it is regulating. Additionally the new system will be provider or organisation based like the Annual Health Check and not location based like the Care Standards Act system.

B3. However, the Annual Health Check also encompasses comparison against National Targets, an assessment of financial management, and checks PCTs' performance as commissioners as well as providers. The Annual Health Check also does not lead to any legally enforceable sanctions against poor performance. There is therefore only so much similarity between the Annual Health Check and the new system of registration.

B4. The new system does also have similarities to the Care Standards Act system for IS providers, in that the registration requirements are legally enforceable. However, as NHS Trusts have never been subject to this system, only approximate comparisons can be made between what current providers pay for regulation under the CSA and what an NHS Trust may pay.

B5. We compare the cost of regulating NHS Trusts under the Annual Health Check with the potential cost of regulating the same Trusts under the Care Standards Act to obtain two estimates of costs. The Healthcare Commission has previously estimated £18.2 million to be the minimum spending for an Annual Health Check on 395 trusts. However, as already mentioned, the 152 commissioners[21] are also subject to this check, and so we must adjust for this to estimate that the cost per provider is £33,270.[22]

B6. We can compare this potential cost of registration for NHS trusts under an Annual Health Check system, to what it may cost for them to be registered under the Care Standards Act. This would then give us an alternative estimate of the costs of a registration system for NHS Trusts.

B7. In 2008/09, an average IS hospital cost the Healthcare Commission £3600 per year to regulate[23]. It would not be appropriate to apply this cost to NHS trusts. NHS Trusts generally provide care over a number of different sites and perform a more complex range of procedures than IS hospitals. The largest NHS Trust in the country has 8 sites. As the Care Quality Commission currently regulates at site level, it would therefore be reasonable to assume that it would cost 8 times as much to regulate an NHS Trust as to regulate an IS hospital. On average, NHS trusts have fewer sites, but in order to allow for the error due to the increase in complexity, we shall assume all NHS Trusts operate on 8 sites. This means that the regulation of an NHS trust under the old rules would be about £29,000.

[21] The CQC carries out checks on 395 Trusts, but carries out two checks on PCTs and Care Trusts, one in their provider function and one in their commissioning function. There are 147 PCTs and 5 Care Trusts, meaning the CQC is actually carrying out 547 checks.
[22] £18.2m/547 = £33.270
[23] Supplied by Healthcare Commission. This includes all fixed costs, and therefore multiplying may lead to an overestimate as doubling the number of sites would not double the fixed costs of regulation.

B8. There are many limitations with this second method, but it is helpful as a way of triangulating our estimate of £33,270 using the costs of the Annual Health Check. It does support the assertion that £33,270 is a sensible estimate.

B9. The main difference between both systems used above and the new system is that the Care Quality Commission would have the power to be more targeted with inspections and use a more risk based approach to regulation. We shall therefore assume there is the capacity for the Commission to make up to 10% of savings, as a 'best case scenario' and no savings as a 'worst case scenario'. This would lead to potential annual savings to the Care Quality Commission of up to £1.3 million for the regulation of NHS Trusts[24].

Social care

B10. It was not possible to obtain any cost information for a regulation system for providers of adult social care devised mainly by the regulator (like the Annual Health Check in health care). We can therefore only make some assumptions on the relative saving opportunities in the regulation of adult social care compared to the IS health care. We expect the overall savings to be lower than in IS health care as:

- working with company headquarters seems to be less efficient[25] in adult social care regulation as the divergences in quality between different outlets of one company seem to be higher, and
- inspections take a greater share of the costs in the regulation of adult social care than in the regulation of IS health care.

B11. Nonetheless, as all of the changes give the Care Quality Commission more flexibility than the CSCI currently has we might expect some cost savings from the move to registration on organisation level, as the internal risk assessment of multi site providers can be used and greater flexibility of the compliance criteria compared to the National Minimum Standards.

B12. It is possible that cost savings will be small, as the CSCI has for some time concentrated its inspections and ratings on only some of the NMS and has with that achieved already a significant part of the flexibilities the new legislation will bring.

B13. We therefore estimate that the Care Quality Commission will be able to make only small savings from the money currently spent on the registration and inspection of providers (around £60 million). We therefore adopt a 'best case scenario' of achieving savings of 5% of the costs of regulating adult social care providers, and a 'worst case scenario' of achieving no savings. This would lead to potential annual savings to the Care Quality Commission of up to £2.2 million for the regulation of adult social care providers[26].

Estimates of costs to the regulator of regulating different providers (cost is per provider and only variable costs are considered for healthcare)

Independent Sector Hospitals	Private doctor (or independent clinic)	Specified technologies (lasers and lights)	Social care provider

[24] £33,270*10%*395 = £1.31 million
[25] This is our conclusion from discussions with CSCI and providers in adult social care.
[26] CQC spend £60m regulating 24,300 providers. Of these providers, 18,500 are adult social care providers (rather than nurses' agencies or domiciliary care agencies). £60m/24,300*18,500*5% = £2.24m

Assessing First time registration	£2100	£1900	£2100	£2500
Assessing Annual self assessment	£2000	£2000	£1900	
Second year inspections	£700	£350		

B14. We have attempted here to only consider the variable costs to CQC of registering each type of provider. Fixed costs are considered separately towards the end of the Impact Assessment. These are Department of Health estimates based on figures supplied by the Care Quality Commission and should be considered to be indicative only.

B15. For transition, based on figures supplied by the Care Quality Commission, we have estimated that it would cost around £110 to process each registration request from an already registered provider. This estimate again does not include any fixed costs associated with the activity, which are dealt with separately. We have used this estimate for calculating the transition costs to the Care Quality Commission of registering existing IS healthcare providers and adult social care providers.

Annex C: Cost of regulation to providers

Provider estimates of their costs due to regulation (not including fees)

	Independent Sector Hospitals	Private doctor (or independent clinic)	Social care provider
First time registration	Up to £37000	£4000	£1020
Annual self-assessment	£1500	£1500	£700
Inspections	£740	£370	£450

C1. The costs to providers of registering are based on discussions with providers.

C2. In interviews, both health and social care providers suggested that the less burdensome registration requirements could save small providers up to 30% of the cost of first time registration, but would have only a marginal impact on larger providers. This is because larger providers can benefit from economies of scale, and therefore to a certain extent can already enjoy lower administration costs. As the majority of providers are small, we estimate savings of 10-20%.

C3. Providers did not feel there would be any particular savings in terms of preparing for an inspection, therefore savings are only assumed for first time registrations and annual self-assessments.

IS healthcare providers

Benefits to providers – option 2

C4. We use an average cost to providers of first time registration of £10000[27], and assume a 10% to 20% saving on these costs. There are currently 1,360 IS providers (excluding providers of non-surgical class 3B and 4 lasers and intense pulsed light treatment). We assume there is a 15% turnover within this group[28], meaning 200 new providers register each year. This leads to savings of between £200,000 and £400,000.

C5. We use an average cost to providers of self-assessment of £1,500, and assume between 10% to 20% savings on these costs. All 1,360 providers need to complete an annual self-assessment, leading to savings of between £200,000 and £400,000.

[27] As the majority of existing IS providers are small we would estimate that the average cost of the range of £4000 to £37000 is £10000. This is based on the fact that one quarter of IS providers are acute hospitals (with costs ranging between £19,000 and £37,000), with the remainder being small providers, with estimated costs of £4000.
[28] Turnover rates supplied by CQC

C6. Only large providers would benefit from savings due to moving to organisational level. We therefore assume that these savings would only benefit a third of all first time registrations and annual self-assessments. With large providers estimating the cost of registration to be £37,000, and an annual self-assessment costing £2,000, we assume savings to be between 5% and 15% of these costs[29]. There are 200 providers obtaining first time registration each year and 1,360 providers overall, leading to savings of around £0.1 to £0.4 million for first time registration and £0.03 to £0.1 million for annual self assessments.

C7. Early work conducted by the Care Quality Commission on the possible transitional costs to providers suggests that the administration associated with filling out the forms for transition should be fairly low. There will, however, also be costs associated with providers satisfying themselves that they have sufficient information to support their declarations.

C8.As it is difficult to estimate these costs, we have assumed that the cost of transition would be similar to those for an annual self-assessment (£1,200 to £1,350). This should be an overestimation, as providers will have also conducted a self-assessment in that year and so should be able to compile all necessary information relatively easily. However, as it is a new process, providers may want to take more time to ensure they have completed it properly, and therefore we shall use the estimate above.

C9. Using the cost of between £1,200 and £1,350 for transition, and with 1,360 IS providers, we estimate that the transition process could cost these providers between £1.6 million and £1.8 million.

Adult social care services

Costs to providers – option 2

C10. We use an average cost to social care providers of first time registration of £1,020, and assume 10%-20% savings on these costs. There are currently 1,230 Local Authority run providers of adult social care[30]. We assume there is a 10% turnover within this group[31], meaning 120 new providers register each year. This leads to savings of between £13,000 and £25,000 per year.

C11. We use an average cost to providers of self-assessment of £700[32], and assume 10%-20% savings on these costs. All 1,230 providers need to complete an annual self-assessment, leading to savings of between £0.1 million and £0.2 million per year.

C12. Only large providers would benefit from such savings due to registration moving to organisational level. However, with 1,230 providers and only 150 local authorities, on average each local authority has over 8 providers and therefore would benefit from savings. We assume that between a third and two thirds of costs can be saved for these large providers, with large providers estimating the cost of registration to be £1,020, and an annual self-assessment to cost £700. Assuming 120 new registrations each year and 1230 providers overall, this leads to annual savings of between £42,000 and £83,000 for first time registration and between £0.2 million and £0.3 million for annual self-assessments.

[29] Further details of the assumptions for this calculation can be found in the Impact Assessment for the Health and Social Care Bill 2008.
[30] The state of social care in England 2007-08, CSCI 2009
[31] Turnover rates supplied by CQC
[32] In interviews, providers estimated they spent between one and five person-days completing their annual self-assessment. We estimate the average to be three days, costing around £700. The variations of this estimate are wide as providers save time if they produce the Annual Care Quality Assessment for a second time.

C13. We assume that social care providers will not incur any significant transition costs. This is because the Care Quality Commission are intending to make the transition as unburdensome as possible, and tie it in with the annual self -assessment. The process may even be simpler than the current self-assessment, but we shall assume that any simplicity will be offset by extra time providers may need to become familiar with the new system.

Benefits to providers – option 2

C14. We use an average cost to social care providers of first time registration of £1,020, and assume 10%-20% savings on these costs. There are currently 17,300 privately run providers of adult social care[33]. We assume there is a 10% turnover within this group[34], meaning 1,700 new providers register each year. This leads to annual savings of between £0.2 million and £0.4 million.

C15. We use an average cost to providers of self-assessment of £700[35], and assume 10%-20% savings on these costs. All 17,300 providers need to complete an annual self-assessment, leading to annual savings of between £1.2 million and £2.4 million.

C16. Only large providers would benefit from such savings due to registration moving to organisational level. We therefore assume the savings would only benefit 25-35% all first time registrations and annual self-assessments. We assume up to two thirds of costs can be saved for these large providers, with large providers estimating the cost of registration to be £1,020, and an annual self-assessment to cost £700. Assuming 1,700 new registrations each year and 17,000 providers overall, this leads to annual savings of between £0.3 million and £0.4million for first time registration and between £2.0 million and £2.8 million for annual self-assessments.

C17. As with LA run providers, we assume that private social care providers will not incur any significant transition costs.

<u>NHS provided healthcare services</u>

Costs to providers – option 2

C18. It is difficult to estimate the annual costs on NHS providers for registration. We would anticipate that the process should be similar to that for the Annual Health Check. However, there may also be additional costs on NHS Trusts as they would now have to notify the Care Quality Commission if they were to make a variation to their registration. It is very difficult to estimate the likelihood of this event, as it depends on what circumstances the Care Quality Commission wishes to be notified on, as well as how often such changes take place. If, for example, the Care Quality Commission only wanted to be notified of the opening of a new site, we would not expect this to happen regularly. We would also not expect this to be an administratively burdensome task. We have therefore chosen not to attempt to quantify these annual costs, although we do acknowledge that, whilst they may not be significant, they are likely to be positive.

C19. The closest comparator we have for the transitional cost for an NHS Trust entering registration is the cost to an Independent Sector (IS) hospital. These have been estimated after discussions with IS hospitals.

[33] The state of social care in England 2007-08, CSCI 2009
[34] Turnover rates supplied by CQC
[35] In interviews, providers estimated they spent between one and five days completing their annual self-assessment. We estimate the average to be three days, costing around £700. The variations of this estimate are wide as providers save time if they produce the Annual Care Quality Assessment for a second time.

C20. We could compare the transition cost to an NHS Trusts to the cost of first time registration for an Independent Sector hospital. This cost is estimated to be around £18,000-£37,000. However, there are various reasons for believing that the cost would be significantly lower for an NHS Trust.

- The main reason is that Trusts are already part of the Annual Health Check and so the Care Quality Commission will already have access to a substantial amount of information. They will therefore not ask for as much information from an NHS Trust, and the information they do ask for should be easier to gather than for a new Independent Sector hospital.
- The new system should also be less burdensome than the old system. The registration requirements are outcome-focussed, rather than process focussed, and Independent Sector hospitals have already predicted this could make it 10-20% cheaper than the current system.
- The new system also allows providers to register at organisational rather than at site level, which should again lead to some economies of scale.

C21. It could be argued that the process will be more similar in cost to an annual self-assessment for an independent sector hospital. This is estimated to be £1,500.

- NHS Trusts are already familiar with the Annual Health Check system, so it would not be so onerous to gather the information necessary.
- However, given it is still a different system to the Annual Health Check system, Trusts will have to take more time to familiarise themselves with the process.
- Trusts are also potentially more complex organisations than Independent Sector hospitals.

C22. Given we expect the process to be far less burdensome than first time registration for IS hospitals, but still more onerous than an IS hospital annual self-assessment, we have used an estimate of between £3,000 and £6,000 for NHS Trusts. This is then multiplied by the 395 trusts to arrive at an estimate of between £1.2million and £2.4million.

Costs to providers – option 3

C23. Option 3 would offer the same costs as option 2.

Prison health services in private prisons

Costs to providers – option 2

C24. We use an average cost to private providers of first time registration of between £3,200 and £3,600, as we have assumed 10%-20% savings on normal costs. This is using hospitals providing listed services as a proxy for costs[36]. There are currently 10 privately run providers of prison health services in private prisons. We assume a 10% turnover rate, meaning 1 new provider registers each year. This leads to annual costs of up to £3,600.

C25. We use an average cost to providers of self-assessment of between £1,200 and £1,350, as we have assumed 10%-20% savings on normal costs. As we believe 7 of the prisons

[36] Interviews with IS providers suggested a range of between £3000 and £37000 for first time registration. For small providers, such as private prisons, we assume a cost of £4000.

have their healthcare managed by another registered provider, we estimate that only up to 3 providers need to complete an annual self-assessment, leading to costs of up to £4,000.

C26. We use an average cost to providers of inspections of £740 and assume 20% of providers would be subject to inspection each year[37]. This leads to annual costs of £1,500 per year.

C27. As private prisons are registering for the first time, there will be transitional costs associated with registration in the first year, and with inspections. We use an average cost to private providers of first time registration of between £3,200 and £3,600, as we have assumed 10%-20% savings on normal costs. We assume that it cost providers £740 to prepare for an inspection. With between 0 and 3 providers registering for the first time, this leads to transitional costs of up to £11,000 for first time registration. We assume all 10 providers will be inspected in the first year, leading to costs of £7,400 for first year inspections.

Costs to providers – option 3

C28. Option 3 would offer the same costs as option 2.

Immigration removal centres

Costs to providers – option 2

C29. We use an average cost to private providers of first time registration of between £3,200 and £3,600, as we have assumed 10%-20% savings on normal costs. There are currently 9 privately run providers of immigration services. Two are already registered with the Care Quality Commission. We assume a 10% turnover rate, meaning 1 new provider registers each year. This leads to annual costs of up to £3,600.

C30. We assume that the cost to smaller immigration services of self-assessment would be similar to those of a private doctor, and assume 10%-20% savings on these costs. There are currently 7 privately run providers of immigration services, offering primary care. However, many of these establishments commission their healthcare from local NHS Trusts or private companies. We assume that up to 4 of the immigration removal centres may actually be registering in their own right. All these providers need to complete an annual self-assessment, leading to costs of up to £5,500.

C31. We use an average cost to providers of inspections of £370 and assume 20% of providers would be subject to inspection each year[38]. This leads to annual costs of £370 per year.

C32. As immigration removal centres are registering for the first time, there will be transitional costs associated with registration in the first year, and with inspections. We use an average cost to these centres of first time registration of between £3,200 and £3,600, as we have assumed 10%-20% savings on normal costs. We assume that it cost providers £370 to prepare for an inspection. With between 0 and 4 providers registering for the first time, this leads to transitional costs of up to £14,500 for first time registration. We assume all 7 newly registered providers will be inspected in the first year, leading to costs of £2,500 for first year inspections.

Costs to providers – option 3

[37] Inspection rates supplied by CQC. We use the same inspection rate for all privately owned providers.
[38] Inspection rates supplied by CQC. We use the same inspection rate for all privately owned providers.

C33. Option 3 would offer the same costs and benefits as option 2.

Transport services using vehicles designed to carry patients

Benefits to providers – option 2

C34. We use an average cost to transport services of first time registration of between £3,200 and £3,600, as we have assumed 10%-20% savings on normal costs. There are currently up to 300 providers of private transport services. We assume a 20% turnover rate, meaning 60 new providers register each year. This leads to costs of up to £220,000.

C35. We use an average cost to providers of self-assessment of between £1,200 and £1,350, as we have assumed 10%-20% savings on normal costs. All 300 providers need to complete an annual self-assessment, leading to costs of up to £410,000.

C36. We use an average cost to providers of inspections of £370, and assume full savings on these costs. We assume 17% of the up to 300 providers would be subject to inspection each year[39]. This leads to costs of up to £40,000 per year.

C37. In the transition year, we assume that all providers (between 0 and 300) need to register for the first time, and be inspected in the first year of registration. Assuming first time registration costs a provider between £3,200 and £3,600, this leads to a transition cost of up to £1.1 million for providers of specialist transport services to register. Assuming it costs a provider £370 to prepare for an inspection, this leads to costs of up to £0.2 million for providers to be inspected in the first year.

Benefits to providers – option 3

C38. Option 3 would offer the same costs and benefits as option 2.

Accommodation with treatment for drug and alcohol misuse

Benefits to providers – option 2

C39. We use an average cost to social care providers of first time registration of £1020, and assume 10%-20% savings on these costs. There are currently 21 privately run substance misuse clinics. We assume there is a 25% turnover within this group, meaning 5 new providers register each year. This leads to savings of between £4,200 and £4,800.

C40. We use an average cost to providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 21 providers need to complete an annual self-assessment, leading to costs of between £12,000 and £13,000.

C41. We use an average cost to providers of inspections of £450 and assume 60% of the 21 providers would be subject to inspection each year[40]. This leads to annual costs of £6,000 per year.

C42. As substance misuse clinics are registering for the first time, there will be transitional costs associated with registration in the first year, and with inspections. We use an average cost to providers of first time registration of between £820 and £920, as we have assumed 10%-20% savings on normal costs. We assume that it cost providers £450 to prepare for an

[39] Inspection rates supplied by CQC
[40] Inspection rates supplied by CQC

inspection. With 21 providers, this leads to transitional costs of between £17,000 and £19,000 for first time registration and £9,000 for first year inspections.

C43. We assume that substance misuse clinics would not benefit from the move to organisational level. We therefore may be underestimating the potential savings to this set of providers.

Benefits to providers – option 3

C44. Option 3 would offer the same costs and benefits as option 2.

Non-surgical class 3B and 4 lasers and intense pulsated light treatment

Benefits to providers – option 2

C45. We use an average cost to providers of first time registration of £4000[41], and assume full savings on these costs. There are currently 1000 providers of non-surgical class 3B and 4 lasers and intense pulsed light treatment. We assume there is a 15% turnover within this group[42], meaning 150 new providers register each year. This leads to savings of £800,000 per year.

C46. We use an average cost to providers of self-assessment of £1,500, and assume full savings on these costs. All 1000 providers need to complete an annual self-assessment, leading to savings of £1.5 million per year.

C47. We use an average cost to providers of inspections of £370, and assume full savings on these costs. We assume 25% of the 1,000 providers would be subject to inspection each year[43]. This leads to savings of £0.1 million per year.

Benefits to providers – option 3

C48. If we were to include these providers into the new system of registration, we would expect all such providers to register, rather than the 1,000 providers that currently do so. We use an average cost to providers of first time registration of £4,000[44], and assume a 10% to 20% saving on these costs. There are currently approximately 5,000 providers of non-surgical class 3B and 4 lasers and intense pulsed light treatment. We assume between 4,000 and 5,000 would register. We assume there is a 15% turnover within this group[45], meaning between 600 and 750 new providers register each year. This leads to costs of between £1.3 million and £2.1 million.

C49. We use an average cost to providers of self-assessment of £1,500, and assume between 10% to 20% savings on these costs. All 4,000 to 5,000 providers need to complete an annual self-assessment, leading to costs of between £3.3 million and £5.2 million.

C50. We assume 25% of all providers are subject to inspection each year, meaning between 1,000 and 1,250 providers would be inspection. Using a cost to providers of £370, this leads to costs of between £0.3 million and £0.4 million.

[41] We use the costs to private doctors as a proxy.
[42] Turnover rates supplied by CQC
[43] Inspection rates supplied by CQC
[44] We use the costs to private doctors as a proxy.
[45] Turnover rates supplied by CQC

C51. In the transition year, we estimate between 4,000 and 5,000 providers would register with the new system. We estimate these transition costs to be similar to those for an annual self-assessment (between £1,200 and £1,350). This implies transition costs of between £4.8 million and £6.8 million. In addition, the 3,000 to 4,000 providers that were registering for the first time would be subject to an inspection in the transition year, leading to additional costs of between £1.1 million and £1.5 million.

Nurses agencies solely providing staff to other registered providers

Benefits to providers – option 2

C52. We use an average cost to social care providers of first time registration of £1,020, and assume full savings on these costs. There are currently 730 privately run providers of nurses' agencies[46]. We assume there is a 10% turnover within this group[47], meaning 70 new providers register each year. This leads to savings of between £7,000 and £75,000.

C53. We use an average cost to providers of self-assessment of £700, and assume full savings on these costs. All 730 providers need to complete an annual self-assessment, leading to savings of between £50,000 and £510,000.

C54. We use an average cost to providers of inspections of £450, and assume full savings on these costs. We assume 60% of the 730 nurses' agencies would be subject to inspection each year[48]. This leads to savings of up to £0.2 million per year.

C55. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

Benefits to providers – option 3

C56. We use an average cost to social care providers of first time registration of £1020, and assume 10%-20% savings on these costs. There are currently 730 privately run providers of nurses' agencies[49]. We assume there is a 10% turnover within this group[50], meaning 70 new providers register each year. This leads to savings of between £7,000 and £15,000.

C57. We use an average cost to providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 730 providers need to complete an annual self-assessment, leading to savings of between £50,000 and £100,000.

C58. We assume that nurses' agencies would not benefit from the move to organisational level. We therefore may be underestimating the potential savings to this set of providers.

C59. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

Domiciliary care agencies solely providing staff to other registered providers

Costs to providers – option 2

[46] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[47] Turnover rates supplied by CQC
[48] Inspection rates supplied by CQC
[49] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[50] Turnover rates supplied by CQC

C60. We use an average cost to social care providers of first time registration of £1020, and assume 10%-20% savings on these costs. There are currently 680 Local Authority run providers of domiciliary care[51]. We assume there is a 10% turnover within this group[52], meaning 70 new providers register each year. This leads to annual savings of between £7,000 and £70,000.

C61. We use an average cost to social care providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 680 providers need to complete an annual self-assessment, leading to annual savings of between £48,000 and £480,000.

C62. We use an average cost to providers of inspections of £450, and assume full savings on these costs. We assume 60% of the 680 providers would be subject to inspection each year[53]. This leads to savings of up to £190,000 per year.

C63. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

Benefits to providers – option 2

C64. We use an average cost to social care providers of first time registration of £1,020, and assume 10%-20% savings on these costs. There are currently 4,450 privately run providers of domiciliary care[54]. We assume there is a 10% turnover within this group[55], meaning 450 new providers register each year. This leads to savings of between £45,000 and £450,000.

C65. We use an average cost to private providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 4,450 providers need to complete an annual self-assessment, leading to savings of between £310,000 and £3.1m.

C66. We use an average cost to providers of inspections of £450, and assume full savings on these costs. We assume 60% of the 4,450 providers would be subject to inspection each year[56]. This leads to savings of up to £1.2 million per year.

C67. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

Costs to providers- option 3

C68. We use an average cost to social care providers of first time registration of £1020, and assume 10%-20% savings on these costs. There are currently 680 Local Authority run providers of domiciliary care[57]. We assume there is a 10% turnover within this group[58], meaning 70 new providers register each year. This leads to annual savings of between £7,000 and £14,000.

C69. We use an average cost to Local Authority providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 680 providers need to complete an annual self-assessment, leading to annual savings of between £48,000 and £95,000.

[51] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[52] Turnover rates supplied by CQC
[53] Inspection rates supplied by CQC
[54] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[55] Turnover rates supplied by CQC
[56] Inspection rates supplied by CQC
[57] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[58] Turnover rates supplied by CQC

C70. We assume that domiciliary care agencies would not benefit from the move to organisational level. We therefore may be underestimating the potential savings to this set of providers

C71. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

Benefits to providers – option 3

C72. We use an average cost to social care providers of first time registration of £1,020, and assume 10%-20% savings on these costs. There are currently 4,450 privately run providers of domiciliary care[59]. We assume there is a 10% turnover within this group[60], meaning 450 new providers register each year. This leads to annual savings of between £45,000 and £90,000.

C73. We use an average cost to private providers of self-assessment of £700, and assume 10%-20% savings on these costs. All 4,450 providers need to complete an annual self-assessment, leading to annual savings of between £311,000 and £624,000.

C74. We assume that domiciliary care agencies would not benefit from the move to organisational level. We therefore may be underestimating the potential savings to this set of providers.

C75. As with other social care providers, we assume that the transition costs to providers would be cost-neutral.

[59] The state of social care in England 2007-08, CSCI 2009. We assume all providers are privately run.
[60] Turnover rates supplied by CQC

Annex D: Benefits to NHS Trusts

D1. The Annual Health Check uses 24 core standards (comprised of 44 part standards). In their self-assessment, trusts declare whether or not they have complied with each of the 44 part standards. Trusts may also declare that insufficient assurance of compliance with a standard was available. From our discussions with the Healthcare Commission, we understand that trusts that declare non-compliance or insufficient assurance for five or more standards are potential candidates for risk-based inspection.

D2. Using non-compliance or insufficient insurance on five or more part standards as our definition of non-compliance, we model the gains from registration by assuming that the formal registration system would make it very unlikely that trusts would be found non-compliant in two consecutive years. If trusts are non-compliant in one year, they will face enforcement action, or the threat of enforcement action, which will give them a strong incentive not to fail for a second time. The subsequent reduction in non-compliant trusts arising from this new constraint is the gain from registration.

D3. We first consider the resultant improvement in performance of PCTs, before considering all other trusts. We then use an index of trust output to estimate the value of the estimated improvement in performance.

D4. In 2006-2007, 38 PCTs were not compliant with five or more part standards, of which 19 (50%) continued to be non-compliant again in 2007/08. Of the 114 trusts that passed in 2006-07, 6 were then non-compliant in 2007-08, bringing the overall number of non-compliant trusts in 2007-08 to 25.

D5. In 2007-2008, 25 PCTs were not compliant with five or more part standards, of which 13 (52%) continued to be non-compliant again in 2007/08. Of the 127 trusts that passed in 2007-08, 2 were then non-compliant in 2008-09, bringing the overall number of non-compliant trusts in 2008-09 to 15.

D6. Without new regulation, we assume that 51%[61] of PCTs who are non-compliant in one year continue to be non-compliant in the next year, and that 4[62] formerly compliant PCTs become non-compliant PCTs in this year, we can predict that the number of non-compliant PCTs would converge on around 8 per year in the medium term[63].

D7. However, if we assume that registering PCTs would lead to no consecutive years of non-compliance by PCTs, then the number of non-compliant PCTs per year would fall to 4, as only formerly compliant PCTs might be non-compliant in every subsequent year. Therefore, the registration system is estimated to reduce the number of non-compliant PCTs by 4 a year.

D8. For all other trusts, the picture is quite similar. Of the 20 instances of non-compliance in 06/07, 9 (45%) continued to be non-compliant in 07/08. In addition to this, 8 trusts who had passed in 06/07 were non-compliant in 07/08, bringing the total number of non-compliant trusts in the second year to 17.

D9. In 08/09, 9 of the 17 instances of non-compliance (53%) in 07/08 continued to be non-compliant. In addition to this, 23 trusts who had passed in 07/08 were non-compliant in 08/09, bringing the total number of non-compliant trusts in the second year to 32.

[61] Found by taking an average of 50% and 52%.
[62] Found by taking an average of the 2 and 6 newly non-compliant trusts.
[63] In this case the number of non-compliant PCTs converges to 8 after six years.

D10. Without new regulation we assume that 49%[64] of trusts who are non-compliant in one year continue to be non-compliant in the next year, and that 16[65] formerly compliant trusts cease to comply in this year, so we predict that the number of non-compliant trusts will converge on around 31 in the medium term[66].

D11. However, if we assume that registering trusts would lead to no consecutive years of non-compliance by trusts, then the number of non-compliant trusts per year would fall to 16. Therefore, a registration system is estimated to reduce the number of non-compliant trusts by 15 a year.

D12. Overall, of the trusts that failed five or more part standards, the average number of failed part standards was 8.7. We have estimated that registration will reduce the number of non-compliant trusts by around 19 per year. On average, each of these trusts must pass at least 4 more standards to avoid sanctions. This would imply a total annual gain of nearly 70 part standards, meaning that in 19 Trusts the number of complied part standards would rise by nearly 10% or the total number of complied part standards would rise by 0.4%.

D13. To value these improvements we have to assess the quality improvement achieved by complying with more standards and then value this improvement.

D14. We treat the improvement gained from compliance with any standard as the same.[67] To assess the quality improvement we note that the difference in terms of quality for patients between complying with a standard and not complying might be very big or very small depending on the practice of the Trust when not complying.

D15. If we assume that a model trust (complying with all standards) is 25% higher quality than a hypothetical trust that fails all standards, which seems a conservative assumption, then we estimate that increasing compliance by 0.4% will raise quality by 0.1%.[68] We estimate that this rise in quality is worth 0.1% of the total spending on secondary healthcare, using the assumption that a 1% improvement in quality is equal to a 1% increase in quantity[69] . In 2006-2007 this spending was £67 billion[70], which gives us an estimate of the value of improvement of £67 million.

[64] Found by taking the average of 53% and 45%.
[65] Found by taking the average of 23 and 6 newly non-compliant trusts.
[66] In this case, the number of non-compliant PCTs converges to 31 after three years.
[67] Although different standards will yield different improvements this is a safe assumption as the standards the Trusts have failed in our dataset are relatively evenly distributed over the standards, so that we can assume that the gains would be evenly distributed too.
[68] 25% x 0.4
[69] This assumption is used, for example, by the recent DH publication "Further Developments in Measuring Quality Adjusted Healthcare Output".
[70] Department of Health, 2008. £6.5 billion was spent by Mental Health Trusts, £11.1 billion by Care Trusts, £37 billion by Acute Hospital and Foundation Trusts and £2.8 billion by Ambulance Trusts. £9.3 billion was spent on Community Services.

Annex E: Compliance costs to providers as a result of registration

Compliance costs

E1. The costs described in the costs to providers section can be defined as the costs that providers must incur to prove that they are complying with the registration requirements. In addition to those costs, the requirements may also cause providers to make improvements in order to comply with registration.

E2. It is important to understand the exact definition of compliance costs in this context. The compliance costs of registration are the costs that an efficient provider would have to bear as a result of the registration. For example, a provider may operate over a number of sites. All these sites may have adequate systems for ensuring they listen to the feedback of their patients. However, as a result of registration, the provider may now need to develop a system at provider level to ensure it can capture this localised feedback, in order to demonstrate it is complying. The cost of this additional system which has now become necessary, although the mechanisms for gathering feedback were already adequate at the local level, would be considered to be a compliance cost..

E3. The size of these extra costs are difficult to estimate at this time as they will be influenced by the exact compliance guidance which, other than for the regulation on healthcare acquired infection, is not yet finalised. Providers must comply with the regulations and may comply in a manner that, in their particular circumstances, is at least or more efficient than that envisaged by compliance guidance. In developing the compliance guidance, the Care Quality Commission is required to be proportionate and will therefore need to consider the costs and benefits of expected forms of compliance. For the purposes of this assessment we assume that the compliance guidance will set similar (though less prescriptive) expectations than existing standards through NMS and the Annual Health Check. If compliance guidance applied by the Commission in judging compliance were to be disproportionately costly to providers in comparison to the benefits of compliance, its decisions could face challenge.

E4. Again, we distinguish between two different types of providers.

- First, we discuss the changes to compliance costs that might affect existing providers.
- Secondly, we analyse the effects of the introduction of the regulation system to existing providers coming into scope of regulation for the first time and the changes to compliance cost we can expect from that. In this section, we will discuss how many providers might have to improve their level of service delivery due to the introduction of the formal registration system and what the impacts on their costs might be.

Compliance Costs of providers already subject to registration

E5. The new regulations and compliance guidance will define in less detail how the registered providers should achieve the required standards as the old system did. As the new regulations will not specify how an outcome is to be achieved, providers will have the scope to comply with the registration requirements in the most efficient way for their own circumstances. This should reduce the compliance costs to providers.

E6. However, since outcome-based regulation is more open to interpretation by inspectors, some providers may be unsure of whether their chosen method of compliance would satisfy the regulator. This may lead some providers to undertake unnecessarily costly actions to ensure that they meet their inspector's interpretation of compliance, increasing the policy costs of regulation. This is especially true of small providers that lack the resources to seek

legal advice. However, we would expect this risk to reduce as the approach taken by the regulator as set out in compliance guidance becomes better understood and hence compliance costs to be lower for providers that are currently registered.

E7. For providers already subject to regulation we would expect lower costs of regulation and with that a positive impact on the availability of services if any at all.

Compliance costs of providers coming into scope of registration for the first time

E8. Providers who are judged as failing to comply with the Regulations, will have to change their behaviour to maintain their registration.

E9. For NHS providers the registration requirements are set at a level that providers should be able to achieve with their current allocation of resources given that, at present, most providers achieve the quality of treatment required by Standards for Better Health and registration requirements are set at a similar level to this. If the funding formula allows all providers to achieve the same quality of provision then all providers should be able to comply. The Care Quality Commission is also required to take into consideration the costs of regulation to providers, and ensure they impose the minimum burden possible to achieve the objectives of regulation[71]. Providers that are not compliant will have to change their behaviour in order to meet the registration requirements.

E10. For services transporting patients requiring special vehicles, indications are that a number of private providers will need to make significant improvements to their service. This will be a new obligation which is likely to give rise to a compliance cost. Private providers are likely to pass on the additional costs of meeting the standards to the NHS when contracts are next negotiated. Again, the Care Quality Commission are required to be proportionate to ensure that the costs of registration to providers are not disproportionate to the benefits of registration.

[71] Statutory code of practice for regulators, BERR, December 2007

Annex F: Enforcement action

F1. Enforcement action taken by CSCI and the Healthcare Commission in 2008/09 under the Care Standards Act is shown in the table below.

Enforcement action	Commission for Social Care Inspection	Healthcare Commission
Requirement notice (social care providers only)	874	n/a
Statutory notice	465	44
Cancellation of registration	101	7
Urgent cancellation of registration	9	0
Prosecution	12	2

F2. The Health and Social Care Act 2008 provides the Care Quality Commission with three new powers to bring about compliance with registration requirements. These are:

- issue a warning notice;
- issue a monetary penalty notice in lieu of prosecution;
- suspend registration.

F3. In addition, under both the Care Standards Act and the Health and Social Care Act, the regulator is able to impose, vary and remove conditions on a provider's registration.

F4. The additional enforcement powers have been introduced in order to give the Care Quality Commission a greater range of options when considering taking enforcement action. In particular, the new options of suspending registration (rather than simply having the option of permanent cancellation) and of issuing a monetary penalty notice in lieu of prosecution should both reduce costs associated with taking enforcement action.

F5. In the case of suspension, this enforcement action will allow the provider an opportunity to resolve significant safety and quality issues during a period of suspension that does not exist in the current arrangements. Assuming that the provider is able to address the issues that led to the suspension, this has the potential to reduce the number of cancellations of registration. In turn, this will reduce the number of appeals by providers to the First-tier Tribunal (the bulk of which relate to cancellation of registration) leading to a saving for the Care Quality Commission in defending its actions before the Tribunal.

F6. Similarly, the option of issuing monetary penalty notices in lieu of prosecution for a number of offences provides the Care Quality Commission with the option of taking action outside of the courts. This again is likely to lead to a reduction in legal costs associated with pursuing such prosecutions.

F7. While we acknowledge that there is no robust empirical basis for estimating the costs associated with the reformed enforcement powers available to the Commission, we anticipate that there is unlikely to be any significant change in costs. This is because while the greater range in powers may increase the level of enforcement action undertaken by the Commission, the option of taking alternative approaches such as suspension or issuing monetary penalty notices has the potential to reduce the average cost of each piece of enforcement action.

Annex G: Competition Assessment

Executive summary

G1. This competition assessment aims to assess the effect on competition of the scope and registration requirements of the new regulator, the Care Quality Commission, which will register all health and social care providers within its scope from April 2010. The new system of regulation is likely to have a small, positive effect on competition in health and adult social care markets.

Main impacts on competition of the new regulatory framework

G2. The move to corporate level registration should have a small, positive effect on competition, by reducing the cost of expanding into new markets.

G3. There is a risk that the extension of the scope of regulation may cause some providers to exit the market due to the costs of registration (or to withdraw parts of their service to avoid registration), reducing competition and coverage in these markets.

G4. A common system of registration will apply to all providers of regulated activities, including NHS providers. The new system will create a more level-playing field for all providers, encouraging competition.

G5. Outcome focused registration requirements will allow providers to deliver services in the most efficient way for their organisation, leading to increased innovation and more competition on the basis of service delivery.

Introduction

G6. The purpose of this competition assessment, within the context of the wider Impact Assessment for the scope of the Care Quality Commission, is to assess whether the changes to the regulatory framework directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete, or reduce suppliers' incentives to compete vigorously in health and social care markets.

G7. In April 2009, the Care Quality Commission took over the functions of the Healthcare Commission (HC), the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC).

G8. In 2009/10, the Commission will continue to regulate independent sector healthcare and adult social care under the Care Standards Act 2000. Starting from April 2010, the Care Quality Commission will operate a new registration system, covering providers of health and adult social care across all sectors, including NHS providers. This will be based in secondary legislation drawn from the Health and Social Care Act 2008.

G9. Under the new registration system, the requirement to register with the new Commission will be based on the activity being provided, rather than the organisation or setting in which a service is provided. Any provider of a regulated activity will be required to register with the Commission to provide that activity. No maximum or minimum limits will be placed on the number of providers.

G10. At present, providers must register all of their sites. Under the new system, the Care Quality Commission (CQC) will register providers at the corporate level. New providers will

need to register with the CQC, but existing providers will not need to register new sites, they will only need to vary their current registration (which is a far less burdensome process).

G11. The new registration requirements will focus on outcomes and not processes. They will specify the essential levels of quality and safety that providers must attain, without being prescriptive about how compliance is achieved. This will allow the new Guidance about Compliance publication (to be developed by the CQC) to be more outcome-based and less process-based than the current National Minimum Standards.

G12. This competition assessment, which was completed following the Office of Fair Trading's competition assessment guidance[72], considers the effect of these changes on competition in health and social care markets.

Counterfactual

G13. The counterfactual for this competition assessment is the continuation of the current regulatory framework set out in the Care Standards Act 2000. Adult social care providers and independent sector healthcare providers are currently regulated by CQC. NHS healthcare providers are subject to an Annual Health Check by the CQC, and can be investigated or inspected by CQC, but are only required to register with CQC to demonstrate compliance with infection control procedures, not to deliver services.

Definition of Markets

G14. All providers of regulated activities will need to register with the Care Quality Commission.

G15. The following activities (allowing for some specific exemptions) will be within the scope of regulation:

- Personal care
- Accommodation for persons who require nursing or personal care
- Accommodation for persons who require treatment for substance misuse
- Accommodation and nursing or personal care in the further education sector
- Treatment of disease, disorder or injury
- Assessment or medical treatment for persons detained under the 1983 Act
- Surgical procedures
- Diagnostic and screening procedures
- Management of supply of blood and blood derived products
- Transport services, triage and medical advice provided remotely
- Maternity and midwifery services
- Termination of pregnancies
- Services in slimming clinics
- Nursing care
- Family planning services

G16. The main changes to the scope of regulation are detailed in the following section.

Effect on competition of changes to the regulatory framework

G17. The following considers the effects on competition in health and social care markets of the main changes to the regulatory framework.

[72] *Completing competition assessments in Impact Assessments: Guidelines for policy makers*, Office of Fair Trading, August, 2007.

a) Introduction of a new system of registration

G18. The new system of registration will replace the current system of registration. We examine the extent to which this will affect competition by considering adult social care and independent sector healthcare providers (which are currently required to register under the Care Standards Act) and providers that are new to registration.

Adult social care and independent sector healthcare providers

G19. The change to corporate level registration will have a small positive effect on competition.

G20. Under the current system of regulation, regulated adult social care providers and independent sector healthcare providers must register all new sites. Under the new system of registration, new providers of regulated activities will be required to register, but new sites opened by existing providers will not require an application as a new service provider, rather they can be dealt with as a variation.

G21. This will reduce the costs of expansion for existing providers, but the costs of entry by new providers will be unaffected, placing new market entrants at a small disadvantage relative to existing providers who wish to open new sites. However, as the barriers to expansion by existing providers are reduced, this will have a small, positive effect on competition among existing providers.

G22. Overall, the costs of entering markets will be lower under the new registration system, and so total market entry is likely to be higher, increasing competition.

G23.The changes may have a further small effect on competition by reducing some of the uncertainty of the registration process. The current registration process for new sites is lengthy, and providers cannot be sure that registration will be granted for a new site. As a result, some providers may incur greater costs than is necessary to ensure that their site is granted registration. As new sites will no longer need a separate registration application, the new system reduces this uncertainty, which may reduce the cost of expansion for some providers and so encourage more competition between existing providers. However, this effect is likely to be small.

G24. By reducing the costs of expansion, corporate-level registration will make it less costly to deliver care and treatment in a greater number of smaller sites, allowing care to be delivered on sites more convenient for patients and service users.

G25. By making expansion less costly, and reducing the uncertainty of creating new sites, corporate level registration should have a small, positive impact on competition.

Providers coming into scope of registration for the first time

G26. NHS providers will be required to register for the delivery of services the first time, as will some social care and independent sector healthcare providers. These providers will have a new duty to meet the registration requirements, which will limit the ability of providers to compete by offering low quality services at a lower price than their competitors.

G27. This will reduce competition between providers offering low quality care and treatment at a low prices. However, this reduction in competition may be desirable, as consultation with patients and service users shows that users want services that meet essential levels of safety and quality. This suggests that users of low quality services are not able to discern

the quality of the services they purchase. By providing assurance that all registered providers meet essential safety and quality levels, the regulator will prevent providers from competing on the basis of unacceptably low levels of quality.

G28. Although the CQC is committed to using proportionate compliance criteria to assess providers' compliance with the registration requirements, there is a risk that some providers coming within the scope of regulation for the first time will not be able to meet the registration requirements. The costs of complying with the requirements, and the costs of proving compliance to the regulator, may cause some providers to exit the market. This would lead both to reduced coverage for patients and service users, and reduced competition between providers. There is also a risk that providers withdraw the regulated activity aspects of their service, to avoid registration. We consider these risks for each of the activities which are being brought into scope below.

Moving into scope

G29. **NHS trusts**: for the first time, NHS trusts (including PCTs and Foundation Trusts) will be required to register with respect to the delivery of services. NHS trusts are already subject to assessment through the Annual Health Check and are already registered with CQC with respect to infection control procedures. Although the new system of registration is legally enforceable, and so is likely to impose higher costs on NHS providers than the current system, the effect on NHS bodies' ability to provide services, and on competition in healthcare markets, is likely to be negligible.

G30. **Services transporting patients requiring special vehicles**: non-urgent, planned patient transport will be included within scope, except for transport in unadapted vehicles. Both NHS ambulance trusts and independent sector firms provide non-urgent transport services. Registration of these services will impose new costs on providers. NHS ambulance trusts are already subject to the Annual Health Check, and so registration by the new regulator is unlikely to have an impact on the ability of trusts to provide services. There is a risk that the costs of registration may cause some independent sector transport providers to withdraw the provision of transport in adapted vehicles, to avoid regulation, or to exit the transport market completely. This would reduce competition.

G31. Competition for day care users who need personal care. However, this is only likely to occur in day care centres operated by the independent sector, as local authorities have a duty to provide for the eligible assessed needs of local residents.

G32. **Surgical procedures and the treatment of disease, disorder or injury**: to create a level playing field between all providers of surgical procedures and treatment of disease, disorder or injury, non-medical led services, walk-in centres and minor injury units will be brought into scope, extending the coverage of the regulation of independent sector healthcare providers. There is a risk that that the costs of regulation may cause some of these providers to exit the market, reducing competition. NHS providers of these services will also be brought into scope, but as NHS providers are already subject to the Annual Health Check, their ability to compete is unlikely to be affected.

G33. **Diagnostic and screening procedures**: diagnostic procedures conducted within an independent hospital are already regulated, but the scope of registration will be extended to all major diagnostic procedures, and non-cancer screening programmes, regardless of their setting. This will bring in NHS providers of major diagnostic procedures, which is unlikely to have an impact on their ability to compete.

G34. **Telemedicine**: all telemedicine services, including NHS Direct, where immediate action or attention is needed, will be required to register. NHS Direct is already subject to the Annual Health Check, and so the inclusion of this within the scope of the Care Quality Commission is unlikely to impact on its ability to compete. There is a risk that the costs of independent sector telemedicine providers may cause some providers to exit the market, or change their advertised services, reducing competition.

G35. **Family planning services and services in slimming clinics**: the scope of regulation is to be extended to include the fitting of an intra-uterine device by or under the supervision of a healthcare professional, and medical services provided in slimming services (i.e. gastric banding and prescribing). There is a risk that the costs of regulation may cause some independent providers of these services to exit the market. There is also a risk that clinics will withdraw the regulated activity aspects of their services, to avoid registration. In both cases, this would lead to reduced competition.

G36. **Nursing care**: scope is to be extended to include outreach services and nursing services in a community setting (i.e. district and school nursing). There is a risk that the costs of regulation may cause some independent sector providers to exit the market, reducing competition.

G37. **Prison and immigration services**: immigration removal centre and prison health services will move into scope. We do not anticipate any effects on competition due to these changes.

Moving out of scope

G38. **Non surgical class 3B and 4 lasers and intense pulsed light treatments**: the non-surgical use of lasers and intense pulsed light services are to move out of the scope of registration with CQC. This may cause some consumers to switch to providers who are subject to other forms of quality assurance, such as professional accreditation or self-regulation. For example, consumers may switch away from treatments offered in beauty salons, and instead prefer treatment by a cosmetic surgeon, who is subject to professional regulation. However, DH is working with the sector and representative bodies on an alternative approach that better targets the specific risks associated with these activities, which should minimise the effect on competition.

G39. **Nursing and domiciliary care agencies**: agencies who only provide nursing or care staff to other registered providers will no longer be required to register. We do not anticipate that registered providers will discontinue their use of nursing or domiciliary care agencies as a result of deregistration.

b) Level playing field between providers

G40. Registration of all providers of regulated activities by a single regulator should have a positive effect on competition.

G41. As regulation moves to an activity based approach, this will mean that all providers of a regulated activity, whether public or independent sector, will be treated in the same way by the regulator. This will create a level playing field between NHS and independent sector healthcare providers, and between public and independent sector providers of social care, which will allow all providers to compete on a more equal basis.

G42. In the past, the HC published its assessment of independent sector providers' performance against the National Minimum Standards (NMS). The CSCI also published its assessment of social care providers' performance against NMS. For NHS providers, the HC

published the performance of NHS trusts against the Standards for Better Health, as part of the Annual Health Check.

G43. Under the new system, all providers will be regulated by the same regulator, and subject to the same registration requirements. Therefore, the information published by the new regulator will be more comparable between providers under the new system. This should reduce the costs to patients of researching the quality of providers, which should encourage patients to switch providers to receive better quality care. In turn, this should encourage providers to compete on quality to attract patients.

G44. As health and social care will be regulated by a single regulator, providers offering both health and social care will no longer have to register with two regulators. This should encourage providers to offer integrated models of care, which should encourage more competition on the basis of innovative service delivery.

G45. By creating a level playing field between all providers, making information for patients and service users more comparable, and encouraging competition on innovative models of care, the creation of a single regulator should have a positive effect on competition.

c) Focus on outcomes

G46. The move to more outcome-focused regulations will allow more competition on the basis of service delivery.

G47. As the new regulations will not specify how providers must meet the registration requirements, providers will have the scope to comply in the most efficient way for their organisation, which should reduce the costs of compliance, and supports the development of more innovative models of care and treatment, allowing more competition on the basis of service delivery.

Small Firm Impact Test for the Impact assessment on the Regulations for the Health and Social Care Act

G48. The effect of regulation can vary with the size of the regulated provider, as larger providers can take advantage of many economies of scale when complying with regulation. Therefore, it is a requirement to publish a Small Firm Impact Test with the wider Impact Assessment, to ensure that the challenges that small providers may face under the new regulations are considered.

G49. The Small Firm Impact Test is organised into the following chapters:

a. The first chapter analyses the types of small providers upon which the regulations might have an impact.
b. The second chapter describes the consultation work we have conducted.
c. In the third chapter, we analyse the impacts of the regulations on providers which are currently regulated under the Care Standards Act.
d. In chapter four, we estimate the costs and benefits to newly registered small providers, and to deregulated providers.
e. In the fifth chapter, we assess the risks of care and treatment provided by small providers in comparison to larger ones.
f. Finally, we consider whether an exemption for small firms is possible, and whether this option is desirable.

What types of small firms will be affected?

G50. Three types of provider will be affected by the changes in the regulations:

G51. Providers that are currently registered under the Care Standards Act, 2000, and that will now register under the Health and Social Care Act, 2008 will face changes to their administrative costs. We distinguish between the following types of providers:
i. Small independent sector (IS) healthcare providers (non-hospital providers)
ii. Social care providers

G52. Providers required to register for the first time will have additional administrative and compliance costs, which have to be justified by the risks that the regulations mitigate

G53. The following groups of providers will be newly registered and will be discussed separately:

i. Substance misuse services
ii. Transport for patients who require special vehicles
iii. Private Prisons
iv. Immigration removal centres

G54. For providers that were under the Care Standards Act, and will move out of the scope of regulation, we expect significant cost savings. The following types of small providers will move out of the scope of regulation:
i. Laser and Light facilities (non surgical use of class 3b and 4 lasers and intense pulsed light equipment)
ii. Nurses Agencies solely providing staff to other registered providers
iii. Domiciliary Care Agencies solely providing staff to other registered providers

Consultation on the new regulatory framework

G55. The Department has undertaken a general consultation which included small providers. We also held a number of bilateral meetings with small providers to understand their concerns.

G56. **General consultations:** we consulted widely, to ensure that our policy reflects the views of our stakeholders. In November 2006, *The future regulation of health and adult social care in England*[73] consulted on the regulatory framework. The response to this consultation[74], published in October 2007, outlined the organisational roles and responsibilities for each of the seven regulatory functions identified by the consultation document, and reinforced the Government's commitment to establish a new integrated health and social care regulator, the Care Quality Commission.

G57. The consultation published 25 March 2008 [75] specifically consulted on the scope of registration and the requirements that providers will be required to meet. The response to that consultation detailed how we had refined our policy to reflect respondents' views. At the same time, a new consultation was launched to gauge whether the wording of the draft legislation achieves our stated policy aims. The response to this latter consultation accompanies this document.

[73] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286
[74] http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227
[75] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625

G58. **Interviews with small providers:** we conducted interviews with small providers, to establish the costs that small providers will incur to secure and maintain their registration with the Care Quality Commission. The interviews were targeted at small providers and trade organisations, and discussed their current experience of regulation (where providers were registered), and their expectations of the costs of the new regulatory framework. We discussed the proposed registration requirements, and as far as possible, the potential administrative features of the new regulations, to gain an understanding of the impacts on small providers.

G59. We interviewed the following types of providers:

a. Social care providers (both care homes and domiciliary care providers)
b. Private doctors
c. GPs (GPs will not be in the scope of regulation for 2010, but they will be registered in future).

The cost changes to small providers currently regulated under the Care Standards Act

G60. From our interviews, we found that the *current system* produces a greater regulatory burden on small providers (e.g. private doctors or single location care homes) than on medium and large providers (e.g. hospitals).

G61. In **IS health Care**, we found that the first time registration of a hospital costs £20,000 – £40,000 in regulatory work, while the first time registration of a private doctor costs around £4,000. For the annual self-assessment, large hospitals providers spend over £30,000 (or £1,500 per hospital site), while a private doctor spends around £1,500. The costs of regulation are therefore much higher in small private doctor practices than for a large hospital provider most likely by the factor 2-3.

G62. The differences are less pronounced in **social care,** as most of the costs to providers are incurred from inspections. As inspections are location-based, the economies of scale are smaller. We found that the costs of the self-assessment are much lower for multi-site providers, generally by a factor of two (around £500 per site for multi-site providers and up to £1,000 for single site providers).

G63. The *new regulations* are also likely to have economies of scale for larger businesses but we are confident that small providers will gain, both in absolute terms and relative to larger competitors. We expect the following changes to reduce costs for all providers:

a. Provider-level registration: the Care Quality Commission will register providers not by location but by organisation, which will reduce costs both to the regulator and to all multi-site providers. This change will reduce the costs of regulation more for larger providers than for smaller providers.

b. The regulations will be more flexible and more outcome focused than the current regulations based on the National Minimum Standards. This will reduce the costs to smaller providers more than the cost to larger providers. This is because the economies of scale referred to above are partly based on process measures that are easier for large providers to comply with.

G64. While it is difficult to estimate the magnitude of these effects, we think the latter effect will be more significant than the former effect, especially in social care. We estimated in the

Impact Assessment that the costs to providers will be reduced by 10-20%. For smaller providers, the savings are likely to be closer to 20%.

G65. We do not expect that the benefits of regulation to providers will change under the new regulations relative to the current system.

The costs and benefits to newly registered small providers

G66. We have analysed the cost and benefits of registering the providers listed in paragraph 8 in the main Impact Assessment, and refer to our estimates here. This assessment concluded that the benefits from regulation (arising from reduced risk of harm to patients and users) justify the costs of regulation.

G67. The additional costs of registering new activities that are likely to be provided by small businesses are summarised in the following table. The fee structure of the Care Quality Commission is not finalised yet, but we assume that a substantial part of the regulator's costs will be funded by fees, that providers will have to pay.

Table 1: Annual costs of the regulation of newly providers

	Number of providers	Cost to Regulator		Cost to Providers	
		Minimum	Maximum	Minimum	Maximum
Accommodation with treatment for drug or alcohol misuse	105 providers already register with the CQC. 21 providers will move into scope	£0.05 million	£0.05 million	£22,000	£24,000
Transport services using vehicles designed to carry patients	Up to 300	£0	£0.7 million	£0	£0.7 million
Prison services	Up to 3	£0	£8,000	£0	£9,000
Immigration removal centres	Up to 4	£0	£10,000	£0	£9,000

Savings and additional risks due to deregulation

G68. There will be substantial savings due to the discontinuation of regulation for non surgical class 3B and 4 lasers and intense pulsed light treatments facilities. In addition, there may be substantial savings for nursing agencies and domiciliary care agencies although, as we do not know how many will fall out of scope of registration, we cannot anticipate these full savings will be realised.

a. Around £4 million per year for laser and light facilities (£2 million for regulated providers and £2 million for the regulator).

b. Up to £2.6 million per year for nurses agencies (£0.8 million for regulated providers and £1.8 million for the regulator).
c. Up to £18.4 million per year for domiciliary care agencies (£5.6 for regulated providers and £12.8 million for the regulator)

G69. Most of these providers are small businesses so some small businesses will face lower costs directly as a result of the change in regulation.

G70. We have analysed the additional risk that these exclusions would cause, and found them not to justify the costs described above. For more details please see the main Impact Assessment.

The risks of care and treatment provided by small providers

G71. As explained above, it is likely that the costs of regulation are higher for small providers than for large providers. This means that the benefits of regulating small providers should be higher to make the regulation of small providers as worthwhile as the regulation of larger providers.

G72. We think that the benefits of regulation are higher for small providers than for large providers. The biggest benefit of regulation is the reduced risk to service users and patients, and most available evidence suggests that smaller providers do produce higher risks for their patients and users when unregulated. This implies that the benefits of regulation are higher.

G73. Although the relationship between the size of a provider and its riskiness holds on average, it is not true of every provider. However, it is often the case that problematic services with higher risks are often very small providers. The main reasons for this are:

a. Peer pressure: in services with few workers, these workers are subject to less peer pressure to improve the quality of care and treatment. For example, performance assessment of GP practices has shown that single-handed practices are more likely to be sub-standard than larger practices. In social care, the CQC is aware that smaller care homes are more likely to fail National Minimum Standards then larger homes.

b. Specialisation: in services with more workers, there is more scope for workers to specialise in different areas, allowing workers to become more competent in their area of expertise. This will also help to improve overall quality, as well as reducing risks to patients and service users.

G74. To summarise, the benefits of regulation are likely to be significantly higher in smaller services, which means that the higher costs of regulation are justified.

Conclusions

G75. **Conclusion 1: no exemption for small and medium enterprises is possible or desirable:** as we have explained above, the benefits of regulation will be more pronounced for the regulation of small providers, which means that an exemption for small providers would reduce the benefits of regulation by a higher than proportional rate. This effect would be reinforced if the goal of health reforms of bringing care closer to the users is achieved. Care closer to the user is often provided by small providers locally, and exempting them from regulation could create significant risks.

G76. It may be difficult for small providers to assure patients and users that they are offer good quality care and treatment if they do not have the independent verification provided by regulation (especially when large businesses providing the same services do have such evidence). Small business could therefore lose custom from patients concerned about their quality.

G77. **Conclusion 2: Care Quality Commission will need to consider impacts on small providers when developing its compliance criteria**: as explained in more detail in the main Impact Assessment, the compliance costs of providers will mainly be determined by the Care Quality Commission, which will decide on the compliance criteria for the different providers. These criteria will be generic, but the Care Quality Commission is committed to applying the criteria proportionately to different providers, both in terms of their size and the potential risks they pose. The Care Quality Commission will need to consider its impact on smaller providers.

Annex H: Equality Impact Assessment

Description of the policy

H1. The Health and Social Care Act 2008 set up the Care Quality Commission as the regulator of health and adult social care services in England. The Care Quality Commission replaces three former regulators – the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission.

H2. The Act created the framework for the regulation of providers of health care and adult social care services, but allowed for much of the detail about what types of services should be regulated and what registration requirements providers would need to meet to be set out in secondary legislation.

H3. In March 2009, the Department of Health consulted on draft regulations setting out the scope of registration and registration requirements. Responses to this consultation have now been considered and regulations are being placed before Parliament setting the activities that will be regulated by the Care Quality Commission, and the registration requirements which providers of these activities must meet. Regulations will also set out further requirements around statutory notifications that providers need to provide to the Care Quality Commission, requirements around the termination of pregnancy and financial viability. The regulations also cover the process of registration such as the keeping of a register by the Care Quality Commission, and set out the arrangements for the issuing of penalty notices in lieu of prosecution for some offences under the Health and Social Care Act 2008.

H4. This Equality Impact Assessment considers the likely effect of the regulations on various groups.

The evidence base

H5. It is anticipated that the new system of regulation will lead to a general improvement in the quality and safety of health care and adult social care services. The full impact assessment identifies two major categories of benefits:

- The new outcome-based regulations will have an impact on the quality of providers already registered with the existing Commissions, which will benefit patients and service users; and
- The inclusion of new providers into the registration system will have an impact on the quality of provision of some providers, especially those that are not currently meeting essential levels of safety and quality.

H6. The regulations will improve the quality of service provision for all users of health care and adult social care services, and the case in support of this is set out in the broader impact assessment. It is reasonable to assume that this benefit will be felt most strongly by groups who are more frequent users of health and adult social care services. The following analysis takes this as its starting point and seeks to identify which groups are more likely to use the regulated activities and are therefore the most likely to experience improvements in safety and quality arising from the new system of regulation.

H7. There are some activities, such as primary medical and dental care, which will be brought into registration for the first time. These activities will be brought into registration on a phased basis. A number of other activities will remain outside of regulation. We do not

anticipate any adverse impact for users of services which remain outside of scope, since there will be no change to the regulatory framework in which they operate.

H8. A risk-based analysis has been undertaken in considering the scope of registration (that is which activities should be regulated). Activities which were considered to be borderline have been subjected to detailed risk-based appraisal to inform whether they should be within or without the scope of the Care Quality Commission. The analysis has considered how often adverse events occur, and the severity of the risk to the individual person (eg how ill could the treatment make the patient if it was poorly performed), the size of the population that receives the care or treatment, the vulnerability of people receiving the care or treatment, and the extent that system regulation would be expected to reduce the risk. A key criteria in this assessment was the vulnerability of the service users.

H9. Assessing the personalised needs of each service user and managing the risks of receiving care or treatment that is inappropriate to those needs is central to the registration requirements that all providers of regulated activities will be required to meet. This strong emphasis on the personalised needs of individual service users is coupled with an explicit requirement about the need to avoid unlawful discrimination, including where applicable, by providing for the making of reasonable adjustments in the provision of care and treatment to meet each service user's individual needs. This will allow the Care Quality Commission to take action where service providers are failing to respond appropriately to the needs of individuals, including needs related to a person's age, disability, gender, race, religion or belief and sexual orientation. The following registration requirements are of particular relevance in this context.

H10. *Care and welfare of service users*

The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of –
(a) the carrying out of an assessment of the needs of the service user; and
(b) the planning and delivery of care and, where appropriate, treatment in such a way as to -
(i) meet the service user's individual needs; and
(iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.

H11. *Safeguarding service users from abuse*

The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of -
(a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
(b) responding appropriately to any allegation of abuse.
The registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body in relation to –
(a) the protection of children and vulnerable adults generally; and
(b) in particular, the appropriate use of methods of control or restraint.

H12. *Meeting nutritional needs*

Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of –
(b)food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
(c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.

H13*. Respecting and involving service users*

The registered person must, so far as reasonably practicable, make suitable arrangements to ensure–

(a) the dignity, privacy and independence of service users; and

(b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.

The purposes of paragraph (1), the registered person must -

(h) take all reasonable steps to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

H14. The registration requirements that service providers will need to meet have been developed with a specific regard to human rights. In developing the registration requirements, we have identified how the principles of human rights provisions might be reflected in principles underpinning the provision of health and social care services. It is anticipated that drawing up registration requirements in this way will help to embed equality issues as a basic consideration in the regulation of service providers. The way in which the registration requirements relate to human rights provisions is described below.

H15. Finally, in carrying out the registration system and its other regulatory functions the Care Quality Commission can consider 'the requirements of any other enactment which appears to the Commission to be relevant'. (Health and Social Care Act 2008). This means that the Commission will be able to consider how service providers are complying with the requirements of the Human Rights Act 1998 and equality legislation. It will be able to address equality, respect for diversity and other human rights in reaching decisions on registration.

What the evidence shows – key facts

Age

H16. England is an ageing society. Since the 1930s the number of people aged over 65 has more than doubled and today a fifth of the population is aged over 60. The oldest age group (80 and over) is the fastest growing group[76]. This age group accounted for five per cent (2.7 million) of the population of the UK in mid-2007 and has increased by more than 1.2 million between 1981 and 2007[77].

H17. Older people are heavier users of both health and social care services. Hospital Episode Statistics show that in 2007-08 more than one-third, 36%, of total episodes of hospital care were provided to people aged over 65[78].

H18. A similar pattern applies to users of adult social care services. Provisional figures for 2007-08 show that of the 1.8 million adults receiving services, 1.2 million (68.8 per cent) were aged 65 and over. The proportion of older people receiving residential care is greater still. In 2007-08, 81.6 per cent of people receiving residential care were aged over 65[79].

H19. We anticipate that the new regulatory system for health and adult social care will result in overall improvements in health and adult social care services across England. Given the relatively heavier use of these services by older people, we anticipate that older people will feel these benefits more strongly.

---

76 http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_4003066

77 www.statistics.gov.**uk**/pdfdir/popest0808.pdf

78 http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=193

79 http://www.ic.nhs.uk/statistics-and-data-collections/social-care/adult-social-care-information/community-care-statistics-2007-2008:-referrals-assessments-and-packages-of-care-for-adults-england--national-summary-%5Bns%5D

H20. Separate regulators already regulated the majority of adult social care services, and independent and voluntary healthcare services. Under the new regulatory system, the Commission will regulate all NHS providers, along with providers of adult social care and independent healthcare. This will have a beneficial impact on older people, who make more use of both health and social care services, as all the services will be regulated by the same regulator, ensuring greater continuity of standards between the services.

Disability

H21. People with disabilities are also likely to be heavier users of both health and social services. Research carried out for the Office for Disability Issues found that fewer than one in five disabled people described their health as good, compared to two in three of the general population. A third of disabled people felt their health had worsened in the last twelve months. More than nine out of ten disabled people had used a health service in the past three months, which is significantly higher than the general population[80].

H22. Given the relatively heavier use of health and adult social care services by disabled people, we anticipate that the benefits of the new regulatory system will be felt more strongly by disabled people.

Gender

H23. A report carried out by the Men's Health Forum for the Department of Health found that men and women use health services differently. However, it also found a 'surprisingly poor' evidence base on the relationship between gender and the use of health services[81]. Similarly, we have not been able to find data to compare the use of social care according to gender.

H24. Given the lack of robust information about the use of health and adult social services by people according to gender it is not possible to predict whether the effect of the new regulatory system will be felt more strongly by either sex.

H25. However, there are clear gender issues in the use of specific services. For example, maternity, termination of pregnancy, fertility treatments and cosmetic surgery or beauty treatments are predominantly or exclusively used by women.

H26. More older people are women and, given that use of health and adult social care services is closely linked to age, there is likely to be a stronger benefit of the new regulatory system experienced by women above the age of 73, which is the age at which women begin to significantly outnumber men[82].

H27. However, there are other treatments that are more likely to have a male bias. Men are between 73-78% more likely to have heart surgery, 60% more likely to have kidney surgery, 64% more likely to have head injuries, 65% more likely to have heart disease, and 68% more likely to suffer from a hernia[83].

H28. In addition, rates of detention under the Mental Health Act 1983 are higher among men. As at 31 March 2007 in England of around 15,200 patients detained in hospital under mental

80 (Experiences and expectations of Disabled People – Executive Summary; Office for Disability Issues, Department for Work and Pensions, July 2008).
81 (The Gender and Access to Health Services Study, Department of Health, December 2008).
82 (Population estimates; National Statistics Online; August 2008).
83 http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=193

health legislation, around 10,200 were men and 5,000 were women[84]. All mental health services are being brought into registration in 2010/11, and this may have a beneficial effect on men who are heavier users of mental health services.

Race

H29. There is limited evidence to identify whether black and minority ethnic (BME) groups are relatively heavy users of health and adult social care services. However, the fifth of areas with the worse health and deprivation indicators, the spearhead areas, contain 44 per cent of the entire black and minority ethnic population of England. This suggests that people from these groups are more likely to experience poor health outcomes and more likely to have heavier demands of health and adult social care services. This may be compounded by issues around access to services in deprived areas. It is anticipated that the considerations of equality legislation by the Care Quality Commission in registration decisions will have some beneficial impact on black and minority ethnic groups although this is unlikely to be substantial.

H30. There is evidence that people from black and minority ethnic groups may be heavier users of certain kinds of services. There is, for example, consistent evidence of inequality in the mental health of BME communities, especially in the incidence of severe mental illness. The 2006 Aetiology and Ethnicity in Schizophrenia and Other Psychoses (AESOP) study indicates that, compared with the White British population, people from African-Caribbean communities are nine times more likely to experience schizophrenia and eight times more likely to experience manic psychosis; people from Black African communities are six times more likely to experience either condition; and other BME groups have more modestly increased rates[85]. We also know from research and the Healthcare Commission and Mental Health Act Commission's annual *Count Me In* census that rates of compulsory admission and detention are significantly higher for some BME groups[86].

H31. All mental health services are being brought into registration in 2010/11, this is likely have a beneficial effect on Black and Minority Ethnic groups who are heavier users of mental health services.

Religion or belief

H32. There is no direct evidence to suggest that use of health and social care services is different according to people's religion or belief. Although, the membership of particular religious communities does appear to have some bearing on health and wellbeing, with the British Muslim community having the worst reported health, closely followed by the Sikh community. Poor reported health is not necessarily attributable to religion or belief, and is more likely to be linked to other factors such as housing and economic and social status[87].

H33. There is therefore no reason to believe that there would be a significant positive or negative impact on specific religious or belief groups as a result of the new system of regulation. However, if any changes were felt, they have the potential to be of most benefit to the Muslim and Sikh communities.

---

[84] http://www.ic.nhs.uk/statistics-and-data-collections/mental-health/mental-health-act/inpatients-formally-detained-in-hospitals-under-the-mental-health-act-1983-and-other-legislation:-1997-98-to-2007-08

[85] http://www.library.nhs.uk/mentalHealth/ViewResource.aspx?resID=273725

[86] http://www.healthcarecommission.org.uk/publicationslibrary.cfm?widCall1=customDocManager.search_do_2&tcl_id=4&top_parent=3541&tax_child=3648&tax_grand_child=3950&search_string=

[87] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093133

Sexual orientation

H34. A recent survey carried out by Stonewall into lesbian and bisexual women's health care experiences found that one in five lesbian and bisexual women have deliberately harmed themselves in the last year, compared to 0.4 per cent of the general population. It also found that one in five say they have an eating disorder, compared to one in 20 of the general population.[88] The findings of the survey are backed up by the findings of a Dutch survey into whether homosexuals use health care services more than heterosexuals. The survey found that, while data was scarce, it appeared that gay men more frequently used mental and physical health services, and that lesbian or bisexual women more frequently used mental health care than heterosexual women[89].

H35. The results of these surveys suggest that when mental health services are brought into registration in 2010/11, this is likely to have a beneficial effect to homosexuals who are heavier users of mental health services.

Challenges and opportunities

H36. The new regulatory framework has not been set up with the aim of addressing inequalities in any single area, but rather to improve the quality and safety of health and adult social services available to all service users. The analysis of the data above has identified that older people and disabled people are more likely to use health and adult social care services than the general population and therefore that the benefits arising from the new system are likely to be felt more strongly among these groups. It is also likely that the regulation of mental health services will have a beneficial impact on black and minority ethnic groups and homosexual people. It is not possible from the available evidence to identify a significant positive impact according to gender or religion or belief. However, there will be no detrimental effect caused by the introduction of the regulation requirements, at worst, the level and quality of services will remain the same for these groups. The emphasis on assessing and meeting the needs of individual service users and on human rights in the registration requirements and the capacity for the Commission to take into account the requirements of human rights and equality legislation establishes mechanisms for ensuring that services better respond to individual needs.

Reflecting human rights provisions

H37. Central to the new system are the registration requirements that providers of registered activities must meet. These have been drawn up in order to focus on the outcomes that are provided to patients in a way that respond to their individual needs. In particular, in developing the registration requirements we have identified how the spirit of human rights provisions might be reflected in the principles underpinning the provision of health and social care. The successful application of these registration requirements by the Care Quality Commission will result in a pattern of service provision which recognises and responds to individual needs.

H38. The registration requirements reflect human rights provisions in the following way:

- **The right to life** – registration requirements ensure that the right to life is not compromised by exposure to unmanaged hazards to safety (covering staff, care and premises) or failure to provide access to adequate nutrition and hydration or failure to manage hygiene and

[88] http://www.stonewall.org.uk/campaigns/2365.asp

[89] http://www.scie-socialcareonline.org.uk/profile.asp?guid=7694ee22-2f99-4376-9086-06ef67f73edd

spread of infection.

- **Freedom from torture and inhuman or degrading treatment** – registration requirements ensure that dignity is not compromised by abusive treatment, care or medication regimes, the failure to prevent, recognise and respond to instances of abuse and neglect, or failure to listen and respond to basic human needs (e.g access to toilet), failure to treat people as individuals with equal value, failure to afford privacy during provision of intimate care or treatment, protection against inappropriate use of restraint and protection against arbitrary deprivation of liberty.

- **The right to liberty** – registration requirements ensure that people's liberty is not compromised by arbitrary deprivation of liberty or inappropriate restriction of freedom of choice and restriction of action in the performance of normal daily activities.

- **The right not to be punished for something that wasn't a crime when you did it -** registration requirements ensure that people are able to complain without prejudice to their treatment and care. Ensure people are not punished by abusive treatment, care or medication regimes.

- **The right to respect for private and family life** – registration requirements ensure that the right to privacy is not compromised by abusive treatment or care regimes, institutionalised care which excludes family involvement and fails to recognise individuals aims, wishes and diverse needs, or inappropriate restriction of freedom of choice and action (for example through restraint) in pursuit of independence, private and family relationships.

- **Freedom of thought, conscience and religion** – registration requirements ensure that freedom of thought, conscience and religion is not compromised through abusive treatment or care regimes, institutionalised care which fails to recognise individual views, ideas and diverse needs, or inappropriate restriction of freedom of choice in holding particular views, ideas and beliefs.

- **Freedom of expression –** registration requirements ensure that freedom of expression is not compromised through the use of abusive treatment or care regimes, institutionalised care which fails to recognise or listen to individuals views, ideas and diverse needs, or inappropriate restriction of freedom of choice and action in sharing views, ideas and beliefs.

- **Freedom of assembly and association –** registration requirements ensure that freedom of assembly and association is not compromised through arbitrary deprivation of liberty (including inappropriate use of restraint) or inappropriate restriction of freedom of choice and action in meeting with others.

- **The right to marry or form a civil partnership and start a family –** registration requirements ensure that the right to marry or form a civil partnership or start a family is not compromised by abusive treatment or care regimes, or by institutionalised care which fails to recognise individual's freedom of choice and action in pursuit of private and family relationships.

- **The right not to be discriminated against in respect of these rights and freedoms** – registration requirements ensure that the right not to be discriminated against in respect of these rights and freedoms is not compromised by abusive treatment or care regimes which fail to recognise people's equality of value as a human being and people's diverse needs with reference to their age, gender, sexual orientation, religion culture and impairments.

- **The right to own property** – registration requirements ensure that the right to own property is not compromised by failure to prevent, recognise and respond to instances of financial abuse.

- **The right to an education** – registration requirements ensure that the right to an education is not compromised by a failure to recognise people's aims and wishes in that respect and the support they need to access education.

- **The right to participate in free elections** – registration requirements ensure that the right to vote is not compromised by a failure to recognise people's freedom of choice and action in relation to political activity and the support they need to vote.

H39. In addition to the consideration of human rights requirements in developing the registration requirements, the Care Quality Commission is able to consider the requirements of other enactments in operating the registration system and carrying out its other regulatory functions. This will enable the Commission to consider whether service providers are meeting the requirements of the Human Rights Act and equality legislation in providing regulated activities. The Commission will be able to consider enforcement action where service providers do not meet the requirements of these pieces of legislation.

Equality Impact Assessment

H40. An adverse impact is unlikely. On the contrary, there is potential to reduce barriers and inequalities that currently exist. The registration requirements have been designed to produce a fairer playing field across all areas of health and social care, reducing any inequalities that exist. As stated we anticipate that the benefits of the registration system will be felt more strongly by older people, disabled people, and Black and minority or homosexual and bisexual individuals in mental health services. There is no evidence to suggest that the regulations will affect members of any religion or a specific gender more than any other.

Next steps

H41. Implementation of the registration system will be carried out by the Care Quality Commission. The Commission is responsible for developing guidance about compliance which will underpin the registration requirements that will be set in secondary legislation. It has consulted on its guidance about compliance and will publish a final version before the registration system comes into effect. An assessment of the impact on equality of the guidance about compliance was published alongside the consultation.[90]

H42. A Code of Practice for the prevention and control of healthcare associated infections will set out how providers can meet the registration requirement on cleanliness and infection control (regulation 29). The Department of Health will publish this Code of Practice and is currently consulting on this document. An assessment of the impact on equality of the guidance about compliance was published alongside the consultation.[91]

Review of implementation

H43. The use of secondary legislation to set scope and registration requirements makes the system more flexible. If the ongoing monitoring of the regulatory system with the Care

[90] http://www.cqc.org.uk/contentdisplay.cfm?widCall1=customWidgets.content_view_1&cit_id=34904
[91] http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_104114

Quality Commission and other stakeholders identifies weaknesses in the system, including in its approach to equality, there is the potential to address this through revised regulations.

H44. As a Non-Departmental Public Body, the Commission remains accountable to the Secretary of State for discharging its functions, duties and powers effectively, efficiently and economically. As such, the Commission and Department will work together to review the Commission's objectives on an annual basis taking into account the Department’s policy priorities and any lessons for health and adult social care policy, including around the registration system.

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of regulation of primary medical and dental care providers under the Health and Social Care Act (2008)**	
Stage: Final	**Version:** 2	**Date: 27 January 2010**
Related Publications: Consultation document and regulations		

Available to view or download at:

http://www.dh.gov/en/consultations/responsestoconsultations

Contact for enquiries: Lisa Walder **Telephone:** 0113 254 5514

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

Current regulatory frameworks for primary medical and dental care services focus on the competency of the individual professional. Without system regulation, competent professionals may be working in premises and systems that are unsafe for practice and this will ultimately put patient care at risk. Most providers of primary care services are currently excluded from system regulation. From April 2010, primary medical and dental care services delivered by PCTs will be registered. Regulations will be required to extend the registration system to all primary medical and dental care providers.

What are the policy objectives and the intended effects?

Four key objectives: 1) Ensure systems are monitored as well as individual professional competency: as these are a contributory factor in many patient safety incidents. 2) Enforce essential requirements: tackle persistently poor performance, all providers must meet essential requirements or face a range of enforcement powers. 3) Consistency: ensure the same requirements apply to all activities identified as posing a risk to patients 4) Provide public assurance: by giving information on a provider's compliance with essential requirements.

What policy options have been considered? Please justify any preferred option.

The Impact Assessment sets out a range of options considered as part of the policy development process. It considers the costs and benefits of the following options:

Option 1: Do nothing option - Use existing processes to quality assure primary medical and dental care providers. This would not deliver the policy objectives.

Option 2: Preferred option - Require all primary medical and dental care providers to register with the Care Quality Commission and ensure the exclusion that will initially apply for providers automatically ends by using a sunset clause in the regulations.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

DH intends to review the liklihood of risk in the activities listed, and will monitor how proportionate the burden of regulation is to the mitigation of those risks within the next three years.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

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

Signed by the responsible Minister:

Mike O'Brien.....Date: ***28th January 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: **Regulate primary medical and dental care providers using a sunset clause in the Scope of Registration Regulations (2009).**

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 8.2m to £9.8m	3
Average Annual Cost (excluding one-off)	
£ 16.2m to £19.2m	

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

Regulatory Bodies: £3.9m to £4.8m one-off, £9.1m to £11.0m annual

PCTs: £0.7m to £0.9m one-off, £1.0m to £1.2m annual

Providers: £3.6m to £4.2m one-off, £6.1m to £7.0m annual

Total Cost (PV) **£ 141.4m - £167.2m**

Other **key non-monetised costs** by 'main affected groups' Compliance costs of providers. CQC is required by the act to be proportionate. This is understood to include a requirement that it ensures that the social benefits of compliance with its standards and its interventions exceed their opportunity costs. Transitional costs to PCTs if providers close down have not been monetised

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ -4.0m to -£3.6m	1
Average Annual Benefit (excluding one-off)	
£ 33.5m to £91.4m	

Description and scale of **key monetised benefits** by 'main affected groups' NON EXCHEQUER BENEFITS

Private Dentists: -£4.0m to -£3.6m one-off, -£1.8m to -£1.6m annual

Patients: £33.5m to £91.0m annual

Total negative benefit: NPV -£16.8m to -£14.9m

Total Benefit (PV) **£ 227.5m - £638.8m**

Other **key non-monetised benefits** by 'main affected groups' Reduced risk of harm for users of primary medical care and primary dental care providers. Patient assurance that providers will meet essential levels of quality and safety. Dis-benefits through transport and health costs for patients registered at a practice that subsequently closes.

Key Assumptions/Sensitivities/Risks The guidance about compliance will be devised by the Care Quality Commission and the criteria they use will determine the scale of costs and benefits associated with compliance.

Price Base Year 2009	Time Period Years 10	**Net Benefit Range** (NPV) **£ -174m to £299m**	**NET BENEFIT** (NPV Best estimate) **£ 62.8m**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			04/2011 and 04/2012	
Which organisation(s) will enforce the policy?			CQC	
What is the total annual cost of enforcement for these organisations?			£ Not known	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£	
What is the value of changes in greenhouse gas emissions?			£	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 1.8m-2.0m Decrease of £ 0 **Net Impact** **£** 1.8-2.0m

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Introduction/Background

1. This Impact Assessment explores the costs and benefits of the options for including primary medical and dental care within the scope of the registration system of the Care Quality Commission (CQC).

2. The Department of Health (DH) first consulted on the regulation of primary medical care in the consultation document *The future regulation of health and adult social care in England*[92] in November 2007. The Department consulted further on primary medical and dental care regulation in the document *A consultation on the framework for the registration of health and adult social care providers*, in March 2008. The overwhelming majority of respondents who commented on primary care providers were in favour of bringing primary medical and dental care into the new registration system. The Department confirmed that primary medical and dental care would be in the scope of registration in the document *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft regulations* in March 2009[93].

3. There have been three previous Impact Assessments on this area of policy and it is important to make this distinction clear:

   - The Impact Assessment for the Health and Social Care Act[94] (2008) included the costs of merging the three previous commissions[95] into the Care Quality Commission. It also gave the expected costs of regulating the same providers as the Commission for Social Care Inspection, the Mental Health Act Commission and the Healthcare Commission previously regulated at a generic level.
   - 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 in England: a consultation on the framework for the registration of health and adult social care providers*[96] in March 2008. Following this consultation some estimates have changed significantly, reflecting the comments received from those responding to the consultation and new information supplied by the Healthcare Commission and, subsequently, the Care Quality Commission. This document sets out our revised Impact Assessment on this policy area.
   - An Impact Assessment was published with the document *Response to consultation on the framework for the 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 will be published at the same time as this document.

---

[92] Link to consultation document:
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286
[93] Link to consultation document:
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991
[94] Link to Impact Assessment:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433
[95] The Care Quality Commission took over from the Healthcare Commission (HC), the Commission for Social Care Inspectorate (CSCI) and the Mental Health Act Commission (MHAC) from 1st April 2009.
[96] Link to consultation document:
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625

4. This Impact Assessment is structured as follows:
    - Firstly the rationale for intervention is discussed below;
    - The objectives of this policy are described from page 13;
    - The approaches considered during the policy development phase are outlined and the remaining options are described from page 15;
    - A cost-benefit analysis of each option is undertaken from page 19 with more detailed analysis in the Annexes (from page 53);
    - Supplementary tests to examine the impact on competition and small firms can be found in Annex G on page 83.
    - The impact of primary care regulation on equality is covered in the Equality Impact Assessment found in Annex H on page 100 and cross-refers to the Equality Impact Assessment accompanying the Impact Assessment of regulated activities from April 2010 onwards.

Rationale for Intervention

5. Primary care services are at the forefront of the interaction between the NHS and patients – indeed, primary medical care controls much of the access to other areas of the NHS in its role as gatekeeper. Each year approximately 304 million consultations take place in GP practices[97] and an estimated 46 million courses of treatment[98] are delivered by dental practices each year[99]. Over 90% of all contact with the NHS takes place outside hospital[100].

6. Given the number of people receiving services every day it is important that providers operate safely, patients receive assurances about the quality of care they receive, and the general public are given enough information to make informed choices on where to seek treatment.

Current regulatory frameworks

7. Current regulatory frameworks for primary medical and dental care services focus on the competency of the individual healthcare professional. They include: registration with the General Medical Council, the General Dental Council or the Nursing and Midwifery Council, which requires the individual to comply with standards of practice; and a requirement for GPs and dentists working in the NHS to be included on a Primary Care Trust (PCT) held Performers List which confirms the competency and suitability of the individual.

8. Most providers of primary care services are currently excluded from system regulation. As set out in the Care Standards Act (2000), and its associated regulations, only wholly private GPs are required to register. GPs with an NHS contract are not required to register, including for any non-NHS services they provide. All primary care dental services, both NHS and private, are outside the scope of the current system registration arrangements. However, any primary care and out of hospital services provided directly by PCTs are considered as part of the assessment of PCTs and all hospitals are required to register. As

[97] Information Centre (2009) "Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database"

[98] Each Course of Treatment, dependent on the complexity of the treatment, represents a given number of Units of Dental Activity and may involve one or more visits to the dental practice.

[99] In 2008-09, there were 37.4m courses of dental treatment in the NHS delivering 81.4m units of dental activity (Information Centre (2009) NHS Dental Statistics for England 2008/09). It is estimated that there were also 9 million courses of private dental treatment (source: Dental Review 2003-04 produced by the Dental Practice Board).

[100] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

a result, the same types of treatment offered by different types of provider can be subject to different registration requirements.

A Changing Service

9. Primary care services are changing rapidly. There is an increasing complexity and widening range of services being offered in primary 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 showed that 75% of patients with diabetes were managed largely outside hospitals.[101]

10. In addition, as noted by the National Patient Safety Agency (NPSA), there have been a range of other changes which all increase the complexity of primary care services and the risk to patients of unintentional harm.[102,103] For example:

    - advances in technology allowing more treatments to be provided in GP and "high street" dental practices;
    - changes to the workforce (such as nurses being able to prescribe and triage);
    - increasing health and social care 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 drugs).

11. The NHS Next Stage Review signalled that these changes will be built upon and more care will be provided closer to home. As a result, more services are likely to be delivered in the community or in primary care settings, such as local clinics, rather than in acute hospitals[104].

12. At the same time, there is an increasing diversity in the types of providers delivering primary care services under a number of different contract types. Where once primary care was delivered exclusively by organisations owned and run by GPs and dentists, there is now an evolving range of organisations providing primary care services. For example, NHS Dental Services advises that some 600 contracts for primary dental care are now held by three large organisations. Providers now include single-handed practices, partnerships involving only GPs or dentists, partnerships involving GPs or dentists together with other health professionals and/ or practice managers, nurse-led services, federations (groupings of practices), private providers, and third sector providers[105].

Risks in Primary Care

13. There is limited information on patient safety in primary care settings as most research into patient safety, in the UK and abroad, has focused on the acute sector. However, given the

[101] Audit Commission (2004) "A Focus on General Practice in England" (available at www.audit-commission.gov.uk)
[102] National Patient Safety Agency (2009) "Seven Steps to Patient Safety for Primary Care" (available at www.nlrs.npsa.nhs.uk)
[103] Wilson T, Pringle M, Sheikh A. "Promoting patient safety in primary care: research, action and leadership are required." *British Medical Journal* 2001; 323:583-4
[104] Department of Health (2008) "High quality care for all: NHS Next Stage Review final report" (available at www.dh.gov.uk)
[105] National Patient Safety Agency (2009) "Seven Steps to Patient Safety in General Practice" (available at www.nlrs.npsa.nhs.uk)

number of consultations each year, even low error rates can equate to a high number of errors.

14. A 2001 literature review of research into errors in primary care by the University of Manchester[106] found wide variations in error rates - between 5 and 80 times per 100,000 consultations, mainly related to the processes involved in diagnosis and treatment. The low error rate is likely to reflect the lack of evidence in this area and could therefore be an underestimate. Errors in diagnosis and prescriptions accounted for 78% of all problems. Between 60% and 83% of errors were found to be "probably preventable"[107].

15. Prescribing and prescription errors have been identified to occur in up to 11 per cent of all prescriptions, mainly related to errors in dose[108]. Most errors do not cause actual patient harm but have the potential to do so. There are approximately 790 million prescriptions issued every year by GPs.[109] Information from the NHS Information Centre shows there were 4.65 million prescriptions issued each year by NHS dentists[110] in 2008.

<u>The need for checks on systems</u>

16. Table 1 shows the proportion of patient safety incidents reported to the National Reporting and Learning Service, part of the National Patient Safety Agency (NPSA), attributable to different causes. This information must be treated with a degree of caution because only 2,803 incidents were reported in 2008/09. This gives an error rate of less than one incident per 100,000 consultations, far below that reported in studies. The rate of events reported that led to death or severe harm in the patient was much higher for general practice than in other sectors (2.6% compared to an average of 1.1% in other settings). This led to the Quarterly Data Summary for August 2009 for England to conclude that general practice reports fewer incidents but is more likely to report serious incidents. Across all healthcare settings, the combined proportion of severe harm or death incidents was highest amongst incidents categorised as infection control (7.4%).

[106] Sanders J, Esmail A. (2001) "Threats to Patient Safety in Primary Care. A review of the research into the frequency and nature of error in primary care. "*University of Manchester*.
[107] Sandars J & Esmail A. (2003) "The frequency and nature of medical error in primary care: understanding the diversity across studies [Review]." *Family Practice* 20, 231-236.
[108] National Patient Safety Agency (2009) "Seven Steps to Patient Safety in General Practice" (available at www.nlrs.npsa.nhs.uk)
[109] The total number of prescriptions in primary medical care which were dispensed in 2007 was 786,145,690 (source Prescription Pricing Division of the Business Services Authority).
[110] Link: http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescribing-by-dentists-2008:-england

Table 1: Patient safety incidents reported to the NPSA by type of incident	
Category of adverse event	**Proportion of reported incidents**
Medication errors	24%
Consent, communication or confidentiality	12%
Documentation (including records)	12%
Clinical Assessment (including diagnosis)	10%
Access, admission, transfer or discharge	10%
Treatment or procedure	7%
Patient accident	6%

17. The NPSA is also runs the National Clinical Assessment Service[111] (NCAS) and Table 2 reports the proportion of GPs referred to NCAS for potential errors relating to different categories of adverse event.

Table 2: Referrals to the National Clinical Assessment Service by category in General Practice[112]	
Category	**Proportion[113]**
Clinical concerns	57%
Governance and safety	41%
Misconduct	27%
Behaviour other than Misconduct	26%
Health and Alcohol	23%
Work environment	14%
Personal circumstances not related to health	5%

18. A consortium led by the University of Manchester[114] undertook a research project using the data held in the litigation databases of the NHS Litigation Authority and the medical defence organisations. In 2004 it reported that:

- By far the most common error in primary care (50% of cases) was a failure or delay in diagnosis. Other common errors included medication prescription errors, failure or delay in referral and failure to warn of, or recognise, side effects of medication (each around 5%). Not all of these errors resulted in serious harm.

[111] The National Clinical Assessment Service, part of the National Patient Safety Agency, helps local healthcare managers to understand, manage and prevent performance concerns.
[112] National Clinical Assessment Service (2009) "*NCAS Casework – The First Eight Years"*
[113] Note that this does not total 100% as, on average, two concerns were raised in each case referred.
[114] Fenn P, Gray A, Rivero-Arias O, Trevethick G, Trevethick K, Davy C, Walshe K, Esmail A, Vincent C. (2004) "The epidemiology of error: an analysis of databases of clinical negligence litigation." *University of Manchester.*

- The most common recorded outcome in these errors in primary care was the death of the patient (in 21% of cases). Other commonly cited outcomes included deterioration in clinical condition (6%) and unnecessary pain (4%).

19. An international study comparing patient safety found that patient harm was reported in around 30% of errors: between 3 and 9 percent of these were "very serious or extremely serious" with the consequences of the error involving a hospital admission in 4% of cases and death in 1% of cases[115].

20. Table 3 reports the proportion of NHS dentists referred to NCAS for potential areas where an adverse event might occur.

Table 3: Referrals to the National Clinical Assessment Service by category in primary dental care[116]

Category	**Proportion**[117]
Clinical concerns	55%
Governance and safety	38%
Misconduct	29%
Behaviour other than Misconduct	18%
Health and Alcohol	23%
Working environment	14%
Personal circumstances not related to health	5%

21. One of the main risks to patients in primary dental care is the transmission of blood-borne infections due to poor decontamination practices. Obtaining data on cross-infection in primary care facilities is difficult due to the lack of surveillance data. However, there are a number of incidents of transmission of infectious agents in dental practice, for example Hepatitis B[118] and Methicillin Resistant *Staphylococcus aureus* (MRSA)[119]. Research also shows that there is a potential risk of person-to-person transmission of variant CJD via re-usable surgical instruments that have been inadequately decontaminated[120]. As a result, for those tissues where evidence suggests this risk is most pronounced, the Chief Dental Officer

[115] Makeham ABM, Dovey SM, County M, Kidd MR. "An international taxonomy for errors in general practice: a pilot study." *Medical Journal of Australia* 2002;177(2):68–72

[116] National Clinical Assessment Service (2009) "NCAS Casework – The First Eight Years"

[117] Note that this does not total 100% as, on average, two concerns were raised in each case referred.

[118] References include: Levin ML, Maddrey WC, Wands JR, Mendeloff AL. "Hepatitis B transmission by dentists." *Journal of the American Medical Association* 1974; 228: 1139-40; Hadler SC, Sorley DL, Acree KH, et al. "An outbreak of hepatitis B in a dental practice." *Annals of Internal Medicine* 1981 95: 133-8; Reingold AL, Kane MA, Murphy BL, Checko P, Francis DP, Maynard JE. "Transmission of hepatitis B by an oral surgeon." *Journal of Infectious Diseases* 1982; 145: 262-8; CDC. "Epidemiologic notes and reports: hepatitis B among dental patients – Indiana." *Morbidity and Mortality Weekly Report* 1985; 34: 73-5; Shaw FE Jr, Barrett CL, Hamm R, et al. "Lethal outbreak of hepatitis B in a dental practice." *Journal of the American Medical Association* 1986; 255: 3260-4; CDC. "Epidemiologic notes and reports: outbreak of hepatitis B associated with an oral surgeon – New Hampshire." *Morbidity and Mortality Weekly Report* 1987; 36: 132-3; Rimland D, Parkin WE, Miller GB Jr, Schrack WD. "Hepatitis B outbreak traced to an oral surgeon." *New England Journal of Medicine* 1997; 296: 953-8.

[119] Martin MV, Hardy P. "Two cases of oral infection by methicillin-resistant Staphylococcus aureus." *British Dental Journal* 1991; 170: 63-64

[120] References include: MEL(1999): "Variant Creutzfeldt-Jakob Disease (VCJD): minimising the risk of transmission" 65 (31/08/99); MEL(1999): "NHS in Scotland infection control: decontamination of medical devices" 79 (25/11/99)
Department of Health (2001) "Risk assessment for transmission of vCJD via surgical instruments: a modelling approach and numerical scenarios"; HDL(2001): "Decontamination of medical devices. (The Old Report)" 10 (09/02/01); HDL(2001) "Healthcare associated infection: review of decontamination services and provision across NHS Scotland" 66 (20/08/01); Scottish Executive Health Department Working Group (2001) "The Decontamination of Surgical Instruments and Other Medical Devices."; Note: MEL and HDL are types of NHS Scottish Executive circulars, before the NHS Scotland/the Scottish government brands were created.

for England has published requirements for endodontic files and reamers to be single-use instruments in all cases.

22. The provision of safe, quality care does not rely exclusively on the professional competence of the individual health professional providing the care. For instance, the management of the provider, the suitability of the premises, the record keeping and referral systems, and the processes for dealing with complaints are also crucial to the effective running of the organisation. In the absence of checks on the systems, competent professionals may be working in premises and systems that are poorly maintained, unfit or unsafe for practice and this will ultimately put patient care at risk. Additionally, the involvement of individuals that are not regulated (e.g. a practice manager) in primary medical care settings can have a real influence on how care is provided.

23. A study in the USA, cited in the NPSA's publication "Seven Steps to patient safety for primary care"[121], demonstrated that "most errors in general practice can be attributed to two main categories: (a) aspects of care delivery systems, for example, administrative errors, failure to investigate, miscommunication; and (b) lack of clinical skills and/ or knowledge, for example a receptionist failing to make an urgent appointment for an acutely ill child".

24. As part of the project using the data held in the litigation databases of the NHS Litigation Authority and the medical defence organisations led by the University of Manchester[122], an analysis of claims in general practice was undertaken. The report of this analysis stated that the researchers had determined there were a significant number of adverse incidents attributed to the organisation of care. The analysis identified a number of inter-related systems in general practice that were integral to the organisation of care:

- A system for enabling access to the doctor
- A system for maintaining medical records
- A system for communicating with secondary care
- A system for screening
- A system for chronic disease management
- A system for monitoring laboratory investigations
- A system for repeat prescribing.

25. It also stated that the main lessons from the case histories were the need for better record keeping, better communication with other agencies, and better use of protocols and guidelines in the management of chronic diseases.

Deficiencies in the Current System

26. There is evidence that there needs to be effective clinical governance systems in place to enable practices to identify healthcare professionals whose poor performance is putting patients at risk. The Public Accounts Committee's (PAC) report on implementing clinical governance in primary care[123] noted serious short-comings – for example only 4% of GPs report untoward events and clinical incidents to the NPSA. The PAC report concluded that:

[121] 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" (available at www.nlrs.npsa.nhs.uk)

[122] Esmail A, Neale G, Elstein M, Firth-Cozens J, Davy C, Vincent C. (2004) "Case studies in litigation: claims reviews in four specialties." *University of Manchester*.

[123] House of Commons Committee of Public Accounts. (2007) "Improving quality and safety—Progress in implementing clinical governance in primary care: Lessons for the new primary care trusts. Forty–seventh Report of Session 2006–07."

"the level of intervention with poorly performing GPs is very low, with only 66 GPs out of 35,000 currently under suspension. Mechanisms for monitoring quality and safety have contributed to better identification of poor performance, but PCTs do not have direct line management of independent contractors. So although PCTs now have greater powers to take action with poorly performing GPs, many PCTs have failed to take local action to address their concerns, reinforcing doubts about monitoring and control of the quality of GPs."

27. In primary dental care, the NHS Dental Services has reported a range of poor decontamination practices and conditions in surgeries that place patients at risk of infection. A survey carried out in Scotland found that[124]:

- Only 47% percent of practices had a policy on the use of devices labelled as 'single use', of which 35% permitted their re-use, i.e. at least 15% of practices overall re-used single use devices.
- In 69% of surgeries, the clean and dirty areas were not clearly defined.
- 52% of surgeries did not have a dedicated sink for the cleaning of contaminated instruments.
- Virtually all (96%) of the surgeries used manual washing as either the sole method or as part of the cleaning process. This was generally poorly controlled with 41% of practices not using any cleaning agent other than water. In the remainder, a range of cleaning agents was used but there was no standardisation of concentration of cleaning agents, nor of the temperature of water used for cleaning. Only 2% of surgeries used a detergent formulated for manual washing of surgical instruments. Many used inappropriate agents, with 37% using surgical hand wash, and others using bars of soap, disinfectants and kitchen cleaning agents.

28. The report of the survey concluded that:

"There was little evidence of clear management processes underlying decontamination procedures in most practices and audit of instrument decontamination was virtually non-existent. Whilst cumbersome management procedures are clearly inappropriate for busy dental practices, guidance for dental staff on the various elements of process control is essential and required urgently, since ensuring and recording the quality of the process of decontamination is the only safeguard for the supply of adequately sterilized dental instruments."

29. However, at present there is not an agreed set of essential requirements for all private and NHS practices that can be enforced against.

Policy Objectives

30. There are four key objectives for this policy, all of which must be achieved in as cost effective a way as possible:

- Ensure systems are monitored as well as individual professional competency as these are a contributory factor in many patient safety incidents.
- Enforce essential requirements – ensure that persistently poor performance is tackled and that all providers must meet the essential requirements or face a range of enforcement powers.

[124] NHS Scotland (2004) "Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice" (available at: www.scotland.gov.uk)

- Consistency – 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 they are provided by.
- Provide public assurance and support patient choice by giving information on a provider's compliance with essential requirements.

Ensure systems are monitored as well as individual professional competencies

31. Professional regulation considers an individual's fitness to practice. They can only take action if the individual has been found not to be acting within the required professional standards which currently do not include standards on the systems they work within. This means that no action can be taken where systems have failed but an individual has acted in a professionally competent way. Revalidation will ensure that healthcare professionals keep their skills up to date and are able to deliver services. But they will not consider the organisations or the systems that they work within in the same way.

32. As a wider range of organisations are now delivering services, increasing numbers of doctors and dentists working in primary care settings are salaried and do not have control over the systems and premises that they work within (for example we know that 3 dental companies now hold around 600 NHS primary dental care contracts[125]). In addition, a report by the National Primary Care Research and Development Centre demonstrated that new NHS contracts have led to greater dependence on nurses, and greater reliance on co-operative working among general practices and between general practice and hospitals. These altered patterns of dependency have reduced the power of GPs to act alone in changing service provision[126]. This increases the importance of ensuring that the systems and premises they work within are checked.

Enforce Essential Requirements

33. At present, there is not a consistent set of standards in place for all settings providing equivalent services. In the absence of nationally agreed requirements, it is unclear what patients have a right to expect and it is difficult for PCTs to take action under the primary care contracts. In addition, the enforcement options available under primary care contracts are limited to either a "notice to improve" or termination of the contract. This makes it difficult to enforce essential safety and quality requirements. Finally, services provided outside the NHS and not registered with the Care Quality Commission are not subject to any enforcement if the systems fail.

Consistency

34. The overall objective for our regulatory framework is to ensure that a fair 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 that the activity is provided in and the type of provider they are provided by. At present different parts of the system are treated in different ways even when the same services are being provided. For example:

    - Wholly private GP practices are required to register with the Care Quality Commission.
    - GP practices providing NHS or mixed NHS and private services are not required to register.

[125] Data provided by NHS Dental Services.
[126] National Primary Care Research and Development Centre. "Personal Medical Services: Impact on working arrangements and service development in primary care." (available at www.npcrdc.ac.uk)

- All services provided in hospital settings are required to register with the Care Quality Commission but equivalent services provided in primary medical and dental care settings are not.
- Neither private nor NHS primary dental services are required to register.
- All services provided directly by PCTs are required to register but those commissioned by PCTs in equivalent settings are not**.**

35. This can encourage providers to configure themselves in a way that will avoid registration, even if this is not the best way to provide services to patients. It can also be confusing for providers, commissioners and patients as it is not clear what can be expected or why various provider types are treated differently. Finally, the approach cannot be justified on the basis of risk; indeed arguably, some services could pose a higher risk when provided in primary care settings rather than in secondary care settings. For example, there are not the same sorts of facilities in primary care as in secondary care and patients could therefore need to be transferred to a hospital if they were taken ill while being treated.

Providing Public Assurance and Supporting Patient Choice

36. Patients want to know that all their services meet essential levels of safety and quality and want to have enough information to make a real choice about the services they need.

37. Patients are currently unable to compare different GP practices or dental 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 have been met. Being confident that the essential requirements have been met in all providers would allow the patient to take account of quality measures (such as accreditation and Quality Accounts) and therefore differentiate further.

38. In addition, increasingly services traditionally provided in hospital settings are being provided in primary care settings. Yet without equivalent checks that essential levels of quality and safety are being met and consistent information being made available on all equivalent services, patient choice cannot be exercised effectively.

The Options

A. Approaches Considered

39. While developing this policy we have considered a number of ways to address the risks identified and meet the policy objectives outlined above. The main options considered (many of which are inter-related and could be used in combination) are outlined below.

Supporting PCT commissioning and contract monitoring

40. The Primary and Community Care Strategy set out work to support and strengthen PCT commissioning and contract monitoring. It cited the World Class Commissioning Programme, which sets out a framework to support PCTs in developing their commissioning and contract management skills. PCTs are being encouraged to manage under-performing practices, building on existing examples of good practice, develop improved quality metrics, and publish information for the local public about the range and quality of primary and community care services.

41. However, in consultation events held on the Care Quality Commission registration system in May 2008, PCT representatives argued strongly that improved PCT commissioning and contract management would not be sufficient and that registration of primary medical care

and primary dental care providers were needed. They advised that the primary medical and dental care contracts had too few specific criteria that they could use to demonstrate breach of contract on grounds of poor performance. They also suggested that the enforcement powers available under the contracts were not sufficiently flexible and were too narrow.

42. Strengthening PCT contract management would not deliver a nationally agreed set of requirements that patients could use to compare providers and that could be enforced against. It would also fail to deliver consistency, as it would only apply to services provided by the NHS, not those provided by other sectors.

Promoting choice and competition

43. A key theme of the Primary and Community Care Strategy is how to provide greater information and choice for patients, so that they can make informed choices and choose the best providers. It also sets out the intention to introduce Quality Accounts for primary care providers.

44. While this improved information will help patients making choices, it will only relate to NHS provided services, and therefore would not provide information on equivalent services provided in the voluntary or private sectors. As a result, it would not deliver consistency for all providers.

45. Although work could be undertaken to develop a set of specific system requirements and to validate the information being supplied, there would not be independent confirmation that all providers have met the requirements and the requirements could not be enforced against.

46. Therefore, this option would need to be linked with other proposals to ensure that the policy objectives of consistency, assurance, enforcement and system monitoring (set out above) were met.

Promoting practice accreditation

47. The Primary and Community Care Strategy signalled that we would work to promote accreditation schemes to improve quality and identify best practice, including working with the Royal College of General Practitioners to develop an accreditation scheme for GP practices. Accreditation schemes focus on system checks and are usually available to all types of providers. However, they are unlikely to deliver the policy objectives in their entirety, as practices will be able to choose whether to take part, the schemes will focus on improving quality rather than confirming that the essential requirements have been met, and, other than a practice failing to be accredited, there would not be a range of enforcement actions available. However, if adopted, accreditation schemes would be able to provide useful additional evidence that could be used in a range of ways by both the general public and the regulators.

Strengthening professional regulation

48. Professional regulation considers the suitability and competence of the individual health professional. It is different to system regulation in that it does not, on the whole, consider the wider organisation or systems that the individual works within, it considers the standards that an individual must conform to.

49. Work to strengthen professional regulation is ongoing. In particular, revalidation processes are being developed for all healthcare professionals to ensure that the individual professional continues to be fit to practise. Medical revalidation will have two core components: relicensure and specialist recertification.

50. For relicensure, all doctors will have a licence to practise that enables them to remain on the medical register. This licence to practise will have to be renewed every five years. In order to bring objective assurance of continuing fitness to practise, the appraisal process will confirm that a doctor has objectively met the standards expected. Specialist recertification will apply to all specialist doctors, including general practitioners, requiring them to demonstrate that they meet the standards that apply to their particular medical specialty. These standards will be set and assessed by the medical Royal Colleges and their specialist societies, and approved by the General Medical Council (GMC).

51. Professional regulation applies to all healthcare professionals, regardless of what setting or type of provider they work within. However, while it is consistent, it does not tackle failings in the systems that those professionals work within. This is because professional and competent professionals may meet all the standards expected of them as an individual but be let down by failings in the systems over which they have no control. To extend professional responsibility to cover system issues would impose a burden and demand expertise that would exceed the capacity of the professional oversight infrastructure as it stands.

52. As noted above, in primary care, there is an increasing diversity in the types of providers and more doctors, dentists and nurses are working as salaried employees. For example, in primary dental care three organisations hold around 600 primary dental care contracts, delivering services all over the country. As services are developing and providers become bigger, the individual's ability to influence the systems they work within diminishes and the corporate body needs to be held to account. A study of the first four wave PMS pilot schemes by the National Primary Care Research and Development Centre found that there was greater reliance on cooperative working, which reduced the power of GPs to act alone in changing service provision[127].

System Regulation for the riskiest services

53. In the partial impact assessment on this policy, we considered bringing only the most complex services provided in primary care into the scope of the registration system. It was suggested that it might be possible to bring only the services provided by GPs with Special Interests (GPwSIs) or Dentists with Special Interests (DwSIs) into the registration system and to exclude all other primary care activities. However, it has not been possible to differentiate between the different types of services provided in primary care based on risk; nearly all the services provided can be risky and that risk is increased if the premises, systems and processes that the services are provided within are not effective. In addition, although PCTs will only commission specialised services from GPwSIs or DwSIs, it is possible for GPs and dentists (who are competent to do so) to provide equivalent services under the standard primary medical care and primary dental care contracts without additional payments being made. It would therefore be difficult to implement such an approach consistently.

System regulation for all providers

54. System regulation for all providers would deliver consistency and provide public assurance that essential system requirements had been met. Three public consultation exercises have confirmed support for extending system regulation to primary medical care and primary dental care.

[127] National Primary Care Research and Development Centre. "Personal Medical Services: impact on working arrangements and service development in primary care" (available at www.npcrdc.ac.uk)

55. In considering how system regulation could be implemented for primary medical care and primary dental care providers, we have reviewed the existing powers of the various regulatory bodies and considered which would be best placed to take on this role.

56. The Care Quality Commission already exists as a system regulator with a remit extending across health and social care. It registers some primary medical care and some primary dental care providers and a range of other providers undertaking similar activities to those provided in primary care settings. It also has wide ranging and flexible enforcement powers available to it.

57. Extending the Commission's remit to include those primary medical care and primary dental care providers currently excluded from system regulation would deliver the policy objectives while utilising existing systems and processes.

58. The methodology to be used by the Care Quality Commission in the new registration system is yet to be finalised. However, it is likely that it will:

- Seek a self-assessment from providers. This will focus their attention on the essential requirements and provide background information for the Care Quality Commission.
- Triangulate all the available information including the self-assessment, contract monitoring information, patient surveys, HES data, QOF data, complaints, and other intelligence available from PCTs to develop a risk profile.
- Include some risk based inspections to follow up any identified issues and some random inspections to check the risk profile.

Conclusion

59. The Primary and Community Care Strategy includes a package of measures that will help to deliver the policy objectives set out above. 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 makes clear that there must be a mechanism for ensuring that all providers meet the essential system requirements and that persistently poor performance can be tackled with a range of enforcement measures. This is backed up by evidence from extensive consultation with key stakeholders and through public consultations.

60. The Care Quality Commission is best placed to draw upon these measures, in its position as an existing regulator for health care systems. We therefore consider registration with the Care Quality Commission to be the preferred option.

B. Options Considered for this Impact Assessment

61. In the light of the conclusion drawn from considering the range of approaches set out in section A, this Impact Assessment therefore considers three options:

- **Option One:** The "do nothing" option. The status quo would be maintained.
- **Option Two:** Require all providers of primary medical care and primary dental care to be registered by the Care Quality Commission. The implementation dates would be set in the regulations that set out the scope of the registration system for 2010.

Option One

62. Option one is the "do nothing" option. This reflects the current situation where NHS primary medical care providers and all primary dental care providers are outside the scope of the registration system for the Care Quality Commission. Any improvements to safety and

quality would have to rely on other aspects of the Primary and Community Care Strategy and the wider quality agenda on primary care.

63. A brief description of the current assurance processes in primary medical and dental care can be found in Annex A. This serves as a baseline against which to compare further options.

Option Two

64. Under Option two, the provision of primary dental care and primary medical care would be required to register with the Care Quality Commission from April 2011 and April 2012 respectively. These dates would be set in the regulations confirming the scope of registration for 2010. The regulations would exclude primary dental care providers from regulation until 1 April 2011 when the exclusion would automatically cease. They would also exclude primary medical care providers from regulation until 1 April 2012 when the exclusion would automatically cease. This is the preferred option. We briefly consider the arrangements for each sector below.

65. **Primary Medical Care**: The costs associated with regulation will be affected by the way that Care Quality Commission may be able to draw on an accreditation scheme that is currently being developed for general practices by the RCGP. This scheme is being developed so that it comprises 90 criteria split over two stages, to encourage improvement and practice development. Stage 1 includes criteria that are broadly equivalent (but not identical) to that of registration requirements. The scheme has been piloted (in a previous version) and is being developed in preparation for rollout.

66. The Care Quality Commission may draw on information gathered by this scheme when making decisions on GP practice registration. However, in the absence of any information on potential rollout and take-up we have assumed that the Commission will draw on a range of information already held centrally and make its decisions on compliance with the registration requirements independently of the accreditation scheme.

67. **Primary Dental Care:** Under the Health and Social Care Act (2008), the Care Quality Commission has powers to 'make arrangements for such persons as it thinks fit to assist it in the exercise of any of its functions'. It may also delegate any of its inspection functions to another public authority. As the NHS Dental Services processes all the payments made to dentists, carries out practice inspections, and assists PCTs with the management of their dental contracts, we expect the Commission to work with the NHS Dental Services, drawing on the information they hold and their existing expertise. The roles and responsibilities are yet to be agreed by the two organisations but it is anticipated that the NHS Dental Service's existing role could be extended to include offering the Commission assistance with developing guidance and methods, and undertaking routine assessment activity in line with agreed principles and clear rules for notifications and escalation. The NHS Dental Service may also extend its role to include the assessment of private dental providers.

Sectors and Groups Affected

68. There are three broad groups that will be affected by this policy; the regulators, providers and patients.

Regulators

69. There are four main organisations that would be affected.
    - The Care Quality Commission would be responsible for registering primary medical care and primary dental care providers. The level of costs will be affected by the amount of information available to them from other sources, the methodology adopted

by the Commission, and the obligations on them set out in the Health and Social Care Act 2008 and the regulations made under it.

- Primary Care Trusts currently have a duty to commission sufficient services to meet the needs of their population, manage those contracts and ensure that primary care provision is of a satisfactory standard. It is expected that they will continue to support providers and assist the Care Quality Commission by sharing the information they hold and commenting on the risk assessments CQC produces.
- The NHS Dental Services process data on NHS dentists and provide clinical monitoring activities. If their existing role is extended to include offering the Care Quality Commission assistance with developing guidance and methods, and undertaking routine assessment activity in line with agreed principles and clear rules for notifications and escalation, this would reduce the need for the Care Quality Commission to train new assessors and gather information on primary dental care.
- Tribunal Services will need to be available to provide the appeal mechanism for any providers the Commission refuses to register or decides to take enforcement action against.

Providers

70. This policy will impact on all primary medical and dental providers in England. By 2012 there are likely to be around 8,600[128] NHS primary medical care providers in England. There are currently around 34,000[129] GPs in England with the average provider having approximately four GPs[130]. There is a wide variation in the number of GPs per practice – 25% of practices have only one GP while the largest practices have over 15 GPs[131]. The total number of consultations in England in 2008-09 is estimated as 303.9m, giving a rate of around 5.5 consultations per person per year[132].

71. There are around 9,000 dental addresses in England and it is estimated that around 1,000 of these are solely private. Of the 8,000 NHS dental addresses, 850 are directly provided by PCTs. As all NHS bodies doing regulated activities, including PCTs, will be regulated by April 2010, these will already be registered and are therefore considered as part of the impact assessment considering the costs of the registration system to be established in 2010 that is published alongside this document. This leaves a figure of 7,150 NHS dental addresses. However, Care Quality Commission will register corporate providers for all the activities they provide and not all the premises that they operate from. As we know that three organisations hold around 600 contracts for NHS work, it is estimated that approximately 6,500 providers will need to register with the Commission.

---

[128] Figure provided by the Care Quality Commission as a best estimate for the number of practices likely to register in 2012. It is based on the number of providers identified by the Information Centre plus the number of new providers being established each year, identified by the Information Centre.

[129] http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-general-practice

[130] In this Impact Assessment, we only consider NHS or mixed practice primary medical care. Wholly private medical providers are currently registered under the Care Standards Act 2000 and will be required to register under the new registration system being introduced in October 2010. The costs of registering this group are considered in the Impact Assessment published alongside this one, which considers the costs and benefits of the regulated activities that will be brought into scope from 2010.

[131] Department of Health Data

[132] QResearch and The Information Centre for health and social care (2009). "Trends in Consultation Rates in General Practice 1995/96 to 2008/09: Analysis from the QRESEARCH database"

72. There are approximately 21,000 dentists working across both sectors at an average of 2.4 dentists per practice. 37% of dental practices are single handed, while 5% have six or more dentists. In 2008-09, there were 37.4m courses of treatment in the NHS[133] in comparison with an estimated 9m courses in the private sector[134].

Patients

73. Anyone using primary medical or dental care services will benefit from this policy. Registration will provide patients with the assurance that providers meet essential levels of quality and safety and that action can be taken to enforce compliance if necessary. This should increase patient confidence and safety to patients and provide the general public with information they can use when exercising choice.

74. If a provider closes, patients may also experience costs if they have to travel to another practice to register, or could see a reduction in access if they choose not to register with an alternative provider.

Mechanism of Impact

75. The registration requirements have been developed after extensive consultation and are intended to reduce the risks to patients identified above. The methodology to be used by the Commission is yet to be finalised. However, the Commission is required by the Health and Social Care Act to act in a proportionate way that places the minimum burden possible on the system. It looks likely that the process will include:

- A requirement for providers to carry out a self-assessment and declare that they are compliant with the registration requirements. This will ensure providers focus on meeting the essential requirements.
- The triangulation of all the available information (including the self-assessment, contract monitoring information, patient surveys, QOF data, complaints data, prescribing data, and other intelligence from PCTs) to develop a risk profile.
- Inspections of providers identified to need follow-up by the risk profiles (estimated at 5% of providers where existing information is held centrally, 100% of new providers and providers where information is not held centrally).
- Random inspections of providers to check the quality of the self-declarations and the risk profiles (estimated at 5% of providers, in line with standard auditing procedures).

76. The Commission will have a range of enforcement powers available to it if providers do not comply with the registration requirements. The Health and Social Care Act 2008 provides the Care Quality Commission with three new powers of enforcement. These are:

- issue a warning notice
- issue a monetary penalty notice in lieu of prosecution;
- Suspend registration.

77. The likelihood of random inspections and threat of sanctions should therefore lead to improved performance by primary medical and dental providers, as the costs of complying are outweighed by the cost of being found to not comply. This should, in turn, lead to better outcomes for patients.

Costs and benefits

78. When presenting the impact of the policy, we distinguish between exchequer costs and non-exchequer costs. Exchequer costs include all positive (and negative) costs to

[133] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

[134] Dental Review 2003-04 produced by the Dental Practice Board

government departments, regulatory bodies funded by government departments and public bodies such as the NHS. Non-exchequer costs are considered in the benefits section. These include all the positive (or negative) benefits to private providers, patients and the public as a result of the policy.

79. The cost benefit analysis for the three Options will be analysed as follows:
    - Firstly, Option 1 will be analysed.
    - This will be followed by analysis of Option 2 for primary medical care and primary dental care.

Option One – "Do Nothing" Option

80. Option One would maintain the status quo. However, it could lead to inconsistencies with other areas of health policy. In particular, pursuing Option one could:
    - Undermine the aims of delivering care closer to home set out in the NHS Next Stage Review;
    - Undermine the quality framework set out in the NHS Next Stage Review Primary and Community Care Strategy as this relies upon an independent check that essential requirements have been met by all providers;
    - It would also maintain the current state where there is no fair playing field in primary medical and dental care
    - It would result in the adverse events in primary care stated in Annex E continuing at the same rate as they do at the moment.

Option Two

81. Under Option two, primary medical care providers will be required to register with Commission by April 2012. Primary dental care providers will be required to register with Commission by April 2011. The exclusions for providers in *The Health and Social Care Act 2008 (Regulated Activities) Regulations 2009*[135] (which set out the scope of regulation from 2010) would automatically cease from those dates. We analyse primary medical care first, followed by primary dental care.

82. In both cases, analysis of the transitional costs to regulators and providers is given, followed by annual costs. The benefits from regulation are quantified last.

Primary Medical Care - Transition costs

83. There will be one-off costs for the CQC, PCTs, the First Tier Tribunal and GP practices in moving to the new regulatory framework. In addition, we consider the compliance costs of providers meeting the registration requirements.

Transition costs on the Care Quality Commission

84. There are three areas that will impose transition costs on the Commission:
    - the costs of registering all existing practices for the first time;
    - the costs of developing the registration criteria and guidance; and
    - The costs of training new analysts and inspectors.

[135] A draft version of these regulations was published in the document *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*, from page 130. Link: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991

Throughout this Impact Assessment, we have worked extensively with the Care Quality Commission to understand the activities and processes that will incur costs on the Commission and to monetise these activities using the best information available.

First time registration

85. For first time registration, the Care Quality Commission will need to undertake five activities; application processing, data acquisition and analysis, risk profiling, cross checking risk assessments with PCTs and follow-up checks (such as an inspection.) Data from the Commission (based on their existing arrangements and assuming approximately 10% of providers will require an inspection) estimates the cost of completing these tasks for 8,600 providers as £3.3m-£4.0m.

Development of criteria, guidance, communications and engagement

86. Based on the work that they have done to prepare to bring NHS bodies and providers registered under the Care Standards Act 2000, the Care Quality Commission estimate the costs of developing guidance, inspection guides and communications with providers and stakeholders to be £0.7m-£0.8m; we therefore use this as our estimate.

Costs of training new analysts and inspectors

87. We have used activity based costing information from the Care Quality Commission to get an idea of the costs of training new analysts and inspectors. While the Commission has inspectors and analysts already, it is expected they would need to expand their capacity in order to cover all primary medical care providers. An estimate for the cost of training on the Commission is £0.2m.

88. This cost estimate does not cover the costs of recruiting new analysts and inspectors, nor the salary costs during the training period. These components are currently unquantifiable but we expect them to be of a modest magnitude.

Transition costs on Primary Care Trusts

89. Primary Care Trusts might incur costs to offer support to help GP practices prepare for registration. PCTs might also incur costs in making sure the Care Quality Commission has all the preliminary information it needs.

90. One of the activities the Commission will conduct for initial registration is crosschecking the self-assessment that providers submit and the risk profile drawn up by triangulating other available data with PCTs to quality assure the information. We estimate the cost on the PCT will be equivalent to the cost imposed on the Care Quality Commission. Across all PCTs, this is estimated to be £98,000-£120,000.

91. It is not clear whether providers would need the PCTs help in preparing for registration and completing the self-assessment. However, if we assume, as a worst-case scenario, that PCTs would need to spend the equivalent of up to one day per practice in the initial registration phase. This would allow time to pull together information to assist the practices and support any practices needing to improve the safety and quality of the services they provide. This would cost £1.1m-£1.4m across all PCTs.

Transition costs on the First Tier Tribunal

92. Registration with the Care Quality Commission would give all regulated providers the right to appeal against a decision made by the Commission if it was deemed to be unreasonable.

93. The probability of appeals to the First Tier Tribunal (Care Standards) under the new regulatory framework is not possible to calculate at present. However, the First Tier Tribunal will need to add extra capacity to make sure it is capable in extending its remit to the newly regulated providers. The First Tier Tribunal spent £116,000 on the fixed costs of their operations for the cases it conducted under CSCI. Taking an appropriate proportion to cover

the 8,600 providers coming into scope under this policy, this is estimated to cost £38,000-£47,000.

Transition costs on providers

94. Current GP practices will incur some transition costs, as they will have to register with the Care Quality Commission for the first time. As NHS GP practices have not had to register with the Commission before we have to make assumptions about how much it will cost practices in terms of money or resources.

95. Under the Care Standards Act (2000) framework, private doctors were required to register with the Healthcare Commission. Interviews with private doctors showed that the cost of registration for them was around £4,000 in terms of administration and time. However, the Care Standards Act system will be different to registration under the Care Quality Commission for at least three reasons:
    - The new framework will be based on registration requirements that prescribe the expected outcome of the service and not the process of how this outcome should be achieved. This makes the work that providers must do less prescriptive and less burdensome to prove.
    - Some GP practices will have been accredited and hence the GP practice will need to provide much less information, reducing costs further.
    - There is already a great deal of centrally-held information on NHS providers (e.g. QOF and prescribing data) and PCTs already hold information and carry out regular visits. We expect the Care Quality Commission to use this information for its risk profiling activities. As a result, the need for providers to supply their own data will be much reduced and the proportion of practices requiring inspection is likely to be lower than for wholly private doctors.

96. For this reason, we believe a first time registration will be more similar to an annual self-assessment for GPs, than an actual first time registration. For private doctors, this annual self-assessment is estimated to cost £1500 in terms of administration and time.

97. In addition, around 30% of GP practices are training practices and the burden for training practices will be reduced further as they will have more information to use for registration[136] and potentially already be meeting standards that are more stringent.

98. Hence, we believe that registration with the CQC will cost around 40-46% less than under the Care Standards Act system. A detailed explanation of this cost reduction can be found in Annex B. Multiplying this across 8,600 providers gives an estimate of £6.9m-£7.7m.

99. A summary of the transition costs for Option two (Primary Medical Care) is shown below.

Table 4: Summary of Transition Costs for Primary Medical Care (Option 2)

Organisation	Cost Detail	Low Estimate	High Estimate
CQC	Processing First Time Registration	£3.3m	£4.0m
	Development of criteria and guidance	£0.7m	£0.8m
	Training new analysts and inspectors	£0.2m	£0.2m
PCTs	Assisting CQC	£98,000	£120,000
	Assisting providers	£1.1m	£1.4m
First Tier	Expanding capacity	£38,000	£47,000

[136] See Annex A for more information on assurance processes for training practices.

Tribunal			
Providers	First Time Registration	£6.9m	£7.7m
TOTAL		**£12.3m**	**£14.3m**

Primary Medical Care - Annual costs

Annual Costs of regulation on Care Quality Commission

100. The Care Quality Commission will undertake five activities that have cost impacts for them. These are:

- The costs of processing new applications;
- The costs of processing individual self-assessments;
- Ongoing compliance (e.g. data acquisition and collection);
- Provider Inspections; and
- Costs of enforcement

Each of these activities is considered in turn.

Processing new applications

101. The Care Quality Commission will need to process the registration forms for new providers. Data from the NHS Information Centre shows around 100 providers being set up each year (including walk-in centres, out of hours providers and separations in partnerships). Assuming this number of new providers need to register each year, based on existing Commission activity costs, this is estimated to cost the Commission £0.1m-£0.2m.

Processing annual assessments from providers

102. The Care Quality Commission will incur costs from processing the annual assessments from existing providers and using this to make a decision on whether further action is needed (e.g. an inspection.) Based on existing activity costs, the Care Quality Commission has suggested an estimate for this cost is £0.2m-£0.3m.

Ongoing compliance

103. This cost covers other activities the Care Quality Commission will need to do, such as data collection, intelligence gathering, data analysis and risk profiling. Using Care Quality Commission estimates based on existing activities, this is estimated to cost £2.9m-£3.5m.

Inspections

104. It is expected that the Commission will inspect around 10% of practices each year. Half of these inspections will be judged using a risk-based approach (i.e. providers that pose the highest risk) while the other half will be inspections made on random practices to check the validity of the analysis and risk profiling. Based on existing activity based costings this is estimated to cost £1.6m-£2.0m.

Enforcement

105. The Healthcare Commission previously spent around £0.7m on investigation actions and enforcement across all the providers it regulated However, some of this cost will be covered by other fixed enforcement expenditure in the accompanying Impact Assessment on the scope of regulated activities under the Care Quality Commission. In addition, the Commission are unlikely to make a large number of enforcement actions in its first year. Hence the Commission estimates enforcement costs of £0.3m in its first year, rising to £0.5m in future years.

Annual Costs on the First Tier Tribunal

106. The First Tier Tribunal would incur annual costs from dealing with the appeals from providers. Previously there were very few appeals to the Tribunal from Independent Sector Healthcare providers and it is not possible to predict if and how this will change in the future.

107. The First Tier Tribunal incurred costs of £0.2m in dealing with the appeals from social care providers. We anticipate a similar proportion of providers to appeal when primary medical care providers are brought in, so an estimate for their costs is £0.1-£0.2m.

Annual Costs on Primary Care Trusts

108. The impact on PCTs is mixed; the Care Quality Commission will ensure that essential requirements are met and so PCTs may be able to focus more on developing quality and potentially less on tackling poor performance. This may mean that enforcement activity will be undertaken by Commission rather than PCTs and so result in a reduction in PCT costs. However, some consultation responses said that PCTs might experience an increase in costs if the Commission requires more information than the PCTs currently collect or if PCTs are informed by Commission of issues that they need to follow up or provide support to practices. In the event of enforcement action being necessary, it could also result in the PCT needing to identify alternative services.

109. In terms of ongoing compliance, the Care Quality Commission would gather intelligence on practices by talking to the PCT. If this takes one day of one official from the PCT's time, then we estimate this will cost around £20,000-£24,000 across all PCTs.

110. In addition, the PCT may incur annual costs from providing information and helping providers complete forms to renew their registration. We do not expect this will require the same amount of time as for initial registration, so this is estimated to cost £0.6m-£0.7m across all PCTs.

Annual Costs to providers

111. There are four main costs that will lead to recurring costs for providers. New primary medical care providers will have to register for the first time, existing GP practices will incur administrative costs for self-assessments and inspections, and all practices may incur compliance costs.

<u>Costs of first time registration – new practices</u>

112. As mentioned above, the NHS Information Centre estimates that the net increase in NHS GP practices is around 100 per year[137]. This may be because of a separation in a partnership or a new practice being established. These providers would need to register with the Care Quality Commission for the first time, so these cost estimates will be based on the cost estimates for transition costs of between £2,133 and £2,400 for a private provider. Multiplying this by the number of new providers each year an estimate for this cost is £0.2m.

<u>Costs of annual assessment – existing practices</u>

113. Existing practices will need to complete an annual self-assessment to show they remain compliant with the registration requirements. This will be less burdensome than registration, as information gathering processes should be in place already.

114. Interviews with private doctors found they spent an estimated £1,500 of their time on their annual self-assessments. Using the arguments in paragraphs 95-98, we assume that the new regulatory framework will bring about a reduction of 64-68% (see Annex B for an explanation of these cost reductions) as a range of information on NHS contract holders is already held and compiled centrally. This gives an estimate of £480-£540. As all providers

[137] This net increase is the difference between the number of new practices starting up and existing providers closing down.

would need to complete an annual assessment, this is multiplied across 8,600 providers. The costs are estimated to be £4.1m-£4.6m.

Costs of extra inspections – existing practices

115. The Care Quality Commission will inspect 10% of providers on a risk-based approach or inspected randomly to provide a comparative sample of GP practices. Using estimates from interviews with private doctors, we estimate the cost to the provider as £370 per inspection. This is multiplied by 860 providers (10% of all providers) and gives a total cost estimate of £0.3m.

Compliance costs on providers

116. In addition to the costs calculated above, the new system may also impose costs on providers in order to demonstrate compliance with the registration requirements each year. The size of these extra costs are difficult to estimate at this time as they depend on the exact compliance criteria, which is currently being finalised by the Care Quality Commission.

117. When considering these costs it is important to remember that The Care Quality Commission is required by the Act to be proportionate in its actions and its manifesto states that it will be tough, fair and proportionate. This is understood to include a requirement that it ensures that the societal benefits of compliance with its standards and of its enforcement interventions exceed their opportunity costs

118. It is anticipated that nearly all NHS providers will already meet the essential requirements as they are already expected to comply with the requirements in their NHS contracts. The Care Quality Commission is required to act proportionately and given the size of primary care providers relative to other healthcare providers (e.g. an Acute Trust) it follows that compliance costs are expected to be low. In addition, compliance with requirements would lead to reductions in adverse events, thus leading to benefits (see Annex E) that we expect to outweigh the compliance costs. Anecdotal evidence suggests that around 2-3% of primary medical care providers would have difficulty demonstrating compliance. It would be for this small proportion of providers that compliance costs are likely to be high.

119. For private primary medical care providers, the transition to the new system is likely to yield a reduction in compliance costs. The CSA involved process-based measures and required providers to show evidence of the processes they used in their work. However, the new system will be more outcome-based, thus giving providers the opportunity to explore different ways of achieving the outcome-based regulations in a manner that is efficient to them.

120. However, outcome-based regulations are more open to interpretation by inspectors and the Care Quality Commission. The Guidance about Compliance will go some way to reduce uncertainty, but it is possible that providers might undertake unnecessary and costly actions to be absolutely sure of satisfying the regulations. In the future, though, we expect this impact to fall as regulators and providers gain a better understanding of what is necessary to demonstrate compliance.

121. We can summarise the annual costs of Option 2 (Primary medical care) in the table below.

Table 5: Summary of Annual Costs for Primary Medical Care (Option 2)

Organisation	Cost detail	Low estimate	High estimate
CQC	Processing Registrations for New Providers	£0.1m	£0.2m

	Processing Self Assessment	£0.2m	£0.3m
	Ongoing Compliance	£2.9m	£3.5m
	Inspections	£1.6m	£2.0m
	Enforcement	£0.3m	£0.3m
First Tier Tribunal	Enforcement cases	£0.1m	£0.2m
PCTs	Helping CQC	£20,000	£24,000
	Helping providers	£0.6m	£0.7m
Providers	First Time Registration	£0.2m	£0.2m
	Annual Assessment	£4.1m	£4.6m
	Inspection	£0.3m	£0.3m
	Compliance costs	unquantified	
TOTAL		**£10.5m**	**£12.4m**

Primary Medical Care – Benefits

122. We can identify five main benefits and two dis-benefits from this policy:
- Consistency of requirements
- Enforcing essential requirements
- Benefits to patients in secondary care
- Improved quality and safety in primary medical care
- Patient reassurance and increased confidence in GPs
- Information to allow patient choice and the delivery of care closer to home
- Costs due to some providers shutting down

123. Quantifying the benefits above is not straightforward but it is important to consider them. Studies suggest the risks in primary care are not as high as they are in secondary care. For instance, Cracknell et al[138] found that adverse events occur in around 11% of all admissions to hospital[139]. However, given the scale of primary medical care provision – as explained earlier, there are nearly 304m consultations each year – means that even a small risk could still impact on a large group of people.

124. In addition, the increasing number of treatments formerly provided in hospitals and now offered in primary and community care settings could lead to higher risks in the future. We have therefore attempted to quantify the benefits as far as possible and compared them with the costs.

Consistency of Requirements

125. As set out in paragraph 34, the overall objective of this policy is to ensure that a fair playing field is in place for all providers. Introducing the same requirements on safety and quality across both public and private providers and across all settings would create a fair playing field and lead to greater contestability for contracts and efficiencies. The value of the benefit of a fair playing field is not quantifiable.

[138] Cracknell, A. Sari, A, B. Sheldon, T. Turnball, A. (2007) "Sensitivity of routine system for reporting patient safety incidents in an NHS Hospital: Retrospective patient case not review," *British Medical Journal,* 344:79

[139] Annex E cites articles showing that adverse events occur in primary care at a rate of between 5 and 80 per 100,000 consultations (0.08%).

Enforcing Essential Requirements

126. The introduction of a national regulator for primary medical care providers would bring consistency on enforcement actions and remove local variability. The essential requirements all registered providers will be required to meet means that the same requirements must be met throughout England. This benefit has not been quantified.

Benefits to patients in secondary care

127. Higher quality in primary medical care can lead to higher quality in other areas of healthcare. As primary medical care is often described as the gatekeeper to other health services, it can be anticipated that some providers of primary medical care could further improve its gate keeping function and manage patients in the community. If done effectively, these patients would not need treatment in secondary care or, if they did require secondary care, could be treated as an elective outpatient or inpatient rather than requiring an emergency admission. The scenario below attempts to place a value on this benefit.

128. Data from the Care Quality Commission's database of emergency admissions to secondary care for chronic conditions that can be effectively managed in the community shows a wide variation in numbers at PCT level. There could be a range of factors that might explain this variation – for instance, demographics and patients not visiting their GPs early enough. However, the variation could also reflect GPs failing to manage patients that suffer from these conditions effectively. If this is the case, we should expect to see fewer emergency admissions and, of those requiring elective hospital treatments, a higher proportion of outpatient treatment. This difference in cost would generate savings for NHS Trusts, which could then be translated into benefits for other patients as the money is reinvested into other care.

129. We cannot be certain of the extent to which the number of emergency admissions will fall by. We have modelled the following scenario to give an idea of how big these estimates are and we believe this is a realistic estimate. We arbitrarily assume that this policy brings a reduction in emergency admission numbers to a level that is no higher than the 75th percentile of the distribution of emergency admissions. From this, we could expect to see a 2.2% reduction in the number of emergency admissions. This would lead to a benefit of £14.3m per year. The calculations behind these figures are explored further in Annex D.

130. There would also be direct benefits to patients of primary care, but we have not attempted to quantify these. We would, however expect them to be significant.

131. There could also be benefits to patients in secondary care through further cost savings to the NHS. We estimate in Annex E the savings to NHS Trusts of registrations lowering the risk of adverse events in primary care, and the subsequent savings to the costs of secondary care treatment. Therefore, we estimate that there would be saved treatment costs to secondary care of £7.0m - £195.9m.

132. Therefore, if we sum the benefits from reductions in emergency admissions, and the benefits from saved treatment costs in secondary care, we have a benefit of £21.3m – £210.2m.

Improved quality and safety in primary medical care

133. In addition to benefits in secondary care, it is important to also consider benefits to patients in primary care. Patient safety and care is of paramount importance in primary medical care, especially given the large number of people that use primary medical care services. Quantifying this benefit is not straightforward but we consider adverse event data in deriving an estimate for this benefit.

134. There are many different types of adverse event in primary medical care and many of them are easily preventable (Annex E cites papers on preventable adverse events in primary

medical care.) It is expected that the introduction of system regulation under the Care Quality Commission will bring about a reduction in the number of adverse events taking place in primary medical care and this will bring two separate types of benefits.

135. In the first place, if there are fewer people suffering an adverse event then there will be a QALY[140] gain for patients. This is calculated using the current rate of adverse events and considering the effectiveness of this policy on specific types of adverse events.

136. It is estimated that Care Quality Commission regulation will bring a benefit to patients of £1.3m-£36.1m, with a mid-point of £18.7m. The wide range of values reflects the varied sources of information on adverse events in primary medical care. The derivation of these figures is explored further in Annex E.

Patient reassurance and increased confidence in GPs

137. System regulation will reassure patients that essential levels of quality and safety have been met. Quantifying individuals trust and reassurance is not straightforward but the analysis below attempts to put a valuation on this benefit.

138. One of the domains under the EQ-5D framework for measuring health states relates to anxiety and depression. The framework asks individuals to rate their health from 1 to 3; a response of 1 means the individual has no problems whereas a response of 3 indicates serious problems. For the purpose of this assessment, we assume that Care Quality Commission regulation of primary medical care providers will increase the health state of individuals who have little confidence or trust in primary medical care professionals and reduce their anxiety of going for a consultation.

139. The EQ-5D scores can be turned into a health state (measured between 0 and 1, where 1 represents perfect health and 0 represents death) using regression analysis. The difference in health state between a person recording 1 and 2 on the anxiety/depression scale is 0.071[141].

140. We can convert this figure into a QALY valuation by considering the duration of time this change in health state would last for. For the purpose of this assessment, we assume that patients will see their anxiety reduced for one week. This is then multiplied by the valuation of a QALY (£60,000) to give a value of £82 per patient.

141. It is now necessary to consider how many people will experience this change in health state and experience this £82 benefit. There are around 55.25m people registered with a GP in England[142], and a study by the Ipsos MORI shows that around 92% of people have trust in their doctor[143].

142. We assume that 1% of the 8% of people who do not have trust in their doctor experience this increase in health state. We additionally multiply this figure by the average number of consultations each year (stated above as 5.5 consultations per year). This gives a valuation of £17.9m-£21.9m, with a midpoint of £19.9m. These figures are an indication of the benefit of patient confidence and it is for this reason that we apply a +/-10% margin on these figures to accommodate for uncertainties.

---

[140] Quality Adjusted Life Year

[141] 0.071 is the difference in health state between an individual EQ-5D score of 11111 and 11112.

[142] Calculated as the 303.9m consultations in NHS primary medical care divided by the average rate of consultations per person (5.5)

[143] http://www.ipos-mori.com/DownloadPublication/1305_sri-trust-in-professions-2009.pdf

Patient choice and delivery of care close to home

143. The NHS Next Stage Review made clear that the aim is to deliver more care closer to home. Patients have made clear that this is something that they want but need reassurance that, wherever they receive the care they need, essential requirements are met. They also need information to allow them to exercise the choices they have on which GP to register with and where to receive the treatment they need. Registration with the Care Quality Commission will, together with a number of other policies (including Quality Accounts) help to supply this information. No attempt has been made to quantify this benefit.

Transition costs of the Care Quality Commission removing registration on patients

144. The Care Quality Commission will have a range of enforcement powers to deal with primary medical and dental care providers in the event of a breach in regulations. These actions vary in severity from issuing a warning notice, to fines or even cancelling registration.

145. We expect providers to have registration removed as a last resort, once other forms of enforcement have been used and failed and where the PCT is unable to support the provider to improve and has options for replacing the service for patients. Although we do not expect it to happen often, it is important to consider the impact on patients if their GP practice is closed down. We consider this impact as a dis-benefit in accordance with Impact Assessment convention.

146. In addition, we have to consider the possibility that system regulation by the Care Quality Commission might act as a sufficient burden on some GP practices that they would voluntarily close down, or not open when they previously would have, since system regulation can be interpreted as a barrier to entry.

147. If a provider is closed down then the PCT can decide to commission another practice in the same location or try to increase capacity at surrounding practices to deal with new patients. What will happen in practice will depend on the PCT and a variety of other factors[144].

148. To get an idea of the inconvenience that this imposes on patients it is necessary to cost the additional time it takes for an individual to travel to their nearest alternative practice. Equally, in the circumstance that the PCT decides to install a new practice on or near the site of the old practice, then we consider the costs the PCT bears in dealing with the closed practice and the commissioning of a new practice.

149. We have modelled several scenarios to calculate a range of different values based on the size of the practice and the distances between practices. These scenarios are described in greater detail in Annex C.

150. It is up to the Care Quality Commission to decide whether they will remove a provider's registration or not and hence, it is not possible at this time to know accurately how many practices will be shut down. For instance, practices that were very close to the level needed for registration may have their registration conditional on them making improvements on their weaker areas, with the possibility of further sanctions in coming months. However, very poorly performing practices might not be treated in the same way and, theoretically, the Commission, after working with the PCT, might opt to refuse or remove the provider's registration.

[144] For instance, if a GP practice in a rural location closed, the PCT may be more likely to get another practice in that location rather than increase capacity at the nearest alternative practice as that could be a long way away.

151. We estimate the costs on patients for each practice that closes will be around £0-£52,000 with a best estimate of £16,000[145]. Because we do not know how many providers might close, we cannot provide a definite valuation, but anecdotally it is believed that up to 0.5% of providers may close down. Using this figure, we can estimate that the total costs of providers closing to be £0m-£2.2million, with a best estimate of £701,000. It should be noted that £2.2million is an upper bound estimate, and we expect the costs to be much lower.

152. Estimates for the cost of the PCT to commission another practice will depend on the extent to which the PCT has contingency plans in place to deal with a practice that has been shut down. The options a PCT might pursue are:

- List dispersal – asking patients to travel to a nearby practice. This is the cheapest option but not popular with patient groups.
- Locums and direct management – these can be expensive and only usually used in urgent situations.
- Tendering a new contract – this can take some time but is comparatively affordable.
- Merger with a nearby practice – unlikely to incur significant costs.

153. Accurate cost estimates for these options are not available because the precise cost impacts will vary from case to case. We expect overall the costs would be of a modest magnitude.

154. A summary of the benefits for Option 2 (Primary medical care) can be found in the table overleaf.

Table 6: Summary of Benefits for Primary Medical Care (Option 2)

Benefit	**Low Estimate**	**High Estimate**	**Best Estimate**
Level playing field	Unquantified; Greater than zero	Unquantified; Greater than zero	Unquantified; Greater than zero
Enforcement actions	Unquantified; Greater than zero	Unquantified; Greater than zero	Unquantified; Greater than zero
Benefits to patients in secondary care	£21.3m	£210.2m	£115.8m
Improved quality and safety in primary medical care	£1.3m	£36.1m	£18.7m
Patient reassurance and confidence in GPs	£17.9m	£21.9m	£19.9m
Patient choice and delivery of care	Unquantified; Greater than zero	Unquantified; Greater than zero	Unquantified; Greater than zero
Costs of shutting providers down	£0	£2.2m	£701,000
TOTAL	**At least £40.5m less**	**At least £266.0m**	**At least £153.7m**

Primary Dental Care

155. Under Option two, primary dental care will fall under the scope of Care Quality Commission registration in April 2011. This implementation date would be set in regulations

[145] This figure is generated using the average distance and the average practice list.

with the exclusion for primary dental care providers automatically coming to an end. As with primary medical care, we analyse the transition costs first, followed by annual costs and finally benefits.

Primary Dental Care - Transition Costs

156. The regulation of primary dental care will have a cost impact on the Care Quality Commission, the NHS Dental Services, the First Tier Tribunal and dental providers. We consider the impacts on each of these in turn. Cost to private dentists are considered in the benefits section, in accordance with Impact Assessment convention.

Transition costs on the Care Quality Commission and NHS Dental Services

157. As set out in the Options section, it is anticipated that the Care Quality Commission and the NHS Dental Services would be working together on the regulation of primary dental care providers. For the purpose of this Impact Assessment, we treat their costs together rather than attempting to separate roles for each organisation as it is not yet clear which organisation will take on which aspects of the tasks envisaged. Transition costs would be incurred for developing guidance and communication with providers, registering providers for the first time and training analysts and inspectors.

Developing guidance and communication with providers

158. The number of primary dental care providers being brought into registration is roughly equivalent to the number of primary medical care providers. It follows that the costs of developing guidance and communication will be roughly similar, so we use the estimates from the primary medical care section. These are £0.7m-£0.8m (see paragraph 86)

Costs of first time registration for current dental providers

159. Existing dental providers would need to be registered for the first time. Registration will involve application processing, data analysis, risk profiling, follow up checks and crosschecking information with PCTs. Data from the Care Quality Commission estimates this to cost £4.5m-£5.4m.

Costs of training new analysts and inspectors

160. NHS Dental Services currently provide some inspections of dental practices but both NHS Dental Services and the Care Quality Commission will need to expand the number of analysts and inspectors they use for primary dental care regulation (in particular, expansion into private dental care providers.) This is estimated to cost £0.2m.

161. There will be additional cost elements that cannot be quantified at this time. This includes the costs on the Commission to recruit the inspectors and salary costs. There may also be other unforeseeable costs that are currently unquantifiable – for instance, the sharing of confidential information between the NHS Dental Services and the Care Quality Commission.

Costs of First Time Inspection

162. NHS Dental Services currently provides clinical monitoring activities to support PCTs' monitoring and management of NHS primary dental services contracts. These activities may include reviewing clinical records, examination of patients and the inspection of dental practice premises and facilities. NHS Dental Services estimate that currently around 20% of PCTs ask them to do inspections on their behalf, with others making their own arrangements.

163. In the future, the Care Quality Commission and NHS Dental Services will conduct inspections on providers in relation to Care Quality Commission registration. Inspections on behalf of PCTs would continue where necessary, but there will be costs from conducting additional inspections on providers. It is anticipated that there will be an inspection rate of

10% for NHS dentists[146] and all private dentists in the first year. This is because the Care Quality Commission will not have any previous data on private dentists, and so will want to inspect them all in order to start to develop a risk profile. Based on this rate, figures from the Care Quality Commission and NHS Dental Services estimate the costs of inspection to be £2.2m-£2.6m in the first full year.

Transition costs on PCTs

164. As with Primary Medical Care, it is likely that PCTs may be asked to provide information to the Care Quality Commission and also to support providers completing applications so that they can obtain registration.

165. We assume that the costs on the PCT to help the Care Quality Commission cross check applications will reflect the costs on the Care Quality Commission. For the providers registered, this will cost £98,000-£120,000.

166. When assisting providers with registration, we anticipate costs of £0.8m-£1.0m, based on the cost of PCT time for each NHS dental practice.

Transition costs on Tribunals

167. The First Tier Tribunal will need to add extra capacity to make sure it is capable of extending its remit to dental practices. Using the same estimates as those for primary medical care in paragraph 92-93, we estimate costs of approximately £40,000-£49,000.

Transition costs on providers

168. The transition costs on providers will depend on whether they provide services as part of the NHS or not. There are 9000 NHS primary dental care addresses of which 850 are directly provided by PCTs (which will be registered from April 2010) and therefore not the subject of this impact assessment. Many providers provide a mix of NHS and private treatments. In addition, there are estimated to be approximately 1000 solely private providers (although these are considered in the benefits section, as they are non-exchequer costs). In total therefore there are estimated to be 8,150 primary dental care premises.

169. By 2011, it is anticipated that as part of routine clinical monitoring, the majority of NHS providers will be completing an annual self-assessment form, which will be submitted to NHS Dental Services. Under the new registration system, this will be supplemented by an additional annual self-declaration confirming that the information in the self-assessment is correct and that they meet the registration requirements. The NHS Dental Services would process the form as usual and it is anticipated that they would use this together with the range of other information they hold and information from the PCTs to make a recommendation to Care Quality Commission whether to grant registration or not.

170. Although NHS providers would have had to complete self-assessments already, the new requirement to complete a self-declaration that says the information they submit is correct and to confirm the regulated activities that they undertake is a new task. Using data from the NHS Information Centre on dental wages, we estimate this could cost around £600-£750 per provider. As 3 companies hold around 600 contracts, and each company has to register but not each practice, we can remove 597 from our figure of 7,150 NHS providers, leaving 6,553. Hence, the total cost for NHS providers is £4.0m-£4.8m.

171. A summary of the transition costs for primary dental care can be found in the table below.

[146] This comprises of inspection of 5% of NHS providers according to their risk profile, and inspection of a further 5% of NHS providers at random.

Table 7: Summary of Transitional Costs for Primary Dental Care (Option 2)			
Organisation	***Detail***	***Low Estimate***	***High Estimate***
CQC and NHS Dental Services	Developing guidance	£0.7m	£0.8m
	Processing First Time Registration	£4.5m	£5.4m
	Training analysts and inspectors	£0.2m	£0.2m
	First Time Inspection	£2.2m	£2.6m
PCTs	Helping CQC	£98,000	£120,000
	Helping providers	£0.8m	£1.0m
First Tier Tribunals	Adding capacity for appeals	£40,000	£49,000
NHS Providers	Self-declarations	£4.0m	£4.8m
TOTAL		**£12.4m**	**£15.2m**

Primary Dental Care - Annual Costs

Costs of regulation on the Care Quality Commission and NHS Dental Services

172. There are five activities that will incur costs for the Care Quality Commission and NHS Dental Services. These are:
    - Processing new applications
    - Processing individual self-assessments
    - Ongoing compliance (e.g. data acquisition and intelligence gathering)
    - Enforcement actions against providers
    - Inspection of dental providers

Costs of processing new applications

173. The Care Quality Commission will incur costs from new providers that require registration or variations in registration from existing providers. It is estimated this would be around 5% of the current total number of all 8,150 dental practices[147]. This is estimated to cost £0.2m.

Costs of processing individual self-assessments

174. There will be costs incurred in processing the annual self-assessments from dental providers and judging whether an inspection is needed. Since the Care Quality Commission will be able to rely on information already collected by the NHS Dental Services, this lowers the overall costs. This activity is estimated to cost £0.1m-£0.2m.

Ongoing compliance

175. Ongoing compliance covers a variety of different activities; data analysis, intelligence gathering, risk profiling etc. These activities are estimated to cost £2.6m-£3.0m.

Costs of enforcement

176. We use the estimates from primary medical care for enforcement actions against dental providers. Since there will be a degree of fixed costs used for enforcement actions against

[147] There has been an increase in the number of dental practices (measured as number of dental addresses) of 3% over the last seven years or 0.4% each year. As a conservative estimate, we estimate in the future a maximum increase each year of 408 practices (or 5% of the current stock of practices.)

primary medical care providers, we use the same estimate here (see paragraph 105). This leads to first year enforcement costs of £0.3m, increasing to £0.5m in future years.

Costs of inspection

177. . As covered in paragraph 163, it is anticipated that there will be an inspection rate of 10% of all NHS Dentists[148] and all private dentists in the first year. Annually, the Care Quality Commission and NHS Dental Services will continue to inspect 10% of all NHS Dentists, yet will inspect only 10% of all private dentists, as they will now have a basis for their risk profiling. Based on these rates, figures from the Care Quality Commission and NHS Dental Services estimate the annual costs of inspection to be £1.0m-£1.3m.

Costs on PCTs

178. PCTs will incur costs from continuing to assist the Care Quality Commission and dental providers with registration and ongoing compliance. PCTs will be asked to help the Commission with its intelligence gathering commenting on Commission and NHS Dental Services information and supplying any further information they hold. Based on wages and time this is estimated to cost PCTs £20,000-£24,000.

179. In terms of assisting NHS providers, we expect that PCTs will need to spend some time supporting providers and helping them to improve so they meet the essential quality and safety standards. Based on wages and time, this is estimated to cost £0.5m-£0.6m

Costs on First Tier Tribunal

180. We use the cost estimates for primary medical care here (see paragraphs 106-107). If we use this cost for 8,150 dental practices, this would generate a cost of £0.1m-£0.2m per year.

Costs to Providers

181. The impact on dental providers will be less than the impact on primary medical care – this is mainly due to the work that the NHS Dental Services currently conducts in relation to NHS providers and the way that Care Quality Commission registration is expected to build on their existing methodologies. There are three main costs on providers: the costs of first time registration for new providers, the additional cost of self-assessments and self-declarations and the costs of inspections. Each is discussed in turn.

Costs of first time registration

182. We assumed in paragraph 173 there is a 5% turnover of practices each year and these new practices would have to register with the Care Quality Commission for the first time. Three large companies hold around 600 contracts. As each company has to register but not each practice, we can deduct 597 from our figure of 7,150, leaving us with 6,553 NHS providers. We apply a 55-60% reduction to the registration estimate used in paragraph 96 (see Annex B for an explanation of these cost reductions) of £4,000 per provider. This leads to costs of £1,600-£1,800 per provider, and an aggregate estimate of £0.5 m-£0.6m.

Costs of self-assessment and self-declarations

183. By 2011, all NHS dental providers are expected to complete a self-assessment, which is submitted to the Dental Services Division. Owing to the arrangement between the Care Quality Commission and NHS Dental Services, NHS providers would not incur any new costs, as they would continue to fill out the same self-assessment.

184. Paragraph 170 states that each provider would need to complete a self-declaration each year and we have assumed this would cost a provider up to £190 per year – this is lower than the transitional costs of self-declaration because the burden on practices would fall over

[148] This comprises of inspection of 5% of NHS providers according to their risk profile, and inspection of a further 5% of NHS providers at random.

time as their processes align with Care Quality Commission regulation. All 7150 NHS providers would have to sign this declaration and confirm the information is correct with all colleagues, this cost is estimated as £1.2m-£1.5m each year.

Costs of inspections

185. As mentioned in paragraph 177 it is expected the Care Quality Commission will inspect 10% of NHS practices each year. Using estimates from interviews with private doctors and cost estimates on dentist's wages, we estimate the cost to the provider as £370 per inspection. If 10% of practices will be inspected each year, this gives a cost estimate of £0.3m.

Compliance costs

186. As with primary medical care, providers that are not compliant with the criteria will not be granted registration and will have to change their behaviour in order to be regulated. It is not possible to determine the size of compliance costs here since there is no information on any types of quality assurance that private dental providers meet.

187. A summary of the annual costs for the regulation of primary dental care is given overleaf.

Table 8: Summary of Annual Costs for Primary Dental Care (Option 2)

Organisation	***Cost detail***	***Low estimate***	***High estimate***
CQC and NHS DENTAL SERVICES	Processing new applications	£0.2m	£0.2m
	Processing self-assessments	£0.1m	£0.2m
	Ongoing compliance	£2.6m	£3.0m
	Enforcement	£0.3m	£0.3m
	Inspections	£1.0m	£1.3m
PCT	Helping CQC	£20,000	£24,000
	Helping providers	£0.5m	£0.6m
FTT	Enforcement Tribunals	£0.1m	£0.2m
NHS Providers	First Time Registration	£0.5m	£0.6m
	Self-Declarations	£1.2m	£1.5m
	Inspections	£0.3m	£0.3m
TOTAL		**£6.8m**	**£8.0m**

Primary Dental Care – Benefits

188. Approximately 1,000 dental providers provide entirely private services. We consider the costs (or dis-benefits) to this group of providers in the benefits section.

Transition costs on providers

189. The transition cost for wholly private providers will be greater than for NHS providers and this is because private providers currently do not complete the risk assessment for the NHS Dental Services. Interviews with private healthcare providers of equivalent size have indicated that the cost of a first-time registration under the Care Standards Act (in terms of dentists' and practice manager's time) is approximately £4,000.

190. However, since the new regulatory framework will be less burdensome than the previous system it is expected a 10-20% saving could be made on this original estimate. This reduces the cost to £3,200-£3,600 per provider. For the 1,000 private providers this would lead to a cost (or dis-benefit) of between £3.2m and £3.6m.

Costs of Inspection

191. As mentioned in paragraph 177 it is expected the Care Quality Commission will inspect all private practices in the first year. Using estimates from interviews with private doctors and cost estimates on dentists' wages, we estimate the cost to the provider as £370 per inspection. This gives a cost estimate of £370,000.

Annual Costs to Providers

Costs of first time registration

192. We assumed in paragraph 173 that there is up to 5% turnover of practices each year and these new practices would have to register with the Care Quality Commission for the first time. With approximately 1000 wholly private dentists, we can assume up to 50 new registrations each year. We apply a 10-20% reduction to the registration estimate used in paragraph 189 of £4,000 per provider. This leads to an aggregate estimate of £160,000 - £180,000.

Costs of self-assessment and self-declaration

193. Only the 1,000 wholly private providers would incur additional costs for completing self-assessments. Interviews with private doctors found that the estimated cost of completing a self-assessment was about £1,500 under the previous regulatory framework. We assume that the new regulatory framework would bring about a reduction in burden by 10-20%. Overall, this imposes a new cost of £1.2m-£1.4m.

194. Paragraph 169 states that each provider would need to complete a self-declaration each year and we have assumed this would cost a provider around £190 per year – this is lower than the transitional costs of self-declaration because the burden on practices would fall over time as their processes align with Care Quality Commission regulation. All 1,000 private dentists would need to supply information, ensure they are complying with the registration requirements, and sign the declaration and confirm the information is correct with all colleagues, leading to an estimated cost of £0.2m each year.

Costs of inspection

195. As mentioned in paragraph 177 it is expected the Care Quality Commission will inspect all private practices in the first year, and then 10% each subsequent year. Using the cost to the provider as £370 per inspection (paragraph 190), this gives an annual cost estimate of £37,000.

Annual Benefits

196. The regulation of primary dental care providers under the Care Quality Commission will also deliver wider benefits similar to those for primary medical care. In particular, four main benefits can be identified:

- Level playing field across public and private sector
- Patient reassurance and increased confidence in dentists
- Patient choice
- Greater controls on decontamination of dental instruments to reduce transmission of vCJD
- Benefits to patients in secondary care

197. Quantifying these benefits has proved difficult – this is mainly due to the lack of relevant information that is currently collected on NHS dental providers and the absence of any information gathered on wholly private dental providers. Each benefit is discussed in turn.

Level playing field

198. As with regulation of primary medical care, putting the same requirements on safety and quality across both public and private providers would lead to greater contestability and efficiencies. Measuring this benefit has not been possible and is not quantified.

Patient reassurance and increased confidence in dentists

199. There is relatively little information, as compared with Primary Medical Care, about what is happening in NHS dentistry, and whether the services patients receive are contributing to oral health[149]. However, existing studies highlight the importance of trust in the patient-dentist relationship, and how this is integral to the high quality of care and health outcomes. For example, a study from Turkey suggests that patient's trust is vital because it affects the health outcomes, facilitates partnership and adherence, reduces anxiety and improves health status and patient satisfaction[150], which is crucial for high quality care. Furthermore, an earlier study[151] states that the advantages of a good patient-dentist relationship include high quality oral health care, better treatment outcome and long-term maintenance of treatment results and increased frequency of dental visits.

200. Another study[152] suggests that trust comes from the assurance that personal information will be kept confidential, and procedures are in the patient's best interest. It states that patients have more confidence in dentists who have the ability to communicate care and compassion, and that integrity and honesty of dentists is very important, as it will encourage patients to adopt a more active role in maintaining proper oral health. This emphasises the importance of the respecting and involving service users registration requirement.

201. However, the study suggests that there is still much work to be done in order to improve the dynamics of the patient-dentist relationship and instil a greater sense of trust in patients. In addition, a review of NHS Dental Services in England[153] claims that

> "around 53.4% of people have visited an NHS dentist in the previous two years but public satisfaction with NHS dentists has fallen fairly steadily over the last 25 years, from over 70% to just above 40%[154]."

202. Results from a survey by the Dental Complaints Service (DCS)[155] show that 26% of dental patients surveyed have wanted to complain about their dental care but didn't, where

---

[149] Steele, J. (June 2009) "NHS Dental Services in England – An Independent review led by Professor Jimmy Steele," *DH,* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_101137

[150] Yamalik, N. (2005) "Dentist-patient relationship and quality 2. Trust" *International Dental Journal,* 55, pp. 168-170.

[151] Yamalik, N. (2005) "Dentist-patient relationship and quality 1. Introduction" *International Dental Journal,* 55, pp. 110-112 (Table 1)

[152] Jacquot, J. (2009) "Trust in the Dentist-patient Relationship: A Review," *Journal of Young Investigators,* http://www.jyi.org/articletools/print.php?id=241

[153] Steele, J. (June 2009) "NHS Dental Services in England – An Independent review led by Professor Jimmy Steele," *DH,* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_101137

[154] Appleby, J. Phillips, M. (2009) "The NHS: Satisfied now?" In Park, A. Curtice, J. and Thomson, K. (eds.) *British Social Attitudes: The 25th Report,* Sage Pulications Ltd: London

as 37% had complained about some aspect of their dental care. The most common cause of complaints was ineffective treatment, yet 53% of those in the survey who did complain felt that their complaint was not resolved satisfactorily.

203. Therefore, we expect as with primary medical care, the levels of quality and safety set by the Care Quality Commission would improve confidence and trust in dental professionals. We consider the approach explained in relation to primary medical care to give an indication of how large this benefit could be for primary dental care. We use the same QALY-gain-per-patient value of £82 (calculated as 0.071 * £60,000 * (1/52) as that in primary medical care. We further assume that confidence rate of dentists is the same as doctors – around 92%[156]. We additionally assume that 1% of the 8% who do not have trust in their doctor/dentist will become reassured through this policy.

204. Information from the NHS Information Centre shows around 27.7m[157] people used an NHS dentist in the last 24 months. Hence, around 22,000 patients will experience this increased reassurance. Data from the NHS Information Centre[158] also shows there were 37.4m courses of treatment per year, leading to an average of 1.4 visits per person each year.

205. However, this source is only looking at NHS patients; we also need to consider the number of patients visiting private dentists. We will assume that the assumption of 1.4 visits per person per year is also applicable to private patients.

206. Ipsos MORI[159] in December 2007 conducted a survey, asking a nationally representative quota sample of all adults that had visited the dentist since April 2006 whether they had had NHS treatment, private treatment or both. 64% said they had visited an NHS dentist, 31% had visited a private dentist, 4% had visited both and 1% didn't know. Therefore, we can use these percentages to scale up and calculate the total number of people using a dentist at 41.1million.

207. We use the earlier assumption (paragraph 202) that 1% of the 8% who do not have trust in their dentist will become reassured by this policy, and multiply this valuation by 1.4 to factor in multiple visits by patients each year. We then multiply this figure by £82 (QALY gain per patient, paragraph 202) giving an estimate of £3.8m, with a range of £3.4m-£4.2m.

Patient choice

208. Patients need information to allow them to exercise the choices they have on which dental practice to register with. Registration with the Care Quality Commission will, together with a number of other policies (including Quality Accounts) help to supply this information. No attempt has been made to quantify this benefit.

---

[155] "Dental patients 'want to complain but don't'" (23/09/2009), http://www.dentistry.co.uk/news/news_detail.php?id=2251

[156] The most recent confidence rate for dentists published by Ipsos MORI on 22 March 2001 was 84%, the equivalent rate for doctors at that time was 89% (http://www.ipsos-mori.com/researchpublications/researcharchive/poll.aspx?oItemId=1443). However, as there has not been a more recent publication for dentists we are assuming the same confidence rate for GPs, as in paragraph 141.

[157] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

[158] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

[159] http://www.ipsos-mori.com/researchpublications/researcharchive/poll.aspx?oItemId=170

Greater controls on decontamination of dental instruments to reduce transmission of vCJD

209. An important benefit of Care Quality Commission registration would be that all primary care dental practices would need to be compliant with Code of Practice, which sets agreed standards around reducing HCAI, minimising the risk of pathogen transfer from both instruments and the environment. Health Technical Memorandum (HTM) 01-05 which is referenced in the Code of Practice sets clear guidelines for dental practices to minimise this infection risk.

210. Animal studies indicate that dental tissues can potentially transfer infectivity including vCJD. Where the risks are highest, in dental pulp tissue, HTM 01-05 in line with Departmental policy recommends single use instruments, where effective cleaning of instruments is not possible.

211. Such is the volume of dental procedures undertaken each year in England that even a small reduction in risk could lead to significant benefits for public health. We estimate this benefit to potentially be between £300,000 and £23.0m every year.

Benefits to patients in secondary care

212. The benefits highlighted with regard to improved decontamination could also lead to benefits to patients in secondary care, as resources that may have been used to treat people infected with vCJD can now be diverted to other patients. We calculate these benefits as £1,200 - £860,000. More details of these calculations can be found in Annex F.

213. A summary of the benefits can be found in the table overleaf.

Table 9 – Summary of Benefits for Primary Dental Care (Option 2)

	Benefit	***Low estimate***	***High estimate***
Transition Benefit – Private Providers	Registration - costs	-£3.2m	-£3.6m
	First Time Inspection	-£370,000	-£370,000
Annual Benefits – Costs on Private Providers	Registration – new providers	-£160,000	-£180,000
	Annual assessment	-£1.2m	-£1.4m
	Self Declaration	-£0.2m	-£0.2m
	Inspection	-£37,000	-£37,000
Annual Benefits - Other	Fair playing field across public and private sector	Unquantified: Greater than zero	Unquantified; Greater than zero
	Patient reassurance and increased confidence in dentists	£3.4m	£4.2m
	Greater controls on decontamination	£300,000	£23.0m
	Benefits to secondary care patients	£1,200	£860,000
	TOTAL (Transition Benefits)	**-£3.6m**	**-£4.0m**
	TOTAL (Annual Benefits)	**£2.1m**	**£26.2m**

Summary

214. We can summarise the overall costs and benefits of Option 2 in the Table below.

Table 10 – Summary of Costs and Benefits for Option 2			
Cost detail	**Area of scope**	**Estimate**	
		Low	**High**
Transition costs	Primary Medical Care	£12.3m	£14.3m
	Primary Dental Care	£12.4m	£15.2m
TOTAL		**£24.7m**	**£29.5m**
Annual Costs	Primary Medical Care	£10.5m	£12.4m
	Primary Dental Care	£6.8m	£8.0m
TOTAL		**£17.3m**	**£20.4m**
Transition Benefits	Primary Dental Care	-£3.6m	-£4.0m
Annual Benefits	Primary Medical Care	£40.5m	£266.0m
	Primary Dental Care	£2.1m	£26.2m
TOTAL		**£42.6m**	**£292.2m**

Opportunity Costs

215. The total Department of Health (DH) budget is fixed, in a given period and as such, any funds committed to new policies must therefore be reallocated away from some other use, elsewhere in DH. To fully reflect the impact of a particular policy, it is therefore important to consider the effect of reallocating funds away from this alternative use. The impact of reallocation is the policy's true cost – or "opportunity cost" – and we must reflect this in Impact Assessments.

216. To calculate the impact of reallocating funds to a new policy, it is necessary to determine how much benefit would have been realised from the alternative use of these funds. This can be done using standard estimates of the amount of benefits generated by, for example, NHS treatments "at the margin" that may be withdrawn if the availability of funding is reduced. The benefits of these marginal treatments are estimated to be approximately 2.4 times more valuable than the cost of the treatments[160].

217. The ratio of 2.4:1 of benefits to costs implies that any policy which involves spending from the DH budget will deprive society of benefits worth 2.4 times as much (before the policy's own benefits are taken into account). Similarly, any cost saving measure that releases DH budget to be spent elsewhere is expected to provide benefits valued at 2.4 times the cost saving.

218. To correctly reflect the cost impacts of policies and programmes, we therefore must multiply any effects on the DH budget by 2.4 in order to calculate their true cost to society. This will produce the amount of benefits lost by diverting spending to the policy in question – and it follows that the policy should itself generate greater benefits, in order to provide an overall positive impact.

[160] These are Department of Health estimates, based on differing valuations of Quality Adjusted Life Years (QALYs).

219. For this proposal, we must therefore consider the costs to Care Quality Commission, PCTs and NHS primary and medical care providers as all being costs incurred by the DH budget. The opportunity cost is found by calculating the total costs to these different bodies and multiplying by 2.4.

220. For this policy, the total discounted opportunity cost for the preferred option is £339.4m - £400.0m. Although these opportunity costs are not included in the values for the total costs and total benefits, the value of the opportunity costs is subtracted from the benefits (along with other costs) to obtain the net benefit.

Administrative Burdens

221. This policy will generate administrative burdens on private dental providers to become registered and remain registered with the Care Quality Commission. The administrative burden will be positive for this area of scope since the new regulatory framework will be introducing organisational regulation to some providers for the first time.

222. The table below outlines the estimated increased administrative burden on private dental providers, showing the burden for 2011, and the average burden for each subsequent year. This leads, on average, to an increase in administrative burden of between £1.8m and £2.0m per year (when we consider the burden for up to 2019/20).

Table 14: Administrative burden as a result of Option Two

Costs to private dentists	2010		2011		2012 onwards	
	Low estimate	High estimate	Low estimate	High estimate	Low estimate	High estimate
Registration costs	£3.2m	£3.6m	£0.16m	£0.18m	£0.16m	£0.18m
Annual assessment	£0	£0	£1.2m	£1.4m	£1.2m	£1.4m
Self-declaration	£0	£0	£0.17m	£0.21m	£0.17m	£0.21m
Inspection	£0	£0	£0.37m	£0.37m	+£0.0m	+£0.0m

Risks and unintended consequences

223. The options have significant risks dependent on future outcomes that cannot be predicted with sufficient certainty.

Risks for Option One

224. There are potential safety implications if there is a continued lack of regulation of primary medical care and primary dental care providers. This would be heightened given the increase in GP practices offering elective services and the increase in out-of-hospital care. There will also be a continuation of the inconsistency around how far practices meet essential levels of quality and safety.

225. There are added complications around the vertical integration between primary and secondary care providers if one is registered and one is not – it makes the remit of work the Care Quality Commission harder to define and makes it easier for providers to shift services between providers and compromising patient quality and safety.

226. In addition, Option one would make it harder to patients to make informed choices about the care they receive. While there will be some improvements to the quality of primary care

through initiatives such as the wider quality framework, the absence of Care Quality Commission ensuring the essential requirements are met there will be added pressure on PCTs to focus on improving quality.

Risks for Option two

227. Option two would result in a dramatic increase in the number of providers that the Care Quality Commission would be responsible for regulating. There is the risk that this would place such a large additional burden on the Commission that it could be unable to regulate this or other aspects of the health and adult social care sector effectively.

228. There are also risks about the level that the guidance about compliance is set at for providers. If it is too low, it will fail to achieve any of the patient safety benefits, and will therefore not be value for money, while if it is set too high it could have serious effects on the provision of these services, especially in areas where there are already a shortage of providers. In particular, if providers were to shut down, it is likely these may be providers in more deprived areas, and therefore we would have to consider the equality impacts of this (the overall equality impacts are considered in the accompanying equality impact assessment).

229. It is therefore crucial that in implementing the registration requirements Care Quality Commission require evidence that brings benefits to patients while minimising the adverse effects on the provision of care.

230. In addition, setting the registration of primary medical and dental care providers in a sunset clause means there is reduced flexibility. If the Commission or providers or the First Tier Tribunal were not ready to implement on time it would be difficult to amend the implementation date as further affirmative regulations would need to be made. The project will therefore need to be well planned and carefully monitored.

Monitoring and evaluation

231. The costs and benefits in this Impact Assessment will be monitored and evaluated through two methods:

- The success of the regulatory scheme as a whole will be evaluated as discussed in the accompanying Impact Assessment considering NHS Trusts, Independent Sector providers and Adult Social Care providers.
- The NHS Next Stage Review and Primary and Community Care Strategy – which this policy is part of – will be reviewed and evaluated by DH to determine whether the benefits of this policy are being fully realised.

Supplementary Tests

232. Supplementary Tests can be found in Annexes G and H.

Conclusion and recommendation

233. Using all available information and best estimates, we conclude that option two could produce benefits of £432 million over a ten-year period. In turn, there could also be opportunity costs of £370 million over the same period, leaving a net benefit of £62.8 million[161].

234. It should be noted that there is a large range of potential benefits, from the policy actually costing £174 million overall, to it producing benefits of £296 million overall. The evaluation which we intend to undertake (see evaluation section) and the responsibility for the Care Quality Commission to take a proportionate approach should mitigate against the risk of there being a negative benefit overall.

235. We therefore conclude that Option 2 would deliver the objectives of this policy and for this reason that we recommend this Option be taken.

[161] All these figures are in terms of net present value

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

Annexes

Contents:

Annex A – Current assurance processes in primary medical and dental care

A1. This annex gives a brief outline of the current assurance processes in primary medical and dental care.

A2. **Primary Medical Care:** These services are mainly delivered through three contractual routes, General Medical Services (GMS), Personal Medical Services (PMS) and Alternative Primary Medical Services (APMS). PCTs commission these services and enter into individual contracts with the service provider. GMS is a nationally negotiated contract, whilst PMS and APMS are locally negotiated (with some nationally prescribed elements).

A3. There are many quality initiatives in place in primary medical care; some concentrate on quality assurance, whereas others look at quality improvement. The three main quality assurance levers are the Medical Performers List and PCT contract management, with revalidation of healthcare professionals due to be introduced in the future. PCTs also run a variety of more local assessment processes.

A4. Action under the medical performer list is limited to sanctions against a single GP. Contract Management is the route to sanction service providers.

A5. Medical Performers List: All GPs providing primary medical services under any of the three contract variants must be on a PCT Performers List. PCTs can refuse applications to the list, remove names from the list or apply appropriate conditions on GPs. In this way the PCT has a local power to control the quality of its workforce akin to those enjoyed in a more traditional employer/employee arrangement and can take quick actions if there are any concerns with individual GPs. GPs can be nationally disqualified under these procedures by the Family Health Services Appeal Authority.

A6. Revalidation: Both NHS and private GPs are professionally regulated through the General Medical Council (GMC). Revalidation will require doctors to renew their licence to practise and their specialist recertification every five years. It will be based on appraisal and will be run by the General Medical Council and the Royal College of General Practitioners for GPs. Revalidation will ensure that doctors remain fit to practise and reassures the public.

A7. Contract Management: The PCT will regularly monitor its contracts with its primary medical care providers and can take action if the contractor fails to meet contractual requirements. With PMS and APMS it has the additional freedom to set its own quality requirements when commissioning new providers or by varying existing contracts. These local conditions can be linked to contract sanctions as the PCT sees fit. GMS is a nationally negotiated contract, which does not have the flexibilities for local variation. It contains mainly broad contractual quality conditions, as opposed to specific key performance indicators (KPI's). There are various GMS provisions for sanctions and termination (these will also be present in PMS contracts). However, the limited use of "absolutes" means that PCTs will often (but not always) need to identify a broad spectrum of evidence (as opposed to a more absolute failure to meet a KPI) to demonstrate that the service providers actions are in breach of their contract.

A8. GP training practices: Training practices (which train GP registrars) have to go through further assurance processes. They are assessed by Deaneries against, among other areas, teaching expertise, premises and equipment.

A9. GPs with special interests (GPwSIs) supplement their generalist skills and experience with additional expertise in a particular field, while retaining an ongoing commitment to their

core generalist role. Both the individual GPwSI and the service they work within must be accredited by the local PCT at least every three years.

A10. **Primary Dental Care:** NHS Dental Services provides a range of services to support PCTs monitoring and management of dental contracts. These services include making payments to dentists providing Dental Services Division and the provision of management information relating to NHS dental contracts, together with a range of risk management and clinical monitoring services.

A11. Since 2008/9, the NHS Dental Services has undertaken clinical monitoring of all practices with NHS contracts using a risk-based approach. Using data on activity, patient questionnaires and complaints, self-assessment, the baseline review of clinical records and previous inspection results (if available) it identifies outliers in terms of practice behaviour.

A12. If routine NHS Dental Services monitoring activities raise concerns about a contract, these are reported to the PCT that holds the contract for the practice. The PCT will then determine whether any further action needs to be taken. Where the NHS Dental Services provides further monitoring activities on behalf of a PCT in relation to a particular contract, these activities may include the examination of additional clinical records, the examination of selected patients, patient questionnaires and/or a practice inspection. The combination of further monitoring activities varies depending on the nature of concerns raised. The NHS Dental Services does not currently carry out any functions for wholly private dental providers.

A13. Like in primary medical care, dental care professionals are professionally regulated through the General Dental Council. Professional regulation does include some parts of the care “system” but the focus of professional regulation is the competence of the individual professional.

A14. **The Revalidation and performers list requirements:** Performers list: all dentists providing primary dental services under an NHS contract must be on a PCT performers list. PCTs can refuse applications to the list, remove names from the list or apply appropriate conditions to dentists. In this way the PCT has a local power to control the quality of its workforce akin to those employed in a more traditional employer/employee arrangement and can take quick action if there are any concerns with individual dentists. Revalidation: Both NHS and private dentists and other dental professionals are professionally regulated by the General Dental Council. Revalidation will initially require all dentists to revalidate their registration on a regular basis by demonstrating that they have kept their knowledge up to date and remain fit to practise. Over time, similar mechanisms will be developed for other dental professionals.

Annex B – Evidence base for deductions and efficiencies - Comparison of costs in the old registration system and the new registration system

B1. This annex looks at the estimated cost reductions on providers in moving to the new system under the Health and Social Care Act 2008. We consider two types of savings on providers: one set of reductions will originate in moving to the new regulatory framework while additional reductions would come from sector-specific activities.

Health and Social Care Act Framework

B2. The regulatory framework under the Health and Social Care Act will be more principle based than the Care Standards Act 2000 system. It will prescribe less detail to providers and this has significant potential to cut the costs for providers.

B3. One way of estimating the scale of these savings is to consider the cost of regulating the Independent Sector if the new system was more like the Annual Health Check. We compare the cost of regulating NHS Trusts under the Annual Health Check with the cost of regulating the same Trusts under the Care Standards Act to obtain a ratio of costs. The Healthcare Commission estimated £18.2 million was the minimum spending for an Annual Health Check on 407 trusts (£44,700 per Trust). The Healthcare Commission also charged Independent Sector providers using a cost-based fee schedule. If this schedule were applied to NHS acute Trusts (not including PCTs and ambulance trusts), it would charge an average fee of £42,600 per Trust. From this, we can conclude that the Annual Health Check was 5% more expensive than the Care Standards Act system.

B4. However, the Annual Health Check was both a performance assessment tool and a minimum quality check. We assume that only two thirds of this money (£29,800) was spent on the minimum quality check. This minimum quality and safety check of the Annual Health Check could therefore be up to 30% cheaper than the Care Standards Act system. This estimate is an upper bound as the Care Quality Commission would not be able to set up a system as informal as the Annual Health Check as the registration system will need to be legally enforceable.

B5. In interviews with Independent Sector health care providers we have tried to test this view and asked them if they could estimate how much of their burden could be reduced if the regulator took away these tasks. Most providers concluded that they would estimate this reduction to be around 10-20%.

B6. As the Care Quality Commission will have to define the registration system in more detail, we have therefore concluded that 20% is an upper bound for the savings that could be made by the new system and 10% is the lower bound.

Sector specific deductions

B7. Above we argue that the new system will be 10-20% cheaper than the old system, so the estimates for the cost of registration using private doctor estimates have to be reduced by this proportion. However, we believe that further reductions could be made by virtue of the work that NHS primary care providers currently supply to PCTs and regulators. These were briefly described in the Options section of this work.

B8. Providers will incur three main activities: registration, self-assessments and/ or self-declarations, and inspections. We believe that providers will be able to make additional savings over and above the 10-20% savings they will make in moving to the new regulatory

framework.

B9. This is because the data NHS providers will need to collect for registration and self-assessment will be information they provide for other levers measuring quality (in primary medical care this would include the QOF, prescribing data, information from training practice assessments, any accreditation scheme the practice might be part of and PCT monitoring. In primary dental care, this would be covered by surgery inspections, payments made under the NHS contracts, or the self-assessment tool for the NHSBSA.)

B10. Hence, for each sector below, we estimate what these additional savings might be and explain where this information could come from.

Primary Medical Care

B11. The table overleaf provides the 16 registration requirements that all providers must comply with, along with possible sources that primary medical care providers could use to show compliance. Overall, half the requirements have a strong overlap with other sources of information, with three more having a reasonable overlap. From this, we estimate the additional savings for registration and self-assessment are 33% and 60% respectively. Since inspections will be largely the same from the old to the new system, we do not anticipate any savings here.

Table B1: Existing data sources and overlap with registration requirements for primary medical care providers			
#	**Description**	**Overlap**	**Justification or Source**
1	Care and welfare of service users	High	QOF. Prescribing data. GPwSI accreditation
2	Assessing and monitoring quality	High	QOF. Complaints data. Patient surveys. GPwSI accreditation. PCT monitoring.
3	Safeguarding vulnerable service users	Low	QOF indicator on access to information about child protection procedures.
4	Cleanliness and infection control	Low	Currently nearly no overlap but with the introduction of the code of practice this could change. Some PCTs are currently introducing an annual infection control inspection.
5	Management of medicines and medical devices	High	QOF, and practices already have an annual visit from a prescribing advisor.
6	Nutritional needs	Not relevant	
7	Safety and suitability of premises	High	More overlap for enhanced services, as practices must demonstrate they have suitable premises. Contract management requires providers to have suitable premises. GPwSI accreditation.
8	Safety, availability and suitability of equipment	Some	QOF. GPwSI accreditation
9	Respecting and involving service users	Some	Some complaints and patient survey data.
10	Consent to care and treatment	Low	Could use Choose and Book to demonstrate that patients are offered a choice.
11	Complaints	High	Practices will have records of complaints and their outcome as these are required by the terms of their contract and NHS regulations.
12	Records	High	QOF/PCT monitoring and compliance with best IT practice. GPwSI accreditation
13	Competence and suitability of workers	High	QOF/PCT/ GPwSI accreditation. Contractual requirements could also be used here.
14	Staffing	Some	GPwSI accreditation
15	Management of staff	Some	QOF will have some information on Human Resources processes. Contractual requirements will cover this as well.
16	Co-operating with other providers	Low	No overlap but possible to use referral rates, which PCTs already have at the practice level. GPwSI accreditation

B12. The overall reductions for primary medical care providers are summarised in Table B2 overleaf.

Table B2: Summary of cost reductions for primary medical care providers

Activity	**Reduction in cost in moving to new system**		**Additional saving**	**Total deduction**	
	Low estimate	High estimate		Low estimate	High estimate
Registration	20%	10%	33%	46.6%	40%
Self assessment	20%	10%	60%	68%	64%

B13. An example should make this table clearer. If the cost of registration under the Care Standards Act framework was £600, we would make a deduction of 10-20% because the new framework will be less burdensome (and hence less costly) than the old framework. We can therefore reduce costs to £480-£540. In addition, we make a further deduction of 33% on these figures because providers already have the information needed for registration from sources like the QOF. This gives us a range of £320-£360. Overall, this represents a reduction of £240-£280, or a 40-46.6% reduction from the original figure of £600[162].

Primary Dental Care

B14. In dental care, the overlap between the registration requirements and other sources of information is larger, so we estimate the additional savings to be larger than in primary medical care. The table overleaf provides the 16 registration requirements that all providers must comply with, along with possible sources that NHS primary dental care providers could use to show compliance. Overall, almost all the requirements have a strong overlap with other sources of information. It is from this that we estimate the additional savings for registration and self-assessment are 50% and 75% respectively.

[162] Note, the cost estimates used in this Annex are for illustrative purposes and should not be taken as a serious consideration of the costs of regulation on primary care providers.

Table B3: Existing data sources and overlap with registration requirements for primary dental care providers.			
#	**Description**	**Overlap**	**Justification or Source**
1	Care and welfare of service users	High	SAT[163], surgery inspection, clinical record reviews, patient examinations
2	Assessing and monitoring quality	High	SAT, surgery inspection, clinical records reviews, complaints data.
3	Safeguarding vulnerable service users	High	SAT, surgery inspection
4	Cleanliness and infection control	High	SAT, surgery inspection, Decontamination and infection control audit tool
5	Management of medicines and medical devices	High	SAT, surgery inspection
6	Nutritional needs	N/A	Not applicable to primary dental care
7	Safety and suitability of premises	High	SAT, surgery inspection
8	Safety, availability and suitability of equipment	High	SAT, surgery inspection
9	Respecting and involving service users	High	Patient questionnaires, clinical record reviews, patient examinations
10	Consent to care and treatment	High	Patient questionnaires, clinical record reviews
11	Complaints	High	SAT, surgery inspection
12	Records	High	SAT, surgery inspection, clinical record reviews
13	Competence and suitability of workers	High	SAT, surgery inspection
14	Staffing	High	SAT, surgery inspection
15	Management of staff	High	SAT, surgery inspection
16	Co-operating with other providers	High	Clinical record reviews

B15. We can summarise these cost reductions in the table below.

[163] SAT = Self Assessment Tool

Table B4: Summary of cost reductions for primary dental care providers					
Activity	**Reduction in cost in moving to new system**		**Further deductions**	**Total deduction**	
	Low estimate	High estimate		Low estimate	High estimate
Registration	20%	10%	50%	60%	55%
Self assessment	20%	10%	75%	80%	77.5%

B16. Example: If registration cost £1,200, we first deduct 10-20%, giving a range of £960-£1,080. We then reduce these figures by 50%, giving £480-£540. This represents a reduction of £660-£720, or a 55-60% reduction from the original figure of £1,200.

B17. It is up to the Care Quality Commission to decide on what sources of information they will ask and rely on when it comes to making decisions on the registration status of primary medical and dental care providers. It is expected they will aim to minimise any additional burden on providers by using existing data sources. Hence, the information in Tables B1 and B3 are only indications of where there is an overlap. In addition, we expect the Care Quality Commission will triangulate data where possible to ensure consistency and minimise the reliance on one dataset under each registration requirement. We expect the Commission will finalise what pieces of information they will use at a later date.

Annex C: Calculations for the estimated costs of providers closing

C1. If a provider is closed by the Care Quality Commission, the local PCT has a range of options to ensure appropriate provision of care. There are four main options available to PCTs – these are not mutually exclusive so a PCT may use different aspects of each option:

a. List dispersal – asking patients registered at the closed down practice to register with another practice in the local area.
b. Tendering out a new contract – the PCT might decide to place a tender for primary care provision in the area where the former practice was closed down.
c. Merger with nearby practice – the PCT might ask a nearby practice to expand its practice list to cover those with the closed practice in return for more money.
d. Locums and direct management – bring management of the failed practice into the hands of the PCT and use locum doctors to provide care.

C2. In the first three options, patients will need to travel to another practice, even if it is temporary while a longer-term solution is found. The analysis below attempts to quantify two cost impacts:

a. Patients having to travel to another practice to register
b. The health damage to patients that do not re-register as a result of reduced access to primary care services.

Patients travelling to another practice to register

C3. Data from the Department of Health shows the distance between GP practices vary significantly based on certain factors – for instance the distances between inner-city practices are much less than practices in a rural area.

C4. We have modelled a range of scenarios in which if a GP practice is closed down then patients have to travel to the next nearest GP practice and register with them. In order to arrive at an estimate, we identify the amount of time taken for one patient to travel from one GP practice to another. We arbitrarily add 15% to the distance of the nearest practice because not all patients are going to go to the nearest practice to register[164].

i. For distances of less than 500m, we assume the patient walks at 6km/h, between 500m and 1500m we assume the patient drives at 32km/h and for distances greater than 1500m the patient drives at 64km/h.
ii. If the patient drives, we add another ten minutes to the estimate to accommodate for parking.
iii. The cost of patient time is measured using the Department for Transport conventions on individuals' non-work time (£3.54/hr[165])
iv. If the patient drove, we add £1 to the estimate for parking and £0.20 per km for the cost of fuel.

Academic research shows that the cost of a 10-minute consultation with a GP costs £8.42[166] and this is added to the estimate.

[164] We assume that some patients would be willing to travel to a practice further away if it provided a service they were more satisfied with.

[165] Based on a rate of 5.9pence per minute. http://www.dft.gov.uk/pgr/economics/rdg/valueoftraveltimesavingsinth3130?page=6

[166] The NHS Information Centre shows the average salary of a GP is £107,667 according to its Earnings and Expenses Inquiry 2006/07. In addition, the GP Workload Survey from July 2007 shows that GPs work on average 44.4 hours per week. Assuming GPs have a four week holiday, this translates into £50.52 per hour, or £8.42 for ten minutes.

We assume that filling out forms with the new practice will take 20 minutes of patient time and 20 minutes of practice time to process the forms. The cost of patient time is calculated as £1.18 and the cost of receptionist time is estimated as £4.83[167]

C5. It is important to make a distinction between one-off costs of registration and recurring costs from travelling for a consultation. If practices were to shut down, we would expect other practices to tender for this business. Therefore, we consider these costs to be only part of the transition process.

C6. This method was applied to different characteristics of practices in order to get a range of estimates for this cost. For instance, if a large practice were closed down then the overall costs to patients would be larger. If a rural practice was shut down then the distance patients would need to travel to another practice would be larger and hence impose greater costs.

C7. We do not know whether the Care Quality Commission will use this enforcement action at all, hence we can only value the transport costs on patients on a per practice basis. The range of costs in transition is estimated to be between £0 and £52,000, with a best estimate of £16,000 for each provider that closes. Because we do not know how many providers might close, we cannot provide a definite valuation, but we use an anecdotal figure of 0.5%. Multiplying this by 8600 providers, we estimate that the total costs of providers closing to be £0m-£2.2m, with a best estimate of £701,000. However, this is an upper bound estimate, and we expect the costs to be much lower.

[167] This figure is based on the NHS Careers Website where the hourly wage for a receptionist is £13-16ph.

Annex D: Evidence base for cost savings in secondary care

D1. Primary care is a vital part of the healthcare system. The World Health Organisation[168] (WHO) conducted a review of various international studies examining primary care services provides evidence of this. The evidence from these papers shows that there is a more appropriate utilisation of services, user satisfaction, and lower costs in health systems with a strong primary care orientation. Therefore, if we can improve the quality of primary care services, it is reasonable to believe this could lead to further savings to secondary care.

D2. It is difficult to estimate the amount of savings that may arise in secondary care as a result of system regulation in primary care. However, we do believe that as registration requirements improve systems in primary care, this will lead through to fewer hospital admissions, thus lower costs and better quality outcomes for patients. The reasoning behind this argument is presented below.

D3. In paragraphs 5-29; we provided a rationale for registration requirements, indicating how they can lead to good systems in primary care. Such systems include record keeping and referrals, assessing and monitoring the quality of provision and the management of the provider. Without such checks and registration requirements in place, providers may be working in systems and premises that are unfit for practice and poorly maintained, thus putting patient care at risk.

D4. Therefore, better system regulation can lead to improved quality of primary care. Evidence of this is presented by Reid and Wagner[169] who determine that strengthened primary care systems such as electronic health records, and good cooperation with other providers allows patients to achieve better health outcomes at lower costs.

D5. From a stronger, well functioning primary care system, we can expect fewer hospital admissions, especially in the areas of Asthma, Diabetes, Epilepsy, Heart Failure and Chronic Obstructive Pulmonary Disease (COPD), which "can be managed with timely and effective outpatient care reducing the need of hospitalization."[170] Evidence of this is provided in the available literature. Bodenheimer et al[171] conducted a review of case studies to determine that good management of chronic conditions in primary care through self-management support, delivery system design, and clinical information systems led to reduced hospital admissions and lower costs.

D6. Dixon and Sanderson[172] interviewed a panel of GPs and hospital specialists in their study, to find that the clear view was that the scope for avoiding admission through better ambulatory care is very substantial, and lies mainly in more timely and effective treatment of

[168] World Health Organisation (2004), "What are the advantages of restructuring a health care system to be more focussed on primary care services?"
[169] Reid, R, J. Wagner, E, H. (2008), "Strengthening primary care with better transfer of information", *Canadian Medical Association Journal,* 179:10
[170] Angelillo, I, F. Bianco, A. Pavia, M. Rizza, p. (2007), "Preventable hospitalization and access to primary health care in an area of Southern Italy", *BMC Health Services Research,* 7: 134
[171] Bodenheimer, T. Grumbach, K. Wagner, E, H. (2002), "Improving primary care for patients with chronic illness: The chronic care model, part 2", *JAMA,* 15
[172] Dixon, J. Sanderson, C. (2000), "Conditions for which onset or hospital admission is potentially preventable by timely and effective ambulatory care." *Journal of Health Services Research and Policy,* 5: 4

existing diseases in primary care. A study in Southern Italy[173] examined 520 medical records of patients suffering from the main chronic conditions, and judged 31.5% of the hospitalizations as preventable through better primary care, and improved access. Furthermore, evidence presented by Rich et al[174] demonstrates that a nurse-directed program of patient education with post-hospital telephone and home visit follow up (self-management support and delivery system redesign) was associated with a 56% reduction in hospital readmissions for congestive heart failure.

D7. Earlier work by DH[175],[176] have in fact identified that chronic conditions contribute most to unnecessary emergency hospital admissions, yet adequate care for these conditions can be safely provided in primary care. By improving systems in primary care such as local feedback systems, service redesign, coding schemes and data, hospital admissions can be reduced and costs lowered.

D8. Good cooperation with other providers can also stem from system regulation in primary care, and this, as much of the literature suggests, is essential for achieving high quality and continuity of care. Kvamme et al[177] state that much of the poor quality care can be linked to problems that arise at the interfaces within the healthcare systems, and that some of the waste in resources might be avoided if there was better communication between primary and secondary care. Studies also look at how the use of expert care for asthma at the community level can reduce hospital admissions and readmissions with improved nurse follow up systems, accurate diagnosis, and better system management[178],[179].

D9. In the current primary care system, there is variation across providers in the rates of patients suffering with chronic conditions admitted to hospital, and variations in the quality of the service provided. This was identified in the IA of NHS Next Stage Review Proposals for Primary and Community Care[180]. The IA highlighted that whilst there is good evidence to show that primary and community care services in England are generally effective and of good quality, evidence also suggests that there remains unwarranted variability in the quality of services between different providers. Rates of emergency admissions for conditions that are preventable by effective primary and community care vary more than two fold across the country.

---

[173] Angelillo, I, F. Bianco, A. Pavia, M. Rizza, p. (2007), "Preventable hospitalization and access to primary health care in an area of Southern Italy", *BMC Health Services Research,* 7: 134

[174] Rich, M, W. Beckham, V. Wittenberg, C. Leven, C, L. Freedland, K, E. Carney, R, M. (1995) "A Multidisciplinary intervention to prevent readmission of elderly patients with congestive heart failure", *N Engl J Med*, 333

[175] DH, "Analysis of admission patterns in selected ambulatory care sensitive conditions at Ealing PCT (2003-2007)"

[176] DH Press Release, (20 March, 2006), "NHS Institute analysis of unnecessary emergency admissions – and alternatives"

[177] Kvamme, J, O. Oleson, F. Samuelson, M. (2001), "Improving the interface between primary and secondary care: a statement from the European Working Party on Quality in Family Practice (EQuiP)", *Quality in Health Care,* 10

[178] Bartter, T. Pratter, P, R. (1996), "Asthma: Better outcome at lower cost? The role of the expert in the care system", *Chest,* 110

[179] Camargo, C, A. Schatz, M. (2006), "Follow-up after an asthma hospitalization." *Chest,* 130

[180] DH, (3 July 2008), "Impact Assessment of NHS Next Stage Review proposals for primary and community care" http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_086029

D10. Therefore, by introducing registration requirements we can expect to bring the poorest performing providers up to a threshold of quality that all providers must reach to retain their registration. If variations in the quality of care, and number of hospital admissions were reduced slightly, then this should filter through to savings in secondary care, as supported by the surrounding literature.

D11. As an attempt to provide a conservative estimate of the savings to secondary care we have examined the reduction in emergency admissions for the chronic conditions Diabetes, Epilepsy, Asthma, Heart Failure and COPD. These conditions were identified in the literature and the NHS Next Stage Review Proposal for Primary and Community Care IA, as conditions where effective management in primary care could reduce hospital admissions and costs.

D12. Data from the Care Quality Commission on standardised secondary care admission rates for the above listed conditions shows a wide variation in emergency admission rates at PCT level. If we assume that those PCTs with high admission rates experience a reduction in emergency admissions to no more than the 75th percentile (that is, the highest 25% would see admission rates fall to the level of other 75%) we would expect to see the reductions for each treatment as presented in Table D1.

D13. NHS Reference Cost data was used to find the weighted national average unit cost for each condition. This was then multiplied by the reduction in emergency admissions, to provide the total number of savings to secondary care from reduced admissions as £6.0m. However, we should treat this number as a benefit rather than a saving to secondary care, as the NHS could reinvest this money elsewhere, such as treatments for other patients with different illnesses who were not able to be treated before.

Table D1: Non-elective admissions savings

Type	Reduction in emergency admissions	Reduction in emergency admissions (%)	Weighted National Average Unit Costs	Savings to Secondary Care
Diabetes	378	1.1%	£996	£377,007
Epilepsy	658	1.9%	£753	£495,756
Asthma	1,366	2.6%	£680	£928,694
Heart Failure	104	0.2%	£1,537	£160,164
COPD	3,541	4.2%	£1,131	£4,005,192
Total Savings	6,048	2.2%		**£5,966,813**

D14. Following the same rationale as in the opportunity cost section (paragraphs 215-220), we believe that any cost savings that releases the DH budget to be spent elsewhere, is expected to provide benefits to patients at 2.4 times that of the cost saving. Hence, the benefits to patients can be valued at £14.3m.

D15. We believe this to be a conservative estimate as we are not considering the additional benefit to the patients with chronic diseases, such as improved quality and safety of care which is difficult to monetise. It is also possible that improved primary care systems would have a wider effect than just on the specific diseases on which we have concentrated. Thus, we expect the overall benefit to be far higher than the figure provided, as we have not attempted to quantify this additional benefit.

Annex E: Risk-based approach for primary medical care

E1. We take a risk-based approach to quantifying the benefits of system regulation. This method considers the risks of a health service or health intervention, looks at the extent to which system regulation would be able to mitigate these risks and calculates a monetary value.

E2. When applying this technique to primary medical care, it is necessary to think about the different risks or adverse events that patients might experience when using primary medical care services. In particular, we look at quantifying the benefit from a reduction in adverse events would mean fewer people would be suffering injuries and hence patient benefit can be calculated using Quality Adjusted Life Years (QALYs).

E3. The following information is needed in order to use this approach:

a. The number of providers and an estimate of the number of providers in ten years time.
b. The number of consultations per year and an estimate of the number of consultations in ten years time.
c. Identification of adverse events, the likelihood of them happening, the reduction in health state following the adverse event and how long that reduction lasts for.
d. The effectiveness of system regulation in reducing the likelihood of an adverse event taking place.
e. The vulnerability of the users when accessing primary medical care services.

E4. Each of these areas is explained in turn. We then calculate the expected benefits for comparison with the costs of system regulation.

Number of providers

E5. Data from the NHS Information Centre shows that there were 8,230 GP practices in England in 2008[181]. In the future, we anticipate an increase in GP practices as a result of a variety of factors – e.g. population growth, increasing numbers of doctors, other policies and initiatives. The costs section of this Impact Assessment predicts that around 100 new practices will have to register with the Care Quality Commission each year and the same assumption is used here. This is to accommodate potential expansion in the number of primary medical care providers when this policy is implemented for primary medical care in April 2012.

Number of consultations

E6. Data from the NHS Information Centre estimates that approximately 303.9m consultations took place in England in 2008/9. This equates to an illustrative number of around 37,000[182] consultations per practice. We anticipate the number of consultations to increase in the future at the rate of 2.2% per year[183].

[181] http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-general-practice

[182] Calculated as 303.9m divided by 8,230

[183] Data from the NHS Information Centre shows consultation rates increasing from 224.5m to 303.9m over 14 years, at a rate of 2.2% each year.

Identification of hazards

E7. The National Patient Safety Agency (NPSA) collects reports on adverse events across all NHS providers through the National Reporting and Learning System. In their quarterly data summaries, they categorise adverse events in primary medical care under the following headings:

- Medication
- Documentation
- Consent, communication or confidentiality
- Clinical assessment (inc. diagnosis)
- Access, admission, transfer, discharge
- Treatment or procedure
- Patient accident
- Infrastructure (e.g. staffing, buildings)
- Implementation of care and ongoing monitoring
- Medical device or equipment
- Infection Control Incident
- Patient abuse
- Self-harming behaviour
- Disruptive or aggressive behaviour
- Other

E8. All of these hazards with the exception of self-harming behaviour, disruptive or aggressive behaviour and incidents classed as "Other" will be used in this analysis. These three categories of hazard will not be explored further because gathering further data was not possible.

The likelihood of adverse events

E9. The NPSA collect reports on adverse events across all NHS providers, including primary care. However, the reporting system is not obligatory on health providers and it is very likely to underestimate the true number of adverse events taking place. As such, it can only be used as a foundation on which further evidence can be based. Their most recent data summary identifies 2,803 adverse events in primary medical care in the 12 months from April 2008 to March 2009. This translates into a rate of approximately one adverse event in every 108,000 consultations[184].

E10. As set out in the rationale section of this document, there is a limited amount of research evidence on adverse advents in primary medical care and what does exist reports a wide range of figures for the rate of adverse events[185]. Academic literature shows that adverse events occur in primary care at a rate of between 5 and 80 in every 100,000 consultations[186,187], much higher than the number of events reported to the NPSA. This

[184] Quarterly Data Summary Issue 13 (August 2009) http://www.npsa.nhs.uk/nrls/patient-safety-incident-data/quarterly-data-reports/

[185] This is in part because each piece of research uses a different method of reporting (for instance, asking GPs to submit an adverse event form to the academics or trawling through medical records of deceased patients or looking at problems involved with prescribing) and the definition of an adverse event.

[186] Sandars J, & Esmail A, (2003) "The frequency and nature of medical error in primary care: understanding the diversity across studies", *Family Practice*, 20: 3, pp.231-6

[187] Royal College of General Practitioners press release (7/12/2004), "RCGP advice to reduce diagnostic error", http://www.rcgp.org.uk/default.aspx?page=1553 (accessed 18th May 2009)

research originates from countries with comparable health systems to the UK and so it is reasonable that these figures can be used in this analysis.

E11. Other academic research identifies diagnostic errors occurring in between 26-78% of all adverse events, treatment errors occurring in 11-42% of adverse events and medication errors occurring in 1-11% of all adverse events[188]. Between 60% and 83% of errors were found to be "probably preventable."[189] Taking the mid-point of these estimates, the likelihood for these types of hazard are summarised in Table E1 below. Where it has not been possible to find academic research on specific types of adverse event, the figures from the NPSA have been used – these are considerably smaller than the lower bound estimates because of the underreporting of events mentioned above.

Table E1: Likelihood of adverse events in primary medical care (number of adverse events per 100,000 consultations)

Hazard	Lower Bound	Upper Bound	NPSA data
Medication	0.05	8.8	
Documentation	0.95	16.0	
Consent, communication and confidentiality	0.7	12	
Clinical assessment (including diagnosis)	1.3	62.4	
Access, admission, transfer, discharge			0.09
Treatment and procedure	0.55	33.6	
Patient accident			0.06
Infrastructure	1.6	36.0	
Implementation of care			0.03
Medical device/equipment	0.26	4.17	
Infection Control Incident			0.01
Abuse			0.01

E12.These figures only capture "visible" risk so actual incidence of adverse events may be higher. Table 1 (Para 16 in the main text) also shows the proportion of patient safety incidents as reported to the NPSA.

E13.Other research[190] has found that the most common error in primary care is a failure or delay in diagnosis (50% of the cases). Other errors include medication prescription errors, failure and delay in referral and side effects of medication.

E14. The likelihood of an adverse blood-borne infection through poor decontamination practices in primary dental care has been reported by the Dental Services Division (Para 27). The report of a survey[191]of dental practices in Scotland concluded that there was little evidence of management processes underlying decontamination procedures in most practices and that the audit of instrument decontamination was almost non-existent. Research also shows that

[188] Sandars J, & Esmail A, (2003) "The frequency and nature of medical error in primary care: understanding the diversity across studies"*, Family Practice*, 20: 3, pp.231-6
[189] Ibid.
[190] Fenn P, Gray A, Rivero-Arias O, Trevethick G, Trevethick K, Davy C, Walshe K, Esmail A, Vincent C. (2004) "The epidemiology of error: an analysis of databases of clinical negligence litigation." *University of Manchester*
[191] NHS Scotland (2004) "Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice" www.scotland.gov.uk

there is a potential risk of person-to-person transmission of variant CJD via re-usable surgical instruments that have been inadequately decontaminated[192].

Severity of adverse events

E15. Adverse events in primary medical care are often considered to be less severe than those in acute care. However, NPSA data shows that a higher proportion of reported incidents result in serious harm than for incidents reported in secondary care. Analysis of litigation cases showed that 21%[193] of errors resulted in the death of the patient. Furthermore, the rate of events reported that led to death or severe harm in the patient was much higher for general practice than in other sectors (2.6% compared to an average of 1.1% in other settings). This led to the Quarterly Data Summary for August 2009 for England concluding that general practice reports fewer incidents but is more likely to report serious incidents. Thus, identifying the appropriate severity of an adverse event is important for this analysis.

E16. The NPSA data mentioned above classifies reports under generic headings and hence there is a wide range of different adverse events that could occur. For instance, a medication error could lead a patient to having a mild headache or the patient might take the wrong medication, leading to a fatality. Equally, the severity of an adverse event involving a medical device would depend on what device is being used. As such, it is very difficult to generalise an adverse event and assign one severity level.

E17. The suggested approach to quantifying the severity of a hazard is to use the EQ5D scale. This approach asks patients to rate their health in five different domains (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) on a scale between 1 (representing no problems) to 3 (extreme/severe problems.) Regression analysis then transfers these results into a health state. A health state of 1 is assigned to an individual in perfect health whereas death is assigned a health state of 0.

E18. The NPSA adverse event reports ask for a description of how severe the adverse event was using a range between "No Harm" to "Low", "Moderate", "Severe" and "Death." Assuming that the range of the severity of hazards reported to the NPSA is representative of all adverse events in primary medical care, it is possible to assign EQ5D scores to the different types of severity and hence calculate the expected reduction in health state following an adverse event[194]. The reduction in health state is shown for the different adverse events in the table below.

---

[192] References include:
MEL(1999) "Variant Creutzfeldt-Jakob Disease (VCJD): minimising the risk of transmission" 65 (31/08/99)
MEL(1999) "NHS in Scotland infection control: decontamination of medical devices" 79 (25/11/99)
Department of Health (2001) "Risk assessment for transmission of vCJD via surgical instruments: a modelling approach and numerical scenarios"
HDL(2001) "Decontamination of medical devices. (The Old Report)" 10 (09/02/01)
HDL(2001) "Healthcare associated infection: review of decontamination services and provision across NHSScotland" 66 (20/08/01)
Scottish Executive Health Department Working Group (2001) "The Decontamination of Surgical Instruments and Other Medical Devices."
Note: MEL and HDL are types of NHS Scottish Executive circulars (before NHS Scotland/ the Scottish government brands were created.

[193] Fenn P, Gray A, Rivero-Arias O, Trevethick G, Trevethick K, Davy C, Walshe K, Esmail A, Vincent C. (2004) "The epidemiology of error: an analysis of databases of clinical negligence litigation." *University of Manchester*

[194] Using the data from the NPSA we can gain an idea of the severity of a hazard by placing appropriate weightings on each category and multiplying this by the proportion of hazards in each category.

Table E2: Reduction in health state and duration of reduction for different adverse events in primary medical care.		
Hazard	**Reduction in health state**	**Duration of reduction in health state**
Medication	0.0964	2 weeks
Documentation	0.0782	2 weeks
Consent, communication and confidentiality	0.0924	3 weeks
Clinical assessment (including diagnosis)	0.1309	2 weeks
Access, admission, transfer, discharge	0.1489	4 weeks
Treatment and procedure	0.1792	8 weeks
Patient accident	0.1932	8 weeks
Infrastructure	0.1244	2 weeks
Implementation of care	0.1934	4 weeks
Medical device/equipment	0.1298	4 weeks
Infection Control Incident	0.1853	1 week
Abuse	0.2331	1 week

Duration of reduction in health state

E19. The duration of the hazard is also an important consideration to make. Since the valuation of a QALY is based annually, it is necessary to take an appropriate portion of time to show how long the adverse event lasts for.

E20. As before, the range of different services and treatments offered in primary medical care makes it difficult to allocate a figure on the duration of adverse events. This is especially important when the effectiveness of regulation could affect the duration or severity of a hazard. There is no available literature that looks at how long adverse events last for and hence the figures used above are assumptions. However, we have given consideration to data on NHS Reference Costs for Non-Elective Inpatient activity, and specifically with regard to average length of stay and total number of bed days.

Effectiveness of System Regulation in mitigating risks

E21. After identifying the risks and finding how severe they can be on an individual, it is necessary to consider the extent to which the introduction of mandatory system regulation will bring about a reduction in these likelihoods.

E22. Paragraph 23 referred to a study[195] that determined most errors in primary care can be attributed to either aspects of care delivery systems such as administrative errors and failure to investigate, or lack of clinical skills or knowledge. This evident failure of systems was also highlighted in part of the project held in the litigation databases of the NHS Litigation Authority and the medical defence organisations led by the University of Manchester[196]. The researchers determined that a significant number of errors was attributed to the organisation of care, to which systems for obtaining medical records, for screening, and for monitoring laboratory investigations amongst many more, were integral to the organisation of care.

[195] 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" (available at www.nlrs.npsa.nhs.uk)

[196] Esmail A, Neale G, Elstein M, Firth-Cozens J, Davy C, Vincent C. (2004) "Case studies in litigation: claims reviews in four specialties." *University of Manchester.*

E23. Evidence exists[197] showing the need for effective clinical governance systems to identify those poor performing practices that put patients at risk. Consideration has to be made to a variety of factors:

- Is the hazard something being specifically addressed by the regulation in the registration requirements?
- Whether the hazard can be perceived as being preventable. If a hazard is unpreventable then regulation is not going to bring about a substantial reduction in its prevalence[198].
- Is management of the hazard is being dealt with by other regulations or organisations?
- Where the source of the hazard comes from – is it something caused by the organisation, device or professional?
- Is there any academic literature on evaluations of the introduction of system regulation in other countries?

E24. Given this, it would be possible to provide an estimate of the extent to which regulation would lead to a reduction in these hazards from occurring. It is difficult to be certain about how all of these work together and there is no statistical way of quantifying the effectiveness. Each hazard is explored in Table E3 below:

[197] House of Commons Committee of Public Accounts. (July 2007) "Improving quality and safety—Progress in implementing clinical governance in primary care: Lessons for the new primary care trusts. Forty–seventh Report of Session 2006–07."

[198] Research on adverse events in primary care finds that on average 60-83% of all adverse events are preventable. Sandars J, & Esmail A, (2003) "The frequency and nature of medical error in primary care: understanding the diversity across studies"*, Family Practice*, 20: 3, pp.231-6

Table E3: Effectiveness of system regulation in primary medical care		
Hazard	**Description**	**Assumed effective-ness**
Medication	Covered under registration requirement "Management of medicines" and research suggests that a significant portion of medication errors are preventable[199].	35%
Documentation	Covered under "Records" registration requirement	15%
Consent, communication and confidentiality	Covered under registration requirement "Consent to care and treatment"	15%
Clinical assessment (including diagnosis)	Will be indirectly covered under the "Assessing quality of provision" requirement and research indicates a large proportion of diagnostic errors are preventable[200]	30%
Access, admission, transfer, discharge	Some of these hazards could be covered by "Care and welfare of service users" as well as "Cooperating with other providers" but may not be fully realised so the assumed effectiveness could be higher.	15%
Treatment and procedure	Unclear whether registration requirements will have any impact here	0%
Patient accident	Would be indirectly covered by "Care and welfare of service users" and "Safeguarding vulnerable service users"	10%
Infrastructure	Covered under "Safety and suitability of premises; Staffing; and Effective management of workers." No literature on effectiveness but system regulation largely targets this kind of quality improvement.	35%
Implementation of care	Would be covered under "Care and welfare of service users"	25%
Medical device/ equipment	This is covered under several other pieces of regulation (dependent on the device being used) and would be covered under the Safety of equipment requirement. Research also suggests that over 80% of hazards relating to devices and equipment are preventable.	35%
Infection Control Incident	Would be covered under the requirement around Cleanliness and Infection Control.	30%
Abuse	This will be covered under the "Safeguarding vulnerable service users" requirement amongst others. It has been suggested that potentially all cases of abuse are preventable.	15%

Susceptibility of users to harm

[199] Bhasale et al. (1998) "Analysing potential harm in Australian general practice: an incident-monitoring study", *Medical Journal of Australia,* 169, pp. 73-76

[200] Bhasale et al. (1998) "Analysing potential harm in Australian general practice: an incident-monitoring study", *Medical Journal of Australia,* 169, pp. 73-76

E25. There is no quantifiable measure of the susceptibility of users to harm and hence this consideration needs to be made qualitatively. Primary medical care providers deal with a wide range of individuals for a variety of different conditions and problems. Because of this wide range, it is difficult to pin down the precise extent of susceptibility among users. Therefore, it is not included in the calculations.

E26. However, as a large proportion of patients receive all the care they need in primary care, and only a small proportion are referred on to secondary care, we can assume that the majority of individuals using primary medical care providers are likely to be for mild or moderate conditions.

E27. Hence, the group of individuals most likely to be at most risk of experiencing an adverse event would be vulnerable groups of people, in particular older patients and young children. We assume, therefore, that the majority of individuals will be of a low susceptibility of harm. However, for the small group of patients who would be at higher risk the likelihood of an adverse event is higher. These vulnerable users make up a high proportion of the number of consultations; hence, the overall risk is increased. In 2008/9 the consultation rate for over 60 years, per person per year ranged from 7.19-13.46 and 7.63-13.96 for females and males respectively[201], the highest rates observed throughout the age ranges.

Saved Treatment Costs

E28. If an adverse event takes place, it is likely that the patient will require treatment on the NHS to treat the hazard. For instance, if a patient experiences a fall because of poor access and injures their knee then they may require additional treatment in secondary care to treat their injury. These figures can be used so that an estimate for the saved treatment costs can be made.

E29. Since there is a wide range of adverse events that could take place under the categories identified above, the average treatment cost is used. Where it is not possible to identify all the different types of treatment available, we have used a figure of £840, calculated by forming an average of the identified categories we did have cost data for. The saved treatment cost for each hazard is shown in the table overleaf:

Table E4: Saved Treatment Costs on NHS for different types of adverse event.[202]

Hazard	Type of treatment	Cost
Medication		£840
Documentation		£840
Consent, communication and confidentiality	Other specified admissions and counselling without complications	£334
Clinical assessment (inc. diagnosis)	Examination, follow up and special screening	£524
Access, admission, transfer, discharge	Falls without specific cause with/without complications	£1,370
Treatment and procedure		£840

[201] Source: NHS Information Centre (2009), "Trends in consultation rates in general practice 1995/1996 to 2008/2009: Analysis of the QResearch database." Section 1.16 and Table 3 of the accompanying Excel workbook.
[202] DH reference cost data used.

Patient accident		£840
Infrastructure		£840
Implementation of care		£840
Medical device/equipment		£840
Infection Control Incident	Major, intermediate and minor infections with/without complications and other non-viral infections	£1,128
Abuse		£840

Calculating the benefits

E30. Using this information it is now possible to calculate the benefits arising from a reduction in adverse events. There are two different types of benefits in this section: the benefits arising from the saved treatment costs imposed in secondary care and the QALY gain to patients from a reduction in adverse events.

E31. **QALY gain:** For saved QALYs through regulation, we identify the QALY value by multiplying the value of a QALY (valued at £60,000) by the expected duration of the hazard and the reduction in health state following the adverse event.

E32. This value is then multiplied by the number of treatments per year, the likelihood of the hazard occurring and the expected reduction in adverse events following regulation.

E33. For instance, the QALY gain from errors in clinical assessment, including diagnosis errors would be:
QALY gain[203] = £60,000 * (2/52) * 0.1309 = £302.08
£302.08 * 303.9m[204] * 0.0624%[205] * 30% reduction = **£17.2m**

E34. Table E4 overleaf summarises the expected value of adverse events using the method explained above.

Table E4: Expected value of adverse events under regulation[206] - QALY Gain

Hazard	**QALY Gain**
Medication	£0.01m - £2.1m
Documentation	£0.08m - £1.3m
Consent, communication and confidentiality	£0.1m - £1.8m
Clinical assessment	£0.4m - £17.2m
Access, admission, transfer, discharge	£0.03m
Treatment or procedure	£0m
Patient accident	£0.03m

[203] Since QALYs are measured on an annual basis, we have to consider the QALY loss for the duration of the hazard. In this case, the QALY loss exists for two weeks, or 2/52 years.
[204] Number of consultations
[205] From Table E1, the upper bound for the likelihood of diagnostic errors is 62.3 per 100,000 consultations. This equates to a rate of 0.0624%, due to rounding.
[206] Costs have been rounded up/down so may not fully add up.

Infrastructure	£0.5m - £11.0m
Implementation of care	£0.02m
Medical device/equipment	£0.2m - £2.7m
Infection Control	£0.002m
Patient abuse	+ £0
Total	**£1.3m - £36.1m**

E35. Hence, the estimated benefit that system regulation would bring to primary care using this method is £1.3m - £36.1m.

E36. **Saved Treatment Costs.** For each hazard, we identify the number of adverse events that take place each year using the figures from the likelihood section (Table E1). Next, we compute how many of these adverse events will not occur with system regulation in place using figures from the effectiveness of system regulation section. We then multiply this by the saved treatment cost figure to arrive at a value.

E37. For instance, if we consider the treatment costs to the NHS of errors in clinical assessment, including diagnosis errors;
0.0624%[207] * 303.9m = 189,634 hazards per year.
189,634 * 30% reduction = 56,890 errors avoided through system regulation per year.
56,890 * £524 = **£29.8m**

[207] Upper bound for likelihood of diagnostic errors is 62.3 per 100,000 consultations. This equates to a rate of 0.0624%, due to rounding.

Table E4: Expected value of adverse events under regulation[208] - Saved Treatment Costs (STC)	
Hazard	**STC**
Medication	£0.04m - £7.9m
Documentation	£0.4m - £7.1m
Consent, communication and confidentiality	£0.1m - £1.8m
Clinical assessment	£0.6m - £29.8m
Access, admission, transfer, discharge	£0.06m
Treatment or procedure	£0
Patient accident	£0.02m
Infrastructure	£1.4m - £32.2m
Implementation of care	£0.02m
Medical device/equipment	£0.2m - £3.7m
Infection Control	£0.01m
Patient abuse	£0.004m
Total	**£2.9m - £81.62m**[209]

E38. As with the savings from non-elective admissions in Annex D, we believe that any cost savings that releases the DH budget to be spent elsewhere, is expected to provide benefits to patients at 2.4 times that of the cost saving following the opportunity cost rationale (paragraphs 215-220). Hence, the benefits to patients of saved treatment costs can be estimated at **£7.0m - £195.9m**

[208] Costs have been rounded up/down so may not fully add up.
[209] Figures are rounded up from calculations.

Annex F – Benefits to dental patients as a result of improved decontamination practices

F1. As explained in paragraph 21, one of the main risks to patients in primary dental care is the transmission of blood-borne infections due to poor decontamination practices. In this annex, we shall concentrate on the risk of transmission of vCJD.

F2. Assessment of the risk of transmission of vCJD as a result of endodontic procedures in dentistry suggests that this risk is low. However, due to the large number of dental operations, even a small risk per procedure could translate into a major concern in terms of infection dynamics.

F3 .The possibility has also now been raised that a proportion of the population may be susceptible to vCJD infection, but would remain in a 'carrier state' indefinitely, rather than developing symptoms. This may increase the risk of the infection being passed on to others and, as a consequence, of the disease becoming self-perpetuating. This argument applies to all secondary infection routes, but is particularly relevant to dentistry given that dental patients can expect to have the full life expectancy typical of their age. By contrast, many blood recipients have poor life expectancy, as do many of those undergoing 'high risk' procedures such as neurosurgery.

F4. Here, we concentrate on the benefits accruing to patients due to reducing the risk of transmission, but it should also be noted that there would also be public health benefits in terms of generally reducing the spread of the disease. We do not attempt to quantify these here.

F5. The most recent risk assessment by DH[210] considered how the potential risk of transmission of vCJD as a result of contaminated instruments may translate in patients becoming infected. They estimated the number of infected patients infected each year could be between 2 and 150 patients. The wide range clearly indicates the high level of uncertainty in this area, and the sensitivity analysis that was conducted.

F6. These figures are based on the risk if 'files and reamers' are not properly decontaminated, and the assessment concludes by recommending that such instruments should be single use only and that this should eradicate the risk involved. This has, indeed been the recommendation from SEAC[211] since 2006, and the Chief Dental Officer for England has now published requirements for endodontics files and reamers to be single-use instruments in all cases.

F7. However, evidence suggests that instruments intended for single-use are not always treated as such. As already described in paragraph 27, a survey of dental decontamination practices in Scotland found that at least 15% of practices re-used single use devices[212]. If we extrapolate this to assume that 15% of the total number of potential infected patients could

[210] Department of Health (2007) Dentistry and vCJD: The implications of a 'carrier state' for a self-sustaining epidemic due to endodontics dentistry
[211] Spongiform Encephalopathy Advisory Committee
[212] NHS Scotland (2004) Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice

therefore still be at risk of infection under the current system, then we can calculate the benefit of registration as acting as a mechanism for eradicating this risk[213].

F8. NICE guidance on reducing the risk of transmission of vCJD[214] estimated that the average number of QALYs lost for every case of transmission of CJD via such a procedure was in the order of 17 for neurosurgery. We believe this would be an underestimate for dentistry, given the arguments above that patients needing neurosurgery generally have a lower life expectancy. If we, however, continue with this assumption of 17 QALYs lost, then we can attempt to calculate the benefit to dental patients of all dentists coming within the scope of registration.

F9. With 15% of between 2 and 150 patients receiving endodontic treatment saving, on average, 17 QALYs we estimate that registration could lead to annual benefits of between £300,000 and £23million.

F10. As well as this cost, we also consider the cost savings to secondary care. Only a proportion of these infected patients may actually go on to develop symptoms. The DH risk assessment referred to in paragraph F5 estimates that as few as 4% or as many as 40% of patients may go on to develop symptoms. If we consider the costs to the NHS of treating these patients, estimated at £40,000 per patient[215], this translates into savings of between £480 and £360,000[216].

F11. Following the same rationale as in Annex D, we should treat this number as a benefit rather than a saving to secondary care, as the NHS could reinvest this money elsewhere, such as treatments for other patients with different illnesses who were not able to be treated before. We therefore must multiply this figure by 2.4 to derive the true benefit to patients (following the same rationale as in Annex D). This therefore produced an additional estimated benefit of up to £860,000.

[213] DH intends to undertake a survey into dental decontamination practices in England in the near future which will allow us to have a more up to date understanding of these issues.
[214] NICE (2006) Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures
[215] ibid.
[216] This is calculated as between 4% and 40% of 15% of between 2 and 150 patients, multiplied by £40,000.

Annex G – Supplementary Tests

G1. This annex provides analysis and results of the Supplementary Tests.

Competition Assessment

Executive Summary

G2. This competition assessment aims to assess the affect on competition of including primary medical and dental care providers within the scope of the registration system of the Care Quality Commission. The Care Quality Commission will register all primary dental care providers from 1 April 2011 and all primary medical care providers from 1 April 2012. Including primary medical and dental care providers under the new system of registration is likely to have a small negative effect on competition in the primary medical and dental care markets.

Main impacts on competition of including primary medical and dental care within the scope

G3. The introduction of a provider level based registration system is likely to have a negative effect on competition, by increasing the costs for new entrants to the market.

G4. A common system of registration will impose the same requirements on all registered providers. This will create a level playing field for all providers; encouraging competition.

G5. The registration requirements may cause some providers to exit the market due to the costs of being compliant. This would reduce competition and coverage in the primary care markets.

G6. Private sector providers not already required to register may find it harder to compete in the market because of the costs of registration.

Introduction

G7. This competition assessment is part of the Impact Assessment for including primary medical and dental care within the scope of the registration system of the Care Quality Commission, and should be read within the wider context of the Impact Assessment for the introduction of the new Care Quality Commission registration system from 2010/11.

G8. The purpose of this competition assessment is to assess if, and to what extent, including primary medical and dental care within the scope of registration will affect competition in the primary medical and dental care markets, and the related health and social care markets.

G9. In particular, it will assess whether the changes will directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously in the affected markets.

G10. This competition assessment was completed following the Office of Fair Trading's competition assessment guidance[217].

[217] Office of Fair Trading (August 2007) "Completing competition assessments in Impact Assessments: Guideline for policy makers"

Definition of Markets

G11. This policy will affect all primary medical care providers with NHS contracts, including all GP practices, out of hours providers and walk in centres. It will also affect all primary dental care providers.

The current state of competition in the market

Primary Medical Care

G12. In England, by 2012 there are likely to be around 8,600 primary medical care contractors (see paragraph 71) with around 34,000 GPs between them. The average provider has 4 GPs. The number of GPs per practice varies greatly; 25% of practices have a single GP while larger practices can have over 15 GPs. The total number of consultations in England in 2008-09 is estimated as 303.9m, giving a rate of around 5.5 consultations per person per year[218].

G13. There are also around 400 wholly private doctors in England, around 1% of all general practitioners. The majority of these are concentrated in London. These are already required to register with the Commission.

G14. Competition in the primary medical care market has opened up in recent years following the 2003 *Health and Social Care (Community Health and Standards) Act*, which allowed PCTs to commission services to "anyone capable of securing the delivery of such services."[219]

G15. Approximately 100 new primary medical care providers open each year. From the implementation of the 2003 Act up until October 2008, new market entrants (i.e. not traditional single-handed GPs/ transitional GP partnerships) were managing over 100 general practices. This makes up about 20% of all new primary medical practices.

G16. Over 30 companies hold commercial contracts[220] for primary medical care and run roughly 100 health centres and GP practices between them[221]. These are made up of GP-led companies, corporate providers and social enterprises.

G17. Despite this, the primary medical care market is not very competitive. On the demand side, patients are quite reluctant to change provider, and most often do so only when they change address. Patients are hindered by access to practices; many practices have closed lists if they have reached capacity, or open-closed lists, if they have capacity but are unwilling to take on new patients.

---

[218] QResearch and The Information Centre for health and social care (2009)."Trends in Consultation Rates in General Practice 1995/96 to 2008/09: Analysis from the QRESEARCH database"

[219] NHS Primary Care Contracting (2006) "Primary medical services contracts—a guide for potential contractors."

[220] http://www.bmj.com/cgi/content/full/335/7618/475?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=1&andorexacttitle=and&andorexacttitleabs=and&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=date&volume=335&firstpage=475&fdate=1/1/1981&resourcetype=HWCIT

[221] http://www.bmj.com/cgi/content/full/338/mar31_1/b1127?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=1&andorexacttitle=and&andorexacttitleabs=and&fulltext=gp+contracts&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=date&fdate=7/1/2008&resourcetype=HWCIT

G18. Private providers may find it hard to compete with their NHS counterparts for the following reasons:

a. Most significantly, private providers find it difficult to compete with the NHS's 'free' service at the point of delivery.

b. Their doctors do not take part in the NHS pension scheme, which can increase costs for providers.

c. NHS providers and mixed NHS/ private providers (unlike wholly private providers) are not currently subject to regulation

d. Many private providers are led by a single GP so regulation can be more burdensome than it might be to a larger practice.

G20. However, providers of NHS primary medical care must comply with the requirements set out in their contracts and the GPs providing the service must be on the Performers List held by a PCT.

Primary Dental Care

G21. In England, there are around 8,150 dental addresses, of which 1,000 are solely private. There are around 7,150 dental practices under contract to the NHS with 21,000 NHS dentists. Three firms hold around 600 contracts, and 850 contracts are directly delivered by PCTs which will be registered from April 2010. Therefore, there are around 6553 NHS contractors. Many practices offer private care alongside their NHS work.

G22. The number of dentists per provider varies greatly; with 37% of practices being single-handed and 5% having six or more dentists. The average practice has 2.4 dentists. In 2008-09, there were 37.4m NHS courses of treatment and an estimated 9m courses of treatment in the private sector (see paragraph 72).

G23. There is little growth in the primary dental care market, under 0.5% per annum. According to Department of Health data, the number of practice addresses grew from 9,081 in 1996 to 9,350 in 2003. The number of dentists registered with the General Dental Council increased by 7% during 2008[222].

Counterfactual

G24. The counterfactual for this competition assessment is the continuation of the current situation where NHS primary medical care providers and all primary dental care providers are outside the scope of the registration system run by the Care Quality Commission. Any improvements to safety and quality would have to rely on other aspects of the Primary and Community Care Strategy and the wider quality agenda on primary care. Private doctors providing primary medical care must currently be registered by the Commission and this would continue if there was no change to the registration system. Such a position would fail to address the current lack of consistency in the arrangements.

[222] General Dental Council (2008), "Annual Review '08"

Will the Registration Requirements:

Indirectly limit the number or range of suppliers?

(i) Significantly raises the costs of new suppliers relative to existing providers

G25.A provider level registration system could disadvantage new entrants relative to existing providers and therefore have a small negative effect on competition.

G26.Under the new system of registration, new providers of primary medical and dental care will be required to register, but new sites opened by existing providers will not need to be registered again. However, an application to vary their registration will need to be made and the Commission will need to be satisfied that the new sites comply with the registration requirements in the same way as for any new provider and for existing sites.

G27.This will increase the costs of expansion to existing providers, as they did not have to register sites under the old system. It will also increase the costs to new entrants and could therefore put them at a small disadvantage relative to existing providers who wish to compete for contracts. This may have a small negative effect on competition.

G28.However, as new entrants are relatively few in number compared to existing providers, the negative effect on competition is likely to be small. New market entrants open around 20% of new sites. Approximately 1%[223] of all primary medical care providers are made up of new entrants to the market since 2004.

(ii) Significantly raises the costs of some existing suppliers relative to other existing suppliers

G29.Bringing primary medical and dental care in under the scope of Care Quality Commission regulation will put providers on a more level playing field and decrease the cost disparities between providers. This will have a positive effect on competition between providers.

G30.Under the old system, only wholly private GP practices were subject to regulation. Under the new system, all GP practices have to be registered. This provides a level playing field, as all providers have to meet the same requirements on quality and safety. As such, patients can compare them on an equal standing, whilst being assured of their quality, and this allows them to make a more informed decision of which practice to choose. This will have a positive effect on competition between providers.

G31.Under the old system where only wholly private GP practices were subject to regulation, the private practice of a GP with a NHS contract was not required to register.

G32.Under the new system, all practices would be registered This may result in a small negative effect on competition, as fewer practices would compete for NHS contracts and some mixed providers who spend little time working for the NHS may wish to terminate their existing contract as they can get a greater return from private work. It is unlikely that this will have a significant impact.

(iii) Significantly raises the cost of entering or exiting from an affected market

[223] 100 market entrants since the implementation of the 2003 *Health and Social Care Act* in 2004, divided by 8400 primary medical care providers

G33.Registration requirements may cause some providers to exit the market, if they are unable to comply. This will reduce competition between providers. However, this should be weighed against the benefit of having essential levels of quality and safety consistent throughout the market and the likelihood that nearly all providers will be able to meet the requirements.

G34.Bringing primary medical and dental care within the scope of Care Quality Commission registration would require providers to register. This means NHS primary medical care and both NHS and private primary dental care will be required to register for the first time. Providers will have a new duty to meet the registration requirements.

G35.Although the Care Quality Commission is committed to using proportionate compliance criteria to assess providers' compliance with the registration requirements; there is a risk that some providers will not be able to meet the registration requirements. The costs of complying with the requirements, and the costs of proving compliance to the regulator, may cause some providers to exit the market. This would lead to reduced coverage for patients, and reduced competition between providers.

G36.However, the number of NHS providers who fail to meet the registration requirements should be small. NHS providers currently have contractual requirements with their PCT, which include checks for assurance of levels of quality and safety. Therefore, most NHS providers should, if not already meeting the requirements, be very close to them. This may vary from area to area depending on PCTs enforcement of current contractual requirements.

G37.The reduction in competition is compensated by some benefits. Any providers who exit the market would not have met essential levels of quality and safety and as such may have posed a risk to patients' health. It is currently difficult for patients to ascertain the quality of care they are receiving and to exercise choice effectively. Consultation with stakeholders shows that users want services that meet essential levels of safety and quality. Introducing registration will provide this assurance and as such prevent providers from competing based on low quality services at a reduced cost.

G38.Any reduction in providers is particularly relevant to rural ares where the choice of practice for patients is limited due to the distances involved between practices.

G39.This may disproportionately affect deprived areas where the number of lower quality providers is relatively high, compared to other areas across England. Any reduction in the number of providers would result in reduced competition between the remaining providers in these areas, and less choice for patients.

Limits the ability of suppliers to compete

G40.Annual self-assessments and inspections may reduce the ability of small providers to compete and have a negative affect on competition.

G41.Practices must complete an annual self-assessment and could be subject to inspections as part of the registration process and ongoing monitoring. This puts an additional administrative burden on providers and requires a certain amount of staff time to complete. Smaller providers are less likely to have the resources and support staff that larger providers have. The GPs and dentists of smaller providers may have to complete the assessment and assist with inspections themselves; reducing the time that can be spent dealing with patients and improving the quality of care. Hence, annual assessments and inspections may have a disproportionate impact on small providers and make them less able to compete with their larger competitors. This will have a negative effect on competition.

G42. The Care Quality Commission will embody the Government's principles of good regulation – to give people the best and safest care and the best possible outcomes for public money. The Commission is required to work in a risk-based and proportionate way and the Commission has already committed to working closely with partner organisations to develop an approach to registration, which draws on existing systems of assurance and sources of information that are relevant to the registration requirements.

G43. The Care Quality Commission intends to use a proportionate approach to regulation.

G44. The impact on small firms of including primary medical and dental care under the Care Quality Commission regulation system is analysed in more detail in the Small Firms Impact Assessment later in this annex.

Private dentists

G45. It is also necessary to consider the potential impact on private dentists of competition. Unlike private medical practices, private dentists have not been subject to regulation before, and therefore there may be a larger impact on dentists. Although there are around a 1000 private dentists, we also know that some NHS dentists also undertake some private practice, and therefore we shall consider the size of the market in terms of the number of private patients (estimated as 13.4m[224]).

G46. Recent estimates suggest the average NHS patient pays £26.50 each year for treatment[225], and generally it is believed that private patients pay approximately double what NHS patients pay[226]. Therefore, we shall take £53 as the estimate for the average amount spent by private patients.

G47. We have estimated that the overall burden to private dentists could be between £3.6 million and £4.0 million in the transition year, falling to approximately £1.7 million in subsequent years. If we consider how this would impact on the cost per patient (if we assume that dentists pass all this additional costs onto patients in the form of higher charges), this translates into an increase of between 27p and 30p in the transition year, and 13p in subsequent years. This could also be presented as a 0.5% to 0.6% increase in the transition year, falling to a 0.2% increase in subsequent years.

G48. Previous studies[227] have found that dental patients tend to respond to increases in price through going to their dentist less often rather than through deciding to stop going to their dentist. Therefore, we would anticipate that the cost to patients in terms of poorer dental health would be low, particularly with regard to the low average increase in costs.

G49. However, to the extent that imposition of regulatory costs frustrates business, we do need to consider the consequent loss of welfare as attendance falls: for each such transaction this will be the gap between what patients would have been willing to pay and what it would have cost the dentists. Given the large number of patients, even a small fall in demand in response to this increase in costs could translate into a significant aggregate welfare loss.

G50. However, a survey of dental care over 20 years in Scotland estimated that the price elasticity of demand related to dentistry is low: between -0.024 and -0.75. Focusing upon the

[224] See paragraph 205 for workings.
[225] Conservative Party (2008)
[226] Internet based research into the costs of primary dental care.
[227] Arinen et al. (1996)

higher estimate, the impact of a 0.5% increase on price would be 0.4% fewer attendance by patients in the transition year.

G51. We calculate the total worth of the private dental market as being approximately £710 million[228], and therefore we can value the loss of business as up to £2.8 million[229] in the transition year and up to £1.1 million in subsequent years. (These estimates depend not only upon the higher elasticity figure, but also the assumption that private dentists pass on the full costs of registration.)

G52. To assess welfare loss, we need to assess what the frustrated patients would have been willing to pay in excess of what it would have cost to treat them. If we assume that the dental market is competitive at the margin, and hence that no supernormal profits are made on the marginal patient, then the loss of the marginal patient incurs to welfare loss – and the resources deployed in treating them will be redeployed elsewhere in the economy. On the assumption (for lack of evidence to the contrary) that over the relevant range there are constant returns to scale, intra-marginal patients would have cost the same, but would have been willing to pay up to 0.5% more. If on average they would have been willing to pay 0.25% more, the total welfare loss comes to up to 0.25% of the lost business: i.e. £7,000 in the transition year and up to £2,750 in subsequent years. In practice, there may well be super-normal profits and barriers to exit that induce dentists to absorb some of these costs, reducing the welfare loss below these already small levels.

G53. As we would further expect some patients to transfer over to an NHS practice[230], rather than to actually decrease the amount of dental care they receive, we can therefore conclude that the loss of consumer surplus as a result of registration of private dental practices would be negligible.

Effect on Competition to Related Markets

G54.In line with the NHS Next Stage Review, primary care providers are increasingly providing services that have previously, only been provided in the secondary care environment (such as some minor surgery).

G55.Extending the scope of registration to include primary medical care providers will ensure consistency in essential levels of safety and quality for activities across all providers.

G56.This will provide a more level playing field between primary and secondary medical care providers, as they will be judged by the same standards. This should have a positive effect on competition.

G57.It will allow patients to choose a provider that is best suited to them, safe in the knowledge that all providers meet essential levels of safety and quality.

[228] 13.4 million patients paying £53 each.
[229] These costs are calculated as 0.01% and 0.4% of £710 million.
[230] This would of course impose costs upon the NHS, but there would be offsetting patient benefits justifying these costs.

Small Firms Impact Test

Executive Summary

G58.It is necessary to complete an SFIT for any change to regulation that imposes or reduces the cost for business [231]. Regulations often have a disproportionate cost on small providers than on large providers. As such, the SFIT assesses the effect a proposal will have on small firms and draws a conclusion on whether small firms should be exempt from regulation.

G59.The changes to regulation will affect the primary medical and dental care markets. The SFIT aims to assess the effect on private sector small firms from the change to regulation. Therefore, this SFIT will address private primary dental care providers only, as private primary medical providers are not considered in this Impact Assessment.

G60.According to European Commission guidelines [232], a business is considered a small-business if it has 50 or less full time employees and a micro-business if it has 10 or less full time employees.

G61.The majority of primary dental care providers would be classified as small-businesses, and a great deal may be considered micro-businesses. Therefore, this SFIT will consider the majority of all providers in the primary medical and dental care markets.

Summary of Conclusion

G62.No exemption for small providers is possible or desirable.

G63.The Care Quality Commission should consider the impact of regulation on small providers when developing guidance about compliance.

Overview of the affected market

G64.There are approximately 9000 primary dental care practices in England of which 1000 are wholly private, making up around 11% of the market. In the market as a whole, 37% of dental practices have only one dentist and only 5% have six or more dentists. It is probable that of the private dental practices, a high proportion have relatively few dentists; the majority may have only one.

G65.Dental practices have a similar staff composition to that of GP practices, but often on a smaller scale. The majority, if not all, of private primary dental practices are classified as small-businesses.

Consultation

G66.The Department carried out a general consultation for all health and social care providers that would be included in the Care Quality Commission's regulation system. This included a number of small dental care providers.

G67. Interviews were held with a number of small primary dental care providers to establish what the costs involved with registering with the Care Quality Commission would be for a

[231] Department for Business Innovation & Skills, (January 2009), "Small Firms Impact Test: Guidelines to policy maker"
[232] ibid.

small provider. They also gave their opinion on the decision to bring primary dental care within the scope of the CQC regulation system.

G68.Primary dental care providers currently are not subject to system regulation. All responses from interview suggested that they were supportive of the decision requiring primary dental care providers to register with the Commission.

Changes to the Costs and Benefits to small provider

G69. The new system of registration will impose additional burdens on all primary dental care providers, as they are not currently registered with the CQC. It is important to establish whether the costs involved with registration will have a disproportionate effect on small providers.

G70. The Care Quality Commission aim to use a proportionate approach to regulation and as such the demands on a provider will be relative to their size. Therefore, the administrative demands required of small providers will be less than those of larger providers.

G71.However, the move to provider level registration will benefit larger providers relative to small providers. This means providers will no longer have to register by site but by provider. This will reduce costs for multi-site providers. Larger providers will benefit from economies of scale from having more practices as the registration cost per site decreases as the number of sites increases.

G72.Furthermore, the costs involved will have a disproportionate effect on small providers as they have fewer administrative staff compared to larger providers and the burden is likely to fall heavily on dentists and other senior clinical staff.

G73.All primary dental care providers will be required to register with the Care Quality Commission for the first time. From interviews, it is expected that the cost to register a private dentist will be between £13,200 - £3,600[233]. All 1000 private primary dental care providers will have to pay this.

G74.Private primary care providers will have to complete a risk-assessment and a self-declaration each year. This is estimated to cost approximately £1,400-£1,550[234] per provider.

G75.Under the new system, the Care Quality Commission intends to carry out inspections on all private dentists in the first year, and subsequently 10% of providers each year; half of which would be random and half would be risk assessed. Random inspections should affect around 50 private providers[235]. An inspection is estimated to cost £370 per provider.

G76.There is roughly a 5% turnover of practices each year for the primary dental care market as a whole. Assuming this is consistent across the private sector, we expect there to be 50 first time registrations each year[236]. The costs of a first time registration will be £3,200 - £3,600.

[233] 10-20% less burdensome than the £4000 cost suggested by private primary care providers during consultation

[234] £1,200-£1,350 per provider for the annual risk assessment and £190 per provider for the annual self-declaration. Based on risk assessments costing 10-20% less than £1,500 under the old system

[235] 10% of 1000 private primary dental care providers

[236] 5% of 1000 private primary dental care providers

Table G1: One-off transition costs of registration with the Care Quality Commission for private primary dental care providers					
Costs involved with registration	**Number of providers**	**Unit Cost**		**Cost to providers**	
		Minimum	**Maximum**	**Minimum**	**Maximum**
Registering with the CQC	1000	£3,200	£3,600	£3,200,000	£3,600,000

Table G2: Annual costs of registration with the Care Quality Commission for private primary dental care providers					
Costs involved with registration	**Number of providers**	**Unit Cost**		**Cost to providers**	
		Minimum	**Maximum**	**Minimum**	**Maximum**
Annual risk assessment and self-declaration	1000	£1,400	£1,550	£1,370,000	£1,560,000
Inspections in 2011	1000	£370	£370	£370,000	£370,000
Inspections in 2012	100	£370	£370	£37,000	£37,000
Registering new providers	50	£3,200	£3,600	£160,000	£180,000

The risks of care provided by small providers

G77.Overall, the costs of the new registration system on private dental providers will be disproportionately burdensome on small providers.

G78.Therefore, in order to justify the greater burden of regulation on small providers, the benefits should also be higher in order to make it just as worthwhile as the regulation on large providers.

G79.A strong argument for the regulation of the primary dental care markets is the risk from the large volume of providers. Although the individual risk of each provider is small, when this is aggregated over all providers in the market, the risk to patients' quality and safety of care becomes substantial. As the majority of primary medical and dental care providers are small, the risks are large for all small providers and therefore the benefits from regulation are large.

G80.The benefits of the Care Quality Commission regulating small private dental care providers are greater than that of large NHS providers. NHS providers have contractual obligations that they are required to meet; this acts as an assurance of quality and safety levels.

However, if private providers were not required to register with the Commission then there would be no assurance that providers meet essential levels of quality and safety of care.

G81. Although there is no evidence that small providers are underperforming clinically; there are concerns over professional isolation and the standards of quality in small providers[237]. The reasons for these concerns are:

a. Professional isolation can occur with small providers. Dentists that work single-handedly or in small practices may have little contact with other professionals. This results in providers not keeping up to date with new developments, both clinically, and more crucially to system regulation, with practice management. This will ultimately affect levels of quality and safety.

b. Small providers experience less peer pressure to improve quality of care. Larger providers with multiple dentists may experience internal competition; all professionals strive to provide the levels of quality of their peers. The lack of peer pressure in smaller providers can lead to complacency.

G82. This would suggest that the benefits of regulation might be more prominent for small providers.

Conclusion

G83. Having assessed the impact on small private providers from introducing primary dental care within the Care Quality Commission registration system, we conclude by making the two following statements:

G84. **No exemption for small providers is possible or desirable.**

a. As outlined above the benefits of regulation will be more prominent for small providers. An exemption from regulation for small providers would heavily reduce the overall benefits of a new regulation system.

b. As the majority of primary dental care providers are small, and the key risk of these markets is from the large volume of providers, it would be counterintuitive to exempt the majority of providers.

c. The majority, if not all, primary dental care providers are defined as small, although there is some variation in the size of providers within the classification of 'small firms'. Therefore, although the regulations will have a disproportionate effect on the smallest providers, the overall difference should not be too substantial.

d. If small providers were exempt from regulation then they would not be able to assure patients that they met essential levels of quality and safety. This would disadvantage providers, as they would find it more difficult to attract and retain patients. Patients concerned about their quality of care would move to the larger regulated providers able to provide assurance.

237 http://www.bmj.com/cgi/content/full/323/7308/320?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=1&andorexacttitle=and&andorexacttitleabs=and&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=date&volume=323&firstpage=320&fdate=1/1/1981&resourcetype=HWCIT

G85.**The Care Quality Commission should consider the impact of regulation on small providers when developing guidance about compliance**.

a. Regulation will have a disproportionate effect on small providers. Therefore the Care Quality Commission should consider this when they are developing guidance about compliance.

b. The Commission intend to use a proportionate and risk based approach to regulation. As such, they should consider if all requirements are necessary and relevant to small providers.

Health Impact Assessment

Executive Summary

G86.This HIA aims to assess the wider and indirect impacts of including primary medical and dental care providers within the Care Quality Commission registration system (referred to, from here as 'the policy') on people's health and well-being.

G87.The assessment will be carried out following the Department of Health's HIA screening questions[238].

Conclusion

G88.There will be no significant impact on people's health through its effect on wider determinants of health.

G89.There will be no significant impact on people's lifestyle related variables.

G90.There will be a significant demand on primary medical and dental care providers.

Screening Questions

(A) Will your policy have a significant impact on human health by virtue of its effects on the following* wider determinants of health?

***Income, Crime, Environment, Transport, Housing, Education, Employment, Agriculture, Social Cohesion**

G91.The policy has no direct effects on any of the above. Therefore, there are no indirect effects on human health because of these wider determinants of health.

G92.It will have benefits on human health, but these will be through its effect on assuring patients receive primary medical and dental care that meet essential levels of quality and safety.

G93.The main section of the Impact Assessment gives a detailed analysis of the benefits to human health.

238

http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Healthassessment/DH_4093617

(B) Will there be a significant impact on any of the following* lifestyle related variables?

***Physical activity; Diet; Smoking, drugs of alcohol misuse; Sexual behaviour; Accidents and stress at home or work**

G94.The policy has no direct effects any of these lifestyle related variables.

(C) Is there likely to be a significant demand on any of the following* health and social care services?

***Primary care, Community services, Hospital care, Need for medicines, Accident or emergency attendances, Social services, Health protection and preparedness response**

G95.The policy will impose demands on primary medical and dental care providers.

G96.Primary medical and dental care providers will have to register with the Care Quality Commission. They will be required to comply with the registration requirements and prove compliance; as such, there will be administrative demands. These demands are examined in further detail in the main section of the Impact Assessment.

G97.There will be no significant demand on any of the other health and social care services.

Human Rights

Executive Summary

G98.It is important that including primary medical and dental care within the Care Quality Commission registration system is compatible with all human rights in accordance with 1998 Human Rights Act[239].

G99.This supplementary test assess whether or not introducing primary medical and dental care within the Commission registration system is incompatible with any articles from The European Convention on Human Rights.

Are any of the articles infringed?

Article 2- Right to life
Article 3- Prohibition of torture
Article 4- Prohibition of slavery and forced torture
Article 5- Right to liberty and security
Article 6- Right to a fair trial
Article 7- No punishment without law
Article 8- Right to respect for private and family life
Article 9- Freedom of thought, conscience and religion
Article 10- Freedom of expression
Article 11- Freedom of assembly and association
Article 12- Right to marry
Article 14- Prohibition of discrimination

[239] Department of Justice (October 2006), "Human rights: human lives; A handbook for public Authorities"

G100.Introducing primary medical and dental care within the Commission registration system will not infringe on any of the articles above.

Conclusion

G101.Introducing primary medical and dental care within the Commission registration system is compatible with all of the articles in The European Convention on Human Rights.

Rural Proofing

Executive Summary

G102.It is necessary to ensure that all domestic policy takes into account rural needs and circumstances. Therefore, it is important to take into consideration the different effect of including primary medical and dental care within the Care Quality Commission registration system there may be on rural communities.

G103.This rural proofing aims to assess whether including primary medical and dental care within the Commission registration system will have a significantly different effect on rural communities than on more urban communities.

Rural Background

G104.The majority of people in rural areas experience a high quality of life. They have an above average life expectancy, enjoy good physical and mental health and live healthy lifestyles.[240]

G105.However, there are areas of significant rural deprivation hidden among affluent rural communities consisting of wealthy retirees and commuters. People working in rural areas earn £4,655 less than the national average. The poorest and most disadvantaged rural residents have poorer health outcomes and experience lower levels of physical and mental health.[241]

G106.A determining factor in rural communities' access to primary medical and dental care is the distance people must travel to receive it. Primary medical and dental care providers are not located in every rural community due to the sparse population distribution. People in rural communities will often have to travel many miles to the next village or town to receive primary medical or dental care. Long distances and infrequent public transport can be the biggest barriers to rural communities' access to primary medical and dental care.

G107.Rural communities tend to have a high proportion of elderly people. This will increase further as the English population ages. This will result in increased demand for primary medical and dental care.

G108.Per capita NHS funding is 30% lower for rural areas than for more deprived urban areas. The formula for funding gives less weight to the demographic profile and the needs of an elderly population and more weight to deprivation and urban needs[242].

[240] Commission for Rural Communities, (February 2009), "Rural Reference Bulletin- No.2"
[241] ibid
[242] Commission for Rural Communities, (February 2009), "Rural Reference Bulletin- No.2"

Effect of policy on rural areas

G109.Including primary medical and dental care providers within the Care Quality Commission registration system will provide assurance that all providers meet essential levels of quality and care.

G110.This is especially important for rural areas. Limited supply of primary medical and dental care in rural areas means rural communities have little choice of provider. Therefore, it is important to ensure that the limited number of providers available to them meet essential levels of quality and safety.

G111. However, because of the Commission registration system, we expect that around 0.5% of providers will exit the primary medical and dental care markets. Of this, half of providers will not be able to comply with the registration requirements and the Commission will shut them down. The other half of providers will find complying with the registration requirements too costly and leave the market on their own accord.

G112.It is difficult to determine what proportion of these closures will be rural providers. Even if it is only a small proportion, the effect on those rural communities will still be large, due to the limited supply of primary medical and dental care and few alternatives.

G113.The effect of a rural provider closing down would be quite adverse on their communities. The largest hindrance to rural communities' use of primary medical and dental care is access. A rural provider closing down may significantly reduce people's access to primary medical and dental care.

G114.The Rural Proofing Guidance states how The Next Stage Review highlights that equitable healthcare is dependent on a locally based health service, offering services in the most convenient settings and delivering more accessible and convenient integrated care[243]. A reduction in access to primary medical and dental care for rural communities goes against these aims.

G115.To determine the effect on a rural community of a provider closing down, it is useful to consider what choices a PCT might make. Once a rural provider is shut down, PCTs have a number of options at their disposal to ensure continuing appropriate provision of care. These are tendering out a new contract; locums and direct management; list dispersal; and merger with a nearby practice.

G116.Tendering out a new contract would be the preferred option as it would minimise disruption to residents and ensure local provision of primary medical and dental care. However, rural providers tend to be single-handed and a high proportion of them are above the average age of GPs and dentists. Finding other professionals willing to locate to rural areas may be a challenge[244] and as such, PCTs may find it difficult to tender out a new contract.

G117.Locums and direct management is used more often for urban providers with large patient lists. It is unlikely a PCT will choose this option for a rural area because of the costs involved. However, this option would ensure a local provision of primary medical and dental care and would not reduce access.

---

[243] Commission for Rural Communities, "Rural proofing guidance"

[244]http://www.ruralhealthgoodpractice.org.uk/index.php?page_name=section1_chapter5_research_results

G118.List dispersal and merger with a nearby practice would not be good options for rural communities because of the large distances between providers. This would reduce access to primary medical and dental care for rural communities. This could have an adverse effect on people's health due to distance decay, the decreasing use of health services with the increasing distance from services.

G119.Primary medical and dental care is a gateway to secondary care. Reduced access would lead to a decrease in early detection and preventative measures and may result in increased emergency admissions.

G120.This may be most significant for elderly people who are not able to travel easily and who have a high demand for primary medical and dental care.

G121.It will also have a significant effect on the poorest rural residents with poor health outcomes and would benefit greatly from a small increase in access to primary medical and dental care.

Conclusion

G122. **No alteration to or exemption from system regulation for rural communities is necessary or desirable.**

G123.The benefits to rural communities of being assured that their primary medical and dental care providers meet essential levels of quality and safety outweigh the potential costs to rural communities from reduced access to primary medical and dental care.

Annex H

Registration of Primary Medical Care and Primary Dental Care Providers with the Care Quality Commission

EQUALITY IMPACT ASSESSMENT

Introduction

H1. This is a supplementary Equality Impact Assessment to examine the impact on equality of the registration of primary dental care and primary medical care providers with the Care Quality Commission. This document builds on and should be read alongside the Equality Impact Assessment covering the full registration system to be operated by the Care Quality Commission from 2010.

Background

H2. Primary care services are at the forefront of the interaction between the NHS and patients – indeed, primary medical care controls much of the access to other areas of the NHS in its role as gatekeeper. Each year approximately 304 million consultations take place in GP practices[245] and an estimated 46 million courses of treatment[246] are delivered by dental practices each year[247]. Over 90% of all contact with the NHS takes place outside hospital[248].

H3. Given the number of people receiving services every day it is important that providers operate safely, patients receive assurances about the quality of care they receive, and the general public are given enough information to make informed choices on where to seek treatment.

H4. Current regulatory frameworks for primary medical and dental care services focus on the competency of the individual healthcare professional. However, the provision of safe, quality care does not rely exclusively on the professional competence of the individual health professional providing the care. For instance, the management of the provider, the suitability of the premises, the record keeping and referral systems, and the processes for dealing with complaints are also crucial to the effective running of the organisation. In the absence of checks on the systems, competent professionals may be working in premises and systems that are poorly maintained, unfit or unsafe for practice and this will ultimately put patient care at risk.

---

[245] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*[246]Each Course of Treatment, dependent on the complexity of the treatment, represents a given number of Units of Dental Activity and may involve one or more visits to the dental practice.

[247] In 2008-09 there were 37.4m courses of dental treatment in the NHS delivering 81.4m units of dental activity(Information Centre (2009) NHS Dental Statistics for England 2008/09). It is estimated that there were also 9 million courses of private dental treatment (source: Dental Review 2003-04 produced by the Dental Practice Board).

[248] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

Policy Position

H5. All primary dental care and primary medical care providers will be required to register with the Care Quality Commission from April 2011 and April 2012 respectively.

H6. All registered providers will need to demonstrate that they are meeting the registration requirements in order to be registered, and the Commission will need to be satisfied that they continue to meet them for the provider to remain registered. This will offer assurance to patients that no matter where they choose to receive a service, the service will meet essential requirements for safety and quality.

H7. The Care Quality Commission has a broad range of enforcement powers available under the Health and Social Care Act 2008. These include warning notices, penalty notices, conditions, prosecution, suspension of registration and cancellation of registration. The power to cancel registration is the most far-reaching enforcement power that the Care Quality Commission will have to respond to failure to meet essential safety and quality requirements. This will only be used in extreme cases, where CQC deems the services in question dangerous and where it is in the public's interest that they are stopped.

Policy Objectives

H8. There are four key objectives for this policy, all of which must be achieved in as cost effective a way as possible:

- Consistency – 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 they are provided by.
- Provide public assurance and support patient choice by giving information on a provider's compliance with essential requirements.
- Enforce essential requirements – ensure that persistently poor performance is tackled and that all providers must meet the essential requirements or face a range of enforcement powers.
- Ensure systems are monitored as well as individual professional competency as these are a contributory factor in many patient safety incidents.

Policy Context

The Health and Social Care Act 2008

H9. The Health and Social Care Act 2008 set up the Care Quality Commission as the regulator of health and adult social care services in England. The Act created the framework for the regulation of providers of health care and adult social care services, but allowed for much of the detail about what types of services should be regulated and what registration requirements providers would need to meet to be set out in secondary legislation.

H10. The Department of Health first consulted on the regulation of primary medical care in the consultation document *The future regulation of health and adult social care in England*[249] in November 2007. The Department consulted further on the registration of primary medical and dental care providers in the document *A consultation on the framework for the registration of health and adult social care providers*, in March 2008. The overwhelming

[249] Link to consultation document:
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286

majority of respondents who commented on primary care providers were in favour of bringing primary medical and dental care into the new registration system. The Department confirmed that primary medical and dental care would be in the scope of registration in the document *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft regulations* in March 2009[250].

The Primary and Community Care Strategy

H11. The Primary and Community Care Strategy sets out a range of measures designed to improve quality and safety, improve access and choice, and deliver care closer to home. It seeks to shape services around individuals, promote healthy lives, see quality improve continuously, and see primary and community care services lead local change.

H12. It also set out a package of measures that will help to deliver the policy objectives set out above. 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;
- work to promote accreditation schemes to encourage improvement in quality and safety and to identify best practice;
- The introduction of registration with the Care Quality Commission to ensure that all providers meet the essential system requirements and that persistently poor performance can be tackled with a range of enforcement measures.

The Evidence Base

The Registration System

H13. Registration of primary medical care and primary dental care providers is intended to deliver the objectives listed above and, as a result, mitigate the risks for all users of the services. The risks in primary medical care and primary dental care are set out in the rationale section of the broader primary care impact assessment. It is reasonable to assume that the benefit of this policy will be felt most strongly by groups who are more frequent users of primary care services. This is considered in detail below but the most frequent users include older people, the very young, disabled people, and women.

H14. All providers will need to meet registration requirements set on the safety and suitability of the premises, the safety, availability and suitability of equipment, and the competence and suitability of those providing the service. They will also have to operate an effective complaints process that is accessible for all service users.

H15. Assessing the personalised needs of each service user and managing the risks of receiving care or treatment that is inappropriate to those needs is central to the registration requirements that all providers of regulated activities will be required to meet. This strong emphasis on the personalised needs of individual service users is coupled with an explicit requirement about the need to avoid unlawful discrimination, including where applicable, by providing for the making of reasonable adjustments in the provision of care and treatment to meet each service user's individual needs. This will allow the Care Quality Commission to take action where service providers are failing to respond appropriately to the needs of

[250] Link to consultation document:
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991

individuals, including needs related to a person's age, impairment, gender, race, religion or belief and sexual orientation. The following registration requirements are of particular relevance in this context:

Care and welfare of service users
The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of –
(c) the carrying out of an assessment of the needs of the service user; and
(d) the planning and delivery of care and, where appropriate, treatment in such a way as to -
(i) meet the service user's individual needs; and
(iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.

Safeguarding service users from abuse
The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of -
(a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
(c) responding appropriately to any allegation of abuse.
The registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body in relation to –
(c) the protection of children and vulnerable adults generally; and
(d) in particular, the appropriate use of methods of control or restraint.

Respecting and involving service users
The registered person must, so far as reasonably practicable, make suitable arrangements to ensure–
(a) the dignity, privacy and independence of service users; and
(b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.
The purposes of paragraph (1), the registered person must -
(h) take all reasonable steps to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

H16. The registration requirements that service providers will need to meet have been developed with a specific regard to human rights. In developing the registration requirements, we have identified how the principles of human rights provisions might be reflected in principles underpinning the provision of health and social care services. It is anticipated that drawing up registration requirements in this way will help to embed equality issues as a basic consideration in the regulation of service providers. The equality impact assessment produced for the introduction of the wider registration system from 2010 sets out the way that the registration requirements relate to human rights provisions.

H17. Finally, in carrying out the registration system and its other regulatory functions the Care Quality Commission can consider 'the requirements of any other enactment which appears to the Commission to be relevant'. (Health and Social Care Act 2008). This means that the Commission will be able to consider how service providers are complying with the requirements of the Human Rights Act 1998 and equality legislation. It will be able to address equality, respect for diversity and other human rights in reaching decisions on registration.

Key Facts and Impact of Registration

1. Primary Dental Care

H18. The Dental Services Division of the NHS Business Services Authority has reported a range of poor decontamination practices and conditions in surgeries that place patients at risk of infection. A survey carried out in Scotland concluded that[251]:

> "There was little evidence of clear management processes underlying decontamination procedures in most practices and audit of instrument decontamination was virtually non-existent. Whilst cumbersome management procedures are clearly inappropriate for busy dental practices, guidance for dental staff on the various elements of process control is essential and required urgently, since ensuring and recording the quality of the process of decontamination is the only safeguard for the supply of adequately sterilized dental instruments."

H19. There is a cleanliness and infection control registration requirement that all practices will need to comply with, ensuring that the safety of all patients is protected.

Age

H20. The physiology of oral disease means that the oral health needs of children and adults are different. Children's teeth require particular care as healthy childhood teeth provide a sound foundation for healthy adult teeth, while adults, who are now keeping their teeth for longer[252], require different types of care and treatment.

H21. The Adult Dental Health Survey 1998[253] found that age was the most significant variable in explaining the variation in the majority of measures of oral health. For example, adults aged 75 years and over were 144 times more likely to be edentate (i.e. had no natural teeth) than adults aged 16 to 44 years, and, dentate adults (i.e. with natural teeth) aged 45 to 54 years were over 60 times more likely to have 12 or more restored (otherwise sound) teeth compared with those aged 16 to 24 years.

H22. Fifty-one percent of dentate adults reported having experienced one or more oral problems that had an impact on some aspect of their life occasionally or more often during the year preceding the survey. In contrast, the survey of children's dental health in 2003 found that the parents of most of the children in all age groups did not think their children had been affected by their oral condition in the preceding year[254]. Some form of impact was reported by the parents of 22 per cent of five-year-olds, 26 per cent of eight-year-olds, 35 per cent of 12-year-olds and 30 per cent of 15-year-olds.

---

[251] NHS Scotland (2004) Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice (available at: www.scotland.gov.uk)

[252] Adult Dental Health Survey 1998 showed that in 1978, 28% of the population of England were edentate (ie had no natural teeth). This fell to 20% in 1988 and 12% in 1998.

[253] Office for National Statistics (2000) Adult Dental Health Survey - Oral Health in the United Kingdom 1998.

[254] Office for National Statistics (2005) Children's Dental Health in England 2003.

Disability

H23. There is evidence that people with a disability experience poorer oral health, and barriers to achieving good oral health and accessing appropriate dental services[255,256].

H24. The British Society for Disability and Oral Health, in its *Guidelines for the delivery of a domiciliary oral healthcare service*[257], makes clear that "people with long term and/ or progressive medical conditions; mental illness or dementia, causing disorientation and confusion in unfamiliar environments; and increasing frailty are not always able to travel to a dental surgery. For some people, access to oral healthcare services is achievable only through the provision of domiciliary oral healthcare."

H25. In addition, research has shown that a reduced use of dental services and poorer oral health tend to correlate with lower socio-economic status[258,259]. The Health Survey for England 2001 showed that disabled people are more likely to fall into Social Class IV and V[260].

Gender

H26. There is evidence that, in line with their use of other parts of the healthcare system, men visit the dentist less often than women. The Adult Dental Health Survey in 1998 showed that 53% of men attend for regular check-ups against 67% of women and that 65% of men had been to the dentist in the last year compared to 77% of women. Younger men were one of the groups least likely to seek regular check-ups. Only 42% of men aged 16 to 24 and 44% of men aged 25 to 34 did so. This has implications for men's oral health.

Ethnicity

H27. We recognise that a disproportionately high number of people from black and minority ethnic (BME) groups live in areas of high social need, which is directly correlated with poor oral health. The Adult Dental Health Survey 1998 found that the social class of the head of household or educational attainment or both were found to be independently related to all the measures of oral health used. However, the effects of all these socio-demographic factors were fairly small compared with the effects of age.

---

[255] British Society for Disability and Oral Health (2000). Oral health care for people with a physical disability.

[256] Department of Health (2007) Valuing People's Oral Health – A good practice guide for improving the oral health of disabled children and adults.

[257] British Society for Disability and Oral Health (2009) – Guidelines for the delivery of a domiciliary oral healthcare service

[258] England Adult Dental Health Survey 1998 showed that the percentages attending for regular dental check-ups were: 65% for those where head of household is in the highest socio-economic classes; 58% for those where head of household is in the middle socio-economic classes; 50% for those where head of household is in the lowest socio-economic classes.

[259] Laura Mitchell, Paul Brunton (2005). Oxford Handbook of Clinical Dentistry.

[260] The Health Survey for England 2001 showed that there was a steady increase from Social Class I to Social Class V in the (age-standardised) prevalence of disability, from 8% in Social Class I, to 22% for men and 24% for women in Social Class IV, which then levelled out with the same rates for Social Classes IV and V. Among those with a disability, the proportion categorised as seriously disabled was also lower Social Classes I and II (about one in four) than in Social Classes IIIM, IV and V (one in three).

H28. There are different underlying levels of oral health across different ethnic communities. Reports have shown that oral cancer is more prevalent among males from South Asia than in White men[261] and that lower levels of caries and tooth loss are found among Asian adults and among Bangladeshi women, although the longer the groups lived in the UK, the more teeth were affected by dental caries[262]. Different cultural behaviours that affect oral health are also found across different ethnic communities[263].

H29. Dental services are also utilised at different levels across different ethnic communities. A study carried out by the Joint Health Surveys Unit[264] found that men and women in all minority ethnic groups were significantly less likely than the general population to visit a dentist for a regular check-up. The age-standardised ratio for regular dental attendance was lowest for Bangladeshi men (0.24), with Indian, Pakistani, Black Caribbean and Chinese men being about half as likely as the general population to visit the dentist for a check-up. Minority ethnic women had similar patterns of attendance to the men. As a result, these groups are more likely to have untreated dental problems or disease[265].

Religion or Belief

H30. There is no direct evidence to suggest that the use of dental services or oral health is different according to people's religion or belief. Poor oral health and lack of use of dental services is more likely to be linked to other factors such as housing and economic and social status.

Sexual Orientation

H31. There is no direct evidence to suggest that the use of dental services or oral health is different according to people's sexual orientation.

Impact of Registration

H32. System regulation will:

- Assure the public in general, and all groups using primary dental services in particular, that all providers meet essential requirements for safety and quality and that action can be taken if the Commission is not satisfied that this is the case[266].

---

[261] Patterns of mortality among migrants to England and Wales from the Indian subcontinent. *British Medical Journal*. 289 (1984)

[262] "Caries experience, tooth loss and oral health related behaviours among Bangladeshi women resident in West Yorkshire" for Community Dental Health (1996)

[263] "Patterns of mortality among migrants to England and Wales from the Indian subcontinent" in the British Medical Journal. 289 (1984) showed that oral cancer is more prevalent among males form South Asia than in White men. This is related to risk factors such as smoking, chewing betel quid with or without tobacco and alcohol consumption. Other practices (such as chewing paan), and dietary differences may also be factors to take into consideration in mapping oral health needs

[264] Joint Health Surveys Unit (on behalf of the Department of Health) (2001) Health Survey for England - The Health of Minority Ethnic Groups 1999.

[265] London Assembly Health and Public Services Committee (2007). Teething problems – A review of NHS dental care in London.

[266] A survey reported in the British Dental Journal found that there are two main barriers to the regular uptake of dental care by the general public; anxiety and cost ("Barriers to the receipt of dental care". BDJ 1988. 164. 195). The provision of information and assurance on the quality and safety of the care on offer may contribute to reducing anxiety.

- Provide more information so that people can choose where to receive treatment.
- Ensure that providers put in place mechanisms to deliver services that meet the individual needs of service users.

H33. The biggest impact will be on those groups that make the biggest use of dental services, who have the greatest oral health needs and who use services of a poorer quality. Providers currently failing to meet the registration requirements will need to make improvements in the quality and safety of the services they deliver. Although it will not tackle many of the utilisation levels and oral health issues set out above, it will be implemented alongside a range of government and local initiatives that are seeking to:

- Increase access to dentistry;
- Improve the quality of care provided; and
- Contribute to an overall improvement in the oral health of the general population.

2. Primary Medical Care

H34. There is evidence that there needs to be effective clinical governance systems in place to enable practices to identify healthcare professionals whose poor performance is putting patients at risk. The Public Accounts Committee's report on implementing clinical governance in primary care[267] noted serious short-comings – for example only 4% of GPs report untoward events and clinical incidents to the National Patient Safety Authority. The PAC report concluded that:

"the level of intervention with poorly performing GPs is very low, with only 66 GPs out of 35,000 currently under suspension. Mechanisms for monitoring quality and safety have contributed to better identification of poor performance, but PCTs do not have direct line management of independent contractors. So although PCTs now have greater powers to take action with poorly performing GPs, many PCTs have failed to take local action to address their concerns, reinforcing doubts about monitoring and control of the quality of GPs."

H35. All practices will need to comply with the registration requirements, ensuring that the safety of all patients is protected.

Age

H36. Almost everyone, 99% of the population, is registered with a family doctor[268]. The overall consultation rate for the general population was 5.5 consultations per person per year. However, GP consultation rates vary markedly by age. In 2008/09 the highest consultation rates were for the very young (7.33 for girls under 5 and 7.83 for boys under 5) and the elderly (13.46 for women aged between 85 and 89 years and 13.96 for men aged between 85 and 89 years)[269].

H37. Many risk factors for poor health, such as obesity, hypertension, disability, and poverty increase with age. The prevalence of most acute and chronic diseases increases with age

[267] House of Commons Committee of Public Accounts. Improving quality and safety—Progress in implementing clinical governance in primary care: Lessons for the new primary care trusts. Forty–seventh Report of Session 2006–07. Published July 2007

[268] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

[269] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*

and the proportion of people with a long-term illness or disability that restricts their daily activities also increases with age[270,271]. Older people form the majority of those registered as blind or partially sighted (90% are over age 60[272]) and of those with hearing impairments (580,000 people aged over 60 have severe to profound deafness[273]). This helps explain the higher GP consultation rates for those aged over 60.

H38. The Report on the National Patient Choice Survey for December 2008 included a combined analysis of the previous surveys. This showed that the proportion of patients recalling being offered a choice of hospital for their first outpatient appointment varied by age, although this became less marked as the general level of recall of choice rose. The highest proportion of patients offered choice was for 35-54 year olds and 55 to 64 year olds, whilst there were lower proportions for 16-34 year olds and those aged over 65. The proportion of patients who were able to go to the hospital they wanted increased with age, whilst the proportion who had no preference decreased with age.

Disability

H39. Almost one in five (18%) of people reported a long-term illness or disability that restricted their daily activities in the 2001 census. The lack of inclusion of disability in routine monitoring makes it difficult to measure equity of access and treatment for disabled people.

H40. Approximately 24% of people who are deaf or hard of hearing miss GP appointments because they cannot hear their names being announced[274].

H41. A report by the Disability Rights Commission[275] has shown a number of specific areas in which people with learning disabilities and/or mental health problems have a poorer experience from primary medical care services. This includes around recognising health need, seeking and accessing primary care, and diagnosis and treatment and support. In particular, this report recommends that GP practices and primary care centres need to make 'reasonable adjustments' to make it easier for people with learning disabilities and/or mental health problems to get access to the services offered by the practice. This is covered by a requirement of registration, and the CQC will be able to take enforcement action against primary care providers that do not meet this registration.

H42. The leaflet *You can make a difference: improving primary care services for disabled people*[276] sets out some of the adjustments that may be needed to meet the specific needs of disabled people. The *Secretary of State report on disability equality: health and care services* provides an overview of progress being made in improving the equality of access

[270] Department of Health (2008). Impact Assessment of NHS Next Stage Review proposals for primary and community care.
[271] The Health Survey of England 2000 reported that 70% of those aged 65 and over reported a longstanding illness and tat 10% of people aged 65-79 and 25% of those aged 80 and over reported a serious disability.
[272] RNIB (2005). Older People. www.rnib.org.uk.
[273] RNID (2005) Deaf and hard of hearing adults in the UK.
[274] Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.
[275] Disability Rights Commission (2006) Equal Treatment: Closing the Gap.
[276] Department of Health (2004) - You can make a difference: improving primary care services for disabled people - Good practice guide for primary care service providers

and discusses ongoing action in the health and social care sector to improve outcomes for disabled people[277].

Gender

H43. There are particular issues around risk factors and access for both men and women. Men live, on average, about five years fewer than women (75.4 and 80.2 years respectively). On average, men in England spend 59.1 years in good health and 15.9 years in poor health. For women the corresponding figures are 61.4 years and 18.6 years. Therefore, although women live longer than men, they also spend more years in sub-optimal health[278].

H44. GP consultation rates for women of working age tend to be higher than those for men of working age [279]. However, these differences even out for those aged under 5 and those aged over 60.

H45. The Report on the National Patient Choice Survey for December 2008 included a combined analysis of the previous surveys. This showed that the proportion of patients recalling being offered a choice of hospital for their first outpatient appointment was nearly 2% higher for women than for men. Men were somewhat less inclined to have a preference for the hospital they wished to be treated at than women, slightly more of whom said they went to their hospital of choice.

Transgender

H46. *Trans - a practical guide for the NHS* [280] cites research published in February 2007 that showed that almost 20% of trans people surveyed for the Equalities Review reported that their healthcare was either affected or refused altogether by GPs who knew they were trans.

Ethnicity

H47. The ODPM Social Exclusion Report *A Sure Start to Later Life: Ending Inequalities for Older People* highlighted that ethnic minorities (across all ages) are more likely to be in poor general health, particularly those from Pakistani and Bangladeshi communities.

H48. A study carried out by the Joint Health Surveys Unit[281] found that:

- South Asian and Black Caribbean men were more likely than men in the general population to have consulted their GP in the past two weeks, and to have more than one consultation over this period.
- South Asian and Black Caribbean men had annual GP contact rates[282] between one and a half (for Black Caribbean men) and three (for Bangladeshi men) times as high as men in the general population.

---

[277] Department of Health (2008) - Secretary of State Report on Disability Equality, Health and Care Services

[278] Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.

[279] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*

[280] Department of Health (2008) - Trans: a practical guide for the NHS

[281] Joint Health Surveys Unit (on behalf of the Department of Health) (2001) Health Survey for England - The Health of Minority Ethnic Groups 1999.

[282] number of consultations with a GP each year

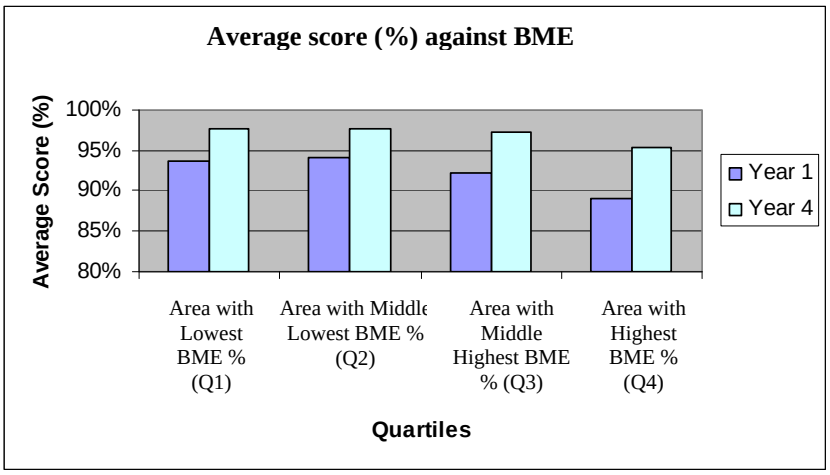
- Age-adjusted GP contact rates were significantly higher for South Asian women (at almost twice that for the general population) and Irish women (at a quarter higher than that for the general population) than for women in the general population.

H49. The average proportion of BME patients registered with a GP practice is 19%. Graph one shows that areas with the lowest levels of ethnicity score more Quality and Outcomes Framework (QOF) points[283] than areas with the highest levels of ethnicity (areas with high levels of ethnicity tend to correspond with the areas with high ratios of patients per GP). This means that practices with the highest proportions of BME patients are performing less well than those practices with lower proportions of BME patients. However, this gap is narrowing over time.

H50. The Report on the National Patient Choice Survey for December 2008 included a combined analysis of the previous surveys. This showed that the proportion of patients recalling being offered a choice of hospital for their first outpatient appointment was higher for patients in the White ethnic group than for BME patients. The Asian or Asian British and Black or Black British ethnic groups were on average 12% below the overall proportion of patients offered choice in the latest four surveys, as was the other group. Those with Mixed ethnicity were slightly closer to average, whilst the Chinese group showed most variability and was not always below average. The variation by ethnic group lessened in the last four surveys. The proportion of patients who were able to go to the hospital they wanted was higher for patients in the White ethnic group than for BME patients. All BME groups were less likely to have a preference of hospital than White patients (even when offered a choice).

Graph One

QOF scores for 2004/5 and 2007/08



H51. Table one shows that, areas with high levels of ethnicity tend to have a high Patient to GP ratio. This may be the reason why areas with high levels of ethnicity score less then other areas.

[283] The Quality and Outcomes Framework (QOF) forms part of the General Medical Services contract and accounts on average for around 15 per cent of total income for GMS practices. Payments are made to GP practices in return for achievement against indicators of organisational and clinical quality. The scheme is voluntary, but virtually all GP practices take part.

Table One

BME Quartile	Average patients per GP
Areas with Lowest BME % (Q1)	1951
Areas with Middle Lowest BME % (Q2)	1962
Areas with Middle Highest BME % (Q3)	2130
Areas with Highest BME % (Q4)	2338

H52. The figures from the 2008/09 GP Patient Survey published in July 2009 highlight that BME groups tend to be less satisfied with all aspects of service. Across the five key access indicators, the gap in average satisfaction between BME groups and the population as a whole has increased for 48-hour access and satisfaction with opening hours but reduced for telephone access, advance booking and seeing a specific GP. Similar patterns can be seen in other areas of the survey, with Bangladeshi, Pakistani and Indian groups indicating less positive responses than other groups.

Religion or Belief

H53. There is no direct evidence that lack of access to GP services or GP consultation rates vary according to religion or belief. However, of all faiths, limiting long-term illness or disability rates are reported to be highest among Muslims (24% for females, 21% for males)[284].

Sexual Orientation

H54. There is currently limited data available on sexual orientation issues. There is no direct evidence on GP consultation rates or access to GP services.

Impact of Registration

H55. The Primary and Community Care Strategy sets out a range of measures designed to improve quality and safety, improve access and choice, and deliver care closer to home. It seeks to shape services around individuals, promote healthy lives, see quality improve continuously, and see primary and community care services lead local change.

H56. System regulation is one strand of this strategy. It will:

- Offer assurance to all patients using primary medical services that all providers meet essential requirements for safety and quality and that action can be taken if the Commission is not satisfied that this is the case.
- Provide more information so that people can choose where to receive treatment.
- Ensure that providers put in place mechanisms to deliver services that meet the individual needs of service users.

H57. The biggest impact will be on those groups that make the biggest use of primary medical services. As set out above, this includes the very young and the elderly, those from black and minority ethnic communities, and those with disabilities.

H58. An impact will also be seen in areas where there are poor practices currently failing to meet the registration requirements as providers will need to make improvements if they are to be registered by the Care Quality Commission. The evidence set out above suggests that

[284] 2001 Census . Cited in Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.

areas with a high proportion of black and ethnic minority patients experience higher patient to GP ratios and lower QOF scores. Patients from black and ethnic minority backgrounds are also more likely to be dissatisfied with the service that they receive from their GPs. Improvements could therefore benefit this group

H59. However, it is possible that a small number of providers could be unable to register if they cannot satisfy the Care Quality Commission that their services meet the registration requirements. This is only likely to involve a handful of providers but, as we know lower quality services tend to be provided in disadvantaged areas, any such outcome would disproportionately impact upon people from black and ethnic minority groups, older people, and those with disabilities. While this could, ultimately, improve the quality of care the groups receive, in the short term it could have implications for access.

H60. When exercising its enforcement powers the Care Quality Commission will therefore need to consider the risk to patients and people using services of stopping a service against those of leaving a substandard service open. They will liaise with the relevant PCT when considering this. The role of identifying alternative services would fall to the PCT**,** who have a duty to arrange primary medical care services for all their population. The PCT would have to arrange for a replacement or alternative services both immediately and in the long term.

Overall Impact of Policy on Equality

H61. The new registration system has not been set up with the aim of addressing inequalities in any single area, but rather to improve the quality and safety of services to all service users. An adverse impact is unlikely. On the contrary there is potential to reduce barriers and inequalities that currently exist as, for the first time, all providers of services within the scope of registration will need to register. The analysis of the data above has identified that some groups are more likely than others to use primary dental and medical care and that the benefits arising from the new system are therefore likely to be felt more strongly among these groups. In particular, the emphasis on assessing and meeting the needs of individual service users and on human rights in the registration requirements and the capacity for the Commission to take into account the requirements of human rights and equality legislation establishes mechanisms for ensuring that services better respond to individual needs. The inclusion of requirements on the safety and suitability of premises, the competence and suitability of those providing the service and the need for an effective complaints system that is accessible to all service users should also help ensure that services meet the needs of all.

H62. As noted previously, this policy is one strand of the Primary and Community and Care Strategy and sits alongside a range of other initiatives tackling inequalities and improving access and quality in primary medical care and primary dental care. These initiatives include the GP access programme, a programme of action to provide practical support and guidance for practices and PCTs to help improve access for BME groups, the world-class commissioning framework and the implementation of the independent dentistry review.

H63. None of the proposals are expected to adversely impact on any particular groups of staff working in primary medical care and primary dental care.

Next Steps

H64. The Care Quality Commission will carry out the implementation of the registration system. In implementing the registration system, the Care Quality Commission will promote and protect the rights and interests of everyone who uses health and adult social care, particularly the most vulnerable. They will seek views of service users and their carers and will use these to inform their work to assess providers.

H65. The Commission is responsible for developing the guidance about compliance that will underpin the registration requirements set in secondary legislation. It has consulted on its guidance about compliance and will publish a final version before the registration system comes into effect. An assessment of the impact on equality of the guidance about compliance was published alongside the consultation.[285] The Commission is also responsible for developing the methodology it will use for assessing providers. It will assess equality issues as it develops this and will publish an assessment alongside any consultation.

H66. A Code of Practice for the prevention and control of healthcare associated infections will set out how providers can meet the registration requirement on cleanliness and infection control. The Department of Health will publish this Code of Practice. A commitment has been made to revise the Code so that it is applicable to primary care providers in advance of primary dental care and primary medical care providers being required to register. An assessment of the equality issues will be published at the same time.

Review of Implementation

H67. The Department, working with the Commission and other stakeholders, will keep equality issues under review. The use of secondary legislation to set scope and registration requirements makes the system more flexible. If the ongoing monitoring of the regulatory system with the Care Quality Commission and other stakeholders identifies weaknesses in the system, including in its approach to equality, there is the potential to address this through revised regulations.

H68. As a Non-Departmental Public Body, the Commission remains accountable to the Secretary of State for discharging its functions, duties and powers effectively, efficiently and economically. As such, the Commission and Department will work together to review the Commission's objectives on an annual basis taking into account the Department's policy priorities, its statutory obligations, and any lessons for health and adult social care policy, including around the registration system.

Equality impact assessment

An adverse impact is unlikely. On the contrary, there is potential to reduce barriers and inequalities that currently exist. There is insufficient evidence, however, for this assessment to be made with as much confidence as is desirable.

For the record

Name of person completing the EqIA
Cathy Morgan

Date EqIA completed
20 October 2009

[285] http://www.cqc.org.uk/contentdisplay.cfm?widCall1=customWidgets.content_view_1&cit_id=34904

Name of Director endorsing EqIA
John Holden

Date EqIA endorsed
21 October 2009