Summary: Intervention & Options

Department /Agency: Department of Health	Title: Impact Assessment of regulation of primary medical and dental care providers under the Health and Social Care Act (2008)	
Stage: Final	Version: 2	Date: 29 October 2009
Related Publications: Consultation document and regulations		

Available to view or download at:

http://www.dh.gov/en/consultations/responsestoconsultations

Contact for enquiries: Alison Smith   Telephone: 01132 54 5709

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:

.... Date: 26/10/09

Summary: Intervention & Options

Department /Agency: Department of Health	**Title:** Impact Assessment of regulation of primary medical and dental care providers under the Health and Social Care Act (2008)	
Stage: Final	**Version:** 2	**Date: 29 October 2009**
Related Publications: Consultation document and regulations		

Available to view or download at:

http://www.dh.gov/en/consultations/responsestoconsultations

Contact for enquiries: Alison Smith **Telephone:** 01132 54 5709

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:

....Date:

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		Description and scale of **key monetised costs** by 'main affected groups' EXCHEQUER COSTS
One-off (Transition)	**Yrs**	Regulatory Bodies: £3.9m to £4.8m one-off, £9.1m to £11.0m annual
£ 8.2m to £9.8m	3	PCTs: £0.7m to £0.9m one-off, £1.0m to £1.2m annual
Average Annual Cost (excluding one-off)		Providers: £3.6m to £4.2m one-off, £6.1m to £7.0m annual
£ 16.2m to £19.2m		**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		Description and scale of **key monetised benefits** by 'main affected groups' NON EXCHEQUER BENEFITS
One-off	**Yrs**	Private Dentists: -£4.0m to -£3.6m one-off, -£1.8m to -£1.6m annual
£ -4.0m to -£3.6m	1	Patients: £33.5m to £91.0m annual
Average Annual Benefit (excluding one-off)		Total negative benefit: NPV -£16.8m to -£14.9m
£ 33.5m to £91.4m		**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**

Question				Answer
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**

Evidence Base (for summary sheets)

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*[1] 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[2].

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[3] (2008) included the costs of merging the three previous commissions[4] 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*[5] 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.

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;

---

[1] Link to consultation document: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286
[2] Link to consultation document: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991
[3] Link to Impact Assessment: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433
[4] 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.
[5] Link to consultation document: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625

- 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[6] and an estimated 46 million courses of treatment[7] are delivered by dental practices each year[8]. Over 90% of all contact with the NHS takes place outside hospital[9].

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 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

[6] Information Centre (2009) "Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database"
[7] 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.
[8] 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).
[9] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

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.[10]

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.[11,12] 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[13].

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[14].

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 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[15] 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

---

[10] Audit Commission (2004) "A Focus on General Practice in England" (available at www.audit-commission.gov.uk)
[11] National Patient Safety Agency (2009) "Seven Steps to Patient Safety for Primary Care" (available at www.nlrs.npsa.nhs.uk)
[12] 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
[13] Department of Health (2008) "High quality care for all: NHS Next Stage Review final report" (available at www.dh.gov.uk)
[14] National Patient Safety Agency (2009) "Seven Steps to Patient Safety in General Practice" (available at www.nlrs.npsa.nhs.uk)
[15] 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*.

underestimate. Errors in diagnosis and prescriptions accounted for 78% of all problems. Between 60% and 83% of errors were found to be "probably preventable"[16].

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[17]. 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.[18] Information from the NHS Information Centre shows there were 4.65 million prescriptions issued each year by NHS dentists[19] in 2008.

The need for checks on systems

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%).

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[20] (NCAS) and Table 2 reports the proportion of GPs referred to NCAS for potential errors relating to different categories of adverse event.

[16] 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.
[17] National Patient Safety Agency (2009) "Seven Steps to Patient Safety in General Practice" (available at www.nlrs.npsa.nhs.uk)
[18] 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).
[19] Link: http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescribing-by-dentists-2008:-england
[20] The National Clinical Assessment Service, part of the National Patient Safety Agency, helps local healthcare managers to understand, manage and prevent performance concerns.

Table 2: Referrals to the National Clinical Assessment Service by category in General Practice[21]	
Category	**Proportion[22]**
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[23] 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.

    - 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[24].

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[25]	
Category	**Proportion[26]**
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] National Clinical Assessment Service (2009) "*NCAS Casework – The First Eight Years"*
[22] Note that this does not total 100% as, on average, two concerns were raised in each case referred.
[23] 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.*
[24] 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
[25] National Clinical Assessment Service (2009) "NCAS Casework – The First Eight Years"
[26] Note that this does not total 100% as, on average, two concerns were raised in each case referred.

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[27] and Methicillin Resistant *Staphylococcus aureus* (MRSA)[28]. 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[29]. As a result, for those tissues where evidence suggests this risk is most pronounced, the Chief Dental Officer 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"[30], 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[31], 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:

---

[27] 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.

[28] Martin MV, Hardy P. "Two cases of oral infection by methicillin-resistant Staphylococcus aureus." *British Dental Journal* 1991; 170: 63-64

[29] 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.

[30] 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)

[31] 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*.

- 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[32] noted serious short-comings – for example only 4% of GPs report untoward events and clinical incidents to the NPSA. 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."

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[33]:

    - 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:

[32] 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."
[33] NHS Scotland (2004) "Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice" (available at: www.scotland.gov.uk)

"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.
- 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[34]). 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[35]. 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

[34] Data provided by NHS Dental Services.
[35] 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)

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.
- 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[36].

---

[36] 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)

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.

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[37] NHS primary medical care providers in England. There are currently around 34,000[38] GPs in England with the average provider having approximately four GPs[39]. There is a wide variation in the number of GPs per practice – 25% of practices

[37] 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.

[38] http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-general-practice

[39] 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

have only one GP while the largest practices have over 15 GPs[40]. 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[41].

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.

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[42] in comparison with an estimated 9m courses in the private sector[43].

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).

Impact Assessment published alongside this one, which considers the costs and benefits of the regulated activities that will be brought into scope from 2010.

[40] Department of Health Data

[41] 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"

[42] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

[43] Dental Review 2003-04 produced by the Dental Practice Board

- 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 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*[44] (which set out the scope of regulation from 2010) would automatically cease from those dates. We analyse primary medical care first,

[44] 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

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.

    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[45] and potentially already be meeting standards that are more stringent.

---

[45] See Annex A for more information on assurance processes for training practices.

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 Tribunal	Expanding capacity	£38,000	£47,000
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.

<u>Processing new applications</u>

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.

<u>Processing annual assessments from providers</u>

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.

<u>Ongoing compliance</u>

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.

Costs of first time registration – new practices

112. As mentioned above, the NHS Information Centre estimates that the net increase in NHS GP practices is around 100 per year[46]. 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.

Costs of annual assessment – existing practices

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 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

[46] This net increase is the difference between the number of new practices starting up and existing providers closing down.

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[47] found that adverse events occur in around 11% of all admissions to hospital[48]. However, given the scale of primary medical care provision – as explained

[47] 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
[48] 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%).

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.

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[49] 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[50].

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.

---

[49] Quality Adjusted Life Year

[50] 0.071 is the difference in health state between an individual EQ-5D score of 11111 and 11112.

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[51], and a study by the Ipsos MORI shows that around 92% of people have trust in their doctor[52].

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.

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[53].

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.

[51] Calculated as the 303.9m consultations in NHS primary medical care divided by the average rate of consultations per person (5.5)

[52] http://www.ipos-mori.com/DownloadPublication/1305_sri-trust-in-professions-2009.pdf

[53] 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.

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.

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[54]. 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.

[54] This figure is generated using the average distance and the average practice list.

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 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[55] 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.

[55] 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.

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.

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[56]. 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 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[57] 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.

[56] 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.)

[57] 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.

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 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[58]. 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

[58] 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

health outcomes, facilitates partnership and adherence, reduces anxiety and improves health status and patient satisfaction[59], which is crucial for high quality care. Furthermore, an earlier study[60] 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[61] 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[62] 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%[63]."

202. Results from a survey by the Dental Complaints Service (DCS)[64] show that 26% of dental patients surveyed have wanted to complain about their dental care but didn't, where 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%[65]. 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[66] people used an NHS dentist in the last 24 months. Hence, around 22,000 patients will experience this

---

[59] Yamalik, N. (2005) "Dentist-patient relationship and quality 2. Trust" *International Dental Journal,* 55, pp. 168-170.

[60] Yamalik, N. (2005) "Dentist-patient relationship and quality 1. Introduction" *International Dental Journal,* 55, pp. 110-112 (Table 1)

[61] Jacquot, J. (2009) "Trust in the Dentist-patient Relationship: A Review," *Journal of Young Investigators,* http://www.jyi.org/articletools/print.php?id=241

[62] 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

[63] 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

[64] "Dental patients 'want to complain but don't'" (23/09/2009), http://www.dentistry.co.uk/news/news_detail.php?id=2251

[65] 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.

[66] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

increased reassurance. Data from the NHS Information Centre[67] 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[68] 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.

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.

---

[67] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/dentistry/nhs-dental-statistics-for-england:-2008-09

[68] http://www.ipsos-mori.com/researchpublications/researcharchive/poll.aspx?oItemId=170

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[69].

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.

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).

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

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[70].

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.

[70] 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
- Annex B: Evidence base for deductions and efficiencies - Comparison of costs in the old registration system and the new registration system
- Annex C: Calculations for the estimated costs of shutting providers down
- Annex D: Evidence base for cost savings in secondary care
- Annex E: Benefits of Care Quality Commission regulation: Using a risk-based approach
- Annex F – Benefits to dental patients as a result of improved decontamination practices.
- Annex G – Supplementary Tests, including Competition Assessment and Small Firms Impact Test
- Annex H – Equality Impact Assessment

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[71].

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.

[71] 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[72], 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.

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%

[72] SAT = Self Assessment Tool

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[73].

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[74])
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[75] and this is added to the estimate.
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[76]

---

[73] 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.
[74] Based on a rate of 5.9pence per minute.
http://www.dft.gov.uk/pgr/economics/rdg/valueoftraveltimesavingsinth3130?page=6
[75] 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.
[76] This figure is based on the NHS Careers Website where the hourly wage for a receptionist is £13-16ph.

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.

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[77] (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[78] 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."[79] Evidence of this is provided in the available literature. Bodenheimer et al[80] 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[81] 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 existing diseases in primary care. A study in Southern Italy[82] 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

---

[77] World Health Organisation (2004), "What are the advantages of restructuring a health care system to be more focussed on primary care services?"
[78] Reid, R, J. Wagner, E, H. (2008), "Strengthening primary care with better transfer of information", *Canadian Medical Association Journal,* 179:10
[79] 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
[80] Bodenheimer, T. Grumbach, K. Wagner, E, H. (2002), "Improving primary care for patients with chronic illness: The chronic care model, part 2", *JAMA,* 15
[81] 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
[82] 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

presented by Rich et al[83] 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[84],[85] 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[86] 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[87],[88].

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[89]. 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.

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

---

[83] 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
[84] DH, "Analysis of admission patterns in selected ambulatory care sensitive conditions at Ealing PCT (2003-2007)"
[85] DH Press Release, (20 March, 2006), "NHS Institute analysis of unnecessary emergency admissions – and alternatives"
[86] 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
[87] Bartter, T. Pratter, P, R. (1996), "Asthma: Better outcome at lower cost? The role of the expert in the care system", *Chest,* 110
[88] Camargo, C, A. Schatz, M. (2006), "Follow-up after an asthma hospitalization." *Chest,* 130
[89] 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

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[90]. 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[91] consultations per practice. We anticipate the number of consultations to increase in the future at the rate of 2.2% per year[92].

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

[90] http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-general-practice
[91] Calculated as 303.9m divided by 8,230
[92] 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.

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[93].

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[94]. Academic literature shows that adverse events occur in primary care at a rate of between 5 and 80 in every 100,000 consultations[95,96], much higher than the number of events reported to the NPSA. This 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[97]. Between 60% and 83% of errors were

---

[93] Quarterly Data Summary Issue 13 (August 2009) http://www.npsa.nhs.uk/nrls/patient-safety-incident-data/quarterly-data-reports/

[94] 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.

[95] 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

[96] 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)

[97] 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

found to be "probably preventable."[98] 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[99] 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[100] 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 there is a potential risk of person-to-person transmission of variant CJD via re-usable surgical instruments that have been inadequately decontaminated[101].

[98] Ibid.
[99] 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*
[100] NHS Scotland (2004) "Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice" www.scotland.gov.uk
[101] 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.

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%[102] 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[103]. The reduction in health state is shown for the different adverse events in the table below.

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

[102] 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*

[103] 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.

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[104] 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[105]. 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.

E23. Evidence exists[106] 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[107].
- 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?

---

[104] 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)

[105] 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.*

[106] 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."

[107] 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

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:

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[108].	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[109]	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%

[108] Bhasale et al. (1998) "Analysing potential harm in Australian general practice: an incident-monitoring study", *Medical Journal of Australia,* 169, pp. 73-76
[109] Bhasale et al. (1998) "Analysing potential harm in Australian general practice: an incident-monitoring study", *Medical Journal of Australia,* 169, pp. 73-76

Susceptibility of users to harm

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[110], 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:

[110] 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.

Table E4: Saved Treatment Costs on NHS for different types of adverse event.[111]		
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
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[112] = £60,000 * (2/52) * 0.1309 = £302.08
£302.08 * 303.9m[113] * 0.0624%[114] * 30% reduction = **£17.2m**

E34. Table E4 overleaf summarises the expected value of adverse events using the method explained above.

[111] DH reference cost data used.
[112] 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.
[113] Number of consultations
[114] 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.

Table E4: Expected value of adverse events under regulation[115] - 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
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%[116] * 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**

Table E4: Expected value of adverse events under regulation[117] - 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**[118]

[115] Costs have been rounded up/down so may not fully add up.
[116] 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.

[117] Costs have been rounded up/down so may not fully add up.
[118] Figures are rounded up from calculations.

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**

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[119] 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[120] 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[121]. If we extrapolate this to assume that 15% of the total number of potential infected patients could 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[122].

---

[119] Department of Health (2007) Dentistry and vCJD: The implications of a 'carrier state' for a self-sustaining epidemic due to endodontics dentistry

[120] Spongiform Encephalopathy Advisory Committee

[121] NHS Scotland (2004) Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice

[122] 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.

F8. NICE guidance on reducing the risk of transmission of vCJD[123] 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[124], this translates into savings of between £480 and £360,000[125].

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.

[123] NICE (2006) Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures
[124] ibid.
[125] 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[126].

[126] 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[127].

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.”[128]

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[129] for primary medical care and run roughly 100 health centres and GP practices between them[130]. 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.

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.

---

[127] 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”
[128] NHS Primary Care Contracting (2006) “Primary medical services contracts—a guide for potential contractors.”
[129]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
[130]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

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[131].

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.

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

[131] General Dental Council (2008), "Annual Review '08"

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%[132] 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

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

[132] 100 market entrants since the implementation of the 2003 *Health and Social Care Act* in 2004, divided by 8400 primary medical care providers

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[133]).

G46.Recent estimates suggest the average NHS patient pays £26.50 each year for treatment[134], and generally it is believed that private patients pay approximately double what NHS patients pay[135]. 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[136] 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 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[137], and therefore we can value the loss of business as up to £2.8 million[138] 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

---

[133] See paragraph 205 for workings.
[134] Conservative Party (2008)
[135] Internet based research into the costs of primary dental care.
[136] Arinen et al. (1996)
[137] 13.4 million patients paying £53 each.
[138] These costs are calculated as 0.01% and 0.4% of £710 million.

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[139], 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.

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 [140]. 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 [141], 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.

---

[139] This would of course impose costs upon the NHS, but there would be offsetting patient benefits justifying these costs.
[140] Department for Business Innovation & Skills, (January 2009), “Small Firms Impact Test: Guidelines to policy maker”
[141] ibid.

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 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[142]. 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[143] 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[144]. 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[145]. The costs of a first time registration will be £3,200 - £3,600.

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

[142] 10-20% less burdensome than the £4000 cost suggested by private primary care providers during consultation
[143] £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
[144] 10% of 1000 private primary dental care providers
[145] 5% of 1000 private primary dental care providers

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[146]. 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.

---

146 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

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.

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[147].

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**

[147] http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Healthassessment/DH_4093617

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.

(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.

<u>Human Rights</u>

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[148].

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

[148] Department of Justice (October 2006), “Human rights: human lives; A handbook for public Authorities”

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

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.[149]

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.[150]

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.

---

[149] Commission for Rural Communities, (February 2009), "Rural Reference Bulletin- No.2"
[150] ibid

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[151].

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[152]. 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[153] 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.

[151] Commission for Rural Communities, (February 2009), "Rural Reference Bulletin- No.2"
[152] Commission for Rural Communities, "Rural proofing guidance"
[153]http://www.ruralhealthgoodpractice.org.uk/index.php?page_name=section1_chapter5_research_results

However, this option would ensure a local provision of primary medical and dental care and would not reduce access.

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[154] and an estimated 46 million courses of treatment[155] are delivered by dental practices each year[156]. Over 90% of all contact with the NHS takes place outside hospital[157].

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.

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.

---

[154] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*[155]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.

[156] 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).

[157] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

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*[158] 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 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[159].

[158] Link to consultation document: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286
[159] Link to consultation document: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991

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 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 all reasonable 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.

Safeguarding service users from abuse
The registered person must make suitable arrangements to ensure, so far as reasonably practicable, 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.

Respecting and involving service users
The registered person must make suitable arrangements to ensure, so far as reasonably practicable –
(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[160]:

---

[160] NHS Scotland (2004) Sterile Services Provision Review Group: Survey of Decontamination in General Dental Practice (available at: www.scotland.gov.uk)

"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[161], require different types of care and treatment.

H21. The Adult Dental Health Survey 1998[162] 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[163]. 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.

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[164,165].

H24. The British Society for Disability and Oral Health, in its *Guidelines for the delivery of a domiciliary oral healthcare service*[166], 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."

---

[161] 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.
[162] Office for National Statistics (2000) Adult Dental Health Survey - Oral Health in the United Kingdom 1998.
[163] Office for National Statistics (2005) Children's Dental Health in England 2003.
[164] British Society for Disability and Oral Health (2000). Oral health care for people with a physical disability.
[165] Department of Health (2007) Valuing People's Oral Health – A good practice guide for improving the oral health of disabled children and adults.
[166] British Society for Disability and Oral Health (2009) – Guidelines for the delivery of a domiciliary oral healthcare service

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[167,168]. The Health Survey for England 2001 showed that disabled people are more likely to fall into Social Class IV and V[169].

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.

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[170] 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[171]. Different cultural behaviours that affect oral health are also found across different ethnic communities[172].

H29. Dental services are also utilised at different levels across different ethnic communities. A study carried out by the Joint Health Surveys Unit[173] 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.

---

[167] 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.

[168] Laura Mitchell, Paul Brunton (2005). Oxford Handbook of Clinical Dentistry.

[169] 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).

[170] Patterns of mortality among migrants to England and Wales from the Indian subcontinent. *British Medical Journal*. 289 (1984)

[171] "Caries experience, tooth loss and oral health related behaviours among Bangladeshi women resident in West Yorkshire" for Community Dental Health (1996)

[172] "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

[173] Joint Health Surveys Unit (on behalf of the Department of Health) (2001) Health Survey for England - The Health of Minority Ethnic Groups 1999.

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[174].

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[175].
- 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[176] 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:

---

[174] London Assembly Health and Public Services Committee (2007). Teething problems – A review of NHS dental care in London.

[175] 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.

[176] 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

"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[177]. 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)[178].

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 and the proportion of people with a long-term illness or disability that restricts their daily activities also increases with age[179,180]. Older people form the majority of those registered as blind or partially sighted (90% are over age 60[181]) and of those with hearing impairments (580,000 people aged over 60 have severe to profound deafness[182]). 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[183].

---

[177] Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care

[178] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*

[179] Department of Health (2008). Impact Assessment of NHS Next Stage Review proposals for primary and community care.

[180] 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.

[181] RNIB (2005). Older People. www.rnib.org.uk.

[182] RNID (2005) Deaf and hard of hearing adults in the UK.

[183] Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.

H41. A report by the Disability Rights Commission[184] 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*[185] 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 and discusses ongoing action in the health and social care sector to improve outcomes for disabled people[186].

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[187].

H44. GP consultation rates for women of working age tend to be higher than those for men of working age [188]. 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* [189] 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.

---

[184] Disability Rights Commission (2006) Equal Treatment: Closing the Gap.
[185] Department of Health (2004) - You can make a difference: improving primary care services for disabled people - Good practice guide for primary care service providers
[186] Department of Health (2008) - Secretary of State Report on Disability Equality, Health and Care Services
[187] Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.
[188] Information Centre (2009) *Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database*
[189] Department of Health (2008) - Trans: a practical guide for the NHS

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[190] 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[191] between one and a half (for Black Caribbean men) and three (for Bangladeshi men) times as high as men in the general population.
- 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.

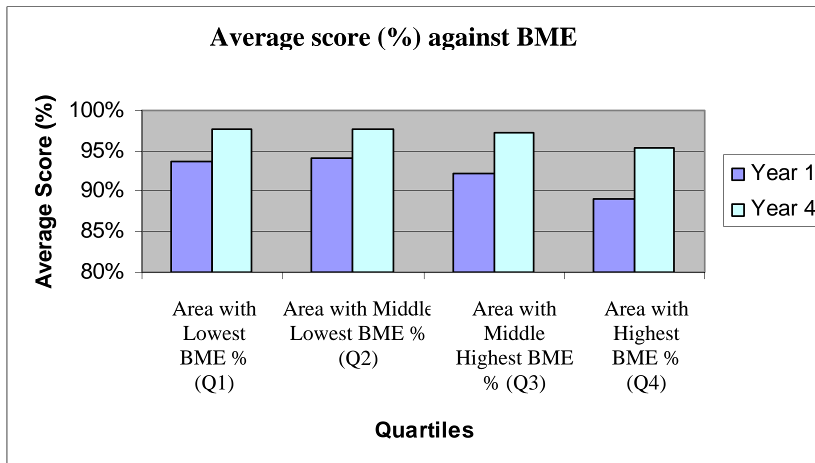
H49. The average proportion of BME patients registered with a GP practice is 19%. Graph one shows that areas with the lowest levels of ethnicity score more Quality and Outcomes Framework (QOF) points[192] than areas with the highest levels of ethnicity (areas with high levels of ethnicity tend to correspond 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).

[190] Joint Health Surveys Unit (on behalf of the Department of Health) (2001) Health Survey for England - The Health of Minority Ethnic Groups 1999.
[191] number of consultations with a GP each year
[192] 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.

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.

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)[193].

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

[193] 2001 Census . Cited in Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.

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 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.[194] 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.

---

[194] http://www.cqc.org.uk/contentdisplay.cfm?widCall1=customWidgets.content_view_1&cit_id=34904

Equality impact assessment

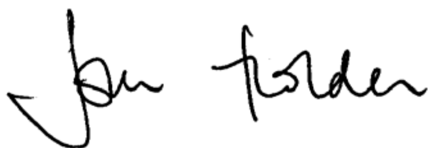
An adverse impact is unlikely. On the contrary, there is potential to reduce barriers and inequalities that currently exist. There is insufficient evidence, however, for this assessment to be made with as much confidence as is desirable.

For the record

Name of person completing the EqIA
Cathy Morgan

Date EqIA completed
20 October 2009

Name of Director endorsing EqIA
John Holden



Date EqIA endorsed
21 October 2009