| Title: | Impact Assessment (IA) |
|---|---|
| **Consultation on proposed changes to regulations for Care Quality Commission registration** | **IA No:** 6011 |
| **Lead department or agency:** Department of Health | **Date:** 15/04/2011 |
| **Other departments or agencies:** Department for Education, Ofsted | **Stage:** Consultation |
| | **Source of intervention:** Domestic |
| | **Type of measure:** Secondary legislation |

# Summary: Intervention and Options

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

Under the Health and Social Care Act 2008, CQC operates a regulatory framework that is intended to be coherent, proportionate to risk, a fair playing field, and cost effective.These objectives were covered in previous impact assessments. Implementation of the framework has identified that in some areas of health and social care regulation these objectives have not been met. In some areas further regulation is required due to asymmetric information and risks to health, and as regulation is a public good government intervention is required. In other areas clarification is required due consistency issues, or less regulation is required due to unnecessary burdens.Government intervention is required to make these legislative amendments to meet the original objectives and streamline regulation.

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

The objective of this review is to improve the regulatory framework, so that it better meets the original policy objectives; is more coherent and consistent, more proportionate to risk, promotes a fair playing field for providers, and removes the burden of regulation where it is not justified.

The proposed changes to the regulations will make them fairer, and allow CQC to be more focussed on where it can address the greatest risks to patients and people who use services - having more impact on the quality of care in those areas, removing the burden of regulation where it is not appropriate, providing a better assurance of safety and quality of care and better value for money.

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

Option 1: Do nothing - this would fail to meet the original objectives of a coherent, proportionate to risk, fair and cost effective framework. Some lower risk providers would continue to be subject to unjustifiable burdens, while some higher risk activities, and their providers, would remain unregulated.

Option 2 (preferred option): Implement all the proposals - this would address the most pressing issues around the regulatory framework for health and adult social care. Taken as a whole these proposals have an aggregate effect of making the framework more consistent, coherent, proportionate to risk, fair, and cost effective.
The marginal costs and benefits (the differential impacts) of Option 2 compared to Option1, do nothing, are assessed in this impact assessment.

| | |
|---|---|
| **Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 4/2014 | |
| **What is the basis for this review?** PIR. **If applicable, set sunset clause date:** Month/Year | |
| **Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?** | No |

**SELECT SIGNATORY 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 and Evidence

Policy Option 2

**Description:**

Implement all proposals of the review of CQC registration regulations

| Price Base Year 2010 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate: £103.9m** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | 1 | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | £0.1m | | £0.6m | **£5.5m** |

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

Where the proposed amendments bring activities into regulation the key cost (mainly to business) is the regulatory burden on providers, such as CQC fees and costs of compliance. (Most of these fall on independent midwives, but are justified by the benefits). Where the proposed amendments take activities out of regulation the key costs are health gains forgone and NHS treatment costs, these are costs to society as a whole. There are no expected costs to DH or NHS central budgets-no financial impacts.

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

It is difficult to predict how a market and providers will react to changes in regulation, therefore there may be costs to businesses and society of changes that have not been captured in the above. For example, adverse incentives for providers being taken out of regulation, or adverse impact on the market if the burden of regulation is large. These potential impacts are not expected to be significant.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | 1 | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | £0.8m | | £11.8m | **£109.4m** |

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

Where the proposed amendment bring activities into regulation the key benefits are health gains and saved NHS resources, these benefit society as a whole, (most of these come from independent midwives) .Where the proposed amendments take activities out of regulation the key benefits are reduced regulatory burden on providers, through reduced fees and compliance costs. These are mainly benefits to business.

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

Some of the key benefits of the proposals are unquantifiable, such as the benefit associated with avoiding loss of research, and reducing barriers to entry in the health and social care market. The reduced burdens to some providers have not been possible to quantify and could be large (dom care).The proposals as a whole make the regulatory framework more consistent, coherent, risk based, and promotes a fairer playing field; this should reduce the risk of successful legal challenge to CQC and DH.

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

A discount rate of 1.5% is used for direct health (QALY) impacts. Health impacts are based on EQ5D, NHS reference costs and literature based assumptions, these are therefore necessarily subjective assessments. A key assumption throughout the analysis is the effectiveness of CQC to mitigate associated health risks in each area beyond other safeguards already in place e.g. professional regulation.

The costs of regulation are based on CQC's latest fee proposal which has been agreed, this represents the current best understanding of the burden of regulation, and for the sector considered here, this generally assumed to cover all the costs (100% cost recovery). In the absence of better information, markets are generally assumed to remain static over the appraisal period.

| Direct impact on business (Equivalent Annual) £m): | | | In scope of OIOO? | Measure qualifies as |
|---|---|---|---|---|
| **Costs:** £0.23m | **Benefits:** £1.51m | **Net:** £1.28m | Yes | OUT |

# Enforcement, Implementation and Wider Impacts

| | | | | | |
|---|---|---|---|---|---|
| What is the geographic coverage of the policy/option? | | | England | | |
| From what date will the policy be implemented? | | | 01/04/2012 | | |
| Which organisation(s) will enforce the policy? | | | Care Quality Commission | | |
| What is the annual change in enforcement cost (£m)? | | | £0 | | |
| Does enforcement comply with Hampton principles? | | | Yes | | |
| Does implementation go beyond minimum EU requirements? | | | No | | |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:** N/A | **Non-traded:** N/A | |
| Does the proposal have an impact on competition? | | | Yes | | |
| What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable? | | | **Costs:** N/A | **Benefits:** N/A | |
| Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price) | **Micro** 70% | **< 20** unknow | **Small** unknow | **Medium** unknow | **Large** unknow |
| Are any of these organisations exempt? | No | No | No | No | No |

# Specific Impact Tests: Checklist

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

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

| Does your policy option/proposal have an impact on…? | **Impact** | **Page ref within IA** |
|---|---|---|
| **Statutory equality duties**[1] Statutory Equality Duties Impact Test guidance | Yes | 44 |
| **Economic impacts** | | |
| Competition Competition Assessment Impact Test guidance | Yes | 45 |
| Small firms Small Firms Impact Test guidance | Yes | 45 |
| **Environmental impacts** | | |
| Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance | No | 46 |
| Wider environmental issues Wider Environmental Issues Impact Test guidance | No | 46 |
| **Social impacts** | | |
| Health and well-being Health and Well-being Impact Test guidance | Yes | 46 |
| Human rights Human Rights Impact Test guidance | No | 46 |
| Justice system Justice Impact Test guidance | No | 45 |
| Rural proofing Rural Proofing Impact Test guidance | No | 46 |
| **Sustainable development** Sustainable Development Impact Test guidance | No | 46 |

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

# Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

### References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

| No. | Legislation or publication |
|---|---|
| 1 | The Health and Social Care Act 2008 (and ammendments): http://www.legislation.gov.uk/ukpga/2008/14/contents |
| 2 | Care Quality Commission (Registration) Regulations 2009: http://www.legislation.gov.uk/uksi/2009/3112/made |
| 3 | The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010: http://www.legislation.gov.uk/uksi/2010/781/contents/made |
| 4 | Consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991 |
| 5 | Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations: http://collections.europarchive.org/tna/20100509080731/http://dh.gov.uk/en/Consultations/Responsestoconsultations/DH_107628 |
| 6 | Impact assessment of registration regulations made under the Health and Social Care Act 2008: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115558 |
| 7 | Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115559 |
| 8 | Consultation on proposed changes to regulations for Care Quality Commission registration (May 2011) |

### Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the Annual profile of monetised costs and benefits (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

### Annual profile of monetised costs and benefits* - (£m) constant prices

| | $Y_0$ | $Y_1$ | $Y_2$ | $Y_3$ | $Y_4$ | $Y_5$ | $Y_6$ | $Y_7$ | $Y_8$ | $Y_9$ |
|---|---|---|---|---|---|---|---|---|---|---|
| **Transition costs** | 0.1 | | | | | | | | | |
| **Annual recurring cost** | 0.5 | 0.5 | 0.5 | 0.6 | 0.6 | 0.6 | 0.7 | 0.7 | 0.7 | 0.7 |
| **Total annual costs** | 0.6 | 0.5 | 0.5 | 0.6 | 0.6 | 0.6 | 0.7 | 0.7 | 0.7 | 0.7 |
| **Transition benefits** | 0.8 | | | | | | | | | |
| **Annual recurring benefits** | 11.7 | 11.7 | 11.8 | 11.8 | 11.8 | 11.8 | 11.8 | 11.8 | 11.9 | 11.9 |
| **Total annual benefits** | 12.5 | 11.7 | 11.8 | 11.8 | 11.8 | 11.8 | 11.8 | 11.8 | 11.9 | 11.9 |

* For non-monetised benefits please see summary pages and main evidence base section

# Evidence Base (for summary sheets)

## Policy Background

1. The safety and quality of health and adult social care providers has been regulated for a number of years. The purpose of system regulation (which is separate to professional regulation and the regulation of medical devices) is to protect patients and people using services by providing assurance that essential levels of safety and quality are met. System regulation ensures that key systems and processes are in place to protect service users, premises and equipment are clean and maintained, and ensures staff are suitably skilled and experienced. The Care Quality Commission (CQC) was established under the Health and Social Care Act 2008 as the independent regulator of health and adult social care, with the role of providing assurance of essential levels of safety and quality of care or treatment. CQC took over this role from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission on 1 April 2009. CQC forms part of the wider quality framework, having responsibility for:

- providing independent assurance and publishing information on the safety and quality of services;
- registering providers of regulated activities (including NHS, adult social care and independent sector healthcare providers);
- monitoring compliance with a set of registration requirements;
- using enforcement powers (if necessary) to ensure service providers meet requirements;
- assessing the performance of providers and commissioners;
- undertaking special reviews of particular services at a national level, looking across providers and commissioners of health and adult social care;
- monitoring the use of the Mental Health Act; and
- helping manage the impact of regulation on service providers and commissioners.

2. Under the Health and Social Care Act 2008, all providers of regulated health or adult social care activities are required to register with the Care Quality Commission. In order to be registered, providers have to meet and continue to meet a set of 16 essential requirements of safety and quality that are set in regulations. The regulated activities and the registration requirements are set out in The Care Quality Commission (Registration) Regulations 2009 and The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. The regulations also establish some offences and procedural arrangements.

3. The 16 registration requirements reflect the essential levels of safety and quality of care that people should be able to expect, and are built around the main risks inherent in the provision of health and adult social care services.

4. Failure to comply with the requirements is an offence, and under the 2008 Act, CQC has a wide range of enforcement powers that it can use where a provider is not compliant. These include issuing a warning notice that requires improvement within a specified time, prosecution, and the power to cancel a provider's registration, removing its ability to provide regulated activities.

5. The original decisions on which services would require registration were informed by analysis of:

- the risk of harm to people, after taking into account any protections offered by other regulatory or management and governance systems;
- how much system regulation would effectively reduce those risks; and
- the burden of regulation for both providers and the regulator.

6. Research evidence was used together with discussions with regulators, experts, stakeholders and responses to formal consultations to help us assess the costs and benefits of system regulation for each activity under consideration.

7. **The evidence base of this impact assessment is structured as follows**:

Section A: Definition of the underlying problem and rationale for government intervention

Section B: Policy objectives and intended effects

Section C: Description of the Options

Section D: Costs and Benefits Assessment of the Options (including specific impacts)

Section E: Equality Impact Assessment & Summary of Specific Impact Tests

Section F: Summary and Conclusion

# A. The underlying problem

8. Before the introduction of the new regulatory framework in 2010, the existing regulatory framework was becoming fragmented and inconsistent with a variety of different sanctions and enforcement procedures. This regulatory framework was based on the type of provider, and establishment or agency rather than the kind of care being delivered. This meant it was not flexible enough to cope with the increasing pace of change in the delivery of services and new forms of care, leading to inconsistencies and giving rise to a situation in which a particular kind of care might be regulated in some settings but not others.

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

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

The new framework was introduced for health and social care providers during 2010. Key features of the regulatory framework are:

- consistency across health and social care providers from both independent and public sectors;
- a single set of registration requirements across both health and social care;
- providers required to manage key risks to the safety, quality and governance of the care they provide;
- registration requirements address the concerns of people using health and social care services;
- clarity about what is required to deliver essential levels of safety and quality;
- an extensive and flexible range of enforcement powers.

10. The Government is committed to keeping all regulatory requirements under review, to keep the burden of regulation to a minimum while providing assurance about the safety of services. When the regulations were made, a commitment was made to carry out a full review of the operation of the regulations that underpin the registration system within three years. As a first step, we have undertaken an initial review of the regulations that underpin the registration system. This review aims to:

- consider issues that have emerged with the practical operation of the registration system by the Commission
- correct oversights in the drafting of the regulations and possible unintended interpretations of the regulations that have come to light following implementation
- tackle issues it was not possible to resolve in advance of the regulations being made

- ensure consistency across the regulatory system and that the requirement to register appropriately reflects the risks to service users
- consider the opportunities for streamlining the existing requirements, thus reducing the burden.

11. The current review has established that there are a number of areas where the underlying objectives have not been effectively met by the regulations. These fit into the following categories:

- ***Unnecessary Burden***: We have reviewed the regulations in the light of the Government's commitment to streamline requirements and reduce the burden of regulation. We have identified a number of areas where an unnecessary burden on providers and/or the regulator should be removed.
- ***Previous Commitments***: At the time of making the regulations, there were a number of areas that a decision about whether an activity should be regulated could not be taken without more consideration or more development work within the sector.
- ***Unintended Consequences***: Following implementation of the new regulatory framework, we have been working with CQC to consider how the regulations work and issues that have emerged with the practical operation of the system. This has resulted in a number of proposals to revise the regulations to correct unintended consequences that have come to light, correct oversights in the drafting of the regulations, make technical amendments to ensure clarity, and ensure consistency across the regulatory system that appropriately reflects the risks to services users.

12. The above issues mean that there are some areas where there are providers that are providing relatively risky activities but are currently excluded from registration with the CQC. This means that people who use those services are not provided with the assurance of safety and quality that the Care Quality Commission was established to provide. There are also areas where registration with CQC is an unnecessary burden that is not proportionate to the benefit of CQC regulation and could be adversely affecting the market. Given these issues, the current regulatory framework requires amendment to ensure the intended effects of DH policy of better care and better value for all are delivered.

13. The review we have carried out so far, through discussion with CQC and policy leads across the Department, identified a number of issues where change might be considered. We then reviewed the list of potential issues against a set of criteria based on:

- how far does the proposal address the risk of harm to service users;
- how much the proposal would change the burden on CQC and providers;
- whether the proposal would clarify arrangements for registration
- whether we were in a position to make a change.

14. Further work, including discussion with policy leads and external bodies, and that carried out as part of this impact assessment identified some issues where a change to regulations was not appropriate. The full list of areas to which amendments to the regulations we are now intending to propose in public consultation is below; these are the areas where we are proposing to change regulations.

- *Unnecessary Burden*: Areas where the burden of regulation could be reduced

| |
|---|
| Fitness of providers (partnerships requirements) |
| Diagnostic and screening procedures |
| Research bodies carrying out diagnostic tests |
| Air ambulance operators |
| Format of Statutory notifications |
| Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home |

- *Previous Commitments*: Areas where we made a commitment to make changes (and we are now able to propose changes)

| |
|---|
| Independent midwives |
| Mixed practice medical practitioners |

- *Unintended Consequences and Oversights*: Areas where oversights have become clear since implementation

| |
|---|
| Surgical sterilisation and sterilisation reversal |
| Absence without authorised leave notifications to CQC |
| Exemption for the Olympics and Paralympics |
| Minor clarifications and technical amendments |

15. These issues are described in more detail in Table A1 below.

**Table A1: The underlying problem by area requiring amendment**

| |
|---|
| ***Unnecessary burden of regulation*** |
| **Fitness of providers (partnerships requirements)** |
| At present all the partners in a partnership must individually meet a range of requirements to demonstrate that they are a fit person[1] and have the necessary skills and experience to provide the regulated activity.<br><br>A legal partnership may, in practice, include partners who have little or no day to day involvement in carrying on the service and who do not therefore need to have the skills and experience required to run a regulated activity. This is particularly the case in social care. In many partnerships, individuals will have a range of skills and experiences that will together combine to produce a partnership that can offer a good quality service. Under the current regulation these partnerships are excluded from the market. |
| **Diagnostic and screening procedures** |
| Any provider carrying out any of the services listed in the regulations under the regulated activity of diagnostic and screening procedures must be registered in order to provide that activity. When the regulations were drafted an attempt was made to exclude any procedures where the risk of harm to the person using the service was relatively low in order to avoid bringing providers into registration unnecessarily. However, since then a number of issues have been raised:<br><br>(a) Lower risk activities – some relatively minor procedures currently trigger the requirement to register with CQC although the risk of harm is not sufficient to justify the burden of regulation.<br><br>(b) Registered providers also carrying out diagnostic and screening procedures must be registered for each regulated activity that they carry out, creating an unnecessary burden in some cases.<br><br>(c) Providers specifically exempt from registering for treatment of disease, disorder or injury may still need to register for diagnostic and screening procedures even where the risk of harm is not sufficient to justify the burden of regulation.<br><br>(d) High street hearing aid providers – it was intended that these providers should be excluded from the requirement to register. However, they may need to register where they use equipment to take physiological measurements.<br><br>(e) The use of ultrasound in in-vitro fertilisation (IVF) clinics results in a requirement for the clinic to register with CQC even though the Human Fertilisation and Embryology Authority (HFEA) already oversees the skills and qualifications of staff. |
| **Research bodies carrying out diagnostic tests** |
| The focus of the registration system is on the needs of patients and of service users. Providers of research carried out on patients to determine whether a treatment or procedure is effective on an illness or disorder they are suffering from are required to register if that research involves a regulated activity. However, because there is not a distinction in the regulations between diagnostic and screening procedures carried out for the purposes of treating a patient and those carried out for other purposes, the regulations currently require some non-patient treating research bodies to register with the CQC, if that research involves a regulated activity. Consequently, research bodies carrying out these procedures on volunteers, including where the research is not part of the individual's care or treatment, must be registered with CQC. This is an unnecessary burden |
| **Air ambulance operators** |

[1] The regulations require that they are a fit person and provide that a fit person involves meeting requirements including (a) of good character, (b) physically and mentally fit and with the necessary qualifications and experience, and (c) able to provide the details required in Schedule 3 to the regulations.

At present, the wording of the regulations does not take into account the differences in provider models in the air ambulance sector and the requirements for providers who use aircraft to register with the Civil Aviation Authority (CAA). Some providers of aircraft ambulances provide transport services only, for which they are already regulated by CAA. CQC has attempted to resolve some of the confusion through guidance. It is still necessary to amend the regulations if we are to avoid duplicating CAA requirements.

The CAA currently regulates the air worthiness of the aircraft and the skills and training of the pilots. CAA regulations include such things as number of passengers, type of passenger, training of pilot, policies and protocols that the pilot is required to follow, maintenance of the aircraft, where and when the aircraft is permitted to be flown, the type of fabric and material used within the aircraft and the type of equipment that may be carried on board. These requirements are very similar in their application to the CQC registration requirements.

**Format of statutory notifications**

Providers are required to notify CQC of a range of events that might indicate that a provider is not meeting essential levels of safety and quality. At the moment regulations do not give CQC the power to specify the format that such notifications should take. Providers are therefore able to return this information in any format.

Providers preparing information submitted to the CQC must take time to create their own format to ensure the right information is submitted and the variety of formats makes the analysis of this information inefficient and time-consuming. If CQC could specify the format for such information this would make it easier for providers to be clear about what needs to be supplied and would help CQC to process the information more efficiently.

**Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home**

While domiciliary care agencies are required to register, where a person is arranging their own personal care with no involvement by an agency, the person they engage does not have to be registered in order to provide their care. That allows greater choice for the person to make whatever arrangements suits them best. This freedom does not apply to independent user trusts, parents or carers arranging care for someone unable to arrange their own care.

We are concerned that the burden on these providers is likely to have an adverse effect on the provision of care because of the financial costs and the additional bureaucracy, that outweighs the assurance of safety provided by regulation. Conversely, the burden of registering agencies or care arranged by the NHS or local authorities is relatively low.

Furthermore, as providers of personal care in the place where the person is living at the time the care is provided should be registered with CQC the regulations are open to interpretation over whether providers of personal care to a person who is on holiday are required to register. Where organisations only operate for a short holiday period, there may be an unnecessary burden on the providers and regulation may not provide any assurance of safety and quality.

***Previous Commitments***

**Independent midwives**

Providers of midwifery services are required to register with CQC. However, there is an exemption from this requirement in the case of midwifery services provided by an individual independent midwife solely providing care in a woman's own home.

This exemption was put in place in 2010 with the intention of giving the sector time to prepare for registration from 2011/12. Registration was delayed despite the risks identified to service users as it was recognised that the sector was not yet sufficiently prepared for regulation. A permanent exemption would not be consistent with proportionate risk based regulation.

**Mixed practice medical practitioners**

There is an inconsistency in the way that the private practice of medical practitioners is registered. Medical practitioners who only provide private services are currently registered with CQC. However, the private practice of medical practitioners who also work for the NHS is not registered with CQC in some circumstances.

The qualification for registration in these cases is based on employment status of the medical practitioner rather than the risk of the services provided. This results in the same services provided privately being registered in some circumstances but not in others.

***Unintended Consequences and Oversights***

**Surgical sterilisation and sterilisation reversal**

Only surgery carried out for the treatment of disease, disorder or injury or for cosmetic purposes or for the purpose of religious observance is within the scope of registration when carried out by a healthcare professional. Surgical sterilisation and sterilisation reversal is therefore excluded from the requirement to register. Although most providers of sterilisation are registered for the provision of surgery for other reasons, this does mean that providers that only undertake this sort of surgery are not required to register with CQC.

Surgical sterilisation and sterilisation reversal carries the same risks as other surgical operations regarding competence of staff, suitability of setting and cleanliness. Its exclusion was an oversight in the drafting of the regulations rather than a deliberate policy position and it is clearly a procedure that carries a high enough risk to justify regulation by CQC.

**Absence without authorised leave notifications to CQC**

The Care Quality Commission (Registration) Regulations 2009 introduced a new requirement for providers registered under the Health and Social Care Act 2008 to notify CQC about unauthorised absences from hospital of people detained or liable to be detained under the Mental Health Act 1983. It has become apparent that there is duplication with the the the mental health minimum data set (MHMDS).In addition, 70% of notifications relate to general mental health wards where the risk associated with an unauthorised absence in relatively low. As such these notifications represent a disproportionate burden. For the remaining 30% of absence notifications, their value as an indicator of provider quality could be improved if they always included information on the length of absence.

**Olympics and Paralympics**

When the regulations were drafted it was a clear intention to exclude healthcare services provided as part of the Olympics (see 2009 consultation response ref. 5 above). The regulations exclude services that fall within the definition of the “treatment for disease, disorder or injury” regulated activity for all one-off sporting events. However, services that fall within other regulated activities are not excluded.

It has now become clear that the Olympics Authority will provide services that fall within a range of regulated activities and that there would therefore be a need to register for those that are not “treatment for disease, disorder or injury”. However, as it has previously been established (See 2009 consultation response ref. 5 above), it would not be practical for the Commission to register such a short-lived service provider which will already be subject to stringent security measures.

**Minor Clarifications and Technical Amendments**

We have been informed that at times the regulations are not entirely clear in some areas and that there is some resulting ambiguity about which providers need to register. In addition, the treatment of providers has been shown to be inconsistent in places. We have looked at the following issues:

- Use of ambulances within events – although first aid and treatment at events is excluded from the requirement to register, there remains a requirement for ambulances that transport an individual from the accident site to the treatment facility to register even if that transport takes place only in the event site itself.
- Second Opinion Appointed Doctors – the regulations require clarification to make clear that there is no requirement for them to register.
- Medical and/ or dental services – the exemptions in relation to insurance provision and occupational health were intended to include all such healthcare services but there has been a question raised as to whether or not dental services have been successfully exempted.
- Consent requirement for those unable to consent - the drafting does not take account of situations when a person lacks capacity to consent.
- Low risk occupational health exemption- the drafting does not take account of low risk occupational health for hospital staff
- Manufacture of blood products-the drafting needs to be made clearer that those not providing care to patients are exempt.
- Enforcement- the drafting of “defence” needs to make clear that the provider would need to prove they had taken all reasonable steps to comply with the requirements, and a change in the notice requirement is needed to enable the prosecution of major one off breaches.

16. There have already been a number of impact assessments on this area of policy including:

- The impact assessment for the Health and Social Care Act 2008, which explored the costs associated with merging the three predecessor organisations into the Care Quality Commission.
- A partial impact assessment of bringing primary care providers into regulation was published at the same time as 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* in March 2008.
- An impact assessment was published with the document *Response to the consultation on the framework for the registration of health and adult social care providers and consultation on draft regulations* in March 2009
- An impact assessment which considered the costs and benefits of the registration regulations made under the Health and Social Care Act 2008 was published in October 2009
- An impact assessment which considered the cost and benefits of requiring primary medical and dental care providers to register with CQC in October 2009.

17. The role of the government in the regulation of health and adult social care in England, and CQC as that regulator has been previously justified in prior policy development and impact assessments, and for the purpose of this impact assessment is taken as given. This impact assessment is not seeking a change to the role of the government in health and adult social care regulation in England or the principles behind it. This impact assessment is considering proposed amendments to the regulations, implemented through secondary legislation, to address issues that have been highlighted that do not fulfil the previously agreed policy objective of a coherent, risk based, fair and cost effective regulatory framework. The proposals, which are subject to a formal 12 week public consultation, address issues where:

- an unnecessary financial and bureaucratic burden is placed on providers, including many small businesses. Removal of the burden will allow those providers to use their resources more effectively, to provide better services.
- some providers of high-risk activities that are not currently regulated will be brought into regulation, and therefore, for the first time, have to demonstrate that they meet the essential requirements of safety and quality.

18. In **only two** of the individual proposals (**surgical sterilisation providers** and **independent midwives**) some providers will be brought **into CQC regulation** due to the risky nature of the services they provide. Asymmetry of information between health and social care providers and consumers, and the potential incentives for providers to provide sub optimal care means in some respects there may be market failure that could be addressed by independent regulation. Regulation of health and social care is a public good, and as such, the market does not always naturally provide it, and has not done so in these areas, hence government intervention is required. The consultation asks if there any alternatives to CQC regulation that would provide an appropriate assurance of safety and quality in these sectors. [Questions 19, 20, 23 and 24]
19. For the **majority** of proposals, some providers will be brought **out of CQC regulation** due to the unnecessary burden it is placing on the system or the unfair playing field it is creating in the market. For the remainder of the proposals, there is no expected change in the number of providers subject to regulation, only minor clarifications of who is in or out is required. As the regulatory framework is implemented through secondary legislation, addressing the above issues requires amendments to legislation and therefore government intervention is required.
20. Some of the issues we have identified above impact more heavily on certain groups. For example, the current exclusion for independent midwives has a disproportionate effect on women. Another example is the proposal around domiciliary care. In the current regulations, a person arranging their own care is able to engage a non-regulated provider should they choose to. Extending this freedom to care arranged by parents, carers and independent user trusts will have a disproportionate effect on people with a disability. These issues are discussed further in the equality impact assessment, see section E below.

# B. Policy objectives and intended effects

21. The objective of this review is to streamline regulatory requirements, deliver previous commitments, and address unintended consequences. This will improve the regulatory framework,

so that it better meets the original policy objectives; **more coherent, more consistent, more proportionate to risk, fairer and removes unnecessary burden where it is not justified.**

22. As discussed above, our initial review of the implementation of the regulatory framework has established that there are a number of areas where the underlying objectives have not been effectively met by the regulations. As a result, there are some areas where there are providers that are providing relatively risky activities but are currently excluded from registration with the CQC. This means that people who use those services are not provided with the assurance of safety and quality that the Care Quality Commission was established to provide. There are also areas where registration with CQC is an unnecessary burden that is not proportionate to the benefit of CQC regulation and could be adversely affecting the market, risking legal challenge. Addressing these issues, by amending the regulatory framework, in line with the original policy objectives, will lead to the ultimate intended effects of: **better care, better value, for all.**

23. Patients and people who use services want to know that the services they use are safe. The key objective of regulation by the Care Quality Commission is to provide an assurance of essential levels of safety and quality for health and social care services in England. All health and social care activities involve some risk to the patient or person using the service. In order for the burden of regulation to be justified, it must be effective, and proportionate to risk. In order to achieve that objective the scope of registration should be focussed on those activities where the risk is enough to justify the burden of regulation and system regulation effectively mitigates that risk. The review established that the framework requires amendments in order to achieve this objective.

24. As discussed in the previous section, the amendments are required to the regulations in order to meet the original policy objectives. Each proposal has been considered in the light of the policy objectives and the intended effects. This is summarised in Table B1:

Table B1: Policy objectives and intended effects by area requiring amendment

| |
|---|
| **Fitness of providers (partnerships requirements)** |
| Objective: To remove unnecessary market barriers and promote a fairer playing field.<br><br>Intended Effects: Better value and better care |
| **Diagnostic and screening procedures** |
| Objective: To remove the unnecessary burden, where CQC regulation is inappropriate or duplicates.<br><br>Intended Effects: Better value |
| **Research bodies carrying out diagnostic tests** |
| Objective: To remove the unnecessary burden, where CQC regulation is inappropriate or duplicates.<br><br>Intended Effects: Better value |
| **Air ambulance operators** |
| Objective: To remove the unnecessary burden, where CQC regulation duplicates CAA regulation.<br><br>Intended Effects: Better value |
| **Format of statutory notifications** |
| Objective: To simplify the process.<br><br>Intended Effects: Better value |
| **Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home** |
| Objective: To remove unnecessary burden of the regulation of personal care arrangements<br><br>Intended Effect: Better value, more freedom of choice and personalised care for people who use services |
| **Independent midwives** |
| Objective: To make system regulation across midwifery more consistent and proportionate to risk<br><br>Intended Effect: Better care for all regardless of the provider of midwifery services. |
| **Mixed practice medical practitioners** |
| Objective: To make regulations more consistent across different sectors, regardless of employment patterns, and to promote a fairer playing field. |

| |
|---|
| Intended Effect: Better care for all regardless of employment patterns of providers and better value for all though promoting a fairer playing field in the market for private health care. |
| **Surgical sterilisation and sterilisation reversal** |
| Objective: To make regulation of all surgical procedures more coherent, consistent and proportionate to risk.<br><br>Intended Effects: Better care |
| **Absence without authorised leave notifications to CQC** |
| Objective: To remove unnecessary burden of notifications where the associated health risk is relatively low and improve the value of notifications where the associated health risk is relatively high.<br><br>Intended Effect: Better care and better value |
| **Olympics and Paralympics** |
| Objective: To remove unnecessary burden of registration for a short-lived service where regulation would not add benefit.<br><br>Intended Effect: Better value |
| **Minor Clarifications and Technical Amendments** |
| Objective: To clarify the regulations to ensure they can be effectively implemented.<br><br>Intended Effect: Better care and better value |

# C. The Options

## Option 1: Do nothing

25. Option 1, doing nothing, would leave the current scope of registration in place, and this would fail to meet the original objectives of a coherent, proportionate to risk, fair playing, and cost effective framework. The issues outlined in the previous sections would remain.
26. Failing to address these issues would mean that some providers would continue to be faced with fees and administrative costs (sometimes duplicated by other regulatory or oversight systems) with little benefit for people who use services. Whilst at the same time, some providers of high-risk activities (eg surgical sterilisation and independent midwifery services provided at home) would continue to be outside of regulation by CQC, and users of those services would, therefore not have the assurance of safety and quality that the framework has been put in place to provide.
27. **The costs and benefits of Option 1, do nothing, are implicitly evaluated in this impact assessment, as it is the marginal costs and benefits of Option 2 over Option 1 that are evaluated in Sections D and E.**

## Option 2: Implement all proposals of the review of CQC registration regulations

28. The review originally identified around 60 issues where change might be considered. In order to make the current task manageable, we reviewed the list of tasks against a set of criteria based on:

- how far does the proposal address the risk of harm to patients. This was seen as the key criteria, because there is a risk that high-risk activities could be left without the assurance of safety and quality that is in place for similar risky activities, potentially putting people at risk of harm that could be mitigated;
- how much the proposal would change the burden on CQC and providers. This was seen as important because of the risk that providers have a considerable burden, in both money and administration terms, that is not justified by the amount that any risk is mitigated, and the effect that has on costs of care and the market;
- whether the proposal would clarify the arrangements for registration. This was also seen as important because CQC could not be effective if the regulations were not legally robust enough for CQC to take effective enforcement action without successful challenge in court; and
- whether we were in a position to make a change. This was considered important because of the need to make sure the review is manageable with the resources we have, and could be carried out in a timely manner to make the changes to the regulations within an acceptable time frame.

29. Consideration of these criteria, and other work on the review has also allowed us to find alternative solutions to some of the issues we identified. This has left us with a short list of pressing issues that are considered here for this public consultation, with a view to laying draft regulations later in the year.

30. **Option 2: implementing all the proposals**, would address the most pressing issues around the regulatory framework for health and adult social care. Taken as a whole these proposals have an aggregate effect of meeting the original policy objectives and making the framework more consistent, coherent, proportionate to risk, fair, and cost effective. This option would resolve the key issues with the current framework that were outlined in the previous sections. This is the preferred option.

31. Each individual proposal is outlined in Table C1 below, and the marginal costs and benefits of each over the do nothing (Option 1) are considered in Section D:

Table C1: Policy proposal by area requiring amendment

| |
|---|
| **Fitness of providers (partnerships requirements)** |
| The proposal is to retain the requirement for the registered person to be "fit" but to amend the regulations so that where the provider is a partnership, the partnership as a collective body needs to have the relevant skills and experience, rather than these being held by each individual partner. |
| **Diagnostic and screening procedures** |
| The proposal is to change the regulations in order to meet two main objectives:<br>• removing the bureaucratic burden on providers already registered; and<br>• avoiding unregulated providers from being brought into regulation where they are only brought into regulation because of carrying out a procedure where the risk of harm is not enough to justify the burden of regulation, and CQC regulation would have little or no benefit. |
| **Research bodies carrying out diagnostic tests** |
| The proposal is to amend the regulations to remove the requirement to register providers that are only carrying out research using diagnostics and screening procedures that are not part of a person's care or treatment. |
| **Air ambulance operators** |
| The proposal is to amend the regulations to exclude organisations that solely provide the aircraft transport part of the service and are regulated by CAA. The provision of treatment would still need to be registered, as would any other regulated activity being provided. |
| **Format of Statutory notifications** |
| The proposal is to introduce a power for CQC to specify a standard format for statutory notifications. This would be applied to all providers. |
| **Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home** |
| The proposal is to remove the requirement for providers of care arranged by IUTs, parents or carers to be registered with CQC. This would leave domiciliary care provided by an agency, or arranged by another body (eg local authority, NHS) within regulation. At the same time, anyone arranging care would still be able to choose to use a registered provider if they felt that was the best for them.<br><br>The proposal is also to make changes to the regulations to make clear that providers of personal care should be required to register whether provided in a person's own home or in a holiday setting where the combined length of care periods offered totals more than 4 weeks within a 12 month period. |
| **Independent midwives** |
| The proposal is to remove the exemption from registration for independent midwifery care. |
| **Mixed practice medical practitioners** |
| The proposal is to amend the regulations to reframe the exemption so that it applies consistently to all medical practitioners working for a registered provider. |
| **Surgical sterilisation** |
| The proposal is to change the wording of the surgical procedures activity regulation. |
| **Absence without authorised leave notifications to CQC** |
| The proposal is to amend the regulations so that notifications to CQC of absences from general mental health wards is no longer required but require notifications of absence from more secure wards to include the date of the service user's return. |
| **Olympics and Paralympics** |
| The proposal is to excluding all medical services provided as part of the Olympics and Paralympics. |

| **Minor Clarifications and Technical Amendments** |
|---|
| The proposal is to amend the regulations to clarify some minor points in the wording of the regulations. |

32. The consultation asks whether consultees agree with these proposed amendments, and where extending regulation is considered (sterilisation and independent midwives), if there are any alternatives to consider. [Questions 19,20, 23 and 24]

### Alternative plausible options

33. Apart from the preferred option (where we have selected those issues that we are in a position to address and are most pressing) and the do nothing option, we could have included an option to address the full list of issues we identified as part of this review. However, attempting to address all the issues would have delayed addressing those that are most pressing. We are committed to a full review of the regulations to a longer timescale which will seek to resolve all of the issues we have identified, allowing more time to carry out further impact assessment and stakeholder engagement.
34. We have also considered taking forward only some, or various combinations, of the issues that are included in this proposal. However, the set of proposals as a whole have an aggregate effect of making the whole framework more coherent, consistent, and proportionate to risk, while removing the regulatory burden from some providers where it is not justified. Our view is that all of the proposals contribute to the overall policy objective and are manageable within the context of this review.
35. Where the proposal is bringing provider into regulation, the consultation asks whether there are any other plausible alternative to options 1 and 2 [Question 5].

## D. Costs and Benefits of Option 2

36. This section considers the costs and benefits of the preferred option 2, marginal to the do nothing option 1. First, the costs and benefits of each proposed amendment to the regulations are considered in turn, and then the costs and benefits of option 2 as a whole are brought together in a key summary of the economic impact of the policy proposal overall.
37. This consultation asks whether the assessment of costs and benefits below is reasonable and whether there is any other evidence available to inform this policy. [Questions 1 and 32]

### General Assumptions and Information

38. There are some key assumptions and information that will apply throughout the analysis of the individual proposals, that are outlined here.

CQC registration Requirements

39. When a provider is required to register for CQC regulation, they must comply with the 16 registration requirements as set out under paragraphs 8 to 24 Part 4 of The Health and Social Care Act 2008 (Regulated Activities) Regulation 2010, as summarised in the below table.

Table D1: CQC registration requirements

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

40. This analysis depends on assumptions about the effectiveness of CQC regulation, thus requiring providers of regulated activities to meet the above registration requirements, in further mitigating health risks over and above other regulations and standards.

Costs of Regulation

41. Table D2 below sets out the main assumptions around the costs of CQC regulation

Table D2- Costs of CQC regulation

| | | |
|---|---|---|
| **Annual fee** | £1,500 for "other" non-NHS providers with single location.<br>£8,500 for non-NHS hospitals with single location.<br>£250-£1000 for adult social care | Fee varies depending on number of locations. Payable from first year of regulation. |
| **Extending regulation** | Normal annual fee applies for every activity that requires the provider to register for a NEW regulated activity under Schedule 1. | No fee for extending regulation ONLY when the activity in question falls within a regulated activity that the provider is already registered for (example: surgical procedures activity definition extended to encompass sterilisation, would not lead to an additional fee) |
| **Initial compliance costs** | £4200 doctors / clinics<br>up to £38,850 for a hospital<br>£1070 social care | Assumption taken from the Primary Care IA (2008/09) and inflated to 2010/11. This compliance costs was estimated for first-time regulation of small private providers. See Primary Care IA for more details. |
| **Annual inspection costs** | £390 doctor / clinic<br>£780 hospital<br>£470 social care | Reference - as above (Primary Care IA).<br>This assumes that the inspection takes approximately 1/2 of a day and is carried out on a risk-based approach for 10% of providers (20% for dental care providers).The cost covers costs beyond just monetary impact. |
| **Cost Recovery** | Assumed to be 100% for the proposed amendments | Where cost recovery is 100%.The annual fees should reflect all regulatory costs, as CQC is meant to "break even", so all CQC expenses resulting from regulating a provider should be covered by the annual fee. No changes in DH Grant in Aid to CQC is expected as a result of these changes. |

Accounting for distribution of impacts, opportunity and marginal costs

42. Where there is enough information about those affected by the impacts of the proposals adjustments are made to reflect more accurately reflect the economic cost to them:

- Impacts on the Exchequer are multiplied by 2.4 to reflect the opportunity costs of resources; DH uses the assumption that at the margin £1 of NHS or Exchequer resources can yield £2.4 worth of benefit.
- Impacts on self-employed private individuals are split into income tax implications (where applicable) and impacts to the individual. Tax implications are an Exchequer impact thus multiplied by 2.4 and individual impacts are attached a weight to reflect that the marginal value of a £1 is relative to the income bracket of that individual.
- Impacts on profit making companies are split into corporation tax implications (where applicable) and impacts to the business. Tax implications are Exchequer impact thus multiplied by 2.4. Where there is little information about the provider organisation no income distribution considerations are made, and they are thus assumed to be at the median.
- Where there is little information about providers, and/or a wide variety of providers are affected by a proposal, no tax or income distribution considerations are made. In these cases some providers could be charities, some could be non-profit, some could be PLCs, some could be individuals etc.

## Fitness of Provider Partnerships

43. Under the current CQC registration requirements, under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, Part 3, Para 4, each partner within a partnership must satisfy the requirements of an individual provider in order to provide a regulated activity. Option 2, the proposal, is to amend the above regulation legislation to state that a provider partnership collectively, rather than individually, must meet the requirements.

44. CQC estimates that there are 1200 dental provider partnerships and 1800 social care provider partnerships currently registered. When primary care comes into regulation in April 2012 CQC estimate that there will be 6500 GP provider partnerships. There is no data on how many potential provider partnerships are currently being excluded from the market due to this regulation requirement.

45. It could be argued that few dental and GP partnerships would consist of non-practising healthcare professionals, and thus there may be few potential partnerships that cannot enter the market. Social care provider partnerships, may be more likely to draw on specific individual skills and attributes and bring them together. It is possible to imagine instances of provider partnerships consisting of relatives or involving a silent funding partner in relation to the provision of care and nursing homes, and thus there may be a significant number of potential providers being excluded from the market.

Benefits

46. CQC advises that this proposal will not significantly reduce the burden of regulation, but will reduce the barriers to market entry and mitigate against regulation preventing business opportunities in the health and social care market.

47. As there is no data on how many potential provider partnerships are currently excluded from the market it is impossible to estimate the extent to which the market would be opened up under this proposal. However, under the current policy direction of “any qualified provider”, it may be expected that there will be an increase in the number of provider partnerships that would benefit from this proposal.

48. Reduced barriers to market entry in the private provision of health and social care may lead to an increased supply of providers, thus increased competition and innovation which then may lead to: improved access to care, improved choice of provider, improved quality of care and improved value for money of care.

49. Given the extent of the lack of data and uncertainties involved it is not possible to quantify these benefits. This consultation may highlight benefits and evidence that are not yet apparent.

Costs

50. It is not expected that there will be any significant costs of amending this requirement.

51. There is negligible risk that this proposal would have any negative impact on the quality and safety of the provision of health and social care, requiring a partnership provider to meet the requirements collectively would mitigate no less risk than an individual meeting the requirements.

52. It could be argued that there may be a cost to current providers, who may prefer barriers to entry to remain to avoid adapting to increased supply in the market. However, this could be negligible if demand for health and social care increases with the ageing population and advances in technology.

53. Given the extent of the lack of data and uncertainties involved it is not possible to quantify these costs. This consultation may highlight cost implications, risks and evidence that are not yet apparent.

Value for Money

54. Although it is not possible to quantify the impacts, as the costs are expected to be minimal whilst there is a potential for significant benefits in the health and social care market, it is expected that this proposal will offer value for money.

## Diagnostic and screening procedures

55. At present providers are required to register with CQC to provide diagnostic and screening procedures as defined under Schedule 1, 8 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulation 2010. Under this current regulation procedures range from monitoring the neurological system to pin prick blood samples; these procedures have differing levels of risk associated with them from high to low. Option 2, the proposal, is to exempt some low risk diagnostic and screening procedures from the above regulation for those already registered for other regulated activities and avoid unregulated providers being brought into regulation only for providing certain low risk diagnostics.

56. Exempted low risk diagnostics for otherwise unregulated providers would include: taking and analysing blood through pin prick or from a vein, taking a urine sample, analysing a urine or stool sample, taking a tissue sample involving a `swab specimen` from any part of the body, or skin scrapings or nail clippings, recording of blood pressure, non-ambulatory recording of blood pressure.

57. Exempted low risk diagnostics for providers of other regulated activities would include the above and: 12 lead electrocardiography, pulse oximetry when used for the purpose of 'spot' recording, peak expiratory flow measured by a peak flow metre, spirometry when carried out for screening or non diagnostic purposes.

58. The costs and benefits of the proposal to exempt these activities, marginal to the do nothing are considered below.

Benefits

59. Providers of the above activities range from Chinese herbalists to Hospices. CQC estimates that around 1900 care homes, 330 palliative care providers and 300 Ambulance providers currently register with CQC to provide the above activities. It is not know how many other providers, such as complimentary medicine providers, are currently required to register for the above activities; there is no data but given the nature of this market there could be thousands. As a result, these providers are not included in the calculations, and the benefits may be underestimated.

60. The main benefit of this proposal is the savings to the providers of not paying the annual registration fee of £250 (social care) to £1500 (for "other" health care) to CQC. The care home, palliative care, and ambulance providers are all already registered with CQC for providing other regulated activities, so there will be no savings in initial compliance and inspection costs. The savings in reduced burden amount to around £1.4m a year (£250*1900 + £1500*(330+300)).

61. Not enough is known about the organisational form of the variety providers to reflect tax and income distribution consideration in the calculation of benefits; it is assumed that the average effect of those adjustments is neutral (some will be non-profit charities, some may be wealthy individuals).

Costs

62. There are some health risks associated with low risk diagnostic procedures the provision of which will not be regulated. These risks include: infections and cross-infections, bruising (from improper use of blood pressure diagnostic equipment), social stigma / embarrassment / mental health (insensitive treatment of personal health information), losing patients' data (resulting in delays in treatment),unnecessary referral to secondary care.

63. The non-invasive nature of most of these low risk procedures suggests that the majority of the health hazards have very low incidence rates, but minimal adverse effects with minimal severity. In addition, most of these risks are associated with incompetent use of equipment and lack of skills. It is unlikely that CQC regulation of this specific activity would mitigate any additional risks than professional regulation, and the so far identified providers are already regulated by CQC to provide other regulated activities.

64. Given the above, there are no significant expected costs of the proposal.

Value for Money

65. Table D3 below shows the estimated net present value of this proposal:

Table D3: NPV of Diagnostics and Screening Proposal

| £'000s | Year 2012/13 | Year 2013/14 | Year 2014/15 | Year 2015/16 | Year 2016/17 | Year 2017/18 | Year 2018/19 | Year 2019/20 | Year 2020/21 | Year 2021/22 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | **TOTAL** |
| Annual Fee Savings | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £14,300 |
| | | | | | | | | | | | |
| **Total Benefits (undiscounted)** | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £1,430 | £14,300 |
| | | | | | | | | | | | |
| **Total Costs (undiscounted)** | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 |
| | | | | | | | | | | | |
| **Net Present Value** | £1,430 | £1,380 | £1,330 | £1,290 | £1,250 | £1,200 | £1,160 | £1,120 | £1,090 | £1,050 | **£12,300** |

66. The above table shows that the benefits of this proposal outweigh the costs and represent value for money, with a net present value of around £12.3m, and an equivalent annual benefit of £1.3m.

## Research bodies carrying out diagnostic tests

67. At present, research bodies carrying out diagnostic tests and screening procedures are included in regulation by the Care Quality Commission, as these services fall under; "diagnostic and screening procedures involving…the use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging; the use of instruments or equipment which are inserted into the body to (i) view internal parts or (ii) gather physiological data" - Schedule 1, 8(1)(a)& (b) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

68. The remit of CQC is intended to cover provision of health and social care. Other diagnostic and screening procedures such as the removal and examination of tissues and the use of equipment to monitor physiological data are only a regulated activities where they are carried out in the treatments of disease, disorder or injury. Option 2, the proposal, is to amend the regulation by applying the same condition, and thus exempt all diagnostic and screening procedures that are not part of the provision of health or social care from CQC regulation.

69. The number of research bodies that the current regulation would apply to is at best unclear. It is estimated that there are around 90 universities, 90 medical schools and an unknown number of pharmaceutical companies.

70. The costs and benefits of the proposal, marginal to the do nothing are considered below.

Benefits

71. The underlying assumption provided by the CQC is that under the current regulation CQC would be required to close down these research bodies as they would be providing a regulated activity and yet they would not meet the registration requirements; for example… "that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe... by means of... planning and delivery of care... to meet the services user's individual needs". As a result, the main source of benefits of the proposal stem from the fact that the research produced by the providers in question has an inherent scientific and social value that would be lost under the do nothing, Option 1.

72. It is not possible to monetise the impact of the lost research, and thus the benefit from avoiding this. The outcomes may range from nothing (if it is assumed that the healthcare in the UK could copy research outcomes from abroad) to billions of pounds (if one of the research activities contributes to advancements in treatment of common diseases).

73. A second source of benefits originates from the savings in regulation compliance costs (a one-off cost of approximately £4,200 per provider), annual CQC fees (£1,500) and inspection costs (£39 per provider, assuming 10% of providers are inspected annually). Assuming 190 providers these costs amount to around £800k one off, and £290k annually. It is important to note that these benefits are realised only if no research bodies are closed down. As such, we use these benefits as a lower estimate – the assumption is that the benefits of research are much greater than the costs of regulating research bodies.

Costs

74. The main health risks associated with carrying out research can be grouped into three categories:

- The procedure itself causing health damage – mainly related to incompetence or lack of skills.
- Lack of follow-up related to health problems that were identified in volunteers –
- Problems related to the transfer of status from being a volunteer to becoming a patient – e.g. information sharing

75. The potential health loss to research participants from any of the above, due to removal of CQC regulation should be limited due to:

- low incidence rate and severity of adverse events resulting from research activities
- a high level of regulation by the various Research Ethics Committees, Medicines and Healthcare products Regulatory Agency (MHRA) and Ionising Radiation Medical Exposure Regulations 2000 (IRMER) leading to relatively low effectiveness of system regulation to reduce adverse events further.

76. The main adverse event that CQC regulation may have mitigated further may be related to lack of appropriate follow-up.

77. In order to arrive at an estimate of this cost, the following assumptions are used:

- The cost of misdiagnosis of primary care to patients was estimated at £1.80 per consultation (see sources)
- no more than 1% of British population takes part in voluntary health research (this is most likely to be an overestimate at approximately 600,000);
- no more than 5% of research participants should be referred for further treatment (once again, this is likely to be an overestimate, resulting in 30,000 research participants having underlying health problems that were discovered during the research activities);
- none of the research participants with health problems are referred for further treatment.

78. Under these assumptions, a cost estimate of forgone health benefits of CQC regulation are estimated at £55,000 per year (£1.80*30,000). This is thought to be an overestimate of the actual forgone benefit.

Value for Money

79. Table D4 below shows the estimated net present value for this proposal.

Table D4: NPV of Research Bodies Proposal

| | Year 2012/13 | Year 2013/14 | Year 2014/15 | Year 2015/16 | Year 2016/17 | Year 2017/18 | Year 2018/19 | Year 2019/20 | Year 2020/21 | Year 2021/22 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| £'000s | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | **TOTAL** |
| **BENEFITS:** | | | | | | | | | | | |
| One-off Compliance Costs | 800 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 800 |
| Annual Costs (fees and inspections) | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 2,925 |
| Total Benefits (undiscounte | 1,090 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 3,720 |
| **COSTS:** | | | | | | | | | | | |
| Lack of follow-up | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 550 |
| Total Costs (undiscounted) | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 550 |
| Net Present Value | 1,035 | 230 | 220 | 215 | 205 | 200 | 195 | 185 | 180 | 175 | **2,840** |

(note: the above table is in a constant price base of 2010/11 prices, and all costs and benefits are assumed to reduce at a rate of 3.5% a year to reflect the social time preference for resources now)

80. The above table shows that the benefits of this proposal outweigh the costs and represent value for money, with a net present value of around £2.8m, and an equivalent annual benefit of £340k. This is thought to be an underestimate of the likely benefits as the main benefit of the proposal (as identified by the fact that CQC would have to close the research bodies in question), avoided lost research, cannot be quantified and is potentially very large.

## Air Ambulance Operators

81. Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, providers of the regulated activity '*Transport services, triage and medical advice provided remotely*', are required to register with the CQC. Providers of this service include NHS Ambulance Trusts, Independent Ambulance Providers and Air Ambulance services and they are also required to register for other regulated activities they provide.

82. There are some providers that only provide air transport services and are regulated by the Civil Aviation Authority (CAA) that are required to register for CQC regulation due to the above regulation. CQC have advised that the CAA's regulation is more extensive than there own, and therefore CQC regulation represents a duplication and thus an unnecessary burden. Option 2, the proposal is to amend the above regulation so that these providers would be exempt.

83. CQC advise that there are around 6 to 8 providers, providing transport only services to air ambulance charities and some repatriation, that would be brought out of CQC regulation under the proposal.

84. The costs and benefits of this proposal, marginal to do nothing are considered below.

Benefits

85. CQC advise that this would affect around the 6-8 providers of transport services only to air ambulance charities and for repatriation services. Compared to the do-nothing option, these providers would no longer be required to pay the CQC registration fee of £1500 per annum. This would result in a total reduction in the regulatory burden of £9,000-£12,000. (In the absence of information, no assumptions are made about the income distribution of providers). As this reduced cost would presumably increase the profits of these providers, there may be tax implications of this change. Assuming marginal corporation tax of 26%, £2520-£3360 per annum would be a benefit to the Exchequer; this increased tax revenue should be multiplied by 2.4 to reflect the opportunity cost of Exchequer resources. This gives a best estimate total annual benefit of around £14,320, (£7,770 to the provider and £6,550 to the Exchequer).

Costs

86. As the current CQC regulation of transport services only where there is CAA regulation represents duplication, there are no assumed costs of making the exemption, compared to the do-nothing.

Value for Money

87. This consultation may highlight costs and risks that are not yet apparent.

Table D5: NPV of Air Ambulance Proposal

| **£'000s** | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 | Year 8 | Year 9 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2012/13 | 2013/14 | 2014/15 | 2015/16 | 2016/17 | 2017/18 | 2018/19 | 2019/20 | 2020/21 | 2021/22 | Total |
| Reduced Burden to Providers | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 7.8 | 77.7 |
| Increased tax to the Exchequer inc opportunity costs | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 65.5 |
| Total Benefits (undiscounted) | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 14.3 | 143.2 |
| **Net Present Value** | 14.3 | 13.8 | 13.4 | 12.9 | 12.5 | 12.1 | 11.7 | 11.3 | 10.9 | 10.5 | **123.3** |

(note: the above table is in a constant price base of 2010/11 prices, and all costs and benefits are assumed to reduce at a rate of 3.5% a year to reflect the social time preference for resources now. Numbers may not sum due to rounding)

88. The table above shows that it is expected that over the 10-year period the proposal would lead to a net present value of around £123.3k, with an equivalent annual benefit of £14.8k.

## Format of Statutory Notifications

89. Providers are required to notify CQC of a range of events that might indicate that a provider is not meeting essential levels of safety and quality. The regulations do not state that this must be in a format specified by CQC. As a result, providers must take time to create their own format to ensure that the right information is submitted and the variety of formats makes analysis inefficient. Allowing CQC to specify the format will make the process more straightforward for providers, and by reducing the time taken to carry out analysis will improve CQC's efficiency. It has not been possible to assess the costs and benefits in any detail, but they are not expected to be significant.

## Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home

90. At present, all providers of domiciliary care that involves personal care, as defined in the regulations, have to be registered with CQC unless the person receiving the care has arranged their own care without the involvement of an agency (there is also an exemption for care provided by a family member or friend without payment). The exemption does not apply where the care is organised by another person, for example, parents acting on behalf of their child, carers acting on behalf of a vulnerable adult or Independent User Trusts.

91. Therefore, providers must be registered if they provide domiciliary care for disabled children or vulnerable adults and are being paid to do so. However, these providers may not be aware of the requirement to register.

92. We do not know the exact number of providers affected, but it may be in the tens of thousands. In addition, it should be noted that the number of affected providers is likely to increase further as the government realises its commitment set out in the Vision for Adult Social care to ensure that by April 2013 all eligible individuals will receive a personal budget, preferably as direct payment.

93. The Department does not have any information on the number of Independent User Trusts. However, we expect this number to be small. There is also no central information about the number and nature of providers of domiciliary care away from home.

94. The proposal is to exempt domiciliary care for an individual arranged by an IUT, parents or carers without the involvement of an agency. Providers of care away from home will be exempted from regulation requirements if they provide care below an annual threshold that will be derived below.

**Domiciliary care for disabled children**

Benefits of keeping providers in regulation

95. If providers were kept in regulation, they would need to pay registration fees and would be submitted to CQC control. This would generate benefits by mitigating risks occurring in domiciliary care.

96. A provider registering with CQC must comply with 16 registration requirements (which have been outlined in Table D1). Compliance with these requirements may mitigate against hazards deriving from the fact that providers of domiciliary care usually assist their clients with activities such as toileting, washing, eating, dressing, taking or injecting medicine and checking and looking after medical equipment. These activities are either intimate or intrusive. Recipients of care are particularly vulnerable individuals who may be dependent on the care provider or may not be able to voice concerns.

97. Table D6 below considers the role of CQC regulation in mitigating the potential hazards associated with the provision of domiciliary care. We have made assumptions about the effectiveness of CQC regulation based on the nature and preventability of the hazards in questions and the degree to which they would be affected by CQC enforcement of compliance with the registration requirements.

98. It should be noted that some of the risks inherent in the provision of domiciliary care are already mitigated where parents employ friends or relatives. For instance, criminal record checks may not add any insights to parents' personal knowledge of a friend or relative. Therefore, there is less role for CQC where parents employ friends or relatives.

99. Health impacts and their duration have been derived using the EQ5D framework, assumptions and information on patient incidents from the National Patient Safety Agency. The application of EQ-5D to disabled children or vulnerable adults is not straightforward. We have adjusted EQ-5D severity estimates to account for the fact that the affected individuals do not start out from a state of perfect health.[2]

100. The likelihood of hazards is derived from academic literature. However, as there is little literature quantifying the risks in domiciliary care for disabled children, we have used appropriate proxies where necessary.

Table D6: Potential hazards of domiciliary care and the effectiveness CQC regulation

| Hazard | Likelihood per person-year | Reduction in health state | Average duration of effects (excluding long term consequences) | Effectiveness of mitigating risks if care is provided by a professional | Effectiveness of mitigating risks if care is provided by a friends or relatives |
|---|---|---|---|---|---|
| Verbal and psychological | 3.1% | 0.1 | 2 months | 2% | 1% |

| | | | | | |
|---|---|---|---|---|---|
| abuse | | | | | |
| Verbal and psychological abuse (severe) | 0.1% | 0.586 | 6 months | 5% | 2% |
| Physical abuse | 1.3% | 0.173 | 2 months | 2% | 1% |
| Physical abuse (severe) | 0.04% | 0.807 | 43.38 years (= quality-adjusted life expectancy of a 10 year old) | 5% | 2% |
| Physical abuse (death) | 0.01% | 1 | 43.38 years | 5% | 2% |
| Sexual abuse (non-physical) | 0.2% | 0.1 | 2 months | 2% | 1% |
| Sexual abuse (physical) | 0.15% | 0.709 | 6 months | 5% | 2% |
| Medication error (low harm) | 0.14% | 0.173 | 5 days | 2% | 2% |
| Medication error (moderate harm) | 0.04% | 0.567 | 11 days | 5% | 3% |
| Medication error (severe harm) | 0.002% | 0.724 | 43.38 years | 5% | 3% |
| Medication error (death) | 0.0005% | 1 | 43.38 years | 5% | 3% |
| Physical maltreatment and neglect (low harm) | 4.9% | 0.2385 | 5 days | 2% | 2% |
| Physical maltreatment and neglect (moderate harm) | 1.35% | 0.291 | 11 days | 5% | 3% |
| Physical maltreatment and neglect (severe harm) | 0.13% | 0.724 | 43.38 years | 5% | 3% |
| Physical maltreatment and neglect (death) | 0.02% | 1 | 43.38 years | 5% | 3% |
| Emotional maltreatment/ neglect | 6.45% | 0.039 | 43.38 years | 2% | 2% |
| Long term consequences of the above (where unaccounted) | 8% | 0.039 | 43.38 years | 2.5% | 1.93% |

101. Where CQC regulation mitigates hazards to health and well-being, it will also reduce treatment costs faced by the NHS. Our assumptions on these prevented treatment costs – based on NHS reference costs - are presented below. Note that the above hazards may have many different health consequences requiring different treatments. The cost assumptions below are approximations based on representative health consequences.

Table D7: Avoided NHS treatments costs through CQC regulation

| **Hazard** | **Avoided NHS treatment costs** |
|---|---|
| Verbal and psychological abuse | £0 |
| Verbal and psychological abuse (severe) | £2,600 |
| Physical abuse | £0 |
| Physical abuse (severe) | £1,800 |
| Physical abuse (death) | £3,000 |
| Sexual abuse (non-physical) | £0 |
| Sexual abuse (physical) | £2,800 |
| Medication error (low harm) | £40 |
| Medication error (moderate harm) | £700 |
| Medication error (severe harm) | £42,500 |
| Medication error (death) | £3,000 |
| Physical maltreatment and neglect (low harm) | £40 |
| Physical maltreatment and neglect (moderate harm) | £700 |
| Physical maltreatment and neglect (severe harm) | £42,500 |
| Physical maltreatment and neglect (death) | £3,000 |
| Emotional maltreatment/ neglect | £39,500 |
| Long term consequences of the above (where unaccounted) | £39,500 |

102. These cost savings then need to be multiplied by 2.4 to reflect the opportunity cost savings of saved NHS resource.

103. Based on the above information, we estimate that, for each hour of domiciliary care provided to a disabled child, regulation generates benefits of £0.51 where the provider is a professional provider and £0.37 where the provider is a friend or family member.

Costs of regulation

104. Costs of regulations include the annual fee for CQC registration, assumed to be £1,000 per provider, and annual inspection costs, assumed to be £470 per provider with 10% of providers being inspected (equivalent to a cost of £47 per provider). In addition, there will be one-off costs of complying with CQC regulation of £1,070.

105. This brings the annual equivalent costs of regulation to £1,176 per provider. 30% of this cost is borne by the exchequer through a reduction in tax income and national insurance contribution. This loss in income needs to be multiplied by 2.4 to reflect the opportunity cost of exchequer funding. The remaining 70% of costs are borne by the care provider. On average, we assume professional home care providers to fall in the second quintile of the income distribution. As £1 is worth more to a person in that income bracket than to the median person, we weigh these costs by a factor of 1.5, i.e. we use the upper bound of the distributional weights proposed by the Green Book. We assume that friends and relatives providing care fall, on average, in the middle income bracket.[3]

106. The social value of the costs of regulation to a professional home care provider is £2,081. The social value of the cost of regulation to friends and family members is £1,669.

Estimating the Threshold – value for money

107. We derive how many hours of care a provider needs to deliver for regulation to represent value for money by dividing the annual costs of regulation by the benefits of regulation per regulated hour of care.

108. We estimate that the benefits of regulation outweigh the costs where the regulated provider works for more than 4,071 hours per year (for professionals) or for 4,505 hours (friends & relatives). Assuming that there are effectively 46 working weeks in a year (excluding annual leave and public

[3] For instance, they may have income other sources/other household members. Friends and family are unlikely to work full-time as a domiciliary care provider. On average, they will be representative of the population as a whole.

holidays), this would suggest a threshold of 88 hours a week for professional providers and 98 hours per week for friends and family.

Applying the threshold and deriving the preferred option

109. Ideally, only those providers working above the threshold would be registered. For all other providers, the costs of regulation outweigh the benefits. We expect that virtually no providers work more than 88 (or 98) hours. Therefore, the preferred option is to exempt individual, non-agency providers of domiciliary care.

110. As the number of affected providers is unknown, we do not monetise the benefits of taking providers out of regulation. Note also that – if regulation were to be applied - the costs of regulation might have pushed providers out of the market. We have not quantified this effect, but assume that it might have been large as the fees payable by individual providers are substantial compared to the average income of such providers. Preventing this adverse effect of regulation is a further, unquantified benefit of the proposed option.

111. We acknowledge that there are uncertainties around the above estimates – in particular around our assumptions for the effectiveness of CQC regulation. However, it should be noted that the estimated threshold of 88 hours per week (for professionals) while we estimate that the average professional provider works for 34 hours a week. Registering such a provider would only justify the costs if the average effectiveness of CQC regulation was 6.6% rather than our best estimate of 2.33%.

**Domiciliary care for vulnerable adults**

112. We assume that hazards in domiciliary care for vulnerable adults are the same as in domiciliary care for disabled children. However, we adjust the duration of adverse health impacts (presented in Table D7 above) to account for the shorter life expectancy of adults.

113. Consequently, the benefits of regulation are lower for adult care than they are for care for children: £0.36 for each hour of care provided by a care professional and £0.26 for each hour of care provided by a friend or relative (compared to £0.51 and £0.37 for children's care). The benefits of regulation would only outweigh the costs where a professional provider (friend or relative) worked more than 127 (138) hours per week.

114. Therefore, the preferred option is to exempt all individual, non-agency providers of domiciliary care. The net benefit of taking these providers out of regulation may be substantial, but has not been quantified.

**Independent User Trusts**

115. We expect that the net benefits of deregulation per provider employed through an IUT will be similar in scope to those described under care for adults. However, we expect that this will only affect a small number of providers.

**Personal Care away from home**

116. In deriving a threshold of activity below which regulation of providers of care away from home is not value for money, we need to take into account that care away from home will be provided by an organisation employing several care workers rather than an individual care provider. In addition, care will be provided to a group of individuals rather than to one person at their home. This affects the effectiveness of CQC regulation. It also affects the value for money threshold.

117. It is assumed that, the risks of domiciliary care away from home are overall the same as those identified above for care provided in individuals' homes. While some risks may be more likely in unknown environments, others will be less likely as those most dependent on care are least likely to participate in activities requiring care away from home.

118. It is assumed that the impact of CQC regulation on care away from home will be higher than its impact on domiciliary care at home where parents/carers are able to chose trustworthy individuals and where there is only one care worker and one person receiving care at a time, thus allowing closer oversight by the parent/carer.

119. Table D8 presents our assumptions on the effectiveness of CQC regulation for care away from home.

| Potential Hazard | CQC Effectiveness |
|---|---|

| | |
|---|---|
| Verbal and psychological abuse | 5% |
| Severe verbal and psychological abuse | 10% |
| Physical abuse | 5% |
| Physical abuse (severe) | 10% |
| Physical abuse (death) | 10% |
| Sexual abuse (non-physical) | 5% |
| Sexual abuse (physical) | 10% |
| Medication error (low harm) | 2% |
| Medication error (moderate harm) | 5% |
| Medication error (severe harm) | 5% |
| Medication error (death) | 5% |
| Pain and other health impact from maltreatment or physical neglect (low) | 2% |
| Pain and other health impact from maltreatment or physical neglect (moderate) | 5% |
| Pain and other health impact from maltreatment or physical neglect (severe) | 5% |
| Pain and other health impact from maltreatment or physical neglect(death) | 5% |

120. Based on these assumptions and using the same method as above, we estimate that the benefits of regulation outweigh the costs if a provider provides care to children for more than 1,836 hours a year. Where care away from home is provided to adults, this threshold is higher: 2,671 hours per year. As above, this reflects the lower life expectancy of adults.

121. We assume that, on average, individuals on care away from home receive just as much personal care as they receive when at home, i.e. 21 hours per week. The benefits of registering a provider would thus outweigh the costs of doing so if care was provided for more than 87 weeks a year (for children) or more than 127 weeks a year (for adults). For instance, the benefits of regulating a provider offering four weeks of holiday per year would outweigh the costs if that provider offered his services to at least 22 children or 32 adults.

122. The proposal is to set a an annual threshold of 4 weeks activity above which providers will be required to register. The threshold will vary dependant on the number individuals receiving care.

123. As noted above, there is no information on the number of providers affected by this.

## Independent Midwives

124. At present, independent midwifery services are excluded from regulation by the Care Quality Commission, as these services are exempted as “midwifery services…carried on by an individual…who provides such services only to service users in their own homes” under Schedule 1, 11(2)(a) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. When the regulations were made, independent midwifery services were exempted, as it was felt the sector was not sufficiently prepared for system regulation. This is felt to no longer be the case, and a permanent exemption would not be consistent with policy objectives. Option 2, the proposal is to remove the exemption and bring independent midwifery services into regulation, thus requiring independent midwives to register with CQC.

125. Independent midwives are assumed to be self-employed individuals and thus are considered micro businesses. Although this proposal would bring these micro businesses into regulation, the costs to any one individual are not thought to be large enough to put independent midwives out of business. Due to the associated health risks, the benefits of regulation of independent midwives can be reasonably expected to outweigh the costs. This shown in the analysis below

126. It is not known exactly how many registered midwives practice as self-employed independent midwives. However, it is likely that there are around 150 to 200 practising independent midwives in England (compared to around 27,000 practicing in the NHS). It has been estimated that a full-time independent midwife could support 15-20 births a year on the assumption that care from an independent midwife means that an individual midwife would provide a package of one on one

support to a mother and baby for around a year. This suggests a best estimate of 3000 births a year are attended by independent midwives, the care for which is not currently regulated by CQC.

127. The benefits and costs of Option 2, bringing the care of these births into regulation, compared to Option 1, are considered below.

Benefits

128. During maternity care, there are a number of potential adverse events which can occur for a mother and/or her baby; each has an associated health loss (in terms of severity and duration). Some of these events are unavoidable but others are influenced by the care provider. If an independent midwife is required to register with CQC, they must comply with the 16 registration requirements, and compliance with these requirements may mitigate against avoidable adverse events beyond those which are already mitigated by professional regulation.

129. Table D9 below considers the role of system regulation in mitigating the potential adverse events during pregnancy, birth and the postnatal period and thus during the period independent midwifery service is offered. Many of the events identified below are generic to pregnancy, childbirth and the postnatal period regardless of provider, and some of them are unavoidable. The analysis below considers the adverse events in the specific context of independent midwifery care where possible. There has been concern raised by some research[4], which suggested perinatal mortality may be higher for high risk births supported by independent midwives than the NHS.

130. The likelihood of adverse events is based on relevant literature and assumptions with some clinical input. The reduction in health state is based on the EQ5D framework on which the likely health impact of each hazard can be assessed over 5 key areas of health; mobility, self care, usual activity, pain/discomfort and anxiety/depression. The duration of hazards is based on relevant literature and assumptions. The assumptions are intended to reflect a central best estimate; of course, there will be cases at either end of extreme.

131. The effectiveness of CQC regulation is based on how meeting the registration requirements will mitigate the health risks in addition to professional regulation. In particular registration requirements 9, 17 and 24 (see Table D1 above) are expected to lead to mitigation of the impact of the potential adverse events. It is assumed that where the impact of the adverse event would be influenced by the care provided by independent midwives and relevant CQC requirements go beyond professional regulation, CQC registration would result in a reduction of the impact of 5%. This is thought to be a prudent assumption. Where events are unavoidable or already mitigated as far as possible by professional regulation, CQC regulation is assumed to have no impact. Please see Annex 2 for sources.

Table D9: Potential adverse events during pregnancy, birth and postnatal period and the effectiveness CQC regulation to mitigate their impact for independent midwifery care

| **Adverse Event** | **Likelihood** | **EQ-5D score** | **Reduction in health state** | **Duration** | **Effectiveness of system regulation to mitigate** |
|---|---|---|---|---|---|
| ***Adverse events for the mother*** | | | | | |
| Pregnancy complications minor | 75% | 11221 | 0.2 | 3 months | 0% |
| Pregnancy complications major | 1% | 12222 (~) | 0.4 | 3months | 5% |
| Miscarriage | 5% | 11113 (~) | 0.4 | 1 year | 0% |
| Labour complications minor | 50% | 11222 | 0.2 | 3 days | 0% |
| Labour complications major | 4% | 12232 (~) | 0.8 | 3 days | 5% |
| Psychological distress during labour | 2% | 11113 | 0.5 | 1 day | 5% |
| Death | 0.01% | N/A | 1 | 33 years* | 5% |
| Postnatal complications minor | 100% | 11221 | 0.2 | 6 weeks | 0% |
| Postnatal complications major | 10% | 11321 (~) | 0.4 | 9 months | 5% |
| Postnatal depression | 12% | 11213 | 0.5 | 9 months | 5% |
| Postnatal psychosis | 0.1% | 13313 | 0.8 | 3 months | 5% |
| ***Adverse events for the baby*** | | | | | |

[4] Symon, Winter, Inkster, Donnan, 2009, Outcomes for births booked under an independent midwife and births in NHS maternity units: matched comparison study, *BMJ* 2009; 338:b2060

| | | | | | |
|---|---|---|---|---|---|
| Pregnancy complication | 4% | 22221 | 0.4 | 1 year | 0% |
| Major pre-term birth | 4% | 22221 | 0.4 | 1 year | 0% |
| Birth complications major** | 0.2% | 32322 | 0.8 | 47 years* | 5% |
| Perinatal death including still birth | 1.7% | N/A | 1 | 47 years* | 5% |
| Neonatal complications minor | 60% | 11221 | 0.2 | 3 months | 0% |
| Neonatal complications major | 0.4% | 22222 | 0.4 | 6 months | 5% |

** major birth complications are assumed to be issues such as cerebral palsy. * Death reduces quality of life to zero. This does not necessarily suggest a severity of 1. In fact, where the person dying has had a quality of life lower than 1, they will only lose as much. However, this is accounted in the use of the quality-adjusted life expectancy for the duration of the event- 16-44 average age assumed for mothers and 0 average age assumed for babies.

132. It is assumed that one year in full health for one person (a QALY) is worth £63,000 (in 2010/11 prices) to society. Taking this assumption and the above analysis, it is possible to quantify the expected avoided health loss from CQC regulation using the following calculation: Benefits = A x B x C x D x E x £63,000, where: A = Number of procedures, B = likelihood of adverse event, C = severity of adverse event, D = duration of adverse event, E = reduction through system regulation.

133. In addition to the health (QALY) benefits, if CQC regulation can mitigate the impacts of adverse events there may be avoided treatment costs to the NHS. Table D10 below identifies possible treatments associated with each adverse event, the associated cost for these is taken from 2009/10 NHS reference cost data and is uplifted to reflect 2010/11 prices.

Table D10: Avoided NHS treatments costs through CQC regulation

| **Adverse event** | **Treatment code** | **Cost** |
|---|---|---|
| ***Adverse events for the mother*** | | |
| Pregnancy complications minor | NZ05C- Ante-natal or Post-natal Investigation age between 16 and 40 years with length of stay 0 days | £300 |
| Pregnancy complications major | NZ09Z & NZ10Z-Ante-natal or Post-natal Full Investigation with length of stay 1 day or more & Diagnostic and Therapeutic Procedures on Fetus | £2340 |
| Miscarriage | MB08Z-Threatened or Spontaneous Miscarriage | £540 |
| Labour complications minor | Unlikely to require NHS treatment in addition to what IM would provide. | £0 |
| Labour complications major | PS24A & NZ12G-Pregnancy / Childbirth / Miscarriage paramedic care & Assisted Delivery with Post-partum Surgical Intervention (used as a proxy for surgery required due to major labour complication) | £2800 |
| Psychological distress during labour | Unlikely to require NHS treatment in addition to what IM would provide | £0 |
| Death | PS24A & NZ14Z- Pregnancy / Childbirth / Miscarriage paramedic care & Emergency or Upper Uterine Caesarean Section (proxy for extreme emergency intervention in labour) | £3450 |
| Postnatal complications minor | Unlikely to require NHS treatment in addition to what IM would provide | £0 |
| Postnatal complications major | WA10Z or MB02Z Genito-urinary infections or Genital Prolapse or Incontinence | £1780 |
| Postnatal depression | MHCSOPSSFAMBU & MHCSOPSSFUMBU- Mother and Baby Unit mental health services one first attendance out patient appointment and four follow up face to face appointments | £800 |
| Postnatal psychosis | MHIPMB – Mother and Baby Unit mental health inpatient care plus above care for postnatal depression | £1480 |
| ***Adverse events for the baby*** | | |
| Pregnancy complication | XA02Z- Neonatal Critical Care High Dependency | £820 |
| Major pre-term birth | XA05Z- Neonatal Critical Care Normal Care | £460 |
| Birth complications major | The costs of treating a significant disability will be considerable and involve hospital care, primary health care, drugs, and equipment. This is an assumption based on some literature (see sources) | £50,000 |
| Perinatal death including still birth | XA01Z & XA06Z- Neonatal Critical Care Intensive Care & Neonatal Critical Care Transportation | £2500 |
| Neonatal complications | Unlikely to require NHS treatment in addition to what IM would provide | £0 |

| | | |
|---|---|---|
| minor | | |
| Neonatal complications major | XA02Z- Neonatal Critical Care High Dependency | £820 |

134. It is possible to quantify the expected benefits of avoided NHS treatments costs from CQC regulation using the following calculation: Cost savings= A x B x E x F, where: A = Number of procedures, B = likelihood of adverse event, E = reduction through system regulation, F = Saved treatment cost on NHS. These cost savings then need to be multiplied by 2.4 to reflect the opportunity cost savings of saved NHS resource.

135. Table D11 below brings together the health (QALY) benefits and the avoided treatment costs to give a best estimate and a range of the expected benefits of this proposal. The best estimate is based on the assumptions above, whilst the range reflects the potential variation if assumptions were pushed towards the reasonable maximum and minimum impacts.

Table D11: Expected annual benefits of Sterilisation regulation amendment proposal

| **Benefit** | **Estimate** | |
|---|---|---|
| | **Range** | **Best** |
| QALY savings | £2.4m - £22.8m | £9.0m |
| NHS Saved Treatment Costs | £50,000 - £130,000 | £85,000 |
| NHS Saved Treatment Costs + opportunity costing | £120,000 – £305,000 | £200,000 |
| **Total Benefit** | £2.5m - £23.1m | £9.2m |

(note: figures may not sum due to rounding)

136. There may also be benefits of regulation to independent midwives themselves, as registration with CQC provides a quality assurance signal to potential service users, and thus may improve their business.

Costs

137. In future more independent midwives may organise themselves into co-operatives, groups or social enterprises and this may have an impact on how CQC registers them in terms of provider fees. However, in the light of current arrangements, this analysis assumes CQC would register independent midwives on an individual basis. The CQC registration fee for an individual provider with one location is around £1500. However, CQC have advised that for independent midwives new to regulation the fee is may be set at a lower rate as a transitional arrangement and will increase slightly over time. The lower fees will be maintained through efficiencies and no additional DH Grant in Aid will be provided to cover gaps. This analysis models the fee, as £800 initially in 2012/13, increasing by £100 a year until it reaches £1200 in 2016/17 from then it remains constant.

138. Assuming there are 150 to 200 independent midwives the total cost of all registration fees would be around £140k (800*175) pa in 2012/13 and £210k (1200*175) pa from 2016/17 onwards. A registration fee is assumed to be tax deductible. Assuming a midwife earns above £35,000, around 50% (marginal tax rate of 40% and national insurance of 10%) of the fee cost represents lost tax revenue. The tax lost should be multiplied by 2.4 to represent the opportunity cost of Exchequer resources. Whilst the 50% of fee cost to the midwife should be multiplied by 0.7 to reflect that at the margin a £1 is worth less to a person in the second quintile income bracket than to the median person. The total economic cost of all registration fees is therefore estimated to be around £220k pa in 2012/13 (£170k to the Exchequer and £50k to the midwives), and £325k pa by 2016/17 (£250k to the Exchequer and £75k to the midwives).

139. Annual inspections will be required which are assumed to be equivalent to a £390 cost per provider, with 10% of providers being inspected. Once again, noting that the costs should reflect the IM relative income, the 0.7 multiplier is used, giving an estimated total cost of £5k per year- (note the tax implications of the costs of inspection are not clear so none is assumed).

140. There will also be costs of compliance. Complying with the CQC registration requirements may mean extra time and effort required in the provision of care by independent midwives, e.g. where they need to co-operate with other health care providers. In the absence of better information, an assumption, based on compliance costs in the Primary Care IA, of a cost equivalent to £1000 per independent midwife is used, but is assumed to recur annually. Again reflecting the weight of costs at the margin for the midwife, the 0.7 multiplier is used, giving an estimated cost of £125k per year.

141. Complying with the CQC requirements could lead to independent midwives providing care to fewer mothers and babies, in particular those births deemed high-risk. This could have costs such as loss of income for independent midwives, loss of tax revenue to the Exchequer, and costs on the NHS due to increased demand. There is not enough information to quantify these potential impacts at this stage.

Value for Money

142. The above quantified costs and benefits can be brought together and assessed over the policy appraisal period to consider whether this proposal (part of Option 2) represents value for money over the do-nothing (Option 1). This is shown in table D12 below.

Table D12: NPV of Independent Midwives Proposal

| **' 000s** | Year 2012/13 0 | Year 2013/14 1 | Year 2014/15 2 | Year 2015/16 3 | Year 2016/17 4 | Year 2017/18 5 | Year 2018/19 6 | Year 2019/20 7 | Year 2020/21 8 | Year 2021/22 9 | **Total** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| QALY Benefits | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 90,250 |
| Saved Treatment Costs including op costs | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 2,000 |
| Total Benefits (undiscounted) | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 9,225 | 92,250 |
| **Total Benefits** (discounted) | 9,225 | 9,085 | 8,945 | 8,810 | 8,675 | 8,545 | 8,415 | 8,285 | 8,160 | 8,040 | 86,185 |
| Registration Fees- cost to IMs | 50 | 55 | 60 | 65 | 75 | 75 | 75 | 75 | 75 | 75 | 680 |
| Registration Fees- Exchequer lost income tax (inc op costs) | 170 | 190 | 210 | 230 | 250 | 250 | 250 | 250 | 250 | 250 | 2,300 |
| CQC Inspection- cost to IMs | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 50 |
| Extra Time & Effort of IMs | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 125 | 1,250 |
| Total Costs (undiscounted) | 345 | 370 | 400 | 425 | 455 | 455 | 455 | 455 | 455 | 455 | 4,270 |
| **Total Costs** (discounted) | 345 | 360 | 370 | 385 | 395 | 380 | 370 | 355 | 345 | 330 | 3,635 |
| **NPV** | 8,880 | 8,725 | 8,575 | 8,425 | 8,280 | 8,165 | 8,045 | 7,930 | 7,820 | 7,705 | **82,550** |

(note: the table is expressed in constant 2010/11 prices, most costs and benefits are assumed to reduce at a rate of 3.5%, a QALYs at 1.5%, a year to reflect the social time preference for resources and health)

143. The above table shows that the benefits of this proposal clearly outweigh the costs and thus represent value for money, with a net present value of around £82.5m, with an equivalent annual benefit of £8.9m. The assumptions underpinning the analysis are thought to be prudent, and sensitivity testing the key assumptions around the benefits in particular shows this result to be robust:

- If the assumed effectiveness of system regulation reduced from 5% to 0.25% the proposal would still be expected to yield a positive NPV, even if the effectiveness was only for the impact of perinatal mortality.
- Most of the health gains are generated by mitigating perinatal mortality. However, even if this risk was removed from the benefit calculations, all other assumption remaining, this proposal would still have an NPV of around £11.7m.

## Mixed Practice Medical Practitioners

144. There is an inconsistency in the way that the private practice of medical practitioners is registered: medical practitioners who work for the NHS do not need to register their private practice they carry out in a surgery or consulting room, unless they are providing a specifically listed risky activity. However, medical practitioners who work for a registered non-NHS provider (e.g. private hospital) are required to register their private practice.

145. The proposal is to amend this exemption so that it is based on a risk-based approach and is consistent across sectors. First, the cost and benefits of regulating the private practice of medical practitioners who are also meaningfully employed by any registered provider are estimated. Based on this, we derive a threshold of weekly hours of private practice below for which regulation does not represent value for money. The total costs and benefits of implementing this threshold exemption marginal to the do-nothing are then considered also.

Estimating the Threshold - Benefits

146. Medical practitioners in private practices falling under the current mixed practice exemption will provide services that are very similar to that in NHS primary care. The services that private medical practitioners offer could range from a simple consulting service – including prescriptions - to a small medical procedure such as endoscopy.

147. For every consultation, there are a number of potential hazards and adverse events each with an associated health loss (in terms of severity and duration). When a provider is required to register for CQC regulation, they must comply with the 16 registration requirements, and compliance with these requirements may mitigate against these hazards beyond that that is already mitigated by: professional regulation, device regulation and meaningful employment for other practice with a registered provider.

148. Table D13 below considers the role of system regulation in mitigating the potential hazards associated with the independent private health care provision by providers who also meaningfully practice under registered providers. The likelihood of hazards is based on relevant literature, assumptions and the Primary Care IA (see sources). The reduction in health state is based on the National Patient Safety Agency data and definitions of adverse events and the EQ5D framework on which the likely health impact of each hazard can be assessed over 5 key areas of health; mobility, self care, usual activity, pain/discomfort and anxiety/depression. The duration of hazards is based on relevant literature and assumptions. Finally, the effectiveness of CQC regulation is based on assumptions on the extent of other regulation and the additional hazard-mitigating role it can play in the mixed practice context.

Table D13: Potential hazards of private clinic consultations of doctors currently under the mixed practice exemption and the effectiveness CQC regulation

| **Hazard** | **Likelihood per million consultations** | **EQ-5D score** | **Reduction in health state** | **Duration as share of a year** | **Effectiveness of system regulation to mitigate** |
|---|---|---|---|---|---|
| ***Low Harm*** | | | | | |
| Patient accident | 17.26 | Midpoint between 11111 and 21121 | 0.2385 | 0.01 | 5% |
| Medication | 9.59 | Midpoint between 11211 and 11121 | 0.1605 | 0.01 | 30% |
| Treatment, procedure | 50.95 | In between patient accident and medication | 0.1995 | 0.01 | 0% |
| Access, admission, transfer, discharge (including missing patient) | 15.01 | | 0.1995 | 0.01 | 15% |
| Documentation (including records, identification) | 7.58 | | 0.1995 | 0.01 | 15% |
| Implementation of care and ongoing monitoring / review | 33.99 | | 0.1995 | 0.01 | 10% |
| Infrastructure (including staffing, facilities, environment) | 20.40 | | 0.1995 | 0.01 | 20% |
| Clinical assessment (including diagnosis, scans, tests, assessments) | 45.92 | | 0.1995 | 0.01 | 3.5% |
| Disruptive, aggressive behaviour | 1.07 | | 0.1995 | 0.01 | 0% |
| Consent, communication, confidentiality | 9.36 | | 0.1995 | 0.01 | 5% |
| Other | 17.05 | | 0.1995 | 0.01 | 3.4% |
| Self-harming behaviour | 5.26 | | 0.1995 | 0.01 | 0% |
| Medical device / equipment | 3.84 | | 0.1995 | 0.01 | 5% |
| Infection Control Incident | 3.21 | | 0.1995 | 0.01 | 5% |
| Patient abuse (by staff / third party) | 1.50 | | 0.1995 | 0.01 | 5% |
| ***Moderate Harm*** | | | | | |
| Patient accident | 1.85 | Midpoint | 0.291 | 0.03 | 5% |

| | | | | | |
|---|---|---|---|---|---|
| | | between 21121 and 21221 | | | |
| Medication | 2.55 | Midpoint between 11221 and 11231 | 0.4035 | 0.03 | 30% |
| Treatment, procedure | 21.97 | In between patient accident and medication | 0.34725 | 0.03 | 0% |
| Access, admission, transfer, discharge (including missing patient) | 5.08 | | 0.34725 | 0.03 | 15% |
| Documentation (including records, identification) | 2.05 | | 0.34725 | 0.03 | 15% |
| Implementation of care and ongoing monitoring / review | 13.79 | | 0.34725 | 0.03 | 10% |
| Infrastructure (including staffing, facilities, environment) | 5.52 | | 0.34725 | 0.03 | 20% |
| Clinical assessment (including diagnosis, scans, tests, assessments) | 23.02 | | 0.34725 | 0.03 | 3.5% |
| Disruptive, aggressive behaviour | 0.12 | | 0.34725 | 0.03 | 0% |
| Consent, communication, confidentiality | 2.81 | | 0.34725 | 0.03 | 5% |
| Other | 5.20 | | 0.34725 | 0.03 | 3.4% |
| Self-harming behaviour | 0.97 | | 0.34725 | 0.03 | 0% |
| Medical device / equipment | 1.02 | | 0.34725 | 0.03 | 5% |
| Infection Control Incident | 2.16 | | 0.34725 | 0.03 | 5% |
| Patient abuse (by staff / third party) | 0.50 | | 0.34725 | 0.03 | 5% |
| ***Severe Harm*** | | | | | |
| Patient accident | 0.16 | Midpoint between 22221 and 32211 | 0.772 | 4.58 | 5% |
| Medication | 0.15 | | 0.772 | 22.69 | 30% |
| Treatment, procedure | 1.49 | | 0.772 | 22.69 | 0% |
| Access, admission, transfer, discharge (including missing patient) | 0.37 | | 0.772 | 22.69 | 15% |
| Documentation (including records, identification) | 0.08 | | 0.772 | 22.69 | 15% |
| Implementation of care and ongoing monitoring / review | 1.36 | | 0.772 | 22.69 | 10% |
| Infrastructure (including staffing, facilities, environment) | 0.52 | | 0.772 | 22.69 | 20% |
| Clinical assessment (including diagnosis, scans, tests, assessments) | 3.04 | | 0.772 | 22.69 | 3.5% |
| Disruptive, aggressive behaviour | 0.01 | | 0.772 | 22.69 | 0% |
| Consent, communication, confidentiality | 0.19 | | 0.772 | 22.69 | 5% |
| Other | 0.72 | | 0.772 | 22.69 | 3.4% |
| Self-harming behaviour | 0.09 | | 0.772 | 22.69 | 0% |
| Medical device / equipment | 0.07 | | 0.772 | 22.69 | 5% |
| Infection Control Incident | 0.26 | | 0.772 | 22.69 | 5% |
| Patient abuse (by staff / third party) | 0.07 | | 0.772 | 22.69 | 5% |
| ***Death*** | | | | | |
| Patient accident | 0.02 | N/A | 1 | 4.58 | 5% |
| Medication | 0.03 | | 1 | 22.69 | 30% |
| Treatment, procedure | 0.53 | | 1 | 22.69 | 0% |
| | | | 1 | 22.69 | 15% |
| Access, admission, transfer, | 0.10 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| discharge (including missing patient) | | | | | |
| Documentation (including records, identification) | 0.02 | | 1 | 22.69 | 15% |
| Implementation of care and ongoing monitoring / review | 0.23 | | 1 | 22.69 | 10% |
| Infrastructure (including staffing, facilities, environment) | 0.06 | | 1 | 22.69 | 20% |
| Clinical assessment (including diagnosis, scans, tests, assessments) | 1.23 | | 1 | 22.69 | 3.5% |
| Disruptive, aggressive behaviour | 0.00 | | 1 | 22.69 | 0% |
| Consent, communication, confidentiality | 0.06 | | 1 | 22.69 | 5% |
| Other | 1.29 | | 1 | 22.69 | 3.4% |
| Self-harming behaviour | 0.12 | | 1 | 22.69 | 0% |
| Medical device / equipment | 0.02 | | 1 | 22.69 | 5% |
| Infection Control Incident | 0.15 | | 1 | 22.69 | 5% |
| Patient abuse (by staff / third party) | 0.01 | | 1 | 22.69 | 5% |

149. It is assumed that one year in full health for one person (a QALY) is worth £63,000 (in 2010/11 prices) to society. Taking this assumption and the above analysis, it is possible to quantify the expected avoided health loss from CQC regulation using the following calculation: Benefits = A x B x C x D x E x £63,000, where: A = Number of procedures, B = likelihood of adverse event, C = severity of adverse event, D = duration of adverse event, E = reduction through system regulation.

150. In addition to the avoided health costs, if CQC regulation can mitigate the hazards there may be avoided treatment costs to the NHS.

Table D14: Avoided NHS treatments costs through CQC regulation

| **Incident** | **Treatment** | **Expected NHS Cost** |
|---|---|---|
| Low harm (all incidents) | GP consultation | £19 |
| Moderate harm (all incidents) | Day case in hospital | £347 |
| Severe Harm (all incidents) | As death plus quarterly follow up treatments for rest of life, valued at the weighted average of "follow up attendance multi-professional non-admitted, non face to face". | £13,337 |
| Death (all incidents) | Paramedic services + weighted average of the upper quartile cost of non-elective long stays. | £2,997 |

151. It is possible to quantify the expected benefits of avoided NHS treatments costs from CQC regulation using the following calculation: Cost savings= A x B x E x F, where: A = Number of procedures, B = likelihood of adverse event, E = reduction through system regulation, F = Saved treatment cost on NHS. These cost savings then need to be multiplied by 2.4 to reflect the opportunity cost savings of saved NHS resource.

152. Overall, taking the best estimates of health benefits and avoided treatment costs together, for each consultation provided by a doctor, regulation is expected to generate benefits of £0.84 of which £0.82 are QALY savings and £0.02 are the saved NHS treatment costs.

Estimating the Threshold - Costs

153. Costs of regulations, involve the annual fee for CQC registration, assumed to be £1,500 per provider and annual inspection costs, assumed to be £390 per provider, with 10% of providers being inspected (equivalent to a cost of £39 per provider).

154. There are also one-off compliance costs to providers, estimated to be £4,200. Over an appraisal period of 10 years and discounting with 3.5%pa, this is equivalent to an annual cost of £505.

155. This brings the costs of regulation to £2,044 per provider per year. We assume that 60% of the annual fees fall on the exchequer through lost tax income and national insurance payments. As above, this is multiplied by 2.4 to reflect the opportunity cost of exchequer funding. The remaining 40% of fees as well as the costs of inspections fall on consultants whose income puts them in the fifth quintile distribution. To take into consideration that £1 is worth less to a person in that income bracket than to the median person, we apply a distributional weight of 0.5, i.e. the upper bound of the weights proposed by the Green Book. Overall, the cost of regulation to society is thus £3,308 per private practice.

Estimating the Threshold – value for money

156. Based on the above, we can derive how many private consultations a mixed practice medical practitioner needs to provide for regulation to represent value for money. Dividing the annual costs by the per consultation benefit gives the necessary number of consultations per year a practitioner must do for benefits to offset costs. Based on the above analysis the best estimate is that this point will be reached at 3,970 consultations per year. Assuming that, on average, a doctor fits 5 consultations in one hour of work, and there are effectively 46 working weeks in a year (excluding annual leave and public holidays), this would suggest a threshold of 17.3 hours a week.

Applying the Threshold

157. It is assumed that most of the exempted doctors will be consultants in hospitals. While most GPs do some private practice, they will do so in their own premises, i.e. their registration status would not be affected by the any of the present options.

158. A 2006 NAO study suggests that about 20,000 NHS consultants carry out private practice. These are currently exempt from CQC regulation. On average, consultants who carry out private practice do so for 8.4 hours per week. Setting the threshold as suggested by the above analysis at 17.3 hours a week would thus mean that they remain exempt.

159. Practitioners who have their main employment with non-NHS providers are currently not exempt. We suggest to extend the exemption to these practitioners where their workload is below the above threshold. CQC estimates that 105 consultants are currently registered who work in a private hospital and carry out independent private practice. We expect that their private practice does not exceed the above threshold. Therefore, the proposed change would bring these 105 consultants out of regulation.

160. For these practitioners, there will thus be a reduction in the costs of regulation of £1,539 (annual fees of £1,500 and inspection costs of £39). The one-off compliance costs of £4,200 are sunk costs and cannot be recuperated. As above, we assume that 60% of this cost reduction falls on the exchequer and is worth £2.4 for every £1 saved, while the remaining 40% falls on the practitioner and is worth £0.5 for every £1 saved. The total social value of savings to practitioners is thus £35,600 (£1,500 * 40% * 0.5 *105 + £39 * 0.5 *105= £35,548). The total social value to the exchequer is £226,800 (£1,500 * 60% * 2.4 * 105 = £226,800)

161. At the same time, there will be a loss of the benefits generated by regulatory oversight. As it is assumed that these consultants work 8.4 hours, for each consultant, currently, the total health benefits of regulation amount to £1,586 (8.4 hours * 5 consultations = 42 consultations per week, 42*46 weeks = 1,932 consultations per year, health benefits of £0.82 per consultation: 1,932*£0.82 = £1,631) while the value of prevented NHS treatments is £45 (1,932 consultations * £0.02 per consultation = £45). When removing 105 consultants from regulation, this would suggest an annual loss of health benefits worth £166,500 (105 * £1,586 = £166,500) and an increase in NHS treatment costs of £4,700 (105 * £45 = £4,725).

162. However, removing these consultants from regulation will not mean that all of these benefits are lost. For instance, where CQC oversight has prompted changes to facilities and equipment, the benefits of these past investments will not be lost simply by removing registration requirements. We assume that, in the first year, only 5% of the benefits of regulation will be lost. This amounts to QALY losses worth £8,325 (=£166,500 * 0.05) and an increase in NHS treatment costs worth £235 (=£4,700 *0.05). This loss will then gradually increase to 90% after ten years. Table D15 below presents the costs and benefits of the proposal:

Table D15: costs and benefits of the proposal[5]

[5] Note that figures the presented figures are round to the next £5,000.

| £'000s | Year 2012/13 0 | Year 2013/14 1 | Year 2014/15 2 | Year 2015/16 3 | Year 2016/17 4 | Year 2017/18 5 | Year 2018/19 6 | Year 2019/202 7 | Year 2020/21 8 | Year 2021/22 9 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| QALYs forgone | 10 | 25 | 40 | 55 | 70 | 85 | 105 | 120 | 135 | 150 | 795 |
| Value of NHS treatment costs | 0 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 4 | 4 | 22 |
| Total costs (undiscounted) | 10 | 26 | 41 | 57 | 72 | 87 | 108 | 123 | 139 | 154 | 817 |
| Total costs (discounted) | 10 | 25 | 40 | 55 | 70 | 85 | 95 | 110 | 120 | 135 | 745 |
| Reduction in registration fees and inspection costs to consultants | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 350 |
| Reduction in registration fees to the exchequer | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 2,250 |
| Total benefits (undiscounted) | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 2,600 |
| Total benefits (discounted) | 260 | 255 | 245 | 235 | 230 | 220 | 215 | 205 | 200 | 195 | 2,260 |
| NPV | 250 | 230 | 205 | 180 | 160 | 135 | 120 | 95 | 80 | 60 | 1,515 |

(note: the table is expressed in constant 2010/11 prices, most costs and benefits are assumed to reduce at a rate of 3.5%, a QALYs at 1.5%, a year to reflect the social time preference for resources and health)

163. Over the ten year appraisal period, cost savings strongly outweigh the lost benefits of regulation. The net present value of this proposal is calculated as £1.5m.

164. As discussed above, the do-nothing option is not viable as it is inconsistent in its treatment of private and NHS consultants. Therefore, maintaining the status quo expose the Department to the risk of legal challenge. We have not quantified this benefit, but assume that it is substantial.

## Surgical Sterilisation

165. At present, surgical sterilisation procedures are excluded from regulation by the Care Quality Commission, as these services do not fall under "surgical procedures…[for] the purpose of treating disease, disorder or injury" under Schedule 1, 7(1)(a) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Moreover, female sterilisation does not fall under regulation of family planning (Schedule 1, 15), as this regulation includes only insertion/removal of an intrauterine contraceptive device (IUCD). Option 2, the proposal, is to amend the regulation so that the regulated activity of surgical procedures for treatment of disease, disorder or injury includes surgical sterilisation, and thus providers of sterilisation must register with CQC.

166. Surgical sterilisation is provided both by the NHS and by the private sector. However, most of the sterilisation providers (inc. all NHS) provide other surgical procedures for which they are already regulated by CQC. Changing the definition of what is regulated under surgical procedures to include sterilisation is not expected to lead to any costs or benefits for these providers, as they will already be meeting the registration requirements for providing surgical activities and there will be no change in their fees.

167. It is assumed that there are around 160 private providers of sterilisation services in total, and the majority provide both male and female procedures. CQC estimates that approximately 25 (~15%) male sterilisation private providers (mostly sexual health clinics) and 10 (~5%) female sterilisation providers are currently not registered to provide surgical procedures and thus would be brought into CQC regulation under the proposal. The costs and benefits of this proposal (Option 2), i.e. effectively bringing the private providers who only provide surgery for sterilisation procedures into regulation, marginal to the do-nothing (Option 1) are considered below.

Benefits

168. It is assumed that the private market for sterilisation in 12/13 will consist of 2,650 female sterilisation procedures and 33,000 male sterilisation procedures. Female sterilisations are

assumed to follow their historical decreasing trend until they level off at 2,000 after 5-7 years, whilst the number of male sterilisations is assumed to remain stable.

169. For every procedure, there are a number of potential hazards and adverse events each with an associated health loss (in terms of severity and duration). When a provider is required to register for CQC regulation, they must comply with the 16 registration requirements, and compliance with these requirements may mitigate against these hazards beyond those that are already mitigated by professional and device regulation.

170. Table D16 below considers the role of system regulation in mitigating the potential hazards associated with sterilisation. The likelihood of hazards is based on relevant literature and assumptions. The reduction in health state is based on the EQ5D framework on which the likely health impact of each hazard can be assessed over 5 key areas of health; mobility, self care, usual activity, pain/discomfort and anxiety/depression. The duration of hazards is based on relevant literature and assumptions. Finally the effectiveness of CQC regulation is based on assumptions on the extent of other regulation and the extent to which private providers are already regulated, (e.g. CQC regulation 30% effective in reducing infection rates for male sterilisation but only 15% of private providers are not already registered to provide surgery, so effectiveness becomes 30%*15%=4.5%). Please see Annex 2 for sources.

Table D16: Potential hazards of sterilisation procedures and the effectiveness CQC regulation

| **Hazard** | **Likelihood** | **EQ-5D score** | **Reduction in health state** | **Duration** | **Effectiveness of system regulation to mitigate** |
|---|---|---|---|---|---|
| ***Male Sterilisation*** | | | | *assuming regulation impacts 15% of providers* | |
| Infection | 3.4% | 11121 | 0.11 | 1 month | 4.5% |
| Allergic reaction to anaesthesia | 0.0022% | 11121 | 0.114 | 1 week | 2.25% |
| Post operative pain | Non-Chronic: 32%<br><br>Chronic: 8.6% | Non-chronic: 11121<br><br>Chronic: 11131 | 0.114<br><br>0.221 | Non chronic: 2 weeks<br><br>Chronic: 2 years (until further treatment takes place) | 0% |
| Bruising and swelling | 75% | 11121 | 0.11 | 3 weeks | 0% |
| Bleeding | 5% | 11221 | 0.15 | 1 week | 0% |
| Haematoma | 2% | 11221 | 0.15 | 2 months | 0% |
| Sperm granuloma | 20% | 11121 | 0.15 | 3 months | 0% |
| Painful sperm granuloma | 2.5% | 11131 | 0.646 | 3 months | 0% |
| Congestive epididymitis | 4% | 11221 | 0.15 | 5 weeks | 0% |
| Negative psychological effects | 5 to 10% | 11112 | 0.062 | 6 months – 5 years | 1.5% |
| Failed operation - immediate | 1% | 11113 | 0.496 | 9 months | 0% |
| Death (mainly from infection) | 0.0001% | n/a | 1 | 31.2 years | 6% |
| ***Female Sterilisation*** | | | | *assuming regulation impacts 5% of providers* | |
| Infection | 1% | 11121 | 0.13 | 1 month | 0.5% |
| Allergic reaction to general anaesthesia | 0.0022% | 11121 | 0.134 | 2 days – 1 month | 0.75% |
| Post operative pain | Pre-discharge: 35% | Pre-discharge: 11122<br>Post-discharge: | 0.205 | Pre-discharge: 1 day<br>Post- | 0% |

| | | | | | |
|---|---|---|---|---|---|
| | Post-discharge: 41% | 11121 | 0.134 | discharge: 2 weeks | |
| Post operative nausea and vomiting | 27% | 21221 | 0.239 | 4 hours – 1 day | 0% |
| Bleeding | 0.1% | 11221 | 0.17 | 1 week | 0% |
| Internal Organ Damage | 0.19% | 21231 | 0.771 | 3 months | 0% |
| Negative psychological effects | 5% | 11112 | 0.082 | 6 months – 5 years | 1% |
| Failed operation - immediate | 0.5% | 11113 | 0.516 | 9 months | 0% |
| Failed operation – pregnancy | 0.25% | n/a – see above | n/a – see above | n/a – see above | 0% |
| Death | 0.0015% | n/a | 1 | 33.9 years | 0.5% |

(Note: Death reduces quality of life to zero. This does not necessarily suggest a severity of 1. In fact, where the person dying has had a quality of life lower than 1, they will only lose as much. However, this is accounted in the use of the quality-adjusted life expectancy for the duration of the hazard)

171. It is assumed that one year in full health for one person (a QALY) is worth £63,000 (in 2010/11 prices) to society. Taking this assumption and the above analysis, it is possible to quantify the expected avoided health loss from CQC regulation using the following calculation: Benefits = A x B x C x D x E x £63,000, where: A = Number of procedures, B = likelihood of adverse event, C = severity of adverse event, D = duration of adverse event, E = reduction through system regulation.

172. In addition to the health (QALY) benefits, if CQC regulation can mitigate the hazards there may be avoided treatment costs to the NHS. Table D17 below identifies possible treatments associated with each adverse event, the associated cost for these is taken from 2009/10 NHS reference cost data and is uplifted to reflect 2010/11 prices.

Table D17: Avoided NHS treatments costs through CQC regulation

| **Adverse event** | **Treatment code** | **Cost** |
|---|---|---|
| Infection | PA18B – minor infection | £1120 |
| Allergic reaction to anaesthesia | PA50Z – allergies | £927 |
| Post operative pre-discharge pain | AB06Z – minor pain procedures | £2,104 |
| Post operative pain | N/A – it is assumed that this pain could be mitigated through over-the-counter painkillers, hence no cost on the NHS. | £0 |
| Post operative chronic pain | AB06Z – minor pain procedures | £2,104 |
| Post operative nausea and vomiting | PA28A – feeding difficulties and vomiting –extends stay in hospital | £2,164 |
| Bruising and swelling | There is no follow-up treatment for this area | £0 |
| Bleeding | MB01B – lower genital tract disorders | £1348 |
| Haematoma | LB34B - Scrotum, Testis or Vas Deferens Open Procedures | £1,418 |
| Sperm granuloma | | |
| Painful granuloma | | |
| Congestive epididymitis | | |
| Negative psychological effects | WA22Y – specific admissions and counselling (day case) | £305 |
| Failed operation (postop) | Male – LB33Z – vasectomy procedures | £1,269 |
| Failed operation (late) | Female – NZ11B – normal delivery | £1,702 |
| Death | PA16A – It is assumed that death results either from infection or from allergic reaction to anaesthesia. An upper-quartile average of the two treatments is taken, as the condition has to be more serious than the “average”. | £4,696 |

173. It is possible to quantify the expected benefits of avoided NHS treatment costs from CQC regulation using the following calculation: Cost savings= A x B x E x F, where: A = Number of procedures, B = likelihood of adverse event, E = reduction through system regulation, F = Saved treatment cost on NHS. These cost savings then need to be multiplied by 2.4 to reflect the opportunity cost of saved NHS resource.

174. Table D18 below brings together the health (QALY) benefits and the avoided treatment costs to give a best estimate and a range of the expected benefits of this proposal. The best estimate is based on the assumptions above, whilst the range reflects the potential variation if assumptions were pushed towards the reasonable maximum and minimum impacts.

Table D18: Expected annual benefits of Sterilisation regulation amendment proposal

| **Benefit** | **Estimate** | |
|---|---|---|
| | **Range** | **Best** |
| QALY savings | £55,000 - £1,500,000 | £335,000 |
| NHS Saved Treatment Costs | £10,000- £650,000 | £70,000 |
| NHS Saved Treatment Costs + opportunity costing | £20,000- £1,555,000 | £165,000 |
| **Total Benefit** | **£70,000- £3,050,000** | **£500,000** |

(Note: figures may not sum due to rounding)

Costs

175. Registered providers must pay an annual fee to the CQC of £1500. As mentioned above, a high proportion of sterilisation providers (all female sterilisation providers) are currently registered with the CQC for various other regulated activities they provide, and as a result, will incur no additional annual costs resulting from this proposed regulation amendment.

176. It is assumed that the male sterilisation providers that are not currently regulated by CQC are likely to engage in selective provision of treatments – such as sexual health clinics offering only vasectomy and no other regulated services. This leads us to expect that the unregistered providers will be highly fragmented, small clinics that are not a part of a large company. Assuming that there are 25 providers of male sterilisation that will be newly registered as a result of the proposal, the new total annual burden in registration fees will be around £37,500.

177. In addition to the annual fees there will be the costs of inspection, which costs around £390 with 10% of providers being inspected each year (equivalent cost of £39 per provider). The total cost of this is around £980, and with the above brings the annual costs of the proposed regulation change to around £38,500.

178. It is also assumed that there may be some transition costs for the newly registered providers as they make some changes in order to comply with the CQC registration requirements. Based on previous interviews with private doctors, initial compliance costs are estimated to be £4200 for a small private provider. This gives an estimated one off compliance cost of around £105,000.

179. Finally, it is assumed that the 10 female sterilisation providers that provide sufficiently unrelated activities and would need to be registered under this proposal would face some costs in order to comply with the registration requirements in the context of surgical procedures. This gives an additional estimated compliance cost of around £42,000. These providers would also be required to pay the annual fee to provide the regulated activity of surgical procedures, which is estimated to have an annual burden of £15,000 (10*£1500).

Value for Money

180. The above quantified costs and benefits can be brought together and assessed over the policy appraisal to consider whether this proposal (part of Option 2) individually represents value for money over the do-nothing (Option 1).

Table D19: NPV of Sterilisation Proposal

| | Year 2012/13 | Year 2013/14 | Year 2014/15 | Year 2015/16 | Year 2016/17 | Year 2017/18 | Year 2018/19 | Year 2019/20 | Year 2020/21 | Year 2021/22 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| £'000s | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| **BENEFITS** | | | | | | | | | | | TOTAL |
| QALY benefits | £335 | £335 | £335 | £335 | £335 | £335 | £335 | £335 | £335 | £335 | £3,345 |
| NHS benefits | £165 | £165 | £165 | £165 | £165 | £165 | £165 | £165 | £165 | £165 | £1,645 |
| | | | | | | | | | | | |
| Total Benefits (undiscounted) | £500 | £500 | £500 | £500 | £500 | £500 | £500 | £500 | £500 | £500 | £4,985 |
| Total Benefits (discounted) | £500 | £490 | £480 | £470 | £460 | £450 | £440 | £430 | £420 | £410 | £4,545 |
| | | | | | | | | | | | |
| **COSTS** | | | | | | | | | | | |
| Initial Compliance Costs | £145 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £145 |
| Annual Fees | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £525 |
| Inspection | £1 | £1 | £1 | £1 | £1 | £1 | £1 | £1 | £1 | £1 | £10 |
| Total Costs (undiscounted) | £200 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £55 | £680 |
| Total Costs (discounted) | £200 | £50 | £50 | £50 | £45 | £45 | £45 | £40 | £40 | £40 | £605 |
| | | | | | | | | | | | |
| **NPV** | £300 | £440 | £430 | £420 | £410 | £405 | £395 | £390 | £380 | £375 | **£3,935** |

(note: the table is expressed in constant 2010/11 prices, most costs and benefits are assumed to reduce at a rate of 3.5%, a QALYs at 1.5%, a year to reflect the social time preference for resources and health, figures are rounded to nearest £5k)

181. The above table shows that the benefits of this proposal outweigh the costs and thus represent value for money, with a net present value of around £3.9m with an equivalent annual benefit of £436.5k. The assumptions underpinning the analysis are thought to be prudent, and sensitivity testing the key assumptions around the benefits in particular shows this result to be robust:

- reducing the health loss or duration of health loss estimates by half would still yield a positive NPV of £2.4m
- reducing the assumed extent of private provision by five fold would still yield a positive NPV of £0.3m
- the effectiveness of regulation assumptions could be reduced by 87% the proposal would still yield a positive NPV.

## Absence without authorised leave notifications

182. At present, the regulations require registered providers to notify CQC about unauthorised absences from hospital of people detained or liable to be detained under the Mental Health Act 1983. The purpose of the notifications is to enable CQC to be able to assess variation in the number of absences from different providers. A high number of unauthorised absences are an indicator that there might be a problem with a provider's arrangements for keeping service users safe and secure.

183. Feedback has suggested that these notifications are burdensome and this may not be proportionate to risk for general mental health wards where the risk to patients and service users of an unauthorised absence is relatively lower than for more secure units. In addition, information about unauthorised absences is also collected via the mental health minimum data set (MHMDS) for NHS providers of general, psychiatric intensive care, low and medium secure wards. Therefore, a significant proportion of CQC notifications represent duplication.

184. In addition, for the psychiatric intensive care and secure mental health wards, it has been suggested that the notifications would be a better indicator of the quality of care if they included information about when the unauthorised absence ended.

185. It is estimated that CQC receive around 4000 notifications a year and of these around 70% relate to absences from general mental health wards, and 30% relate to psychiatric intensive care and secure mental health wards. Most of these notifications are from the NHS, but some are from independent providers. There are some 1100 locations at which service providers are registered to provide assessment or medical treatment for persons detained under the Mental Health Act 1983. Some 230 of these locations are registered through independent sector providers, the rest are registered through 182 NHS organisations. Many of these locations are only rarely used to detain patients under the Act.

186. The proposal, Option 2, is to remove the requirement for notification of absence without leave for general mental health wards, and add the requirement for an absence end date for psychiatric intensive care and secure mental health wards. The costs and benefits of this, compared to the do nothing, Option 1, are considered below.

Benefits

187. Under the proposal around 70% of 4000 notifications (2800) CQC receive would no longer be required. In practice, the vast majority of notifications come from providers of specialist mental health services. Most such NHS and some independent providers cover a range of services and wards, therefore the proposal will not significantly reduce the number of those providers who have to notify unauthorised absences, but it will significantly reduce the frequency with which they must do so and the number of locations involved. Some specialist independent providers who only provide general mental health wards, they will no longer be required to submit notifications. The burden on providers, and on CQC will be reduced. Due to a lack of information, it is not possible to quantify this burden.

188. Under the proposal, the remaining 30% of the 4000 notifications (1200) CQC receive would include additional information about when the absence ended. This will increase the value of the notifications as an indicator of the quality of provision, and should improve CQC's ability to identify issues and improve the quality and safety of care. It is not possible to quantify this benefit.

Costs

189. There should be limited costs associated with removing the need for notifications from mental health wards due: the information being captured by the MHMDS if required (so there is no lost information) and the relatively low risk to service users and the public of people detained under the mental health act on cared for on general mental health wards.

190. There will be a cost of increased burden to providers of the requirement to provide an absence end date. It is not possible to quantify this burden. It is estimated this will apply to around 30% of notifications and this burden will be a relatively small addition to the notification. Therefore, this cost should be less than the burden being saved by removing the requirement for general ward notifications.

Value for Money

191. The costs of the additional information requirement for the 30% of notifications that relate to psychiatric intensive care and secure wards are expected to be less than the reduced burden from exempting 70% of notification that relate to general wards. In addition, there will be benefits from the notifications that remain being improved indicators. Therefore this proposal is expected to yield value for money compared to the do nothing.

**Exemption for the Olympics and Paralympics**

192. The proposal is to put in place a general exemption for the services put into place for the Olympics and Paralympic games to ensure that there is not a requirement to register those services. Given how limited a time these services will be provided for and the security arrangements that will be in place, it would be extremely difficult and ineffective for CQC to register these services. There are no expected costs of this proposal as if not exempt it would not be possible for CQC to mitigate any of the health risks in such a short-lived services. The benefit of this proposal is the avoided burden of the formal registration both on the provider and to the CQC. As a result, the exemption is expected to yield value for money.

**Minor clarifications and technical amendments**

193. The clarifications proposed will not increase costs to providers or CQC, as they are not expected to change the current extent of regulation. The benefit of amending the regulations is clarity and ensuring that policy intentions are delivered.

## Summary of Costs and Benefits of Option 2

194. The tables below summarises the costs and benefits of all the proposal together as Option 2 marginal to the do nothing Option 1. There are no expected impacts on DH or NHS central budgets, and thus no financial affordability table is presented.

195. Table D20 below summarises the total social impacts of all the proposals and shows Option 2 is expected to provide an overall net benefit to society of £104m.

Table D20: Total NPV of the total social impacts of Option 2

| £('000)s | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 | Year 8 | Year 9 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description of Costs and Benefits** | **2012/13** | **2013/14** | **2014/15** | **2015/16** | **2016/17** | **2017/18** | **2018/19** | **2019/20** | **2020/21** | **2021/22** | **Total** |
| **Fitness of Providers Partnerships** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Diagnostics & Screening Services** | | | | | | | | | | | |
| *Benefits (saved resources)* | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 1,430 | 14,295 |
| *Costs* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Diagnostics & Research Bodies** | | | | | | | | | | | |
| *Benefits (saved resources)* | 1,090 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 290 | 3,720 |
| *Costs (QALYs forgone)* | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 550 |
| **Air Ambulance Transport Services** | | | | | | | | | | | |
| *Benefits (saved resources)* | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 145 |
| *Costs* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Statutory Notifications** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Independent Midwives** | | | | | | | | | | | |
| *Benefits (saved resources)* | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 2,005 |
| *Benefits (QALYs)* | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 9,025 | 90,230 |
| *Costs* | 345 | 370 | 400 | 425 | 455 | 455 | 455 | 455 | 455 | 455 | 4,255 |
| **Mixed Practice Exemption** | | | | | | | | | | | |
| *Benefits (saved expenditure on fees)* | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 260 | 2,625 |
| *Costs (QALY loss)* | 10 | 25 | 40 | 55 | 70 | 85 | 105 | 120 | 135 | 150 | 790 |
| *Costs (Treatment costs)* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 |
| **Sterilisation** | | | | | | | | | | | |
| *Benefits (saved resources)* | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 1,645 |
| *Benefits (QALYs)* | 335 | 335 | 335 | 335 | 335 | 335 | 335 | 335 | 335 | 335 | 3,370 |
| *Costs* | 200 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 680 |
| **AWOL Notifications** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Exemption for Olympics and Paralympics** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Minor Clarifications and Technical Amendments** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| | | | | | | | | | | | |
| *General Discount Rate* | *0.000* | *0.035* | *0.071* | *0.109* | *0.148* | *0.188* | *0.229* | *0.272* | *0.317* | *0.363* | |
| *QALY Discount Rate* | *0.000* | *0.015* | *0.030* | *0.046* | *0.061* | *0.077* | *0.093* | *0.110* | *0.126* | *0.143* | |
| | | | | | | | | | | | |
| Total Transition Benefits | 800 | | | | | | | | | | |
| Total Annual Benefits | 11,730 | 11,745 | 11,760 | 11,780 | 11,795 | 11,810 | 11,825 | 11,840 | 11,860 | 11,875 | 118,025 |
| **Total Benefits (undiscounted)** | 12,530 | 11,745 | 11,760 | 11,780 | 11,795 | 11,810 | 11,825 | 11,840 | 11,860 | 11,875 | 118,825 |
| **Total Benefits (discounted)** | 12,530 | 11,525 | 11,330 | 11,130 | 10,940 | 10,750 | 10,565 | 10,385 | 10,205 | 10,030 | 109,400 |
| | | | | | | | | | | | |
| Total Transition Costs | 145 | | | | | | | | | | 145 |
| Total Annual Costs | 460 | 505 | 545 | 590 | 635 | 650 | 665 | 680 | 695 | 715 | 6,140 |
| **Total Costs (undiscounted)** | 610 | 505 | 545 | 590 | 635 | 650 | 665 | 680 | 695 | 715 | 6,290 |
| **Total Costs (discounted)** | 610 | 490 | 515 | 540 | 560 | 560 | 555 | 555 | 555 | 550 | 5,485 |
| | | | | | | | | | | | |
| **Net Benefits (undiscounted)** | 11,920 | 11,240 | 11,215 | 11,190 | 11,160 | 11,160 | 11,160 | 11,160 | 11,160 | 11,160 | 112,535 |
| **Net Benefits (discounted) NPV** | 11,920 | 11,040 | 10,815 | 10,595 | 10,380 | 10,195 | 10,010 | 9,830 | 9,650 | 9,480 | **103,910** |

(note: figures may not sum due to rounding. Costs and benefits are expressed in a 2010/11 price base and are assumed to reduce at a rate of 3.5% a year to reflect the social time preference for resources and health)

196. Table D21 below summarises the Exchequer impacts only, these are generally expected changes in tax revenue and NHS treatment costs as a result of Option 2. It is shows that overall Option 2 is expected to provide a net benefit to the Exchequer of £3.1m.

Table D21: Total NPV of the Exchequer impacts only of Option 2

| £('000)s | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 | Year 8 | Year 9 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description of Costs and Benefits** | **2012/13** | **2013/14** | **2014/15** | **2015/16** | **2016/17** | **2017/18** | **2018/19** | **2019/20** | **2020/21** | **2021/22** | **Total** |
| **Fitness of Providers Partnerships** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Diagnostics & Screening Services** | | | | | | | | | | | |
| *UNQUANTIFIED (tax implications)* | | | | | | | | | | | |
| **Diagnostics & Research Bodies** | | | | | | | | | | | |
| *Benefits - UNQUANTIFIED* | | | | | | | | | | | |
| *Costs (NHS treatment costs)* | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 11 |
| **Air Ambulance Transport Services** | | | | | | | | | | | |
| *Benefits (increased tax rev)* | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 6.6 | 66 |
| *Costs* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Statutory Notifications** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Independent Midwives** | | | | | | | | | | | |
| *Benefits (saved NHS treatment resources)* | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 2,005 |
| *Costs (lost tax rev)* | 170 | 190 | 210 | 230 | 250 | 250 | 250 | 250 | 250 | 250 | 2,310 |
| **Mixed Practice Exemption** | | | | | | | | | | | |
| *Benefits (increased tax rev)* | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 225 | 2,270 |
| *Costs (NHS treatment costs)* | 0.1 | 0.3 | 0.5 | 0.7 | 0.9 | 1.0 | 1.2 | 1.4 | 1.6 | 1.8 | 9 |
| **Sterilisation** | | | | | | | | | | | 0 |
| *Benefits (saved NHS Treatment Costs)* | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 165 | 1,650 |
| *Costs - UNQUANTIFIED (tax considerations)* | | | | | | | | | | | |
| **AWOL notifications** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Exemption for Olympics and Paralympics** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| **Minor Clarifications and Technical Amendments** | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | |
| *General Discount Rate* | *0.000* | *0.035* | *0.071* | *0.109* | *0.148* | *0.188* | *0.229* | *0.272* | *0.317* | *0.363* | |
| | | | | | | | | | | | |
| Total Transition Benefits | 0.0 | | | | | | | | | | |
| Total Annual Benefits | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 5,990 |
| **Total Benefits (undiscounted)** | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 600 | 5,990 |
| **Total Benefits (discounted)** | 600 | 580 | 560 | 540 | 520 | 505 | 485 | 470 | 455 | 440 | 5,155 |
| | | | | | | | | | | | |
| Total Transition Costs | 0 | | | | | | | | | | |
| Total Annual Costs | 170 | 190 | 210 | 235 | 255 | 255 | 255 | 255 | 255 | 255 | 2,330 |
| **Total Costs (undiscounted)** | 170 | 190 | 210 | 235 | 255 | 255 | 255 | 255 | 255 | 255 | 2,330 |
| **Total Costs (discounted)** | 170 | 185 | 200 | 210 | 220 | 215 | 205 | 200 | 195 | 185 | 1,985 |
| | | | | | | | | | | | |
| **Net Benefits (undiscounted)** | 430 | 410 | 385 | 365 | 345 | 345 | 345 | 345 | 345 | 345 | 3,660 |
| **Net Benefits (discounted) NPV** | 430 | 395 | 360 | 330 | 300 | 290 | 280 | 270 | 260 | 250 | 3,170 |

(note: figures may not sum due to rounding. Costs and benefits are expressed in a 2010/11 price base and are assumed to reduce at a rate of 3.5% a year to reflect the social time preference for resources and health)

197. Table D22 below reflects the direct impacts on business only. The figures are presented in 2009 prices, and the present value base year is 2010/11 as required for the One In One Out initiative. The table below shows that Option 2 has **two "INs" and ten "OUTs"** and that the quantified "OUTs" more than compensate for the "INs", with a net benefit of £11.5m. Note to highlight the difference between INs and OUTs, figures are presented as costs, i.e. benefits as negative costs.

Table D22: Total NPV of the direct business impacts only of Option 2, OIOO calculation

| | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 | Year 8 | Year 9 | Year 10 | Year 11 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description of Costs and Benefits** | **2010/11** | **2011/12** | **2012/13** | **2013/14** | **2014/15** | **2015/16** | **2016/17** | **2017/18** | **2018/19** | **2019/20** | **2020/21** | **2021/22** | **NPC** | **EAC** | **IN or OUT?** |
| **Fitness of Providers Partnerships** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| **Diagnostics & Screening Services** | | | | | | | | | | | | | | | |
| *Reduced Burden (fees and inspections)* | | | -1430 | -1430 | -1430 | -1430 | -1430 | -1430 | -1430 | -1430 | -1430 | -1430 | | | |
| *DEFLATED TO 2009 PRICES* | | | -1385 | -1385 | -1385 | -1385 | -1385 | -1385 | -1385 | -1385 | -1385 | -1385 | | | |
| *Net Cost to Business (discounted)* | | | -1295 | -1250 | -1210 | -1165 | -1130 | -1090 | -1055 | -1015 | -985 | -950 | -10190 | -1130 | OUT |
| **Diagnostics & Research Bodies** | | | | | | | | | | | | | | | |
| *Reduced Burden (fees, inspections, compliance)* | | | -1090 | -290 | -290 | -290 | -290 | -290 | -290 | -290 | -290 | -290 | | | |
| *DEFLATED TO 2009 PRICES* | | | -1060 | -285 | -285 | -285 | -285 | -285 | -285 | -285 | -285 | -285 | | | |
| *Net Cost to Business (discounted)* | | | -985 | -255 | -245 | -240 | -230 | -225 | -215 | -210 | -200 | -195 | -2805 | -310 | OUT |
| **Air Ambulance Transport Services** | | | | | | | | | | | | | | | |
| *Reduced burden (fees)* | | | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | -7.8 | | | |
| *DEFLATED TO 2009 PRICES* | | | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | -7.5 | | | |
| *Net Cost to Business (discounted)* | | | -7.0 | -6.8 | -6.6 | -6.3 | -6.1 | -5.9 | -5.7 | -5.5 | -5.3 | -5.2 | -55.4 | -6.2 | OUT |
| **Statutory Notifications** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| **Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| **Independent Midwives** | | | | | | | | | | | | | | | |
| *Cost to IMs (fees, inspection, and extra time)* | | | 175 | 180 | 190 | 195 | 200 | 200 | 200 | 200 | 200 | 200 | | | |
| *DEFLATED TO 2009 PRICES* | | | 170 | 175 | 185 | 190 | 195 | 195 | 195 | 195 | 195 | 195 | | | |
| *Net Cost to Business (discounted)* | | | 160 | 160 | 160 | 160 | 160 | 155 | 150 | 145 | 140 | 135 | 1510 | 170 | IN |
| **Mixed Practice Exemption** | | | | | | | | | | | | | | | |
| *Reduced burden (fees and inspections)* | | | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | | | |
| *DEFLATED TO 2009 PRICES* | | | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | | | |
| *Net Cost to Business (discounted)* | | | -65 | -60 | -60 | -60 | -55 | -55 | -50 | -50 | -50 | -45 | -555 | -60 | OUT |
| **Sterilisation** | | | | | | | | | | | | | | | |
| *Cost to providers (fees, inspections, compliance costs)* | | | 200 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | | | |
| *DEFLATED TO 2009 PRICES* | | | 195 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | | | |
| *Net Cost to Business (discounted)* | | | 180 | 45 | 45 | 45 | 40 | 40 | 40 | 40 | 35 | 35 | 550 | 60 | IN |
| **AWOL Notifications** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| **Exemption for Olympics and Paralympics** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| **Minor Clarifications and Technical Amendments** | | | | | | | | | | | | | | | |
| *UNQUANTIFIED* | | | | | | | | | | | | | | | OUT |
| | | | | | | | | | | | | | | | |
| *Discount Rate* | *0.000* | *0.035* | *0.071* | *0.109* | *0.148* | *0.188* | *0.229* | *0.272* | *0.317* | *0.363* | *0.411* | *0.460* | | | |
| **OPTION 2 TOTAL NPC/EAC TO BUSINESS** | | | -2010 | -1370 | -1320 | -1270 | -1220 | -1180 | -1140 | -1100 | -1065 | -1025 | -11550 | -1285 | OUT |

(note: figures may not sum due to rounding. Costs and benefits are assumed to reduce at a rate of 3.5% a year to reflect the social time preference for resources and health)

198. **The above tables show that Option 2 is expected to yield a net benefit to society and business annually and up to 2021/22. Therefore, Option 2 represents value for money over the do nothing.**

# E. Equality Impact Assessment

**Fitness of Providers (Partnership requirements)**

199. We do not consider this proposal to have an equalities impact on the protected groups, except in instances where age, sex, race, disability might have prevented an individual from acquiring the necessary skills required to be a partner. In those instances, the proposed changes would be beneficial.

**Diagnostic and screening procedures**

200. The proposal removes from registration services where we do not consider there to be a risk to effectively mitigate. Therefore, this change should not have an impact on the quality and safety of services received by any of the protected groups, for example individuals with a disability such as hearing loss.

**Research bodies carrying out diagnostic tests**

201. While there are clearly risks to the volunteers taking part in medical research, it is not clear that registration as a healthcare provider with CQC is the most appropriate way to mitigate that risk. Furthermore, regulation of research activities is undertaken by a number of bodies (including the Medicines and Healthcare products Regulatory Agency, the Administration of Radioactive Substances Advisory Committee and the National Research Ethics Service) and therefore it is difficult to see what additional risks would be mitigated through CQC regulation. This remains true, even where research is carried out with individuals from the protected groups as participants.

**Air ambulance operators**

202. We do not consider this proposed change will have an equalities impact on any of the protected groups, as the regulations enforced by the CAA offer sufficient assurance of safety and efficacy to service users.

**Statutory notifications**

203. We do not consider this proposed change will have an equalities impact on any of the protected groups. The burden of the data collection on the provider will not change only the format in which the data is provided. We would expect CQC to undertake an analysis of impact in equality as to the format in which the data is provided and make any reasonable changes to ensure the new format will not disadvantage any protected groups i.e. those with sensory impairments.

**Domiciliary Care for Children and Vulnerable Adults & Personal care away from home**

204. For most of the protected groups, changes to the regulations for the provision of personal domiciliary care will have some impact. The removal from regulation, of domiciliary care provided by non-agency providers will mean that users of these services are no longer offered assurance about the safety and quality of the care they will receive. While this does raise concerns about the level of safeguards provided to service users, many of whom will be vulnerable, to keep them in regulation would place a high burden on the providers, and CQC, to have to register large numbers of individual providers. The mitigation of risks in tens of thousands of individual cases, where the providers themselves may not be aware that they should be registered with CQC is limited. Our view is that the removal of these providers from regulation will not have significant overall impact on the safeguards in place to protect users of care services.

205. Personal care is a low paying role, but may be the only work available to individuals in poorer communities. As the work is low paying and where the service users are unable to afford higher fees for care, the financial burden of a registration fee with the CQC could be a disincentive for providers to continue operation. The risks to service users of having care provided outside of the scope of regulation should be balanced against the risks of service users being unable to access the care they want and need.

206. Although the number of organisations providing care aware from home is small, this change is likely to affect a broad demographic as personal care is provided to individuals in all the protected groups. Individuals from all the protected groups are in receipt of personal care but it is unknown what percentage of each group will seek to go on the holidays offered by these providers.

**Independent midwives**

207. Requiring independent midwives to register with the CQC will impose a burden both financial and regulatory. As most independent midwives are women this change significantly affects one gender more than the other and will therefore have an equalities impact on a protected group.

208. The regulatory burden, in terms of taking the necessary steps to comply with the regulations, is likely to vary considerably depending on whether the applicant is a single-handed practitioner or a midwife in a social enterprise.

209. The financial burden on independent midwives has not yet been determined, as the setting of fees is a matter for CQC, subject to approval by the Secretary of State. However, we consider benefits to women and families who use services will outweigh the costs as by registration the providers will demonstrate that they have complied with the essential standards of quality and safety.

**Mixed practice medical practitioners**

210. We do not consider this proposed change will have an equalities impact on any of the protected groups. The proposal is intended to offer more risk based assurance of safety and quality for all providers and service users.

**Surgical sterilisation**

211. Our view is that the proposed change to the regulations will have a beneficial impact to both sexes undergoing surgical sterilisation, as regulation by the CQC will require providers to demonstrate their compliance with the essential requirements of safety and quality. However, although women undergo the riskier procedure, many more men undergo a vasectomy and therefore benefit to men is greater.

**Absence without authorised leave notifications to CQC**

212. Despite these differences in use of detention, the proposed changes to these notification requirements are unlikely to have any significant differential effect (either positive or negative) on people by virtue of protected characteristics. Because notifications of absences from general mental health wards are not thought to be a useful regulatory information, ending the requirement is unlikely to have any effect on the services provided to users of such services . There may be some benefit to people detained in more secure facilities, if data on their length of absence can be used as a regulatory tool to help decrease both the number and duration of such unauthorised absences.

213. Detailed information is not available on the protected characteristics of the providers of services which detain people under the Mental Health Act – but the vast majority of such providers are bodies corporate, rather than individuals.

**Exemption for the Olympics & Paralympics**

214. This proposal will mean that the healthcare provided to participants at the games, including Paralympic participants, will not be required to comply with the essential standards of safety and quality. Therefore individuals with a disability will be the main protected group to be effected by this change. However, as the Olympic services will only last for a month, this presents a considerable challenge to CQC's ability to mitigate risk. Indeed, even if CQC were to inspect the Olympic facilities immediately at the start of the game and produce a very rapid report, the service would have concluded before the Commission could determine if the services had taken necessary action.

# E. i. Summary of specific impact tests

215. Below summarises the results of the specific impact test screening questions for Option 2. The analysis indicates no significant impacts in any of these areas.

Competition

216. In any affected market, would the proposal:

217. Directly limit the number or range of suppliers?

No. The proposals do not involve the award of exclusive rights to supply services, procurement will not be from a single supplier or restricted group of suppliers. There is fixed limit on the number of suppliers.

218. Indirectly limit the number or range of suppliers?

This might be the case in some of the proposals. The proposal to bring independent midwives into regulation could indirectly affect the supply of this service if the midwives choose to cease practising rather than register, although this is not expected to happen. Similarly, providers of surgical sterilisation who do not provide any other service will be brought into registration. However, proposals such as the removal of requirements for all partners in a partnership to meet fitness standards will decrease the barriers to market entry.

219. The increase in barriers to market entry for sterilisation and independent midwives are not expected to have a significant impact on competition (as all suppliers would be subject to the same regulation) but are necessary to safeguard the quality and safety of Healthcare provision. The reduced barriers to market entry for provider partnerships and inconsistency around the mixed practice exemption are expected to have positive effects.

220. Limit the ability of suppliers to compete?

No The proposals do not control or substantially influence the price a supplier can charge. However, the characteristics of the product supplied could be influenced by, for example, CQC's essential requirements of safety and quality. The proposals do not limit the scope for innovation for the introduction of new products or supply existing products in new ways. They do not limit the sales channels a supplier can use, or the geographic area in which a supplier can operate. They do not substantially restrict the ability of suppliers to advertise their products or limit the suppliers' freedoms to organise their own production processes or their choice of organisational form.

221. Reduce suppliers' incentives to compete vigorously?

The proposals do not exempt the suppliers from general competition law. They do not require or encourage the exchange between suppliers, or publication, of information on prices, costs, sales or outputs. The proposals could indirectly increase the costs to customers of switching between suppliers, eg. where providers are brought into registration and increase their own fees as a result of paying the registration fee.

Small firms

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

Two of the proposals will bring a relatively small number of providers of high-risk services into regulation. For independent midwives these will be micro businesses. The costs and benefits of the proposal have been considered in the main cost benefit analysis, where it is demonstrated that the benefits to society in terms of health gains outweigh the costs to the micro business (see Section D above). However, there could also be benefits of regulation to small providers by giving assurance to users of their good quality care, and giving them the potential to compete on a level playing field with larger companies.

Legal Aid/ Justice Impact

223. Will the proposals create new civil sanctions, fixed penalties or civil orders with criminal sanctions or creating or amending criminal offences? Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? Create a new right of appeal or route top judicial review? Enforcement mechanisms for civil debts, civil sanctions or criminal penalties? Amendment of Court and/or tribunal rules? Amendment of sentencing or penalty guidelines? Any impact (increase or reduction on costs) on Legal Aid fund? (criminal, civil and family, asylum) Any increase in the number of offenders being committed to custody (including on remand) or probation? Any increase in the length of custodial sentences? Will proposals create a new custodial sentence? Any impact of the proposals on probation services?

224. No significant risks were identified.

225. Providers whose services have been suspended by CQC have the right of appeal to the First - tier Tribunal. However we expect the numbers of applications and cases to be small and therefore we do not expect a significant increase in demand on the Tribunals service.

Sustainable Development

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

227. The proposals are not expected to have a wider impact on sustainable development. There will be no impact on climate change, waste management, air quality, landscape appearance, habitat, wildlife, levels of noise exposure or water pollution, abstraction or exposure to flood.

Health Impact

228. Do the proposals have a significant effect on human health by virtue of their affects on certain determinants of health, or a significant demand on health service? (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)

229. The proposals are expected to impact on health as they change the extent and scope of CQC regulation and thus mitigation of health and social care risks. These potential costs and benefits have been assessed in the main cost benefit analysis of this impact assessment. There are no expected health risks in association with, diet, lifestyle, tobacco and alcohol consumption, psycho-social environment, housing conditions, accidents and safety, pollution, exposure to chemicals, infection, geophysical and economic factors, as a result of the proposals

Rural Proofing

230. Rural proofing is a commitment by Government to ensure domestic policies take account of rural circumstances and needs. It is a mandatory part of the policy process, which means as policies are developed, policy makers should: consider whether their policy is likely to have a different impact in rural areas because of particular circumstances or needs, make proper assessment of those impacts, if they're likely to be significant, adjust the policy where appropriate, with solutions to meet rural needs and circumstances.

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

Wider impacts

232. The main purpose of the proposals is to reduce the burden of regulation, correct oversights and ensure consistency across the regulatory system.

Economic impacts

233. The costs and benefits of the proposals on businesses have been considered in the main cost benefit analysis of this impact assessments. Under the majority of the proposals the regulatory burden on businesses is reduced, where as for a minority it is increased. It has not been possible to quantify any potential impact on competition, but for those brought in to regulation, all suppliers will be subject to the same rules. The proposals are designed to promote a fair playing field, and thus not expected to adversely affect competition.

Environmental impacts and sustainable development

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

Social impacts

235. No impact has been identified in relation to rural issues or the justice system. Although providers of services suspended by the CQC do have the right of appeal to the First-tier tribunal, the numbers of applications are expected to be small.

Human rights issues are covered within the separate Equality Impact Assessment.

236. No major health risks were identified in association with the proposals. Determinants of health such as, diet, lifestyle, housing conditions, accidents and safety etc were considered.

# F. Summary and Conclusion

237. This impact assessment has demonstrated that, based on the available evidence, Option 2, *implement all proposals*, offers value for money and is not expected to have any significant negative impacts on equality. It is therefore the recommended preferred option for consultation.

# Annexes

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

# Annex 1: Post Implementation Review (PIR) Plan

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

| |
|---|
| **Basis of the review:** [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];<br>The use of secondary legislation to set the scope of registration and registration requirements made the system more flexible than it was under the Care Standards Act. If the ongoing monitoring of the system with CQC and other stakeholders identifies weaknesses in the system we can address this through regulations.<br><br>We have a commitment to carry out a full review of the regulations within three years of implementation in 2010. |
| **Review objective:** [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]<br>The review will consider whether the original objectives of being coherent, proportionate to risk, a fair playing field, and cost effective remain the correct approach, and whether any amendments are required to meet these, or any revised objectives. |
| **Review approach and rationale:** [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]<br>There will be in depth evaluation, including consideration of the views of CQC and other stakeholders, including providers, professional bodies, people who use services etc. There will be formal consultation on any proposals for changes, which will also need to go through the affirmative Parliamentary procedure. |
| **Baseline:** [The current (baseline) position against which the change introduced by the legislation can be measured]<br>The regulatory framework is continuously monitored against the original objectives to ensure it is coherent, proportionate etc and takes account of developments in service provision and better regulation principles. |
| **Success criteria:** [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]<br>The policy objective will be achieved by meeting the original objectives. We are already planning to carry out a wide ranging review within three years of the implementation of the new framework and any issues that are identified will be addressed, by further amendments to the regulations if appropriate. |
| **Monitoring information arrangements:** [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]<br>We have arrangements in place for a systematic collection of monitoring information from CQC - including regular meetings specifically to discuss these issues. We have plans to work continuously with a wide range of stakeholders and experts in the key areas covered by regulation within three years of the initial implementation. |
| **Reasons for not planning a review:** [If there is no plan to do a PIR please provide reasons here] |

# Annex 2 - Sources and references

Fitness of Provider Partnerships
There is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Diagnostic and Screening Procedures:
There is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment. CQC have provided data on various provider groups, but not all of them could be easily identified.

Other data sources:

1. Mixed Practice Medical Practitioners clinical assumptions.

Research Bodies Carrying out Diagnostic Tests:
Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Theoretical assumptions based on:

1. Zwaan, L., de Bruijne, M., Wagner, C., Thijs, A., Smits, M., van der Wal, G., Timmermans, D., 2010. Patient Record Review of the Incidence, Consequences, and Causes of Diagnostic Adverse Events. Arch Intern Med 170 (12), 1015-1021.

Air Ambulance Operators
CQC have provided data on the number of air ambulance transport only providers, the level of regulatory burden on them and information on the extent of CAA regulation.

Format of Statutory Notifications
There is limited information on this area. Discussions between DH policy and CQC have informed this impact assessment.

Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs and personal care away from home

Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Key theoretical assumptions based on following key sources:

1. EQ5D framework for assessing changes in health states, further explanation found at: http://www.euroqol.org/eq-5d/what-is-eq-5d.html

Key clinical assumptions based on following key sources

A. Corso, Pheadra et al, 2008, Health-Related Quality of Life Among Adults Who Experienced Maltreatment During Childhood, *American Journal of Public Health*, 98(6), found at: http://ajph.aphapublications.org/cgi/reprint/98/6/1094.pdf
B. Walsh, Kathleen et al, 2008, Using Home Visits to Understand Medication Errors in Children, found at http://www.ncbi.nlm.nih.gov/books/NBK43769/pdf/advances-walsh_74.pdf

Key data sources:

I. NHS reference cost data 2009/10
II. Skills for Care, 2010: the state of the adult social care workforce in England, 2010, found at http://www.skillsforcare.org.uk/nmsruntime/saveasdialog.aspx?lID=4457&sID=237
III. IFF Research, 2008, Employment Aspects and Workforce Implications of Direct Payments, found at http://www.skillsforcare.org.uk/nmsruntime/saveasdialog.aspx?lID=799&sID=416
IV. National Patient Safety Agency, 2010, National Reporting and Learning Service Quarterly Data Workbook up to September 2010, found at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=94740

V. NICE/SCIE, 2010, Promoting the quality of life of looked after children and young people – costing report, found at: http://www.scie.org.uk/publications/guides/guide40/files/PH28CostingReport.pdf
VI. University of Kent, Personal Social Services Research Unit, 2010, Unit costs of health and social care
VII. Information obtained from CQC, March 2011

Independent Midwives

Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Key theoretical assumptions are based on the following key sources:

1. Nursing & Midwifery Council, UK, 2010, Midwives Rules and Standards, found at http://www.nmc-uk.org/Documents/Standards/nmcMidwivesRulesandStandards.pdf
2. EQ5D framework for assessing changes in health states, further explanation found at: http://www.euroqol.org/eq-5d/what-is-eq-5d.html

Key clinical assumptions are based on the following key sources:

A. Symon, Winter, Inkster, Donnan, 2009, Outcomes for births booked under an independent midwife and births in NHS maternity units: matched comparison study, *BMJ* 2009; 338:b2060
B. British Medical Journal, 2011, Clinical Evidence, found at http://clinicalevidence.bmj.com/ceweb/index.jsp
C. British Medical Journal, 2011, Journals, found at
D. http://group.bmj.com/group/media/bmj-journals-information-centre
E. Patient information website, 2011, found at www.patient.co.uk
F. Centre for Maternal and Child Enquiries (CMACE) Perinatal Mortality 2008:United Kingdom. CMACE: London, 2010, found at http://www.cemach.org.uk/getattachment/60bc0b7b-e304-4836-a5e7-26895c97ab20/Perinatal-Mortality-2008.aspx
G. Centre for Maternal and Child Enquiries (CMACE) Saving Mother Lives 2006-2008:United Kingdom. CMACE: London, found at http://www.cemach.org.uk/Publications-Press-Releases/Report-Publications/Maternal-Mortality.aspx

Key data sources are:
I. NHS reference cost data 2009/10

Mixed Practice Medical Practioners

Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Key theoretical assumptions based on following key sources:
1. EQ5D framework for assessing changes in health states, further explanation found at: http://www.euroqol.org/eq-5d/what-is-eq-5d.html
2. National Audit Office, 2007, Improving Quality and Safety, Progress in Implementing Clinical Governance in Primary Care: Lessons for the New Primary Care Trusts, found at http://www.nao.org.uk/publications/0607/primary_care_governance.aspx

Key clinical assumptions based on following key sources

A. Department of Health, 2009, Impact assessment of regulation of primary medical and dental care providers under the Health and Social Care Act 2008, found at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_115559

Key data sources:

I. NHS Information Centre, 2009, Trends in Consultation Rates in General Practice 1995/1996 to 2008/2009, found at

http://www.ic.nhs.uk/webfiles/publications/gp/Trends_in_Consultation_Rates_in_General_Practice_1995_96_to_2008_09.pdf

II. National Patient Safety Agency, 2010, National Reporting and Learning Service Quarterly Data Workbook up to September 2010, found at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=94740
III. NHS reference cost data 2009/10
IV. Information obtained from CQC, March 2011

Surgical Sterilisation

Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Key theoretical assumptions based on following key sources:

1. Rowlands, S., Hannaford, P., 2003. The incidence of sterilisation in the UK. BJOG: An International Journal of Obstetrics and Gynaecology 110, 819–824.
2. Royal College of Obstetricians and Gynaecologists*., 2004.* Male and Female Sterilisation: Evidence-based Clinical Guidelines No. 4*,* London : *RCOG Press.*
3. Macran S, Kind P., 2005. An Illness Atlas for EQ-5D. Outcomes Research Group Centre for Health Economics University of York, 22nd Plenary Meeting of the Euroqol Group, Norway.

Key clinical assumptions based on following key sources:

A. Awsare et al., 2005. Complications of Vasectomy. Annals of the Royal College of Surgeons in England 87 (6), 406-410.
B. Schwingl, P., Guess, H., 2000. Safety and Effectiveness of sterilisation. Fertility and Sterility 73 (5), 923-936.
C. Walsh J., Lythgoe H., Peckham S., 1998. Contraceptive Choices: Supporting Effective Use of Methods. London: Family Planning Association.
D. Filshie, G., 2007. Controversies in Female Sterilisation. The Yearbook of Obstetrics and Gynaecology 12, RCOG Press.
E. Chi I., Feldblum P., 1981. Luteal phase pregnancies in female sterilization patients. Contraception 23, 579–89.
F. Mertes, M., Laxenaire M., 2004. Allergy and anaphylaxis in anaesthesia. Minerva anestesiologica.
G. Gibbison B., Kinsella S., 2009. Postoperative analgesia for gynecological laparoscopy. Saudi Journal of Anaesthesia 3(2), 70-6.
H. Jansen F., Kapiteyn K., Trimbos-Kemper T., Hermans J., Trimbos J.., 1997. Complications of laparoscopy: a prospective multicentre observational study. British Journal of Obstetrics and Gynaecology 104, 595–600.
I. Varma R., Gupta J., 2007. Predicting negligence in female sterilization failure using time interval to sterilization failure: analysis of 131 cases. Human Reproduction 22(9), 2437-43.

Key data sources:

I. NHS Contraceptive Services Report: England 2009/10
II. NHS reference cost data 2009/10
III. NHS Hospital Episode Statistics 2009/10
IV. Information obtained from CQC, March 2011

Absence without leave notifications

There is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Exemption for the Olympics and the Paralympics

There is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Minor Clarifications and Amendments

There is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.