Title:	Impact Assessment (IA)
Changes to regulations for Care Quality Commission registration **IA No:** 6011 **Lead department or agency:** Depatment of Health **Other departments or agencies:** Department of Education, Ofsted	**Date:** 15/12/2011 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation

Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£5.0m	£4.0m	- £0.42m	Yes	OUT

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 aims to be coherent, proportionate to risk, and cost effective.These objectives were considred in previous impact assessments. A review has identifed areas where the regulatory framework can be recast to reduce regulatory burdens, to increase consistency and to improve clarity. Government intervention is necessary to make these legislative amendments.

What are the policy objectives and the intended effects?

The objectives of the review are to remove the burden of regulation where it is not justified, and to improve the regulatory framework, so that it is clearer, more coherent and consistent, more proportionate to risk, promotes a fairer playing field for providers, and hence better meets the original policy objectives.
The proposed rationalisations will 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 unnecessary burdens, while a higher risk activity, and its 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, preferred option, compared to Option 1, do nothing, are assessed in this impact assessment.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2017

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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: 15.3.12

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing - no change to regulations for CQC registration

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
Year 2010	Year 2012	Years 10	**Low:** Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	0

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

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

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

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	0

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

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

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

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

Key assumptions/sensitivities/risks **Discount rate (%)** N/A

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline. The do nothing options 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.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits: 0**	**Net: 0**	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Implement all proposals of the initial review of CQC registration regulations

FULL ECONOMIC ASSESSMENT

Price Base Year **2010**	PV Base Year **2012**	**Time Period** Years 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** £5.0m

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		£0.4m	£3.4m

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

Under the sterilisation proposal surgical sterilisation will become a regulated activity and the key cost (mainly to business) is the regulatory burden to providers, such as CQC fees and costs of compliance. For the rest of the proposals where activites come 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.

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

It is difficult to predict how both 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	£0.5m		£0.9m	£8.3m

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

Under the sterilisation proposal surgical sterilisation will become a regulated activity and the key benefits are health gains and saved NHS resources, these benefit society as a whole. For the rest of the proposals, where activities come out of regulation, the key benefits are reduced regulatory burden on providers achieved 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. It may not have been possible to quantify all of the reduced burden for some areas.The proposals as a whole make the regulatory framework more consistent, coherent, risk based, and creates a level playing field.

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, thus are necessarily subjective assessments.

A key assumption is the scope for CQC to mitigate associated health risks. The costs to CQC of regulation are based on current fee strucutre, which is subject to change, where 100% cost recovery is assumed. The burden on providers is assumption based. Markets are assumed to remain static.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: £0.06m	**Benefits: £0.48m**	**Net: - £0.42m**	Yes	OUT

Evidence Base

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 by providers. 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.

2. 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.

3. 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.

4. The 16 registration requirements set 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.

5. Failure to comply with the requirements is an offence. 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.

6. 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.

7. 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.

8. **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 and summary of specific impact tests

Section F: Summary and conclusion

A. The underlying problem

9. 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 changes 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.

10. 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 setting;
- 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.

11. 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 aimed 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; and

- consider the opportunities for streamlining the existing requirements to reduce regulatory burdens.

12. The current review has established that there are a number of areas where the underlying objectives have not been effectively met by the regulations and there is an opportunity to recast the regulatory framework to reduce the regulatory burden. 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 where 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 service users.

13. 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, which is not deemed 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, and unjustified regulatory burdens removed.

14. The review we have carried out so far identified a number of potential areas for change. 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; and

    - whether we were in a position to make a change.

15. 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, and with further work, including discussion with policy leads and external bodies, we arrived at a list of most pressing issues;

    - *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 and screening procedures
Air ambulance operators
Format of Statutory notifications
Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs
Personal care away form home

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

Mixed practice medical practitioners
Independent Midwives

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

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

16. A public consultation on the above areas and our proposals was held and concluded on October 7th 2011. Following this consultation and further policy development, we have decided to address the issues around independent midwives and personal care away from home to a different timetable. The revision of regulations concerning independent midwives will be aligned with DH policy development and regulations on professional indemnity. Personal care away form home will be considered in the wider review of CQC regulations. As a result, these issues are no longer part of this impact assessment, nor regulation amendments. *To note: it is due to independent midwives no longer being in scope that the overall impacts of this IA are substantially lower than at consultation stage.* A final impact assessment for each of these areas will be completed in due course.

17. This leaves the remaining issues in scope, and these 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 carry on the regulated activity. 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, which when combined 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: (a) Lower risk activities – some relatively minor procedures, including hearing assessments, currently trigger the requirement to register with CQC, even for providers specifically exempt from registering for treatment of disease, disorder or injury. However, for these activities, as the risk of harm is relatively low, and there is limited scope for CQC to mitigate the risks, the burden of regulation is deemed unnecessary. (b) Providers must register for each regulated activity they carry out. Therefore, providers who are registered for other regulated activities are required to register specifically for carrying out diagnostic and screening procedures including IVF clinics using ultrasound. As CQC already oversees these providers for provision of more risky activities, requiring registration specifically to cover these lower risk procedures is deemed an unnecessary burden.
Research bodies carrying out diagnostic and screening procedures
The role of the CQC is around regulating health and social care providers to assure minimum standards of safety and quality for patients and service users of health and social care. However, there is not a specific distinction in the regulations between diagnostics and screening procedures carried out for the purposes of treating a patient and those carried out for other purposes, such as research. As a result, the regulations currently require some non-patient treating research bodies to register with the CQC if that research involves the regulated activity of diagnostics and screening procedures. However, the statutory requirements that a registered provider must meet are not appropriate for research

[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.

bodies, as they are not providing care to meet an individual's health or social care needs. As a result, CQC would have to either; 1) not apply the majority of the registration requirements on the grounds of them being inappropriate; or 2) take enforcement action against the provider for failing to meet the requirements, including stopping them providing the regulated activity and closing them down. In addition, a number of bodies, including the Research Ethics Committee, regulate research, and thus CQC regulation would represent duplication for the most part.
Given the above, CQC regulation is deemed inappropriate and an unnecessary burden.

Air ambulance operators

At present, the regulation requires providers of aircraft ambulances that only provide transport services, to register with CQC despite already being regulated by the Civil Aviation Authority. The CAA's regulation is more extensive than CQC's in relation to transport. As a result, CQC registration for transport services only represents duplication, and thus an unnecessary burden. The provision of any other regulated activity, such as treatment of disease, disorder or injury, would still require registration with the CQC.

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. Currently, 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 were able to specify the format for such information, it 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, arranged by parents, carers or IUTs

While domiciliary care agencies are required to register with CQC, where a person arranges 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 trusts, parents or carers arranging care for someone unable to arrange their own care; in these instances providers must be registered if they provide domiciliary care for disabled children or vulnerable adults and are being paid to do so. Yet, the nature of this care provision is such that there are a large number of providers (60k-200k), many of which are individuals providing care in service user's own homes, some of which is carried out under less formal arrangements. Under CQC's current regulatory model and resource constraints, it is not possible for CQC to regulate effectively this type of provision. CQC has advised that it has no independent domiciliary care providers, who only provide care arranged by a parent, carer or trust, currently registered with them. This leads to false assurance and unintentionally having providers operating outside of the regulations.

Previous commitments

Mixed practice medical practitioners

There is an inconsistency in the way that the private practice of medical practitioners is registered. The independent private practice of medical practitioners is: (a) currently registered if the practitioner in question also works for non-NHS providers; (b) in some cases not registered if some of the work is done for the NHS.

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. This creates a non-level playing field.

Unintended consequences and oversights

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 some duplication with 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. 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 there was a clear intention to exclude healthcare services provided as part of the Olympics. 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 - this was an unintentional oversight.

It has now become clear that the LOCOG 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 has previously been established, 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. As a result, CQC regulation would add little benefit and represent an unnecessary burden.

Minor Clarifications and Technical Amendments

At times, the regulations are not entirely clear in some areas and there is some resulting ambiguity about whether a provider needs to register. In addition, the treatment of providers has been shown to be inconsistent in certain situations. 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 an accident site to treatment facility to register even if that transport takes place only in the event site itself.
- Second Opinion Appointed Doctors – the regulations need to make clear that there is no requirement for SOADs 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 are exempted under the current wording.
- 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 from registration.
- 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 of the regulation requirements.

Surgical sterilisation and sterilisation reversal

Surgery carried out for: (a) the treatment of disease, disorder or injury, (b) cosmetic purposes, or (c) 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 similar risks to other surgical operations. 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.

18. 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

- An impact assessment which considered the costs and benefits of deferral of the registration of primary medical care providers, in October 2011
- A consultation stage impact assessment preceding this one, that consulted on the costs and benefits of the proposed changes to CQC regulation, April 2011
- There is also a consultation response document, which is published alongside this impact assessment.

19. The role of the government in the regulation of health and adult social care in England, and CQC as that regulator has been justified in earlier 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 have been subject to a formal 12 week public consultation, concluding on October 7th 2011, address issues where:

    - an unnecessary financial and/or bureaucratic burden is placed on providers (including small businesses) and/or CQC, where the scope for benefit is relatively low. Removal of the burden will allow those providers and/or CQC to use their resources more effectively, to provide better services.
    - some providers of a high-risk activity (surgical sterilisation) that are not currently regulated will be brought into CQC regulation, and therefore, for the first time, have to demonstrate that they meet the essential requirements of safety and quality.

20. Overall the proposal is to address areas where the regulatory framework can be recast to reduce regulatory burdens. 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 non-level playing field it is creating in the market. For some of the proposals, there is no expected change in the number of providers subject to regulation, only minor clarifications are required. As the regulatory framework is implemented through secondary legislation, addressing the above issues, and reducing or simplifying regulatory burdens, requires amendments to legislation and therefore government intervention is required.

21. In **only one** of the individual proposals (**surgical sterilisation**) 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 that 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 asked if there are any alternatives to CQC regulation that would provide an appropriate assurance of safety and quality in this sectors; no viable alternatives were proposed (see Para 36 for details).

22. Some of the issues we have identified above impact more heavily on certain groups. For example, the proposal around domiciliary care. In the current regulations, a person arranging their own care is able to engage an unregistered provider should they choose to. Extending this freedom to care arranged by parents, carers and 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

23. The objectives of the review are to remove the burden of regulation where it is not justified, and to improve the regulatory framework, so that it is clearer, more coherent and consistent, more proportionate to risk and fairer, and hence better meets the original policy objectives. The proposed rationalisations will allow CQC to be more focussed on where it can address the greatest risks to patients and service users- 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

24. As discussed above, 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. 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.**

25. 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, and the scope for CQC to mitigate the risk, is enough to justify the burden of regulation. The review established that the regulatory framework requires amendments in order to achieve this objective.

26. 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. Intended Effects: a freer and more consistent market leading to better value and better care.
Diagnostic and screening procedures
Objective: To remove the unnecessary burden, where the activity has relatively low risk of harm, and there is limited scope for CQC to mitigate the risks. Intended Effects: potential cost savings and fewer constraints leading to better value.
Research bodies carrying out diagnostic and screening procedures
Objective: To remove the unnecessary burden, as CQC regulation is inappropriate and duplicates other regulatory arrangements. Intended Effects: potential cost savings and fewer constraints leading to better value.
Air ambulance operators
Objective: To remove the unnecessary burden, where CQC regulation duplicates CAA regulation. Intended Effects: potential cost savings leading to better value.
Format of statutory notifications
Objective: To simplify the process. Intended Effects: potential cost savings and efficiency gains leading to better value.
Domiciliary care for disabled children and vulnerable adults, arranged by parents, carers or IUTs
Objective: To make regulations consistent with practical application, and to remove false assurance and prevent unintentional provision of care outside of regulations. Intended Effect: clearer regulations reflecting practical application leading to better care and better value, including more freedom of choice and personalised care for people who use services.
Mixed practice medical practitioners
Objective: To make regulations more consistent across different sectors, regardless of employment patterns, and to promote a level playing field. Intended Effect: clearer and more consistent regulations and a level playing field leading to better care and better value for all.
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. Intended Effect: improved value of the indicator leading to better care and better value
Olympics and Paralympics
Objective: To remove unnecessary burden of registration for a short-lived service where regulation is not practical and would not add benefit. Intended Effect: potential cost savings and fewer constraints leading to better value
Minor Clarifications and Technical Amendments
Objective: To clarify the regulations to ensure they can be effectively implemented. Intended Effect: clearer and more consistent regulations leading to better care and better value
Surgical sterilisation and sterilisation reversal
Objective: To make regulation of all surgical procedures more coherent, consistent and proportionate to risk. Intended Effects: mitigation of avoidable health risks leading to better care and better value.

C. The Options

Option 1: Do nothing

27. Option 1, doing nothing, would leave the current scope of registration in place. This would fail to meet the original objectives of a coherent, proportionate to risk, fair, and cost effective framework. The issues outlined in the previous sections would not be resolved.

28. 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. At the same time, some providers of surgical sterilisation and reversal (a higher- risk activity) would continue to be outside of regulation by CQC. As a result, users of those services would not have the assurance of safety and quality that the framework has been put in place to provide.

29. **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

30. The review originally identified around 60 issues where change might be considered. In order to make the current task manageable, the list of tasks was reviewed 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 danger that high-risk activities could be left without the assurance of safety and quality that is in place for similarly-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 there was a burden on providers, both monetary and administrative, that is not justified by the amount of risk mitigation, and the effect it has on costs of care and the wider market;
    - whether the proposal would clarify the arrangements for registration. This is important, as CQC's effectiveness could be compromised if the regulations were not legally clear enough for CQC to take effective enforcement action; and
    - whether it was possible to make a change. This is important because of the need to make sure the review is manageable with the resources at hand, and could be carried out in a timely manner to make the changes to the regulations within an acceptable time frame.

31. Consideration of these criteria resulted in a short list of pressing issues, which have been subject to a 12-week public consultation. Following this public consultation, some of the proposals were

amended and assessment of the likely impacts was updated. **Overall, the public consultation found that there was strong support for the proposals.** For further information of how the public consultation has informed this policy please see the Consultation Response that is published alongside this impact assessment.

32. **Option 2: implementing all the proposals**, would address the most pressing issues around the scope of regulation 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.

33. 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 so that; 1) providers of other regulated activities do not have to register separately for certain diagnostic and screening procedures, including adult hearing assessments, and 2) otherwise unregulated providers do not come into scope of CQC regulation just for providing lower risk diagnostics and screening procedures.
Research bodies carrying out diagnostic and screening procedures
The proposal is to amend the regulations so that research that involves diagnostic and screening procedures, where this is not part of a person's care or treatment, does not require registration with CQC.
Air ambulance operators
The proposal is to amend the 'transport services, triage and medical advice provided remotely' regulated activity so that a provider of an aircraft, that is regulated by the CAA, does not have to register with CQC in respect of the transport only. 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, arranged by parents, carers or IUTs
The proposal is to remove the requirement for providers of care arranged by trusts, 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 by CQC. At the same time, anyone arranging care would still be able to choose to use a registered provider if they felt that it was the best option for them.
Mixed practice medical practitioners
The proposal is to amend the mixed practice exemption so that it applies where a medical practitioner or group of medical practitioners are employed by a registered provider and relate to the responsible officer (for professional appraisal and revalidation) of that provider. This would mean that the exemption applied consistently to all medical practitioners working for a registered provider, and thus would remove the preferential treatments enjoyed by medical practitioners employed by a NHS provider. The proposal also includes an amendment to the listed services to which the exemption does not apply.
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 are no longer required, but to 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 exempt services as part of the Olympics (rather than only those that are treatment of disease, disorder or injury) put in place solely for the purpose and duration 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.
Surgical sterilisation
The proposal is to change the wording of the surgical procedures regulated activity to bring surgical sterilisation and sterilisation reversal into regulation.

Alternative plausible options

34. Apart from the preferred option (where both most-pressing and achievable issues were selected) and the do nothing option, an option to address the full list of issues identified as part of this review could have been included. However, attempting to address all the issues would have delayed addressing those that are most pressing. There is a commitment to a review of the regulations to a longer timescale, which will seek to resolve all of the identified issues, allowing more time to carry out further impact assessment and stakeholder engagement.

35. Taking forward only some (or various combinations) of the issues that are included in this proposal was also considered. However, the updated proposal as a whole, following public consultation, has 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 deemed unjustified. All of the proposals contribute to the overall policy objective and are manageable within the context of this review.

36. The sterilisation proposal is the only proposal where providers will be brought into regulation. As part of the public consultation, it was asked whether there are any other plausible alternatives to options 1 and 2. Some respondents suggested that General Medical Council oversight or contract management might be alternatives. However, neither of these takes account of the different settings in which this activity could be provided nor do they address system related risks (see Section D below). Therefore, these alternatives were not considered viable.

D. Costs and Benefits of Option 2

37. 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.

38. **This assessment has been updated since the consultation stage to reflect responses, and the latest policy thinking and analysis. It is important to note, that despite the consultation, and specific questions calling for information, there is limited hard evidence and data to inform the quantification of impacts, and the assessment has been prepared within this constraint.**

General Assumptions and Information

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

CQC registration requirements

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

Table D1: CQC registration requirements

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

41. This analysis depends on assumptions about the scope for CQC regulation to mitigate risks, by requiring providers of regulated activities to meet the above registration requirements, over and above other regulations and standards.

CQC Fees and Regulation

42. CQC advises that most providers will pay one fee for all the regulated activities they provide within a single category or sub-category. However, if they provide regulated activities, which span across two or more categories or sub-categories, they will pay the fees associated with each of those.

43. It is assumed that at the margin CQC fees charged to providers cover 100% of the regulator's costs. Therefore, any fee income offsets the cost to CQC, and changes in fees represent a net impact on the provider with no net impact on CQC. Therefore, where a provider comes out of regulation, the provider no longer pays the fee, and CQC lose the fee income - yet, at the same time, they lose the associated cost of regulation.

44. Finally, the fee levels assumed are based on CQC's current fee proposals and represent current understanding. They are however subject to change.

45. Based on the current model it is assumed that providers registering for the first time will incur costs (e.g. staff time) associated with initial registration and compliance. In addition, it is assumed all providers required to register would incur costs associated with planned annual reviews and inspection visits. There may also be ad hoc responsive reviews. However as the proposals generally only affect small numbers of providers at the margin, and the lower frequency and ad hoc nature of potential responsive reviews, we assume no costs to the affected providers in this assessment .

Accounting for distribution of impacts, opportunity and marginal costs

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

- Impacts on self-employed private individuals are split into income tax implications (where applicable) and impacts to the individual. 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. Where there is little information about the provider organisation no income distribution considerations are made, and are therefore 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

47. 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.

48. CQC estimates that there are 1200 dental provider partnerships and 1800 social care provider partnerships currently registered. When the majority of NHS primary medical care providers come into regulation in April 2013, CQC estimates 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.

49. 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 likely that there are 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

50. 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.

51. As there is no data (despite the consultation) 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.

52. 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.

53. Given the extent of the lack of data and uncertainties involved it is not possible to quantify these potential benefits.

Costs

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

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

56. It could be argued that there may be a cost to current providers, who may prefer to maintain current barriers to entry 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.

57. Given the extent of the lack of data and uncertainties involved it is not possible to quantify these potential costs. The consultation did not highlight any additional costs, risks nor evidence.

Value for Money

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

Diagnostic and screening procedures

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

60. Exempted lower risk diagnostics for all providers include: non-ambulatory recording of blood pressure; 12 lead electrocardiography; pulse oximetry when used for the purpose of 'spot' recording; peak expiratory flow measured by a peak flow meter; spirometry when carried out for screening or non diagnostic or monitoring purposes; taking and analysing blood through pin prick or from a vein – where it does not require sending away for analysis; taking and analysing a urine sample – where it does not require sending away for analysis; taking and analysing a wound swab or hair or nail sample. In addition to this list, adult hearing assessments will also be exempt.

61. The associated patient health risks of these activities, including incorrect screening results, are expected to be low in general and, most, if not all, of these risks are mitigated as far as possible through professional, device and health and safety regulation. As a result, the scope for CQC to mitigate risks further is expected to be close to zero. Given this, the proposal is to exempt the above activities, so that providers who provide no regulated activities are not required to register with CQC only because they carry out these lower risk procedures.

62. Exempted low risk diagnostics for providers of other regulated activities include the above and: taking blood; taking a urine sample; analysing a urine or stool sample by means of `dip stick` or other reagent; taking a `swab specimen` from any external part of the body, or skin scrapings or nail clippings; taking a swab specimen from the mouth, ear, nose or throat. In addition to this list we also propose to exempt the use of ultrasound in IVF clinics (which are registered to provide IVF related regulated activities).

63. The associated patient health risks of these activities, including incorrect screening results, are expected to be low, but higher than the activities which will never require registration. In addition to professional and device regulation, the oversight of CQC for the provision of other regulated activities is expected to leave little room for additional risk mitigation. Given this, the proposal is to exempt providers from registering to provide these low risk diagnostics, where they are already registered to provide other regulated activities.

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

Exempted low risk diagnostics for otherwise unregulated providers

Benefits

65. CQC does not currently have any providers of only lower risk diagnostics, including hearing assessments, registered with them. It is not known how many providers, such as complementary medicine providers, are currently required to register for the above activities; there is no data. However, given the nature of this market, there could be tens of thousands.

66. For unregistered providers (mainly complementary/alternative medicine providers and high street hearing aid providers) the benefits could include: (a) savings of not paying the annual registration fee, (b) savings related to avoided initial registration and compliance costs, and (c) reduction of overall administrative burden. As the number of providers is unknown, it is not possible to quantify these savings. In addition, given the nature and size of the market, CQC has not, and probably would not, be able to register these providers. Therefore, there is unlikely to be a real marginal change compared to the do nothing.

Costs

67. There are health risks associated with these lower 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), inappropriate or missing referral to secondary care, and incorrect screening results.

68. The non-invasive nature of most of these lower risk procedures suggests that the majority of the above mentioned health hazards will have very low incidence rates and minimal severity. The risk of incorrect screening results could affect the NHS (false positive leading to a GP consultation and, at times, additional screening or a referral) or patient's health (false negative leading to delayed or lack of treatment). The expected impact of a false positive result is partially offset by its low severity, even in light of higher likelihood. At the same time, the relatively higher impact of a false negative is accompanied by low incidence (as it would require both a false test result and underlying health problems). As a result, the overall risks are perceived to be relatively low. In addition, most of these risks are associated with incompetent use of equipment and lack of skills or incorrectly functioning / inappropriate equipment. It is therefore unlikely that CQC regulation would mitigate any additional risks over and beyond what is already mitigated by professional, equipment, and health and safety regulation.

69. Finally, as in practice, given the nature and size of the market, CQC has not, and probably would not, be able to register these providers there is unlikely to be a real marginal change compared to the do nothing.

Exempted low risk diagnostics for providers of other regulated activities

Benefits

70. CQC estimates that around 1900 care homes, 330 palliative care providers and 300 ambulance providers are currently registered with CQC to provide diagnostic and screening activities. In addition, IVF clinics are also registered to carry out ultrasounds. All of these providers are already registered with CQC for other regulated activities. They will experience no change to their annual fee. This results in unquantifiable, albeit relatively low, savings in general regulatory burden (such as filling out review response forms, facilitating longer inspections, etc.).

Costs

71. As above, the forgone benefits of additional risk mitigation by CQC are expected to be low. The potential risk may be higher in the case of the additional exempted activities, but this is expected to be offset by further risk mitigation through CQC oversight for the provision of other regulated activities. Therefore, as above, the costs of forgone risk mitigation are not expected to be significant.

Value for Money

72. In the case of unregistered providers, there is expected to be little marginal difference compared to the do nothing. The risks are low and there is limited scope for CQC regulation to mitigate risk. Thus, if there were any cost savings realised, they are expected to outweigh the benefits forgone through no CQC oversight.

73. Where providers are already registered with the CQC for delivering other regulated activities, such as care homes, palliative care, and ambulance providers, it is expected that any cost savings or benefits forgone would be very low, if not negligible. As such, for these providers, the proposal is judged to be cost-neutral.

74. Despite the consultation, there is limited evidence in this area. The expected impacts of this proposal have been arrived at through our analysis and extensive policy and stakeholder discussions.

75. Overall, we expect the proposal to yield value for money by removing an unnecessary, albeit small, burden of regulation.

Research bodies carrying out diagnostic tests

76. At present, some 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, paragraph 8(1)(a)& (b) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

77. The regulatory framework under which CQC operates is intended to cover the provision of health and social care. It is not intended to include activities carried out as part of research. CQC has advised that although these bodies would be providing a regulated activity, they would not be able to meet most of 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, CQC would have to either; 1) not apply many of the registration requirements on the grounds of that they are inappropriate and not relevant; or potentially 2) close down some of the research bodies.

78. In addition, even where CQC requirements could be applied, it would mostly duplicate existing regulation around research (Research Ethics Committee) and diagnostic devices (IRMER and MHRA).

79. Option 2, the proposal, is to exempt all diagnostic and screening procedures that are not part of the provision of health or social care from CQC regulation. This would be consistent with regulations around the regulated activity of "treatment of disease disorder or injury".

80. The number of research bodies that the current regulation would apply to is unclear. It is estimated to include 90 universities, 90 medical schools and an unknown number of pharmaceutical companies.

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

Benefits

82. 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, and there is a risk that some, or all, could be lost under the do nothing, Option 1. This risk would not materialise under this proposal.

83. Research could be lost in a situation where CQC had to close research bodies down, or prevent them from providing diagnostic procedures, as they did not meet the registration requirements. Even if CQC were to register providers for carrying out diagnostics, some of the CQC registration requirements could undermine or even compromise the research results. For example, there would be a requirement to "(...) obtain relevant professional advice (...)" in order to "(...) protect the service users (...) against the risks of inappropriate or unsafe care and treatment (...)" - Part 4, 10(1) and (2)(a) of The Health and Social Care Act 2008. This could require an additional clinical step in every research activity in order to discover any underlying patient health problems. This could undermine patient confidentiality, leading to research sample bias, and ultimately discredit the research results. It would also contradict Research Ethics Committee guidance on anonymisation of research. This demonstrates that not only would it be difficult to apply CQC registration requirement to research, but it could also lead to a loss in research output.

84. 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 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).

85. A second source of benefits originates from the reduced burden of regulation. Even if CQC did not apply many of the registration requirements, the costs of regulation would in general still be incurred in full. Under this proposal, these costs would be saved, as CQC have advised that it does not currently register any research bodies. Therefore, under the preferred option, there would be savings in initial registration and compliance costs of around £2500 (based on longer-than-usual admin time burden due to inappropriate registration requirements; overall two weeks of administrative time). Providers would also save annual CQC fees (£1,600), and annual visit costs (assumed to be around £550 per provider, assuming all providers are inspected annually). Assuming 190 providers, these costs amount to around £470k initial costs, and £407k annual costs. Given the varied nature of these provider types and funding arrangements no tax or distributional adjustments are made.

86. It is important to note that the above-quantified benefits are realised only if no research bodies are closed down. As such, these benefits serve as a lower-bound estimate – the assumption is that the benefits of research (and thus the benefits of not losing research) are much greater than the costs of CQC regulation of research bodies.

Costs

87. The main costs of removing CQC regulation originate from the foregone health benefits, resulting from reduced risk mitigation. However, as discussed above, many of CQC regulation requirements do not apply in the context of research. Moreover, CQC regulation overlaps with other regulation in this area, which further reduces these costs.

88. 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, lack of skills or inappropriate equipment;
- 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.

89. 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, severity and duration of adverse events resulting from research activities,
- a high level of regulation by the Research Ethics Committee, Medicines and Healthcare products Regulatory Agency (MHRA) and Ionising Radiation Medical Exposure Regulations 2000 (IRMER) leading to reduced scope for system regulation to reduce adverse events further.

90. The main adverse event that CQC regulation may mitigate beyond the existing safeguards relates to lack of appropriate follow-up, referral, and information sharing. At the same time, it is important to note that even this aspect of regulation may be difficult to enforce due to overlaps and contradictions between CQC requirements and Research Ethics Committee requirements. This significantly reduces CQC's ability to mitigate patient risks in this area.

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

- Approximately 1 million of Britons take part in voluntary health research (this was derived from National Institute for Health Research and Clinical Research Network data);
- Approximately 50% of volunteers participate in clinical trials;
- No more than 5% of these trials use "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";
- No more than 1 in 20,000 of research participants should be referred for further treatment, resulting in approximately 1 research participant having underlying health problems that were either discovered during the research activities, yet were not referred for further treatment;
- No more than 1 in 2,200 of research participants (cumulatively, approximately 13 individuals) suffers minor harm as a result of the research activities;
- A £60k value of a QALY;
- CQC could mitigate 30% of high severity and 5% low severity cases, where research participants with health problems are not referred for further treatment.

92. Under these assumptions, a cost estimate of forgone health benefits of CQC regulation are estimated at £313k per year *(see Annex 2 for derivation).*This estimate is at best uncertain, but thought to be at the higher end of what CQC could reasonably mitigate in this sector.

Value for Money

93. Based on the above costs and benefits, Table D2 below shows the estimated net present value for this proposal.

Table D2: NPV of Research Bodies Proposal

	Year 2012/13	Year 2012/14	Year 2012/15	Year 2012/16	Year 2012/17	Year 2012/18	Year 2012/19	Year 2012/20	Year 2012/21	Year 2012/22	
£000's	0	1	2	3	4	5	6	7	8	9	TOTAL
Benefits											
One-off Compliance Costs	£470	£0	£0	£0	£0	£0	£0	£0	£0	£0	£470
Annual Costs (including inspections)	£407	£407	£407	£407	£407	£407	£407	£407	£407	£407	£4,067
Total Benefits (undiscounted)	£877	£407	£407	£407	£407	£407	£407	£407	£407	£407	£4,538
Costs											
No diagnosis and low-severity adverse events	£298	£298	£298	£298	£298	£298	£298	£298	£298	£298	£2,982
Total Costs (undiscounted)	£298	£298	£298	£298	£298	£298	£298	£298	£298	£298	£2,982
Net Present Value	£579	£99	£90	£82	£74	£66	£58	£51	£44	£38	£1,180

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

94. 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 £1.2m, and an equivalent annual benefit of £175k. This is thought to be an underestimate of the likely benefits as the main benefit of the proposal (as identified by the risk that CQC would have to close the research bodies in question), avoided lost research, cannot be quantified and is potentially large and significant.

Air Ambulance Operators

95. 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 these providers are also required to register for any other regulated activities they provide.

96. Some providers that only provide air transport services who are regulated by the Civil Aviation Authority (CAA), that are also required to register for CQC regulation. CQC advised that the CAA is the principal regulator for air operators, as its requirements are specialised and tailored to the specific characteristics of this sector, and therefore CQC regulation represents a duplication and thus an unnecessary burden. Option 2, the proposal, is to amend the above regulation so that providers of air transport only are exempt from CQC registration.

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

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

Benefits

99. CQC advises that this would only affect the 6-8 providers of transport services only to helicopter emergency medical services (air ambulance charities) and fixed wing ambulance services (principally repatriation services). Compared to the do-nothing option, these providers would no longer be required to pay a CQC annual fee of £800 per annum. This would result in a total reduction in the regulatory burden of £4,800-£6,400, central estimate £5,600. 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 25% from 2012, £1200-£1600 per annum (central estimate £1,400) would be a benefit to the Exchequer.

100. In addition to the fee, CQC has advised that although there may be duplication of regulation and CQC utilises CAA findings where possible, the providers may still currently incur a further burden of regulation, such as inspection visits. It is assumed that given the duplication this burden would be lower than usual. In order to try and quantify this forgone burden it is assumed that overall two days of one administrator's time is required (0.5 day preparing for visit, 0.5 day to facilitate visit, 1 day in total of other information gathering etc over the year). Based on a total administrative staff hourly cost of £22 (based on NHS and UK wide admin salaries includes on-costs and overheads), this gives an overall avoided burden of £330 (15hrs*£22) per provider, and around £2,300 pa in total.

Costs

101. As the current CQC regulation of air transport services only duplicates CAA regulation, there are no assumed costs of making the exemption, compared to the do-nothing.

Value for Money

Table D3: 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
Providers; fee saved	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	42.0
Exchequer; increased tax rev	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	14.0
Providers; reduced burden	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	23.1
Total Benefits (undiscounted)	7.9	7.9	7.9	7.9	7.9	7.9	7.9	7.9	7.9	7.9	79.1
Net Present Value	7.9	7.6	7.4	7.1	6.9	6.7	6.4	6.2	6.0	5.8	**68.1**

(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)

102. 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 £68k, with an equivalent annual benefit of £8.2k.

Format of Statutory Notifications

103. 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 submit the information and the variety of formats makes analysis inefficient. The proposal is to allow CQC to specify the format. This will make the process more straightforward for providers, and by reducing the time taken to carry out analysis will improve CQC's efficiency. In addition, the proposal makes some changes to the requirements around when a notification is required. These changes are expected to create minimal additional work, but be sufficient to increase the value of the notifications CQC receives.

104. Given the nature of this change, it is not expected that there will be any significant impacts. Initially there may be costs as providers and CQC get used to a standard form, but over time this should be offset by the benefits and increased efficiency associated with a standard process and form. Despite the consultation, it has not been possible, nor deemed proportionate analysis, to assess the impacts of this proposal in any detail, but it expected to yield value for money.

Domiciliary care for disabled children and vulnerable adults, and care arranged by IUTs

105. At present, all providers of personal care in a person's own home are required to register with CQC unless the person receiving the care arranged it themselves without the involvement of an employment agency or business. The exemption does not apply where the care is arranged by another person, for example, parents acting on behalf of their child, carers or trusts acting on behalf of a vulnerable adult. Therefore, providers must be registered if they provide domiciliary care for disabled children or vulnerable adults and are being paid to do so.

106. However, the nature of this care provision is such that individuals provide care in service users own homes, and a significant proportion of this activity is carried out under less formal arrangements. Given this, these providers are unlikely to be aware that the care they are providing is currently a regulated activity and there is no obvious way for CQC to identify them. There is no list or register that CQC could consult. Although some providers may have formal contracts with parents, carers or IUTs, there is no routine way of identifying them. In addition, some providers may be working cash in hand; without constituting a formal business; and with no business premises. CQC could search advertisements, but as providers may be providing the service informally or through word of mouth, that would not, even if it were practical, reach all the providers. Even if CQC could identify a provider, it would then be very difficult, and resource intensive, for CQC to prove in a court of law that someone was providing domiciliary care if they denied it. Therefore, under CQC's current regulatory model and resource constraints it is not possible for CQC to effectively regulate domiciliary care providers who provide care arranged by a

parent, carer or IUT. Due to the above difficulties, CQC has advised that they have no independent domiciliary care providers who only provide care arranged by a parent, carer or IUT currently registered with them. Further evidence of the above difficulties is that these providers were not regulated under the Care Standards Act, which was the regulatory framework pre CQC.

107. The exact number of providers affected is not known. However, it is estimated that this is in the region of between 60k and 100k providers. This could increase to around 200k in 2012/13 and beyond as the government realises its commitment to ensure that by April 2013 all eligible individuals will receive a personal budget, preferably as direct payment to the parent, carer or IUT to arrange the care they feel appropriate.

108. The proposal is to exempt paid domiciliary care for an individual arranged by an IUT, parents or carers without the involvement of an employment agency.

109. The total benefits and costs of implementing this proposal marginal to the do-nothing are considered below.

Benefits

110. The proposed exemption will mean that the estimated 60k-200k providers of domiciliary care will no longer be required to register with CQC. In theory, this would mean the providers no longer incurring registration fees or any costs associated with compliance and monitoring. However, as discussed above, the key rationale for the proposed exemption is that, given the nature of domiciliary care and its providers, many providers will be unaware that they are providing a regulated activity and CQC is unable to identify them. CQC has advised that they have no independent domiciliary care providers, who only provide care arranged by a parent, carer or IUT, currently registered with them. As a result, it is expected that there will be no actual cost savings that could be realised.

111. Given, that the current requirement cannot be enforced systematically as there are no routine data to identify unregistered services, there is a false assurance to the public that domiciliary care not organised through an agency is subject to system regulation. Under the proposed exemption this false assurance would be removed and the system would be more transparent for service users and the public.

112. In addition, there is risk of paid domiciliary care providers, providing care arranged by parents, carers or IUTs, unintentionally providing a regulated activity without being registered. Under the proposed exemption, this risk would be removed.

113. Finally, there could be a benefit to potential providers and service users as a perceived market barrier of system regulation is removed, and the market for domiciliary care is liberalised. This is in line with policy around personal choice agenda and Vision for Adult Social care to ensure that by April 2013 all eligible individuals will receive a personal budget, preferably as a direct payment.

Costs (benefits forgone)

114. The proposed exemption will mean paid domiciliary care providers providing care arranged by parents, carers or IUTs will no longer have to register with CQC for their independent practice. As a result, there would be a loss of the benefits generated by CQC regulatory oversight mitigating risks in the provision of care.

115. However, as discussed, many providers do not know they need to register and/or are unidentifiable, therefore not registered. As a result, CQC is currently not able to mitigate risks, and thus the marginal benefits forgone under the proposed exemption are expected to be zero.

Value for money

116. The proposed amendment is not expected to make any practical difference to the regulation of domiciliary care. It is not expected that there will be any cost savings from a reduced burden of regulation nor any loss of risk mitigation and health benefits. The proposed exemption would mean the regulations reflect what is happening and is possible in practice and thus remove false assurance and avoid unintentionally having certain providers of domiciliary care operating outside the regulations. As a result, it is expected to have a small and unquantifiable net benefit.

Mixed Practice Medical Practitioners

117. There is an inconsistency in the way that the independent private practice of medical practitioners is registered. Medical practitioners who work for the NHS do not need to register the independent practice they carry out in a surgery or consulting room, unless they are providing a specifically listed activity. However, medical practitioners who work for a registered provider that is not an NHS body (e.g. a private hospital) are required to register their independent private practice. As a result, there is an inconsistent approach across providers. The proposal is to amend this exemption so that it is consistent across sectors and is based on relative risk and the potential for CQC registration to mitigate this risk.

118. It is assumed that most of the exempted doctors will be hospital-based consultants. The independent practice of medical practitioners mainly includes initial consultations and referral and follow up work they carry out under their practising privileges with their registered employer. These services could range from a simple consulting service – including prescriptions - to a minor medical procedure such as curettage of a skin lesion, and thus are similar to those carried out in primary medical care. Primary medical care has been identified as a sufficiently risky activity to warrant registration with CQC, as there is no additional or system risk mitigation, beyond professional and device regulation.

119. The proposal is to change the mixed practice exemption so that a medical practitioner is exempt from registration with CQC for their independent private practice in a surgery or consulting rooms where they are employed by a provider that is registered with CQC *and* where the practitioner relates to the responsible officer of that provider, or they are on the performers list of a designated body.

120. The rationale for this proposal is that unlike primary medical care there is additional, system related, risk mitigation in place. The employment of the doctor by a registered provider can offer indirect but sufficient system risk mitigation as the entire work and practice of the doctor will be subject to the registered provider's quality assurance and governance arrangements and systems through the responsible officer. A responsible officer has oversight of all of the medical practitioner's care, including any independent practice. Further, the registered provider will be responsible for making sure that the doctor's clinical development as well as their mandatory training is updated as necessary

121. In addition, the mixed practice doctors will be have experience of providing a regulated activity within a CQC registered provider, and thus has understanding of, and practice of meeting, the essential levels of safety and quality.

122. As a result, the scope for CQC to further mitigate risks is significantly reduced, compared to other circumstances in which similar care may be provided.

123. Mixed practice doctors may provide higher risk activities than those considered above. The regulations include a list of these activities, such as endoscopy, and states that the exemption from registration does not extend to these procedures. This proposal does include making some amendments to this list as follows;

- treatment of disease, disorder or injury carried out under anaesthesia or intravenously administered sedation remains a listed activity, except for surgical procedure that are exempt from the regulated activity surgical procedures (paragraph 7(2) and (3),
- endoscopy activity remains a listed activity except for lower risk procedures such as the use of an auroscope and proctoscope,
- The following activities are added to the list; intravenous, intrathecal or epidural chemotherapy and interventional radiology and radiotherapy, diagnostic or therapeutic use of MRI, CT and PET scans and X-rays, and physiological testing, including adenosine stress testing, tilt-table testing

124. The total costs and benefits of implementing this proposal marginal to the do-nothing are considered below.

Meaningful relationship with Non-NHS registered providers

Benefits

125. Changing the exemption in the manner described above will mean that the independent practice of medical practitioners who are employed by a non-NHS registered providers and relate to the responsible officer of that provider will become exempt from CQC regulation. CQC estimate that they currently have the independent practice of around 420 doctors registered with them. Based on discussion with CQC and stakeholders it is estimated that around 40 consultants (~10%) are currently registered who are also employed by a private hospital and carry out independent private practice, and it is assumed that these medical practitioners would no longer be required to register.

126. Each of these providers will no longer have to register with CQC for their independent practice which means they will save the associated costs. The costs of regulation, involve the annual fee for CQC registration, assumed to be £1,500 per provider and annual review costs assumed to be around £2300 per provider (1.5 days self assessment and 1 day to prepare and 0.5 day to facilitate an observational visit and hourly cost of ~£100 *–based on primary care staff costs*). We assume any initial registration or compliance costs were sunk when the provider originally registered. This brings the costs of regulation to £3,900 per provider per year.

127. We assume that 60% of the annual fees fall on the exchequer through lost tax income and national insurance payments. 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.

128. The total social value of savings to practitioners is thus £58k pa ((£1,500 * 40% * 0.5 *40) + (£2300 * 0.5 *40) = £58,000 pa) *(note for one-in one-out calculations the 0.5 weight is removed).* The total social value to the exchequer is £36k pa (£1,500 * 60% * 40 = £36k).

129. In addition, the proposed amendments will mean that the mixed practice exemption will apply consistently to all medical practitioners employed by a registered provider. This results in fairer competition. It is not possible to quantify this benefit but it could be significant.

Costs

130. We estimate that there are 40 medical practitioners who will no longer have to register their private practice with CQC as a result of the change to the regulations. In theory this would result in a loss of the benefits generated by CQC regulatory oversight mitigating risks in the provision of care. However, as discussed above, the scope for CQC registration to mitigate risks would be reduced to near zero in this instance so this loss of risk mitigation is not expected to be significant.

Non-meaningful relationship with NHS registered providers

131. Changing the exemption in the manner described above will mean that the independent practice of medical practitioners who are employed by a NHS registered providers, but do not relate to a responsible provider of that provide would come into CQC regulation for the first time. This impact is hypothetical; the change to the exemption would mean in theory this could happen, however it is expected that there are no medical practitioners that would fall into this group.

132. The independent practice of these providers would not be subject to the additional risk mitigation offered by oversight of a responsible officer and experience of providing a regulated activity to CQC standards. The care provided by these practitioners is assumed to be similar to that of primary medical care providers, who are in scope of CQC registration. Therefore, there would be scope for CQC registration to mitigate risks in the provision of their independent care. As a result, the associated costs and benefits of regulation would be realised. However, as discussed above this impact is hypothetical; it is expected that there are no practitioners that would be affected by this. As a result, the total impact for these providers is expected to be zero.

Listed activities to which the exemption does not apply

133. These changes and additions are relatively minor and it is not expected that this will change the number of providers required to register with CQC no the burden involved. Therefore, a zero marginal impact is expected.

Overall

Value for money

134. The change in exemption is expected to result in around 40 independent practitioners coming out of CQC registration. As a result, we expect the overall burden of regulation will be reduced by up to £94k pa with an NPV of £0.8m over ten years.

Table D4: NPV of Mixed Practice Exemption Proposal

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Costs and Benefits (£'000s)	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	TOTAL
Cost Savings											
Annual costs to provider;fees	£12	£12	£12	£12	£12	£12	£12	£12	£12	£12	£120
Annual cost to government; loss of tax rev	£36	£36	£36	£36	£36	£36	£36	£36	£36	£36	£360
Provider cost of review	£46	£46	£46	£46	£46	£46	£46	£46	£46	£46	£460
Provider cost of ongoing compliance	UNQUANTIFIED										
Total Cost Savings (undiscounted)	£94	£94	£94	£94	£94	£94	£94	£94	£94	£94	£940
Total Cost Savings (discounted)	£94	£91	£88	£85	£82	£79	£76	£74	£71	£69	£809

135. As discussed above, the do-nothing option is not viable as it is inconsistent in its treatment of private and NHS consultants which does not promote fair competition. We have not quantified this benefit, but assume that it could be significant.

136. Given the above, this amendment to the mixed practice exemption is expected to yield value for money overall.

Absence without authorised leave notifications

137. 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 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.

138. 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 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 and low and medium secure wards. Therefore, a significant proportion of CQC notifications represent duplication.

139. 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.

140. It is estimated that CQC receives around 4,000 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 1,100 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.

141. 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

142. 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 will no longer be required to submit notifications. The burden on providers, and on CQC will be reduced. Despite the consultation, due to a lack of information, it is not possible to quantify this burden.

143. Under the proposal, the remaining 30% of the 4,000 notifications (1,200) 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

144. There should be limited costs associated with removing the need for notifications from mental health wards due to 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 and cared for on general mental health wards.

145. 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.

Value for Money

146. Although the consultation did not provide any additional data or info, there was overall support for this proposal.

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

Exemption for the Olympics and Paralympics

148. The London Organising Committee of the Olympic and Paralympic Games (LOCOG) is responsible for preparing and staging the London 2012 Games. As part of this LOCOG will be a temporary provider of some regulated activities. LOCOG is only a provider of regulated activities as long as the games are running. Successful registration requires the provider to demonstrate that they are capable of meeting the requirements and have the necessary premises, processes and staff in place. Given the temporary and one off nature of the games, LOCOG will not have its infrastructure for providing regulated activities set up in advance; for example, many the staff will be volunteers that will not start until day one of the games. As a result, LOCOG would find it difficult to apply for registration before the games start.

149. The games will run from 27th July 2012 until 9th September 2012; a duration of 30 working days (45 days in total). The duration of the games is shorter than the expected length of time it takes for CQC to process an application. This means the provision of activities is likely to be over before CQC would be able to register LOCOG, let alone review and monitor compliance. Security considerations will also make physical inspection prior to or during the games all but impossible.

150. In addition to this, as LOCOG will only exist as a provider of regulated activities in this one off occasion; thus no retrospective review of compliance would inform or mitigate any risks in any future provision.

151. Given the above, it means it is not possible for CQC to provide oversight or mitigate any system related health risks in the provision of care by LOCOG. As a result, the proposal is to put in place a general exemption for provision of the regulated activities put into place for the Olympics and Paralympics games to ensure that there is not a requirement to register those services.

152. The costs and benefits of this proposal marginal to the do nothing are considered below.

Benefits

153. The proposed exemption will take LOCOG out of the scope of registration. As a result, it will not incur the associated costs of regulation. As discussed above it is assumed CQC would not be able to review or monitor compliance and thus it is the costs associated with registration only that LOCOG will not incur. There is also a small avoided burden to CQC, as they would not need to register this provider. It is not possible to hypothesise what fee CQC would charge nor how much of a burden registration would pose for LOCOG.

Costs

154. As the proposed exemption would take LOCOG out of scope of registration, theoretically there are forgone health benefits due to a loss of CQC oversight and risk mitigation. However, as discussed above, it is likely that the provision of activities will be over before CQC could register LOCOG. Further, as LOCOG exists for a one off purpose there would be no value in a retrospective review. As a result, CQC will not be able to enforce compliance with its requirements and thus is unable to mitigate any system related health risks, and thus there are no expected costs of this proposal.

Value for money

155. Based on the above, this exemption is expected to yield a small one off net benefit of reduced burden on the provider and CQC, and thus provide value for money.

Minor clarifications and technical amendments

156. 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.

Surgical Sterilisation

157. At present, surgical sterilisation procedures are excluded from regulation by the Care Quality Commission, as these services do not fall under the definition of "surgical procedures...[for] the purpose of treating disease, disorder or injury" under Schedule 1, paragraph 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). This was an unintended oversight in the drafting of the regulations. The risks of surgical sterilisation are similar to those of other surgical procedures, which have been deemed sufficiently risky to warrant CQC regulation. Therefore, Option 2, the proposal, is to amend the regulation so that the regulated activity of surgical procedures includes surgical sterilisation and reversal, and thus providers of sterilisation must register with CQC to provide that activity.

158. Surgical sterilisation is provided both by the NHS and independent providers. However, CQC has advised that most of the sterilisation providers (inc. all NHS and all providers of female sterilisation) provide other surgical procedures, for which they are already registered. Therefore, a change to 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. These providers will already be meeting the registration requirements for providing surgical activities (so most system related risks will be mitigated as far as possible already) and there will be no change in their fees or inspections.

159. It is assumed that there are around 160 non-NHS providers of sterilisation services in total. As male sterilisation can be carried out using only local anaesthetic, it is estimated that some (~15%= ~24) of male sterilisation providers may not be currently registered to provide surgical procedures or any other regulated activity. Therefore, under the proposal these providers would be brought into CQC regulation for the first time.

160. The costs and benefits of this proposal (Option 2), i.e. bringing the providers who only provide surgery for sterilisation procedures into regulation (assumed to be ~24 male sterilisation providers), marginal to the do-nothing (Option 1) are considered below.

Benefits

161. It is assumed that the independent sector market for male sterilisation in 2012/13 will consist of 33,000 male sterilisation and this is assumed to remain stable over future years.

162. 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 with the CQC, they must comply with the 16 registration requirements. Compliance with these requirements may mitigate against these hazards beyond those that are already accounted for by professional and device regulation.

163. Table 1 in Annex 1 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, in 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 about the extent of overlap with other regulation and the extent to which private providers are already regulated by the CQC (e.g. CQC regulation 30% effective in reducing infection rates for male sterilisation but only 15% of independent providers are not already registered to provide surgery, so effectiveness becomes scaled down accordingly: 30%*15%=4.5%). Please see Annex 1, Table 1 for detailed assumptions and sources.

164. It is assumed that one year in full health for one person (a QALY) is worth £60,000 to society (based on current willingness to pay estimates). 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 £60,000, 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.

165. In addition to the health (QALY) benefits, mitigation of health hazards by the CQC may lead to avoided treatment costs to the NHS. Table 2 in Annex 1 below identifies possible treatments associated with each adverse event. The associated cost estimates are taken from 2009/10 NHS reference cost data, which are then uplifted to reflect 2010/11 prices.

166. It is possible to quantify the expected benefits of avoided NHS treatment 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 to the NHS.

167. 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 in Annex 1, whilst the range reflects the potential variation if assumptions were pushed towards the reasonable maximum and minimum impacts.

Table D5: Expected annual benefits of Sterilisation regulation amendment proposal

Benefit	**Estimate**	
	Range	**Best**
QALY savings	£49,000 - £1,356,000	£308,000
NHS Saved Treatment Costs	£8,000 - £647,000	£68,000
Total Benefit	**£56,000 - £2,004,000**	**£376,000**

(Note: figures may not sum due to rounding)

Costs

168. Providers registering for the first time will incur costs associated with regulation. It is assumed the costs will only be incurred by the 15% (~24) male sterilisation providers registering for the first time. As mentioned above, a high proportion of sterilisation providers (inc. all NHS and all female sterilisation providers) are currently registered with the CQC for various other regulated activities they provide, and as a result, are assumed to incur no additional costs resulting from this proposed regulation amendment.

169. Based on the current fee structure, registered providers with one location are assumed to pay an annual fee to the CQC of £1600. 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 24 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 £38,400 (24*£1600). The providers may range from charities to public limited companies so no tax or distributional adjustments have been made.

170. In addition to the annual fees, each provider will incur the cost of annual review and inspection. In order to try and quantify this cost, it is assumed to take on 2 days manager time *(~£24 per hour inc on costs and overheads proxy based on NHS managers)* for information sharing, 1 day manger time for preparation for visit, and half a day manager and clinician time *(~£60 per hr inc on costs and overheads proxy based on surgeon/specialty NHS doctor)* for facilitating the visit. This amounts to approximately £830 per provider. The total annual cost of review and inspection visits may therefore be around £19,920 (24*£830).

171. It is also assumed that there may be some transition costs for the newly registered providers associated with applying for initial registration and making some changes to their practice in order to comply with the CQC registration requirements. In order to try to quantify this, it is assumed that initial registration takes 3 days of a manager and a clinician's time, giving a cost of £1900 per provider, and £46k in total. In addition, it is assumed that making initial changes to processes and practice to become compliant could take on average a week of a manager's time, giving initial compliance costs of £885 per provider, and £21k in total. This gives an estimated total one off compliance cost of around £67k.

Value for Money

172. Based on the above costs and benefits, Table D6 below brings together the above quantified costs and benefits, to consider whether this proposal (part of Option 2) individually represents value for money over the do-nothing (Option 1).

Table D6: NPV of Sterilisation Proposal

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
	2012/13	2013/14	2014/15	2015/16	1016/17	2017/18	2018/19	2019/20	2020/21	2021/22	
£'000s	0	1	2	3	4	5	6	7	8	9	
Benefits											**Total**
QALY benefits	308	308	308	308	308	308	308	308	308	308	3,077
NHS benefits	68	68	68	68	68	68	68	68	68	68	680
Total Benefits (undiscounted)	376	376	376	376	376	376	376	376	376	376	3,757
Total Benefits (discounted)	376	369	362	356	349	343	337	331	325	319	3,466
Costs											
Annual fees	38	38	38	38	38	38	38	38	38	38	384
Provider initial compliance costs	21	0	0	0	0	0	0	0	0	0	21
Provider initial registration costs	46	0	0	0	0	0	0	0	0	0	46
Provider cost of planned review (inc call & visit)	20	20	20	20	20	20	20	20	20	20	200
Total Costs (undiscounted)	125	58	58	58	58	58	58	58	58	58	651
Total Costs (discounted)	125	56	55	53	51	49	48	46	44	43	570
Net Present Value	250	312	308	303	298	294	289	285	280	276	2,896

(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 £1k)

173. 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 £2.9m with an equivalent annual benefit of £314k. The assumptions underpinning the analysis are thought to be prudent, and sensitivity testing the key assumptions 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 £1.2m
- reducing the assumed extent of private provision five-fold would still yield a positive NPV of £0.1m
- the effectiveness of regulation assumptions could be reduced by around 84%, yet the proposal would still yield a positive NPV.

Summary of Costs and Benefits of Option 2

174. The tables below summarise the costs and benefits of all the proposals 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.

175. Table D7 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 **£5.0m**.

Table D7: 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											
UNQUANTIFIED											
Diagnostics & Research Bodies											
Benefits (saved resources)	875	405	405	405	405	405	405	405	405	405	4,540
Costs - NHS treatment costs UNQUANTIFIED											
Costs (QALYs forgone)	300	300	300	300	300	300	300	300	300	300	2,980
Air Ambulance Transport Services											
Benefits (saved resources)	10	10	10	10	10	10	10	10	10	10	80
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											
UNQUANTIFIED											
Mixed Practice Exemption											
Benefits (saved expenditure on fees)	95	95	95	95	95	95	95	95	95	95	940
UNQUANTIFIED											
AWOL Notifications											
UNQUANTIFIED											
Exemption for Olympics and Paralympics											
UNQUANTIFIED											
Minor Clarifications and Technical Amendments											
UNQUANTIFIED											
Sterilisation											
Benefits (saved resources)	70	70	70	70	70	70	70	70	70	70	680
Benefits (QALYs)	310	310	310	310	310	310	310	310	310	310	3,075
Costs to providers (fees, initial registration & inspections etc)	125	60	60	60	60	60	60	60	60	60	650
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	470										
Total Annual Benefits	885	885	885	885	885	885	885	885	885	885	8,845
Total Benefits (undiscounted)	1,355	885	885	885	885	885	885	885	885	885	9,315
Total Benefits (discounted)	1,355	860	835	815	790	770	750	730	710	690	8,315
Total Transition Costs	65										65
Total Annual Costs	355	355	355	355	355	355	355	355	355	355	3,565
Total Costs (undiscounted)	425	355	355	355	355	355	355	355	355	355	3,635
Total Costs (discounted)	425	350	345	340	330	325	320	315	310	305	3,360
Net Benefits (undiscounted)	930	530	530	530	530	530	530	530	530	530	5,680
Net Benefits (discounted) NPV	930	510	495	475	460	445	430	415	400	390	**4,955**

(note: figures may not sum due to rounding- rounded to nearest £5k. Costs and benefits are expressed in a 2010/11 price base and are assumed to reduce at a rate of 3.5% a year, except QALY impacts to which a 1.5% rate is applied, to reflect the social time preference for resources and health)

176. Table D8 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 £0.9m.

Table D8: 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											
Air Ambulance Transport Services											
Benefits (increased tax rev)	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	14
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											
UNQUANTIFIED											
Mixed Practice Exemption											
Benefits (increased tax rev)	35	35	35	35	35	35	35	35	35	35	360
Costs - UNQUANTIFIED											
AWOL notifications											
UNQUANTIFIED											
Exemption for Olympics and Paralympics											
UNQUANTIFIED											
Minor Clarifications and Technical Amendments											
UNQUANTIFIED											
Sterilisation											
Benefits (saved NHS Treatment Costs)	70	70	70	70	70	70	70	70	70	70	680
Costs - UNQUANTIFIED (tax considerations)											
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	105	105	105	105	105	105	105	105	105	105	1,055
Total Benefits (undiscounted)	105	105	105	105	105	105	105	105	105	105	1,055
Total Benefits (discounted)	105	100	100	95	90	90	85	85	80	75	910
Total Transition Costs	0										
Total Annual Costs	0	0	0	0	0	0	0	0	0	0	0
Total Costs (undiscounted)	0	0	0	0	0	0	0	0	0	0	0
Total Costs (discounted)	0	0	0	0	0	0	0	0	0	0	0
Net Benefits (undiscounted)	105	105	105	105	105	105	105	105	105	105	1,055
Net Benefits (discounted) NPV	105	100	100	95	90	90	85	85	80	75	910

(note: figures may not sum due to rounding-rounded to nearest £5k. 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)

177. Table D9 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. Overall, the changes to the regulatory framework, reduce the regulatory burden, with a net benefit of £3.8m (based on OIOO methodology). *(Note to highlight the difference between IN and OUTs, figures are presented as costs, i.e. benefits as negative costs)*

Table D9: Total NPV of the direct business impacts only of Option 2, OIOO calculation

Description of Costs and Benefits	Year 0 2010/11	Year 1 2011/12	Year 2 2012/13	Year 3 2013/14	Year 4 2014/15	Year 5 2015/16	Year 6 2016/17	Year 7 2017/18	Year 8 2018/19	Year 9 2019/20	Year 10 2020/21	Year 11 2021/22	NPC	EAC	IN or OUT?
Fitness of Providers Partnerships															
UNQUANTIFIED															OUT
Diagnostics & Screening Services															
UNQUANTIFIED															OUT
Diagnostics & Research Bodies															
Reduced Burden (fees, inspections, compliance)			-875	-405	-405	-405	-405	-405	-405	-405	-405	-405			
DEFLATED TO 2009 PRICES			-850	-395	-395	-395	-395	-395	-395	-395	-395	-395			
Net Cost to Business (discounted)			-795	-355	-345	-330	-320	-310	-300	-290	-280	-270	-3325	-370	OUT
Air Ambulance Transport Services															
Reduced burden (fees)			-6.5	-6.5	-6.5	-6.5	-6.5	-6.5	-6.5	-6.5	-6.5	-6.5			
DEFLATED TO 2009 PRICES			-6.3	-6.3	-6.3	-6.3	-6.3	-6.3	-6.3	-6.3	-6.3	-6.3			
Net Cost to Business (discounted)			-5.9	-5.7	-5.5	-5.3	-5.1	-5.0	-4.8	-4.6	-4.5	-4.3	-46.4	-5.2	OUT
Statutory Notifications															
UNQUANTIFIED															OUT
Domiciliary care for disabled children and vulnerable adults, care arranged by IUTs															
UNQUANTIFIED															OUT
Mixed Practice Exemption															
Reduced burden (fees and inspections)			-115	-115	-115	-115	-115	-115	-115	-115	-115	-115			
DEFLATED TO 2009 PRICES			-115	-115	-115	-115	-115	-115	-115	-115	-115	-115			
Net Cost to Business (discounted)			-105	-100	-100	-95	-90	-90	-85	-85	-80	-75	-905	-100	OUT
AWOL Notifications															
UNQUANTIFIED															OUT
Exemption for Olympics and Paralympics															
UNQUANTIFIED															OUT
Minor Clarifications and Technical Amendments															
UNQUANTIFIED															OUT
Sterilisation															
Costs to providers (fees, initial registration & inspections etc)			125	60	60	60	60	60	60	60	60	60			
DEFLATED TO 2009 PRICES			120	55	55	55	55	55	55	55	55	55			
Net Cost to Business (discounted)			115	50	50	50	45	45	45	40	40	40	515	55	IN
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			-790	-410	-400	-385	-370	-360	-345	-335	-325	-315	-3760	-420	OUT

(note: figures may not sum due to rounding- rounded to nearest £5k. 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)

178. **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)

179. 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

180. The proposal removes from registration services where we do not consider there to be risks that CQC could 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

181. 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

182. 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

183. 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

184. For most of the protected groups, changes to the regulations for the provision of personal domiciliary care may 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. However, currently CQC has advised that it does not have any of these providers currently registered with it, so this impact is not due to this proposal. In fact this proposal will remove false assurance. The consultation responses did raise concerns about the level of safeguards provided to service users, many of whom will be vulnerable. However to keep them within scope of CQC regulation is infeasible and CQC would not be able to register large numbers of individual providers (60k-200k). 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.

185. 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.

Mixed practice medical practitioners

186. 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

187. 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

188. 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.

189. 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

190. 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

191. 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

192. In any affected market, would the proposal:

- Directly limit the number or range of suppliers?

193. 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.

- Indirectly limit the number or range of suppliers?

194. This might be the case in some of the proposals. Providers of surgical sterilisation who do not provide any other service will be brought into registration for the first time. 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.

195. CQC regulation as a barrier to market entry for sterilisation is not expected to have a significant impact on competition (as all suppliers would be subject to the same regulation), but is 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.

- Limit the ability of suppliers to compete?

196. 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.

- Reduce suppliers' incentives to compete vigorously?

197. 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

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

198. Overall, the preferred option reduces the regulatory burden to business, including small firms and micro businesses. This is quantified in Tables D7-9.

199. The only proposal that adds to current regulation is the sterilisation proposal which will bring in a small number of providers of high-risk services into regulation. Some of these may be small firms and charities, and potentially micro businesses (although given the nature of the service this is thought to be unlikely). However, the costs and benefits of this proposal have been considered in the main cost benefit analysis, and it has been demonstrated that the benefits to society in terms of health gains and saved NHS resources outweigh the costs of regulation to providers (see Section D above). There was strong support for this proposal during consultation. In addition to the cost benefit analysis, 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.

200. The other proposals reduce the burden of regulation for a number of providers, some of which will be small firms and micro businesses (e.g. mixed practice doctors). The costs and benefits have been considered in Section D above.

Legal Aid/ Justice Impact

- 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?

201. No significant risks were identified.

202. Providers whose services have been suspended by CQC have the right of appeal to the First -tier Tribunal. However, given the relatively small marginal changes the proposal brings about, we expect any change in 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

- 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?

203. 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

- 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)

204. 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, see Section D above.

205. 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

- 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.

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

Wider impacts

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

Economic impacts

208. The costs and benefits of the proposals on businesses have been considered in the main cost benefit analysis of this impact assessments, see Section D above. 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

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

Social impacts

210. 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.

F. Summary and Conclusion

211. This impact assessment has demonstrated that, based on the available evidence, Option 2, *implement all proposals*, is expected to offer value for money and is not expected to have any significant negative impacts on equality. It is therefore the recommended preferred option. As per guidance on sun setting regulations, this policy will be reviewed 5 years from enactment.

Annex 1: Underlying data and assumptions of sterilisation proposal

Table 1: 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 *assuming new regulation impacts 15% of providers*	Sources
Male Sterilisation						
Infection	3.4%	11121	0.11	1 month	4.5%	Awsare et al (2005), Schwingl and Guess (2000)
Allergic reaction to anaesthesia	0.022%	11121	0.114	1 week	2.25%	Mertes and Laxenaire (2004)
Post operative pain	Non-Chronic: 32% Chronic: 8.6%	Non-chronic: 11121 Chronic: 11131	0.114 0.221	Non chronic: 2 weeks Chronic: 2 years (until further treatment takes place)	0%	Awsare et al (2005); Harvard Medical School
Bruising and swelling	75%	11121	0.11	3 weeks	0%	Assorted websites[2].
Bleeding	5%	11221	0.15	1 week	0%	Uptodate.com, no academic source
Haematoma	2%	11221	0.15	2 months	0%	Awsare et al (2005)
Sperm granuloma	20%	11121	0.15	3 months	0%	Awsare et al (2005)
Painful sperm granuloma	2.5%	11131	0.646	3 months	0%	Schwingl and Guess (2000)
Congestive epididymitis	4%	11221	0.15	5 weeks	0%	Schwingl and Guess (2000)
Negative psychological effects	5 to 10%	11112	0.062	6 months – 5 years	1.5%	Harvard Medical School; Schwingl and Guess (2005)
Failed operation - immediate	1%	11113	0.496	9 months	0%	Awsare et al (2005)
Death (mainly from infection)	0.0001%	n/a	1	31.2 years	6%	Awsare et al (2005); Harvard Medical School

(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)

[2] Main source: www.vasectomy-information.com

Table 2: 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 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
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)		
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

Annex 2 – Underlying assumptions and calculations of research bodies proposal

212. This Annex outlines the underlying assumptions and calculations of the costs and benefits around research bodies carrying out diagnostic tests.

Costs:

213. In order to try and quantify a potential cost, we use the assumptions outlined in paragraph 90 above, and apply them to in the following calculation:

- Number of patients in question is determined by looking at the Clinical Research Network data, which indicates 565k participants in 1,658 trials. On average, a trial would therefore have 341 participants. Taking the perceived number of clinical trials in England (1,500) and accounting for the fact that they make up only 50% of participant base, we arrive at 341 * 1500 / 0.5 = 1m of research participants in England.
- This number is then refined to account for 50% of drug trials being out of scope and of the remaining 50%, only around 5% using the relevant techniques that would warrant CQC regulation (1m * 50% * 5% = 25,575 participants in relevant research activities).
- When estimating patient harm, we assume that 1 in 2,000 patients can suffer minor harm or lack of diagnosis and follow up during research activities, with 90% and 10% split respectively. It is then assumed that minor harm leads to a loss of 0.087 Quality-Adjusted Life Years (QALYs), and lack of follow-up 0.65 QALYs (value derived from the EQ5D model) with corresponding durations of 1 week (0.019 of a year) and 19.89 years respectively. *(Here, lack of follow-up is assumed to be an average outcome between patient death (lack of follow-up on cancer) and severe harm (delayed diagnosis, but leading to recovery).*
- Putting the above assumptions together, a low harm incident would cause 0.087 * 0.019 * 0.9 = 0.0015 QALYs and lack of follow-up 0.65*19.89*0.1 = 1.3 QALYs.
- Accounting for the value of a QALY of £60,000 (current willingness to pay), the estimated monetised value of research participant minor harm health loss equals 25,575 * 1 / 2,000 * 0.0015 * £60,000 = £1,150; for lack of follow-up this equals 25,575 * 1 / 2,000 * 1.3 * £60,000 = £1.0m;
- Accounting for assumed CQC risk mitigation of 5% for minor harm and 30% for lack of follow-up, the foregone benefits of CQC regulation would add up to 5% * £1,150 + 30% * £1.0m = £298k per anum (figures may not sum due to rounding of assumptions for presentation).
- This is an approximation, and an attempt to quantify a potential loss of risk mitigation.

Benefits:

214. Not quantifying the benefits of research, we can estimate the theoretical savings of regulatory burden that CQC regulation places on the providers in question. With approximately 190 provider, the burdens would originate from:

- CQC fees; £1,600 annual payment, adding up to £304k (190 * £1,600);
- One-off compliance and registration cost; assuming registration and compliance takes 15 days of Research Administrator's time (7.5 hour working day, £22 hourly wage), arriving at benefit of £470k (15 * 7.5 * £22 * 190);
- Inspection costs; assuming annual inspection of all providers, and preparation for inspection taking 2 days of Research Administrator's time and ½ day of Research Administrator's and Research Scientist's time (£34 hourly wage), inspection costs for all providers are £103k per anum (2 * 7.5 * £22 + 0.5 * 7.5 * (£22 + £34) * 190);

Summary:

215. The above gives us one-ff benefit of £470k and recurring annual benefit of £407k and recurring annual costs of £298k, resulting in a Net Present Value over a 10 year appraisal period with a 3.5% general discount rate, and a 1.5% QALY discount rate, of £1.2m.

Annex 3 - Sources and references

Fitness of Provider Partnerships

Despite the consultation, there is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Diagnostic and Screening Procedures:

Despite, the consultation, there is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Research Bodies Carrying out Diagnostic Tests:

Despite, the consultation, there is limited information available on this area. 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

Despite, the consultation, there is limited information available 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

Despite, the consultation, there is limited information available on this area. Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

Mixed Practice Medical Practioners

Despite, the consultation, there is limited information available on this area. Discussions between DH policy and CQC have informed this impact assessment, along with other sources of information:

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

Despite, the consultation, 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

Despite, the consultation, there is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.

Minor Clarifications and Amendments

Despite, the consultation, there is limited information available on this area. Discussions between DH Policy and CQC have informed this impact assessment.