# Summary: Intervention & Options

| Department /Agency: | Title: | |
|---|---|---|
| Department of Health | Impact Assessment of the Scope of Registration of Primary Medical and Dental Care | |
| Stage: **Consultation stage** | Version: **2.0** | Date: **7 February 2008** |
| Related Publications: | | |

Available to view or download at:

**http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_083625**

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

**The current regulatory systems for NHS primary and secondary care and IS health care differ significantly as they were designed for a system that largely kept separate the providers of these services. With an increased share of elective services being carried out in primary care and by IS health care providers, this regulatory system is out of date.**

**Additionally, the current system of NHS primary care does not ensure a consistent level of safety and quality across the country, with poorer areas being overrepresented among the areas with lower and even insufficient levels of quality.**

## What are the policy objectives and the intended effects?

- **create a fair playing field for all health care providers**
- **ensure key safety requirements are enforceable in NHS and non-NHS primary care services;**
- **strengthen assurance for patients about safety and quality;**
- **ensure the potential to deliver services closer to people is supported and safety is maintained;**
- **put arrangements in place to address the increasing complexity of primary care services;**

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

**We have presented the impacts of a range of scenarios requiring different primary care providers and dental carers to register with the CQC. These scenarios are to give consultees a view of the likely scale of costs and benefits. Options will be determined in the light of the consultation responses and may well differ in terms of primary medical care and dental care.**

## When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? Following the consultation, further analysis will be carried out to help inform any future legislation.

Ministerial Sign-off **For consultation 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: | Description: The impact assessment is based on scenarios not options meaning costs and benefits cannot be provided in the format required. |
|---|---|

**COSTS**

ANNUAL COSTS

One-off **(Transition)** Yrs

£

Average Annual Cost **(excluding one-off)**

£

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

Total Cost **(PV)** £

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

**BENEFITS**

ANNUAL BENEFITS

One-off Yrs

£

Average Annual Benefit **(excluding one-off)**

£

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

Total Benefit **(PV)** £

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

**Key Assumptions/Sensitivities/Risks**

| **Price Base** | **Time Period** | Net Benefit Range **(NPV)** £ | NET BENEFIT **(NPV Best estimate)** £ |
|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **What is the geographic coverage of the policy/option?** | | | **England** | |
| **On what date will the policy be implemented?** | | | **not yet confirmed** | |
| **Which organisation(s) will enforce the policy?** | | | **CQC** | |
| **What is the total annual cost of enforcement for these organisations?** | | | **£** | |
| **Does enforcement comply with Hampton principles?** | | | **Yes** | |
| **Will implementation go beyond minimum EU requirements?** | | | **Yes/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?** | | | **Yes** | |
| **Annual cost (£-£) per organisation (excluding one-off)** | **Micro** | **Small** | **Medium** | **Large** |
| **Are any of these organisations exempt?** | **Yes/No** | **Yes/No** | **N/A** | **N/A** |

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

**Increase** £ **Decrease** £ Net Impact £

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

# Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

## Scope of Registration IA

### INTRODUCTION

1. The subject of this Consultation stage Partial Impact Assessment is the costs and benefits of the potential options for including primary medical and dental care within the scope of the registration system to be operated by the new Care Quality Commission. The details of the new system are being consulted on in [title], which this Impact Assessment accompanies.

2. The Impact Assessment for the Health and Social Care Bill (available on http://www.dh.gov.uk/healthandsocialcarebill) covered the expected costs of establishing and running the Care Quality Commission if the body regulated the same providers as the Commission for Social Care Inspection (CSCI) and Healthcare Commission (HC) do at present (including NHS Trusts and PCTs which are part of the annual health check). This Impact Assessment therefore considers only the proposal to extend the scope of registration to include a new group of providers – namely the inclusion of primary medical care and primary dental care.

3. There are currently approximately 8,400 NHS primary medical care contractors[1]. There are about 29,000 GPs with the average contractor having 3.4 GPs. There is a wide variation in size with the largest contractor having 18 GPs while 25% of contractors have only one GP. The estimated total number of consultations in general practice in England in 2006 was 289.8m[2], i.e. 5.7 per person and year.

4. The Healthcare Commission currently registers approximately 305 private doctors. Private doctors cover a broad range of services from a single private GP working one day a week to very complex clinics with a number of professionals.

5. There are currently around 9,000 dental practices, of which probably about 1,000 are solely private. There are approximately 21,000 dentists in total with an average practice having 2.4 dentists. 37% of dental practices have only one dentist while 5% have six or more dentists[3]. In 2006-07, there were 28m courses of treatment in the NHS compared with an assumed 9m in the private sector[4].

[1] We are using the terminus "contractor", as there are some primary care contractors that are not led by a GP. Contractors usually mean a GP practice, which may consist of one or more GPs and other medical professionals.
[2] Estimate from The Information Centre report on 'Trends in Consultation Rates in General Practice 1995 to 2006: Analysis of the QRESEARCH database'.
[3] Figures for September 2003 from Dental Review 2003-2004 produced by the Dental Practice Board. Note that some dentists practise at more than one address.
[4] A course of treatment may involve more than visit to the dentist. It is estimated that there are around 75m visits to the dentist per annum.

## Executive Summary of the Cost Benefit Analysis

6. The consultation document this document accompanies seeks comments on the list of regulated activities that will bring providers within the scope of registration. The final list of activities will determine the proportion of primary care providers required to register. The consultation stage impact assessment compares the potential costs and benefits of two main scenarios together with the status quo:

    i. For both primary medical care and primary dental care, one option would be a scenario where all providers would be registered (in case of primary medical care that would be 8,400 GP practices and in dental care that would be 9,000 dental practices).
    ii. Another option would be a scenario where only practices that conduct more complex services[5] would be registered. In primary medical care there are round 1,750 GP practices[6] and in primary dental care there are 750 dental practices that could fall into this category.

7. The final options will be determined in the light of the consultation responses and may well differ in terms of primary medical care and dental care. At this stage the impact assessment can therefore only describe the range of costs and benefits that might be achieved by different options. The one-off and annual costs could be less than presented here by aligning a light-touch system of registration with other systems such as practice accreditation.

8. **Costs:** To estimate the costs of a registration system that will have quite a different scope and content from current system is necessarily difficult and therefore the numbers have to be treated with some caution. We have used the costs of the current regulation of IS health care providers as proxies for the potential costs of a registration, even though we know that these proxies are far from optimal. A longer discussion of the limitations of the numbers is included in the main text.

9. Overall, we would estimate the total annual costs across the system to register all primary medical and dental care providers to be between £16m and £31m while a registration of only the providers of more complex services, would cost between £5m and £9m.

10. This estimate breaks down as follows[7]:

    i. Costs for the Regulator: The regulation of all medical primary care providers would cost between £10.4m and £17.6m, while the registration of all dental care providers would cost between £10.8m and £16.3 m. Concentrating on the more complex services would reduce costs to between £4.2m and £6.3m in primary medical care and to between £1.7m and £2.6m in dental care.
    ii. Savings for PCTs and the Dental Reference Service (DRS): As currently PCTs in primary medical care and the Dental Reference Service in dental care are conducting some functions of a regulation system there would be some savings, if they are able to reduce their efforts (or the regulator can use their work and reduce its effort). We estimate the potential savings to be between £3.5m and £4.5m in primary medical care and around £5.3m in dental care if all providers were to be registered. Concentrating on the more complex services would reduce the savings to around £1.5 in primary medical care and to £0.5m in dental care.

[5] As proxies for more complex services we are using the GPs with special interest in primary medical care and the dental practices that conduct sedation services. For more explanation on the proxies see the next chapter.

[6] There are currently 1,750 GPs accredited as GPs with special interest. We use this as an estimate for the number of practices. On one hand it is likely that there may be more than one GPwSI in one practice reducing the number of practices with GPwSIs but on the other hand there is a number of GPs conducting more complex services without GPwSI accreditation as they have received their authorisation to do so before the introduction of the GPwSI scheme.

[7] Please see table 1 and 2 in the main document for more detail.

iii. Costs for the regulated entities: Registering all primary medical care and dental care providers would cost the providers between £1.7m and £3.3m in primary medical care and between £2.2m and £3.4m in dental care. Focusing on the more complex services would bring costs down to between £0.6m and £1.3m in primary medical care and to around £0.5m in dental care.

11. Benefits: Registering primary care providers may have substantial benefits that are difficult to quantify. Initial calculations that are included in the main text show that these benefits have the potential to significantly outweigh the costs. The benefits will also differ between the main options:
    i. **Patient safety:** The introduction of a registration system to primary medical care providers and dental care providers is aimed at increasing patient safety, as all registered providers would have to meet the same registration requirements. A registration of only the more complex services would achieve a share of this benefit, as the per definition the risk per treatment is higher in these services. However, the volume of the lower risk treatments means that the cumulative risk is great.
    ii. **Quality of care:** Registration will ensure the quality of care of all registered providers is at an acceptable level. The providers offering complex services already receive more scrutiny than other providers in the current frameworks and it is not likely that many members of this group would fall below the quality threshold of a registration system. This implies that these benefits would be far greater if all providers are registered.
    iii. **Enforcement:** The introduction of enforceable requirements will address regional disparities in the provision of care by requiring a common minimum standard in primary medical and dental care. As above, this effect will be only marginal when only complex services are registered.
    **iv.** **Patient reassurance:** The greater the perceived risk of treatments the greater will be the effect of a registration system on on patient reassurance. OnFor that basismatter it can be assumed that the effect of a registration system on patient reassurance will also be higher than proportional if only more complex services were registered as it is likely that patients will need more reassurance when undergoing more complex treatments.
    v. **Fairness to all providers:** The registration of the more complex services would even the playing field for primary care providers that compete with secondary care providers on elective services. The registration of all providers would additionally avoid the creation of a registration system for only a part of primary medical care or dental care providers that might create perverse incentives for providers not to offer complex services in avoidance of registration.

12. A comparative assessment of the benefits of the two main options depends on the weighting of the different objectives of the introduction of a registration system. If the objectives of patient safety and reassurance are the most important then the benefits of a concentration on the most complex services will reap a significant share of the benefits of a registration of all providers. With the costs of the latter being significantly higher, an initial concentration on the most complex services might be judged superior. If the objectives of guaranteeing a minimum quality of care and a fair treatment of all providers were judged to be equally or more important than the other two objectives, the judgement would be different, as the benefits of registering all providers here are significantly higher and would most probably outweigh the additional costs.

## The Options

13. In order to carry out a cost benefit analysis it is necessary to consider the full range of options and the pros and cons of each. As mentioned in the consultation document, services will be included on the basis of the risk they present rather than on where the services are provided. The following options consider various scenarios in terms of the number of primary care providers that could be brought into registration from different conclusions to the risk analysis to give an indication of the potential cost and benefit ranges that could arise.

14. For primary medical care:
    - ***Option 1: the Do-Nothing Option*** represents the current position where NHS primary medical care is not included in scope of registration, while private doctors remain within the scope
    - ***Option 2:*** the scenario where, as a result of the risk analysis, all primary medical care services are included in the scope of registration
    - ***Option 3:*** the scenario where, as a result of the risk analysis, only the most complex services provided in primary care, whether in the NHS or private sector, are included in the scope of registration
    - ***Option 4:*** the scenario where, as a result of the risk analysis, only the most complex services provided in primary care and all services provided by private primary care providers are included in the scope of registration

15. For dental care:
    - ***Option 1: the Do-Nothing Option*** represents the current position where dental care is not included in the scope of regulation
    - ***Option 2:*** the scenario where, as a result of the risk analysis, all primary dental care services are included in the scope of registration
    - ***Option 3:*** the scenario where, as a result of the risk analysis, only those services provided by dentists offering sedation services are included in the scope of registration

16. Impact Assessment work is a process that will support the whole policy development process. The impact assessment will become more detailed and focused, when the Government lays the regulations necessary to define the scope of registration and as and when further extension of scope is consulted upon.

## Proxies used in this Impact Assessment

17. For this Consultation stage Impact Assessment we have provided an initial analysis of the potential costs and benefits using a number of proxies, detailed below. As part of the consultation we would welcome comments on the suitability of these proxies, and the estimates generated and any additional data you may have to enable us to estimate these costs and benefits more accurately.

18. Private doctors are used as a proxy for the costs of regulating both primary medical care contractors and dental practices under option 2, because we are not aware of any existing robust data on equivalent regulatory costs for the NHS, since NHS primary care is not currently subject to this form of regulation. Private doctors are more equivalent in size to primary care practices than any hospital comparator would be.

19. There are clearly a number of differences between private doctors and NHS primary medical care contractors that make this comparison difficult. On average it appears that private doctors are smaller than NHS primary medical care contractors. There is also a lot more information available about NHS contractors, eg QOF data, prescribing data, PCT contract monitoring, and potentially an accreditation scheme that the Royal College of General Practitioners is currently developing, than is the case for private doctors which could mean

that a different methodology of regulation would be applied to NHS primary medical care contractors than is currently applied to private doctors. The greater availability of information could create the potential for the regulator to rely on those systems already in place in most cases and only intervene in a risk-based way, which could lead to lower costs. The legislation that will create the Care Quality Commission (subject to the passage of the Bill through parliament) requires them to minimise the burden of regulation and the Government would therefore expect the Commission to adopt a "light touch" approach to regulation.

20. The differences are arguably even greater between dental practices and private doctors as the services offered are completely distinct although the practices may be similar in terms of size. Again, there is more information available on practices providing NHS dental care than on solely private practices.

21. Recognising these issues, the following analysis uses ranges based on private doctor costs with more detail of the ranges and underlying upside and downside risks included in the accompanying footnotes. It should be noted that because of the limitations of the proxy these figures are 'approximate estimates' based on the data available but may still under- or overestimate the true cost of regulating primary medical care contractors and dental practices.

22. For options 3 and 4 where regulation is extended to cover only those GP practices with contractors providing more complex services to estimate the number of contractors offering these services we have used as a proxy the number of GPs with special interests, which is approximately 1,750. This does not exactly capture the number of providers that may fall into this category, as this is the number of individual accredited GPs with special interests not the number of practices offering these services. There are also a number of practitioners who undertake equivalent work but are not formally GPwSIs. On the cost side, the proxy of current independent sector specified acute services[8] is used with the intention of better reflecting the more complex and potentially riskier procedures carried out by these providers.

23. Likewise for the options in primary dental care where regulation is extended to include only those dental practices where there are more complex procedures the proxy of the number of dentists offering sedation services is used, currently 8.5% of NHS practices. Again on the cost side the proxy of current independent sector specified acute services is used as arguably this better reflects the more complex and potentially riskier procedures carried out by these practices.

24. As before, it is recognised that these are far from ideal comparators, and even with the ranges used in the analysis there remains a risk of over- and underestimating the true cost of regulating these practices. Keeping the cost down will depend on the Care Quality Commission taking a light-tough approach to regulation and aligning successfully with other systems e.g. PCT contract management, performer's lists and practice accreditation schemes.

[8] The Healthcare Commission currently register the following types of services under the heading "specified services": cosmetic surgery clinics; day surgery/ambulatory care hospitals with no overnight beds; dental treatment under general anaesthesia; dialysis units; endoscopy units; type one and type two (not type three) hyperbaric oxygen chambers; IVF clinics; maternity hospitals; refractive eye surgery clinics; and termination of pregnancy clinics.

## RATIONALE FOR INTERVENTION

25. About 80% of patients' contact with the NHS is in primary care. Everyday 800,000 people use primary care services and some 90% will be diagnosed, treated and receive all the care they need from services provided in primary care settings. The rest will be referred by primary care professionals on to community and secondary care services. The key risk is therefore one of volume and it is therefore important that patients can be reassured that providers are operating safely, without producing unnecessary bureaucratic burdens on service providers or erecting unnecessary barriers to system entry.

26. The current regulatory arrangements focus mainly on the competency of the individual professional. However, the way that organisations are managed and that their systems work, together with factors such as the suitability of premises in which services are provided also impacts on the safety and quality of the services provided. Without checks, highly skilled and competent individuals may be working in organisations that have system weaknesses or in premises that do not meet the needs of their patients and, as a result, patients may be put at risk.

27. Currently different organisations and different regulatory settings ensure safety and quality in primary medical care and dental care. While generally IS providers in primary medical care are registered by the Healthcare Commission, providers that have contracts with PCTs do not have to register even though many of them are conducting privately funded work as well.

28. Without any change, the current framework will produce another discrepancy in approach when NHS providers of secondary care are registered following the Health and Social Care Bill. Respondents to the consultation *Future regulation of health and adult social care in England* argued that the increasing complexity of general practice and the widening range of services offered in primary care points to the need for a consistent regulatory framework across both primary and secondary care. Failing to put such a system in place would mean that identical activities would need to be regulated if provided in secondary care, but not if provided in primary care. It would be difficult to justify this on the basis of risk and could be confusing for patients.

29. Similar issues arise in primary dental care where the Dental Reference Service conducts risk assessment and inspection on behalf of PCTs of all practices with NHS contracts, but no similar arrangements are in place for solely private dentists.

30. The current different approaches are becoming out-dated and will not fit the future health and social care system where

    i. In the absence of a national set of standards, PCTs have not always found it straightforward to enforce the requirements in the existing NHS contracts. PCTs face conflicts of interests when at the same time they are responsible for providing access to GPs, and for guaranteeing a minimum quality of their providers.
    ii. The move of services traditionally provided in secondary care settings into primary care settings and these being provided by a range of different types of providers is likely to increase. The interim report of the NHS Next Stage Review has signalled that more care should be provided closer to home and, 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 hospitals. Such an approach could mean that primary care will increasingly be provided by (potentially complex) organisations, rather than it being a service provided by a collection of individual professionals.
    iii. Patients exercise choice and need consistent information on all available providers to be able to exercise this choice effectively.

iv. Different regulatory systems might put in place perverse incentives for primary care providers to configure in particular ways in order to avoid/ become part of the regulatory system. Under the current arrangements there is, for example, an incentive for private doctors (who would otherwise need to be regulated) to attempt to obtain NHS contracts for a small proportion of their time in order to remove the need for regulatory scrutiny of all of their work.

v. The failure to have a level playing field between NHS and independent sector providers (with one group being subject to registration and one not) could lead to inefficiencies if they start to compete for patients exercising choice and for commissioned contracts. This could potentially also cause difficulties with competition law.

31. All of this suggests that there is a need to put in place organisational and system checks designed to ensure that patient safety is not compromised, across all settings and types of providers. However, in the interests of effective services, putting in place sufficient regulation must not be at the cost of producing unnecessary bureaucratic burdens on service providers or erecting unnecessary barriers to system entry. Decisions on the services to be regulated must therefore be based on the risks to patients.

## POLICY OBJECTIVE

32. The objective of any policy in this area would be to act in a proportionate way to:

- Improve the performance of the poorest primary care performers, potentially reducing the costs to other parts of the system;
- strengthen assurance for patients about safety and quality, especially over the performance of GP practices and dental practices as *organisations* in addition to registration of clinicians as individual professionals;
- ensure the potential to deliver services closer to people is supported and safety is maintained without introducing a bureaucratic block;
- put arrangements in place that will be able to address the increasing complexity of primary care services as they develop to address the challenges of the 21st century;
- ensure key safety requirements are enforceable in both NHS and non-NHS primary care services;
- provide comparative information on all primary care providers that will help inform patient choice;
- reduce demands on PCTs to monitor those contractual requirements with primary care providers that are also registration requirements;
- create a fair playing field, with primary care services treated the same as equivalent services provided in other settings, eg where GPs are providing elective surgical services.

33. A registration system for primary medical care and primary dental care would provide for the first time consistent national set of requirements that providers would be required to meet. As a result, regulation can drive improvement in poorly performing practices, and ultimately force the closure of failing practices, which will help achieve access to high quality health care for everyone.

34. This could also address equity issues. It is quite likely that a registration system would mostly have an impact on the quality (and safety) of provision of the weakest performing providers as the others would find it easier to pass the registration requirements without major changes to their practices. The changes will therefore have the biggest impact on the worst performing providers and, in so far as these providers are more concentrated in some PCTs than in others, on the worst performing PCTs.

35. If certain areas suffer from a general scarcity of providers there could be concerns that closing failing providers in these areas would adversely affect the provision and quality of health care. Therefore the CQC will need to consider the relative risk to patient safety before seeking to close failing providers in under-doctored areas. It may take the view, in such circumstances, that other sanctions are more appropriate than closure. However, in the mid and long run the threat of closure could be a necessary incentive to drive up the quality of health care, as PCTs would be forced to find and commission high quality providers and no longer settle for sub-standard providers.

## COSTS AND BENEFITS

36. The baseline for the assessment is the current situation (option 1) taking into consideration the planned changes in the regulation of health care generally, including the changes to professional regulation in the Health and Social Care Bill currently going through parliament.

37. All options are considered in comparison to option 1

*Sectors and groups affected*

38. Different regulatory structures and approaches could lead to costs and benefits for different groups:

*Costs of Regulating Bodies*

- The Care Quality Commission: inclusion of primary medical and dental care providers into the registration system would affect its administrative costs.

- Primary Care Trusts (PCTs) and Dental Reference Service: As current systems cover parts of a potential registration system the new regulator could use the operations to save some effort (or PCTs and the Dental Reference Service would save some of their effort if the regulator takes over).

*Operational Costs of Regulated Bodies*

- Service providers: changes to the regulatory functions would have an impact on the administrative costs of primary medical care contractors and dental practices as service providers as they would have to comply with Regulations and provide information to regulating bodies.

*Benefits*

- Patients and service users: all regulatory functions may have an impact on the quality of services provided (including clinical quality, improved patient experience and access to services), particularly improving the quality of provision offered by the worst performing practices and therefore closing the gap between the middle and worst performing practices.

## PRIMARY MEDICAL CARE

### Options 2, 3 and 4 relative to option 1

#### *Operational Costs of Regulating Bodies*

*The Care Quality Commission*

39. **Introduction into the registration system**: Bringing primary medical care contractors into the registration system would increase the costs of the Care Quality Commission. Currently the Healthcare Commission needs £1,225[9] per doctor per year to keep a private doctor registered. Recognising the limitations of the data (set out elsewhere), this means that it could cost between £980 and £1,715 per year to keep a primary medical care contractor registered in option 2 if the same methodology was used as is currently used for regulating private doctors under the Care Standards Act 2000.

40. We would use a different proxy for options 3 and 4[10]. As the current costs for specified acute services is £2,350 per year, we would estimate the unit costs for these practices to be between £1,880 and £2,820.

41. Based on these figures the options would lead to additional annual costs for the Care Quality Commission of
    i. £8.2m - £14.4m in option 2 (registering 8,400 primary medical care contractors),
    ii. £2.9m - £4.5m in option 3 (registering 1,750 GPs with special interests[11] with a total annual cost of £3.3m to £4.9m and deregistering most or all of the 305 private doctors[12] making a total annual saving of around £0.4m)
    iii. £3.3m to £4.9m in option 4 (registering 1,750 GPs with special interests).

42. The way contractors are introduced to registration will affect potential one-off registration costs. If all are registered automatically (which will be the case with NHS hospitals and is suggested in the consultation paper could also work for primary medical care providers with an NHS contract) then registration costs will be small. If on the other hand all providers have to go through a formal application process then this could potentially lead to significant one-off registration costs for the Care Quality Commission of between £800 and £1400[13] per contractor in option 2 (this is an average value, which will vary with the size of the practice).

43. In options 3 and 4 average costs per provider will be higher as in these options only those contractors providing more complex services, who tend to be larger and more complex, are

[9] As mentioned in the introduction we have used as a proxy the current annual cost for private doctors of being registered, which is £1,225. In most of the analysis for primary medical care contractors we use a range from 20% below the current cost to private doctors, reflecting the potential for the regulation to be less costly due to the more effective use of information, to 40% above the current cost to private doctors reflecting the more complex nature of services offered by GPs and larger size of GP practices. The ranges are based on an average GP practice and the upper limit should not be interpreted as the cost for a large GP practice as this could be considerably higher.

[10] We have used the proxy of IS specified acute services for the practices offering complex services. In all analysis for these practices we use a range of 20% above and below the current cost to these specified acute services, reflecting the perceived balanced upside and downside risks. We have assumed that in option 2 the higher average costs of the more complex providers is counterbalanced by small single GP practices which probably cause lower average costs than assumed in option 2.

[11] As mentioned in the introduction, the number of GPs with special interests is used as a proxy for the number of contractors providing complex services.

[12] Obviously private doctors would be subject to the same risk assessment as GPs which would mean that the ones more complex services will stay registered. We would think that this is only a small minority of the private doctors as the Healthcare commission has a second category "specified services for more complex services.

[13] It is important to note the difference between annual fees for already registered providers (£1,225) and the fee that is charged for first time registration (£990).

registered. In this case, we would estimate the costs per contractor to be between £3,200 and £4,800[14].

44. For the different options this would mean:
    i. Option 2 (registration of all 8,400 contractors) may lead to one off costs for the regulator in the range £6.7m to £11.6m.
    ii. Options 3 and 4 (registration of only the approx. 1,750 GPs with special interests) may lead to one-off costs for the regulator of £5.6m to £8.4m.

45. But these numbers do only emphasize the need for a less bureaucratic approach. In the most likely case that all providers are registered automatically,a, we would estimate the costs to be not more than 10% of the above estimate i.e. up to £1 million one-off cost.

46. Even if existing primary medical care providers are registered automatically the Care Quality Commission could face significant extra costs for the setting up of the system, training and the development of methodologies. Generally, we would assume that set-up costs are one part of the (full-cost) fees for private doctors we use as a proxy and with that will be picked up in the operation costs calculated in this document.

47. **Inspection:** The regulator will also be obliged to carry out inspections of practices. If the new regulator adopts a similar inspection frequency towards primary medical care as the Healthcare Commission does currently with private doctors the inspection probability would be about 20%[15] per year (as some doctors would be visited more than once this would not imply that 20% of all practices are visited). A half-day inspection of a private doctor costs £350. Using this as a proxy it is estimated that for an average primary medical care contractor an inspection would cost between £280 and £420[16].

48. Again, we have to assume that these average figures are suitable for the average contractor but not those providing more complex services covered by options 3 and 4. We would assume that it would need a full day to inspect these doubling the unit costs to £560 - £840.

49. For the different options this would have the following impact on the cost of the regulator:

    i. Option 2 would lead to 1,680 additional inspections and with that to additional costs of between £0.5m and £0.7m.
    ii. Option 3 would lead to 289 additional inspections with additional costs of £0.17m - £0.27m (350 additional inspections at GPs with special interests at a cost of £0.19m - £0.29m and 61 saved inspections at private doctors resulting in a saving of about £21k).
    iii. Option 4 would lead to 350 additional inspections of GPs with special interests and with that to additional costs of between £0.19m and £0.29m.

50. **Enforcement action:** Under registration, service providers would also be subject to enforcement action if they were found to be in breach of registration requirements.

[14] The current flat fee (excluding extra bed charges) for specified acute services is £3,990.
[15] In 2007/08 the HC anticipates making around 61 inspections of the 305 private doctors (20%). There could of course be some practices that are inspected more than once so this does not mean that 20% of establishments are inspected in a year. The inspection frequency for NHS GPs could be lower as there is more information available on them.
[16] For inspection a range of 20% below and 20% above the current cost to private doctors is used rather than the 20% below and 40% above that is used for the other estimates as it is not felt that the upside risks of the larger practice size will have such an influence when it comes to inspection.

51. Using the current expenditure of the HC and the CSCI on enforcement we would estimate that the average costs of enforcement to be on average £200-£300[17] per provider in option 2. Additional enforcement costs would be £1.7m to £2.5m.

52. Again, options 3 and 4 would be more expensive per provider, as providers are bigger and cases will probably be more severe. We would estimate the costs to double to £400-£600 per provider or £0.7m to £1.1m in total.

53. In the case that providers are not registered automatically this might again lead to significant extra costs to deal with legal challenges from unsuccessful applicants.

*Primary Care Trusts (PCTs)*

54. The costs mentioned above imply that the regulation of primary medical care has to start from scratch. As already mentioned this is not a realistic assumption as PCTs currently implicitly register NHS primary medical care by imposing certain conditions on providers in order for them to be offered an NHS contract, along with monitoring compliance against contractual requirements.

55. The costs of the introduction of an registration system by the Care Quality Commission would therefore be less costly than assumed above as either the CQC could rely on the work of PCTs, or PCTs could reduce their effort.

56. PCTs will set different priorities in their commissioning and monitoring work and with that the amount of savings will differ (and logically the scale of additional benefits resulting from a CQC registration). The estimates below are average costs (and cost savings) that will not apply for all PCTs.

57. As the registration requirements are yet to be finalised any estimate of this impact can only be tentative. The initial assessment is that of 18 requirements set out in the consultation document, the GMS/ PMS contracts would cover 2-3 fully and 8-9 partly while 5-7 requirements are not covered at all. This would mean that between 30 and 40 % of the above calculated outlay of the regulator would be not necessary due to the current work of PCTs.

58. This would mean that registration costs would be lower by:
    i. between £3.3m and £4.3m[18] in option 2
    ii. and between £1.3m and £1.5m in options 3 and 4[19]

59. Obviously these estimates depend strongly on the degree of cooperation between PCTs and the Care Quality Commission. If the Care Quality Commission takes the interests of the PCTs into account, when building up its assessment system, and if both parties can and do do rely on the data provided by the other party, savings could be higher than assumed, otherwise they may be much smaller.

60. The same logic applies for the costs investigations and inspections It seems to be the case that most PCTs visit between half and all of their primary medical care contractors every year. If the regulator would use the inspection results of PCTs or the other way around, they

[17] CSCI has spend £2.1m for enforcement work with their 24,000 registered providers (£88 per provider), while the HC has spend £1.3m for the enforcement work with their 2,000 on average significantly larger providers (£650 per provider).

[18] We assume here that the lower bound would be if the PCTs could save 40% of the lower estimate for annual regulation costs of £980 times 8,400 primary medical care contractors (implying that the regulator would have been able to devise a lean regulation and the PCTs would have been able to coordinate their procedures well with the regulator). The upper bound (30% of £1,715 times 8,400 GPs) would imply that the regulation of the regulator is more burdensome and the PCTs were less efficient in streamlining their operations.

[19] Following the same methodology but using the higher proxies explained above.

could most probably either reduce the number of inspections or the duration of every inspection which would have the same cost effect.

61. Assuming (as above) that the regulator would find an inspection probability of 20% to be appropriate but due to PCT work it could save around 30-40% (as the assumed overlap rate of contract and registration requirements) of this work, this would mean that:
    i. Option 2 would save £0.19m to £0.21m[20]
    ii. While option 3 and option 4 would save between £0.08m and £0.09m

62. Likewise, if primary medical care providers were registered with the Care Quality Commission, PCTs or the CQC could also save on enforcement costs. PCTs currently have limited enforcement powers over breaches in contractual requirements, usually serving remedial notices. At present there are relatively few enforcements, partly because of the difficulty in proving that a breach of requirements has occurred, and practises vary widely among the different PCTs. No reduction has therefore been made in calculating the overall costs here.

***Operational Costs for Regulated Bodies***

63. The following costs are the costs to regulated bodies caused by the regulations. Any fees that may be charged are not included as they form a part of the costs calculated above as costs of the regulator.

64. **Introduction into the registration system**: If we assume that in order to be registered, primary medical care contractors would have to provide a self assessment as IS sector providers currently have to do currently, the annual cost of being registered could be about £270 to £470[21].

65. As in the case of the regulator we would assume that the average costs for those contractors providing more complex services would be twice that of the average contractor, that is between £540 and £940.

66. In the different options this could lead to additional costs per year of between
    i. £2.3m and £4.0m in option 2
    ii. £0.8m and £1.5m in option 3 (registering 1,750 GPwSIs at a total cost of between £0.9m and £1.6m and deregistering 305 private doctors saving a total of about £100k[22])
    iii. £0.9m and £1.6m in option 4 (registering 1,750 GPwSIs)

67. Again 30-40 per cent of these costs could be saved if the regulator would use the work of PCTs. This would save between
    i. £0.9m and £1.2m in option 2
    ii. and £0.4m and £0.5m in options 3 and 4

68. While it is expected that arrangements would be put into place to make registration automatic, if they were not, there would be some one-off costs for the initial registration process. In option 2, for the regulator the average one off costs are slightly lower than the average annual costs (£900 compared with £1,225). Given these similarities on the

[20] Calculated as 30% to 40% of £0.3m to £0.5m.

[21] We have used the assessment of a hospital provider which has calculated that the yearly self-assessment costs them about 6-7 working days per hospital per year and an inspection costs them another 6-7 working days. We have assumed above that the inspection of a GP practice does not take more than half a day for two people costing £336 (one GP and one administration staff – average wage £60,000). Additionally we have assumed for GPs the self assessment would also require a similar effort to an inspection therefore also costing about £336. Again, we have set a range of 20% below and 40% above, which gives us the range £270 to £470.

[22] Using the basic estimate of £336 per year for the private doctors.

regulator's side we have assumed that for the regulated bodies the one-off costs are the same as the annual costs. In options 3 and 4 the cost to the regulator is four times as great as in option 2, so we assume that for regulated bodies it is also four times as great. This means that a formal registration process for primary medical care contractors would cause one-off costs of about

i. £2.3m to £4.0m[23] in option 2 (registering 8,400 contractors)
ii. £1.9m to £2.8m[24] in options 3 and 4 (registering 1,750 GPwSIs)

69. Again it is more likely that an automatic registration is chosen and this would drastically reduce these costs and we estimate these to be not more than 10% of the estimate above i.e. less than £0.5 million nationally.

70. **Inspection:** Under a registration system primary medical care contractors would be subject to inspection by the Care Quality Commission. We would expect the Care Quality Commission to take a risk-based approach and for good practices to have far fewer inspections than those which the Care Quality Commission has concerns about. Inspections will differ in length and with that costs but we would assume average costs again to be in the range £270 to £400[25] per inspection for option 2 (and double this at £540 to £800 for options 3 and 4, taking into account the larger size and more complex nature of the services provided). This would add up to

i. £0.5m - £0.7m in option 2 (1,680 additional inspections)
ii. £0.17m - £0.31m in option 3 (289 additional inspections)
iii. £0.19m - £0.33m in option 4 (350 additional inspections)

71. Again 30-40% of these costs could be saved by the providers if the regulator uses the work of PCTs (or the other way around). This could save £180k - £200k in option 2 and £75k - £100k in options 3 and 4.

72. **Enforcement action:** Average costs of enforcement are very difficult to define as by definition they differ widely between compliant providers (enforcement costs of zero) and non-compliant providers (everything from very low to high costs including closure of business).

## Summary of Costs

73. Table 1, below, summarises the monetised annual recurring costs of options 2, 3 and 4. In addition to these are the monetised one-off transition costs mentioned in paragraphs 44-45 and 68-69.

[23] Given the similarities in costs for the regulator under option 2 the range £270 to £470 has again been used to estimate the total cost for the regulated bodies.
[24] Given that in options 3 and 4 the cost to the regulator is four times as great as in option 2, we have assumed the unit cost for the regulated bodies also to be four times as great, at between £1,075 and £1,600.
[25] As mentioned above we would think that a half day inspection would take up the time of half a day of a GP and half the day of administrative with average wages of £60,000 a year.

**Table 1: Monetised Recurring Costs (per annum) of options 2, 3 and 4 for registering primary medical care**

| | Option 2 | | Option 3 | | Option 4 | |
|---|---|---|---|---|---|---|
| | **Upper** | **Lower** | **Upper** | **Lower** | **Upper** | **Lower** |
| **Costs to Regulating Bodies** | | | | | | |
| *Care Quality Commission* | | | | | | |
| Annual registration | £14.4m | £8.2m | £4.5m | £2.9m | £4.9m | £3.3m |
| Inspection | £0.7m | £0.5m | £0.27m | £0.21m | £0.29m | £0.19m |
| Enforcement | £2.5m | £1.7m | £1.1m | £0.7m | £1.1m | £0.7m |
| *Primary Care Trusts* | | | | | | |
| Registration | -£4.3m | -£3.3m | -£1.5m | -£1.3m | -£1.5m | -£1.3m |
| Inspection | -£0.21m | -£0.19m | -£0.09m | -£0.08m | -£0.09m | -£0.08m |
| **Total** | **£13.1m** | **£6.9m** | **£4.3m** | **£2.4m** | **£4.7m** | **£2.8m** |
| | | | | | | |
| **Costs to Regulated Bodies** | | | | | | |
| Annual registration | £2.8m | £1.4m | £1.0m | £0.4m | £1.1m | £0.5m |
| Inspection | £0.5m | £0.3m | £0.21m | £0.09m | £0.23m | £0.11m |
| **Total** | **£3.3m** | **£1.7m** | **£1.2m** | **£0.5m** | **£1.3m** | **£0.6m** |
| | | | | | | |
| **Overall Total** | **£16.4m** | **£8.6m** | **£5.5m** | **£2.9m** | **£6.0m** | **£3.4m** |

### *Benefits*

74. While it is difficult to assess the nature and scale of potential benefits arising from the options it is nonetheless very important to try to analyse these.

75. Patient safety is of paramount importance. It is difficult to assess accurately the level of patient safety incidents in primary medical care as it is strongly suspected that the number of incidents reported to the National Patient Safety Agency (NPSA) from primary medical care is artificially low because there is no contractual requirement to do so. The Public Accounts Committee's (PAC) report on implementing clinical governance in primary care[26] noted only 4% of GPs report untoward events and clinical incidents to the National Patient Safety Authority. In 2006/07 there were only 2,410 incidents reported from general practice – the equivalent of only 0.29 per practice. The most common errors were medication (25%) followed by consent/ confidentiality/ communication (13%) and access/ transfer/ discharge (12%). A registration system should improve systems such as practice clinical governance so that the level of these incidents will fall.

76. While the individual patient safety risks from primary medical care may be viewed to be less than in secondary care (meaning per treatment the risk is lower), there still exist a number of risks that can have a serious impact on patient's health (such as misdiagnosis, delays in diagnosis, prescribing errors and communication problems leading to delays in, or problems in the co-ordination of, treatment) and the very high number of treatments in primary care means that the overall risk may be just as high. However, statistics on these risks are difficult to come by.

[26] 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

77. The effect on patient safety would be proportionally higher for options 3 and 4, as the special interest GPs will perform many more higher risk procedures than “ordinary” practitioners. This would mean that the effect on the safety of patients will be far higher than the 20% (1,750 of 8,400 practices) that the share of special interest GPs would imply.

78. The effect on the safety of patients in options 3 and 4 will depend on the detail of the registration requirements. If the requirements are similar to what is currently required to gain GPwSI accreditation, then it is fair to assume that it will not lead to any significant improvement in the safety of service because that level must already be met to gain accreditation.

79. **Quality of Care:** The potential benefits from improving the quality of care given to patients could be significant and potentially far greater than the costs outlined in the preceding sections. The following example seeks to give some indication of these potential savings and benefits.

80. The number of emergency admissions by PCT for some conditions that should generally be managed in primary care showed a wide variation between PCTs. Whilst there could be a number of factors affecting these admissions ratios, such as deprivation and patients not visiting their GPs early enough, these figures could also reflect to some extent GPs failing to manage and appropriately treat these conditions.

81. The registration system could encourage quality improvement through better systems. To illustrate the potential scale of these benefits we have assumed that this quality improvement could result in the worst–performing contractors reducing their level of emergency admissions to no more than 25% above median by encouraging contractors to put in place more effective quality assurance and clinical governance arrangements. This would reduce emergency admissions by an average of 5.8%[27], which would mean a total of 39,000 less emergency admissions per year. At an average cost of £2000 per emergency admission[28], this could save £78m. It is worth noting that as these figures are at the PCT level so there will be even greater variation (and with that a stronger potential effect of a registration system) at the contractor level.

82. To force a significant number of primary medical care contractors to improve their service at least up to the acceptable level will cause some transitional compliance costs on the side of the regulated bodies but overall these transition costs are unlikely to be high as the contractors have only to improve to a level that is already achieved by the vast majority of the practices and so the right procedures to achieve this are known and tested.

83. As said above the number of emergency admissions is one example of many where a registration system could be used as one measure of driving improvement in the quality of service offered by the lowest performers, and if successful has the potential to achieve significant benefits. Whether this or other similar benefits can be realised will depend on the detail of the registration requirements and criteria of the regulator and the level at which they are set, and whether this is the most cost-effective way to achieve such benefits is still not clear. Nevertheless, the cursory calculation above makes clear that the benefits should be

[27] Using expected admission ratios from 2005/06 data for diabetes, chronic lower respiratory disease, asthma, heart failure, diabetic ketoacidosis and epilepsy bringing the bottom 25% to the lower quartile value would save on average 5.8% of admissions. Applying this percentage to the total number of emergency admissions by ambulatory care sensitive condition which is 669,720 (2003/04 data from NHS Institute) means that on this basis there could be a reduction of approximately 39,000 emergency admissions.

[28] The NHS Institute data for 2003/04 gives an average unit cost of these emergency admissions of £1933, with a range from £714 for ear, nose and throat infections to £6028 for gangrene. We have used an estimate of £2000 to take into account inflation

considered if only one isolated example could quite easily produce enough benefits to outweigh all calculated costs.

84. As the previous example highlights there can be significant variations between PCTs as to the quality of service offered. This also comes through in the recent GP Patient Experience Survey. For example, on average only 14 per cent of respondents were dissatisfied with telephone access to their practices. But there were 12 PCTs with dissatisfaction rates above 20 per cent with the highest even reaching twice the national average. Again, difference within PCTs will be even higher than the differences between PCTs. So a regulator could have some impact on the performance in some PCTs that seem to be lagging behind.

85. The effect on the quality of service in the worst performing contractors will be much stronger in option 2 than in option 3. There will not be many of the worst performing contractors in the group of special interest GPs as these GPs have to go through a special accreditation scheme anyway. Additionally, in option 3 the registration process would have to concentrate on "special interest" related matters in order not to make it too burdensome for special interest GPs compared to "ordinary" practitioners. This would mean that many quality issues would be out of scope of the registration, which would make the effect on quality in option 3 even smaller. Therefore, it is estimated that the effect on quality would be far lower than the number of special interest GPs (1,750 of 8,400 or 20%) would suggest. The effect might even be negligible in option 3.

86. **Patient reassurance:** As around 80 per cent of patient contact with the NHS comes through primary care, it is important that there are appropriate safeguards in place to reassure patients that the quality of care they receive is of an acceptable standard. It is again not possible to put a value on this patient reassurance.

87. As with the benefit in patient safety, this benefit might be higher in options 3 and 4 than the proportion of special interest GPs would suggest. This will be especially so for GPs that are on the choice menu, as it will be quite important that patients have similar, reliable information on them in order to make an informed decision and be re-assured as to the quality of service that they will receive.

88. However, the de-regulation of private sector providers, in option 3, could lead to a fall in patient reassurance about the quality of care they would receive from these providers.

89. **Enforcement action:** The ability to have enforceable national registration requirements in primary care could remove regional variations in the quality of care ensuring the same requirements are met across the country and prevent practices failing to meet them from being allowed to continue offering poor quality care. This has the potential to offer significant benefits through the improvement in the quality of care, providing that the system is managed effectively and that PCTs in areas with a scarcity of contractors are able to provide sufficient access to services of an acceptable quality.

90. **Level playing field:** Having a level playing field for all service providers should lead to increased contestability and as a result greater efficiency and with that quality of providers. Registration might on the other hand result in higher barriers to entry for new practices, but this is unlikely as barriers to entry in the NHS context are mainly determined by PCTs via contracting. A level playing field could also encourage the transfer from hospital to primary care services, because people have more information/ reassurance and so are happier to receive care closer to home, and PCTs may be more willing to commission such services if they know that they are safe and of consistently acceptable quality.

91. This benefit would be stronger in option 2 than in options 3 and 4. Options 3 and 4 would only address the level playing field problem in elective secondary care procedures while

option 2 would additionally avoid creating a negative incentive for GPs to provide more complex services.

## RISKS AND UNINTENDED CONSEQUENCES

92. All options have significant risks dependent on future outcomes that cannot be predicted with sufficient certainty.

*Risks of option 1*

93. One risk of option 1 is the continued lack of regulation of primary medical care and the potential safety implications of this, particularly given the expansion in GP practices offering elective services and the planned increase in out of hospital care generally.

94. This could lead to a potentially unfair playing field if primary medical care contractors are able to offer some of the same services as secondary care providers but not have to register with the regulator, which could also lead to a lack of information for patients exercising choice of referral.

95. Additionally, it will complicate vertical integration between primary and secondary care providers because it will be harder to assess which services offered by the integrated provider have to be regulated, and which do not, as the separation between primary and secondary care becomes less clearly defined.

96. Obviously all downside risks of option 1 are upside risks of the alternative options.

*Risks of option 2*

97. Option 2 would result in a dramatic increase in the number of providers that the regulator would be responsible for regulating. There is the risk that this would place such significant burdens on the Care Quality Commission that could result in it being unable to regulate this or other aspects of the health and adult social care sector effectively.

98. There are also risks about the level that the registration requirements are set at for primary medical care contractors. 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.

*Risks of option 3*

99. Option 3 involves de-regulating some private providers of primary medical care. This risks damaging public assurance in these services and could result in declining standards of safety if there is no effective regulation (except for professional regulation). There is also the risk that should it be decided that all primary medical care should be regulated in the future that it would be far more costly to bring these providers back into registration rather than having kept them in.

100. Option 3 addresses the level playing field issue mentioned above but risks discouraging primary care providers from more complex services, 0especially if it would make up only a small part of their work and therefore the relative cost of registering would be a major barrier to entry.

*Risks of option 4*

101. Option 4 also addresses the level playing field issue mentioned in option 1 in relation to elective services but risks, like option 3, discouraging primary care providers from offering elective services, especially if it would make up only a small part of their work and therefore the relative cost of registering would be a major barrier to entry.

102. This option continues the imbalance between solely private providers of primary medical care who have to be registered and providers that offer NHS treatment who do not and therefore continues to offer reassurance to patients who choose private rather than NHS healthcare.

## PRIMARY DENTAL SERVICES

### Options 2 and 3 relative to option 1

### *Operational Costs of Regulating Bodies*

103. For primary dental care, we have used the proxy of private doctors for option 2 with a range of 20% below and 20% above[29]. In option 3, the proxy of specified acute services is used to reflect the more complex nature of the work of dentists with special interests (or those offering sedation services). Again, a range of 20% below and above is used.

104. **Introduction into the registration system**: The inclusion of all 9,000 dental practices (about 8,000 NHS and 1,000 private) into the current registration system (option 2) could lead to additional annual costs for the Care Quality Commission, based on current private doctors fees, is between £8.8m and £13.2m[30].

105. The costs for option 3 would be lower. Currently 8.5% of all NHS dental practices offer sedation services (i.e provide more than local anaesthesia). If the proportion of services offering sedation is similar in the private sector we would expect around 750 services in total. Using the estimate of specified acute services the annual cost of including these 750 practices in the registration system could be somewhere in the range £1.4m and £2.1m[31].

106. The upper estimate for the one-off registration costs to the Care Quality Commission of including all dental practices into the current registration system (option 2), again based on current private doctor fees, is between £7.1m and £10.7m, while for option 3 the upper estimate is between £2.4m and £3.6m[32]. Again, the more likely case of an automatic registration scheme could reduce these costs significantly to about 10% of the estimate above i.e. up to £1 million.

107. The estimate for the annual costs to the Care Quality Commission of including dental practices with special interests in registration (option 3), again using the proxy of specified acute services, is between £1.4m and £2.1m[33].

108. **Inspection:** The regulator would visit some subset of the dental practices. Under the risk-based approach to NHS assessments that the Dental Reference Service are planning from April 2008, they anticipate visiting about 5-10% of NHS practices[34]. We would assume that the regulator would visit a similar number of practices in order to ensure that registration conditions are met. Assuming again average costs of an inspection to be between £280 and £420 in option 2 and twice that in option 3 we would estimate the cost of inspection to be:

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[29] As discussed in the introduction it is recognised that using private doctors is a far from an ideal proxy for dental practices. A range of 20% below to 20% above the cost associated for private doctors has been used to reflect the potential upside and downside differences that could affect costs, for example the differences in services offered. For dental practices we have assumed the upside and downside risks to be balanced while for primary medical care we have assessed the upside risks to be more likely and have thus used the 40% above, 20% below range.

[30] Calculated as 9,000 practices multiplied by £1,225 (plus or minus 20%).

[31] Calculated as 750 practices multiplied by £2,350 (plus or minus 20%). £2,350 is the current fee charged by the Healthcare Commission to independent specified acute services providers.

[32] It currently costs providers of specified acute services £3,990 to apply for registration with the Healthcare Commission. Assuming full cost recovery and the 20% upper and lower range gives us the estimate for 750 practices of between £2.4m and £3.6m.

[33] Calculated as 750 practices multiplied by £2,350 (plus or minus 20%). £2,350 is the current fee charged by the Healthcare Commission to independent specified acute services providers.

[34] The 5-10% inspection frequency used for dental practices is lower than the 20% used for primary medical care. These reflect the current practices of the Dental Reference Service and HC respectively, although the Care Quality Commission would be able to set the inspection frequency as it deemed appropriate given the level of risk, which may mean that the inspection frequency for dental care is less than medical care.

i. £0.1m to £0.4m in option 2
ii. £20k to £60k in option 3

109. **Enforcement:** Under registration, dental practices would be subject to enforcement action if they were found to be in breach of registration requirements.

110. We would use the same assumptions as in primary medical care for an estimate of the costs to the regulator. This means we would estimate the costs of option 2 to be between £1.8m and £2.7m[35] and the costs of option 3 to be between £0.3m and £0.5m[36].

111. Again, in the case that providers are not registered automatically this might again lead to significant extra costs to deal with legal challenges of potential negative decisions.

**The Dental Reference Service**

112. The estimates above assume that the Care Quality Commission has to build up a registration system for all 9,000 dental practices from scratch. However, this is not the case as the Dental Reference Service has already established a system that covers some functions of a registration system. The regulator would clearly be able to build on this work.

113. The Dental Reference Service currently inspects NHS dental practices, at the request of PCTs as part of their quality assurance of NHS dental services. Other services provided by the Dental Reference Service include the examination of patients to assist in the local resolution stage of complaints and a programme of quality assurance visits to dental practices to examine patients and assess clinical records. The existing budget for the Dental Reference Service is about £5.3m per annum (England only). The Dental Reference Service are currently planning a risk-based approach to NHS assessments from April 2008. This would include the use of a self-assessment tool which would allow services to make an annual declaration, a proportion of which would be visited to validate the declarations made. For NHS primary dental services it is anticipated that a random sample of about 400-800 practices (approximately 5-10%) would be visited each year on this basis. Additionally, any practices where specific concerns had been raised would also be visited.

114. In order to reflect the existing work of the Dental Reference Service in risk assessment and inspection we have reduced the above estimate of the cost of the introduction of a registration system in option 2 by £5.3m (the Dental Reference Service' existing budget for England) to reflect the potential for the CQC to utilise and not duplicate work undertaken by the Dental Reference Service.

115. For option 3, this saving is estimated at about £0.5m[37].

***Operational Costs of Regulated Bodies***

116. **Introduction into the registration system:** As no better comparators are available, the estimate for GP practices that we have developed above, is used for dental practices[38]. It

[35] 9,000 practices multiplied by £200 to £300.
[36] 750 practices multiplied by £400 to £600.
[37] Given that 8.5% of NHS practices offer sedation services, we have assumed that the saving for option 3 would be 8.5% of the Dental Reference Service budget.
[38] For primary medical care under option 2 it was estimated that the cost for completing the self assessment form would be £336, which given the range used in primary medical care gave us an estimated range of £270 to £470. Using the range of 20% above and below for primary dental care this gives us the range £270 to £400. Given the more complex nature of practices with special interests the cost of completing the self assessment exercise is likely to be larger. Given the unit costs for the regulator

has been estimated that it would take two people half-a-day to complete this self assessment and this has been costed at between £270 and £400 per practice in option 2 and £540 and £800 per practice in option 3. The overall cost increase could be between:

i. £2.4m and £3.6m in option 2
ii. £0.4m and £0.6m in option 3

117. The Dental Reference Service estimates that its planned risk based approach to NHS assessments would take the regulated bodies about half an hour on average to fill out its proposed self-assessment form, assuming the appropriate policies and procedures are already in place. We have therefore taken the cost of this time away from the estimates above, which reduces them by £0.2m in option 2 and £30k in option 3[39].

118. Again, if registration is not automatic there will be some one-off costs for the initial registration process. As in primary medical care, the unit costs for option 3 reflect the significantly higher costs to the regulator of introducing these providers into regulation[40]. This means that a formal registration process for dental practices would cause one-off costs of about

i. £2.4m - £3.6m in option 2
ii. £0.8m - £1.2m in option 3

119. We assume again, that in the likely case of an automatic registration process, the costs would be reduced to about 10% of the estimate above i.e. less than £0.5 million nationally.

120. **Inspection:** As the regulator would probably emulate the new Dental Reference Service risk-based inspection and monitoring regime, the additional costs of the inspection regime would be negligible on NHS dental practices but there would be some additional costs for private dental practices since they are not currently under the remit of the Dental Reference Service. The overall sum will not be very substantial, as the total number of inspections of the Dental Reference Service is only about 400-800 there is unlikely to be more than 50-100 extra inspections under option 2, which is estimated to cost in the range £270 to £400 each and therefore up to £40,000 in total. For option 3, while the cost per inspection may be higher, perhaps £540 - £800, even if 20 inspections were undertaken again this would not cost more than £16,000.

121. **Enforcement:** As in primary medical care, average costs of enforcement are very difficult to define as by definition they differ widely between compliant providers (enforcement costs of zero) and non-compliant providers (everything from very low to high costs including closure of business).

122. Table 2, below, summarises the monetised annual recurring costs of options 2 and 3. In addition to these are the monetised one-off transition costs mentioned in paragraphs 106 and 118-119.

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have been estimated to be double that of option 2, the unit costs for option 3 for the practices have also been doubled, that is between £540 and £800.

[39] Using the same cost for time as before, that half a day for 2 people cost £336, then half an hour for one person is estimated at £21. For 8000 NHS practices this totals £168,000. Again for option 3 we have estimated that it might take twice as long so the cost of £42, which for 680 NHS practices offering sedation services is £28,560.

[40] In option 2 the one-off costs to the regulator are very similar to the annual costs so for the regulated practices it is assumed that they are the same as well. For option 3 the one-off costs (per unit) for the regulator are approximately four times as great for option 3 as for option 2, so we have assumed that the costs to the regulated will also be four times as great, that is between £1,100 and £1,600 per practice.

**Table 2: Monetised Recurring Costs (per annum) of options 2 and 3**

| | Option 2 | | Option 3 | |
|---|---|---|---|---|
| | **Upper** | **Lower** | **Upper** | **Lower** |
| **Costs to Regulating Bodies** | | | | |
| *Care Quality Commission* | | | | |
| Annual registration | £13.2m | £8.8m | £2.1m | £1.4m |
| Inspection | £0.4m | £0.1m | £60k | £20k |
| Enforcement | £2.7m | £1.8m | £0.5m | £0.3m |
| Dental Reference Service | -£5.3m | -£5.3m | -£0.5m | -£0.5m |
| **Total** | **£11.0m** | **£5.4m** | **£2.2m** | **£1.2m** |
| | | | | |
| **Costs to Regulated Bodies** | | | | |
| Annual registration | £3.4m | £2.2m | £0.57m | £0.37m |
| Inspection | £40k | £13k | £16k | £5k |
| **Total** | **£3.4m** | **£2.2m** | **£0.6m** | **£0.4m** |
| | | | | |
| **Overall Total** | **£14.4m** | **£7.6m** | **£2.8m** | **£1.6m** |

### *Benefits*

123. **Patient safety:** Improving patient safety is a major benefit. As a result of recent practice visits and assessments the Dental Reference Service has highlighted a number of potential patient safety issues that have increased the risk of cross infection or subjected patients to avoidable risks. Under a registration system more effective action could be taken against practices that fail to meet the registration requirements.

124. There also exist concerns that there are currently no effective systems of monitoring and enforcing decontamination and infection control particularly in private dentistry. Under registration, this would no longer be the case.

125. While the procedures carried out by practitioners covered under option 3 are potentially riskier than in option 2 it is likely that the patient safety benefits are proportionally similar as the main patient safety risk -ineffective infection control and decontamination - does not appear to be related to any particular dental intervention.

126. **Quality of service:** Having primary dental care in a registration system has the potential to increase the quality of service, as practices will have to meet acceptable levels to remain registered. This is likely to drive up quality particularly amongst the poorer performing practices and therefore the benefits of this may be proportionally higher under option 2 compared to option 3.

127. To force a significant number of dental practices to improve their service up to the acceptable level will cause some transitional compliance costs on the side of the regulated bodies but overall these transition costs are unlikely to be high as the practices have only to improve to a level that is already achieved by the vast majority of practices and so the right procedures to achieve this are known and tested.

128. **Enforcement action:** As in primary medical care, the ability to have enforceable national registration requirements in primary dental care could remove regional variations in the quality of care ensuring the same minimum levels across the country and prevent practices where such requirements are not being met. This has the potential to offer significant benefits through the improvement in the quality of care, providing that the system is

managed effectively and that areas with a scarcity of dentists are able to provide sufficient access to services of an acceptable quality.

## RISKS AND UNINTENDED CONSEQUENCES

129. All options have significant risks dependent on future outcomes that cannot be predicted with sufficient certainty.

*Risks of option 1*

130. One risk of option 1 is the continued lack of regulation of primary dental care and the potential safety implications of this.

131. This could lead to a potentially uneven playing field if dental practices are able to offer some of the same services as secondary care providers but not have to register with the regulator.

*Risks of option 2*

132. Option 2 would result in a dramatic increase in the number of providers that the regulator would be responsible for regulating. There is the risk that this would place significant burdens on the Care Quality Commission that could result in it being unable to regulate this or other aspects of the health and adult social care sector effectively.

133. There are also risks about the level that the registration requirements are set at for dental practices. Like in primary medical care, 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 is already a shortage of dental practices.

*Risks of option 3*

134. Option 3 addresses the level playing field issue mentioned above but risks discouraging dental practices from offering more complex procedures, especially if it would make up only a small part of their work and therefore the relative cost of registering would be a major barrier to entry.

## FURTHER WORK, MONITORING AND EVALUATION

135. Through the consultation period further research will be carried out with the assistance of stakeholders to refine and extend the analysis in this Impact Assessment in preparation of a final proposal Impact Assessment to accompany the secondary legislation that would be required to implement any changes.

136. Any changes that are made to the scope of registration would be monitored and evaluated to ensure that they achieve their desired objectives and that any risks are mitigated and minimised where possible.

# 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** | **No** |
| **Small Firms Impact Test** | **No** | **No** |
| **Legal Aid** | **No** | **No** |
| **Sustainable Development** | **No** | **No** |
| **Carbon Assessment** | **No** | **No** |
| **Other Environment** | **No** | **No** |
| **Health Impact Assessment** | **No** | **No** |
| **Race Equality** | **No** | **No** |
| **Disability Equality** | **No** | **No** |
| **Gender Equality** | **No** | **No** |
| **Human Rights** | **No** | **No** |
| **Rural Proofing** | **No** | **No** |

# Annexes