

NATIONAL QUALITY BOARD

REVIEW OF CQC REGISTRATION REGULATIONS

A note from the Director of Finance, Strategy, Quality and Analysis

Summary

1. All providers of regulated activities must be registered with CQC and meet a set of registration requirements, which are set by the Department of Health (DH) in regulations¹ under the Health and Social Care Act 2008. These regulations define the bar between unacceptable and adequate quality of care across both health and adult social care.
2. DH is committed to keeping the regulations under review, to ensure that they reflect regulatory best practice and developments for instance in the way services are delivered. The Department has now started work to review the regulations, which is likely to continue until 2014.
3. This paper sets out the background and purpose of the review, and invites the Board's views on the issues that the review should consider.

Recommendation

4. The Board is asked to advise on the issues that the review should consider to ensure that the regulations that underpin the regulatory framework enable CQC to provide effective and proportionate assurance of essential levels of safety and quality in the context of, and supporting, the new health and social care landscape.

¹ The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, and The Care Quality Commission (Registration) Regulations 2009.

Background to the review

5. DH is responsible for the legislation that underpins CQC's regulatory framework. It has set out in regulations the scope of registration with CQC, the essential safety and quality requirements that providers must meet in order to be registered with CQC, and other requirements that underpin the regulatory framework, including statutory notifications and offences.
6. CQC is responsible for the interpretation and implementation of these regulations. CQC is under a legal duty to publish guidance setting out what compliance with the registration requirements means, and is responsible for developing and consulting on its methodology for assessing whether providers are meeting the registration requirements. CQC published its *Guidance About Compliance* in March 2010².
7. DH has a commitment to keep the registration regulations under review, to make sure they reflect best regulatory practice and support wider developments in the quality landscape. This review is now under way, led by the DH Director of Finance, Strategy, Quality and Analysis, and will be overseen by a reference group including a representative from CQC.
8. The review will be a phased process, and the Board will have a further opportunity to help shape the issues under consideration as it progresses. If the review determines that changes are needed to the regulations, DH will consult on them in late 2012 / early 2013. They would then need to be debated in both Houses of Parliament before they can be implemented. Any such changes are likely to be introduced in 2014. A high level timetable for the review is set out at Annex A.

² <http://www.guidanceaboutcompliance.org.uk/>

Purpose of the review

9. The review will consider changes to the scope of registration and the requirements that providers must meet in order to register with CQC, to ensure they best support CQC to carry out its quality assurance role. In particular, the regulations must:
 - a. effectively enable CQC to hold providers to account for the safety and quality of their services; and
 - b. be proportionate to any risk to people using the provider's services.
10. A number of recent developments might mean that changes to the CQC regulations could improve their effectiveness or proportionality, including the new landscape established by the Health and Social Care Act, the Francis Inquiry, the forthcoming social care white paper, the Government's Red Tape Challenge³, the CQC Capability Assurance Review and DH's review of learning disabilities.
11. The Terms of Reference for the review are attached at Annex B.

Issues to consider during the review

12. DH has compiled a provisional list of issues that it intends to investigate during the review, which is attached at Annex C. These issues each raise questions that have a significant effect on the scope of CQC registration – i.e. which services need to be registered with CQC – or CQC's effectiveness. The review will establish whether these issues should, or can, be addressed by changing the regulations.

³ The Red Tape Challenge is a Cabinet Office consultation on business regulation across Government, with the presumption that all burdensome regulations will be abolished unless Government departments can justify why they are needed.
www.redtapechallenge.cabinetoffice.gov.uk/home/index/

13. Some of the significant issues included in this list are explored in more detail in Annex D:
- a. Enforcement – whether the regulations should be changed to enable CQC to prosecute a provider for a one-off episode of non-compliance;
 - b. Regulated activities – whether “*treatment of disease, disorder or injury*”, “*diagnostics and screening procedures*”, “*personal care*” and “*accommodation for persons who require nursing or personal care*” need to be re-defined to better reflect risks to patients and service users;
 - c. Whistleblowing – whether providers should be required to have a whistleblowing procedure before they can be registered with CQC;
 - d. Statutory notifications – whether the events or issues that providers must notify CQC of are appropriate and justified; and
 - e. Statement of purpose – whether the requirement for each provider to give CQC a statement of purpose can be made less burdensome to providers or more helpful to CQC.
14. When considering these issues, the review will in particular reflect developments in the wider quality landscape; for instance, the focus on outcomes and changes to provider and professional regulation. DH will consider whether changes to the regulations will be necessary to support this new landscape.
15. DH will come back to the Board once the review has progressed further, to provide an update on the issues being considered and seek further views to shape the work.
16. At this initial stage, DH would welcome the Board’s views on the areas that the review should focus on.

The Board is asked to note the issues set out in Annex C.

- **Are there any further issues that the review should cover, to improve how the regulations support CQC's role? For example, are there any gaps in the requirements that providers are required to meet in order to be registered with CQC?**
- **What are the strategic issues that the review of regulations presents an opportunity to consider?**

Next Steps

17. DH will continue to work with stakeholders to develop proposals for consultation later this year, collecting evidence and carrying out analysis of the impact any proposals would have, including any suggestions that the Board makes.

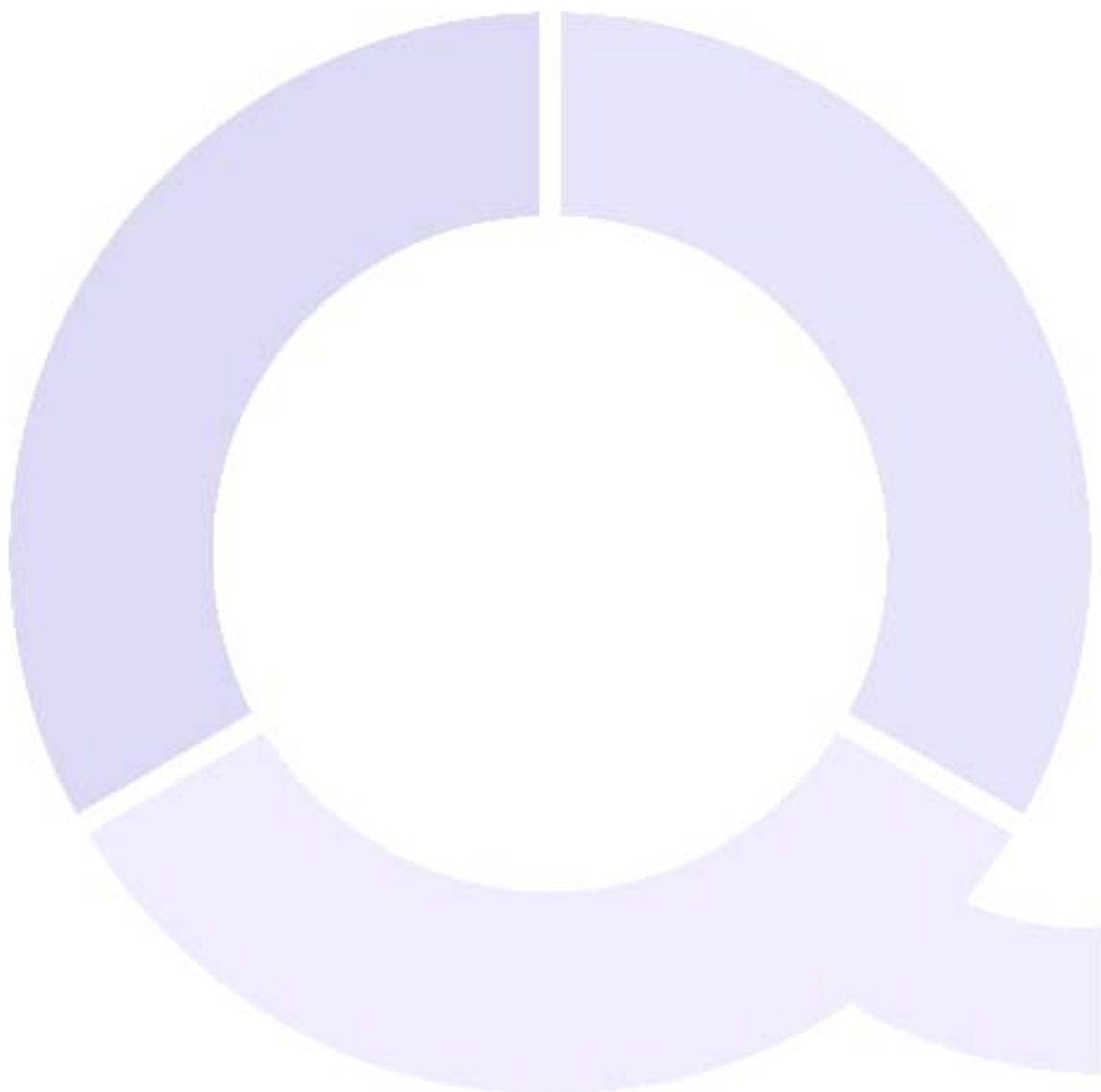
Richard Murray

April 2012

ANNEX A: PROPOSED TIMETABLE

Winter 2011 / Spring 2012	<ul style="list-style-type: none"> • Develop project plan • Engage with CQC, internal policy leads and external experts to identify issues • Finalise work streams and identifying resources • Early analytical work understanding initial issues and evidence • Begin impact assessment, equalities impact assessment etc
Summer 2012	<ul style="list-style-type: none"> • Work with CQC and stakeholders to identify specific proposals to resolve issues • Sense check and engage with stakeholders on detail of proposed changes
Autumn 2012	<ul style="list-style-type: none"> • Finalise a manageable set of proposals for consultation • Finalise a consultation stage impact assessment and other required assessments (equalities, business impact etc) • Red Tape Challenge goes live
Late 2012	<ul style="list-style-type: none"> • Cross Government clearance processes
Late 2012, early 2013	<ul style="list-style-type: none"> • Formal consultation on proposals
Spring to Summer 2013	<ul style="list-style-type: none"> • Analyse consultation responses • Draft amendment regulations • May need to consult again on the revised regulations • Final impact assessment • Cross Government clearance processes

Autumn 2013	<ul style="list-style-type: none"> • Lay revised regulations before Parliament, where they will be debated by both houses
Spring 2014	<ul style="list-style-type: none"> • Revised regulations come into force



Annex B: TERMS OF REFERENCE

Context

In the context of the Government's commitment to reducing the burden of regulation, the Department has a commitment to keep the regulatory framework under review, to take account of developments in the provision of services and to ensure that the regulatory framework is proportionate to the risk of harm.

Purpose

The purpose of the review is to ensure the regulations create a framework for effective risk-based proportionate regulation of health and adult social care providers, which enables CQC to hold providers to account for the safety and quality for patients and people who use services.

Scope

The review will consider the regulations that underpin the regulatory framework, set out in *The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010* and the *Care Quality Commission (Registration) Regulations 2009*. These regulations include the definitions of regulated activities, the essential requirements that providers have to meet, statutory notifications, regulations about offences, regulations about registered managers and other requirements that underpin the regulatory framework.

The review will take account of any relevant recommendations of the National Quality Board, the Francis Inquiry, the Department's Capability Assurance Review of CQC, and the Public Accounts Committee and Health Select Committee reviews of CQC. We will also consider the effect of changes arising from the Health and Social Care Bill, the Social Care White Paper and the Red Tape Challenge.

The review will not consider changes to the Health and Social Care Act 2008.

Governance

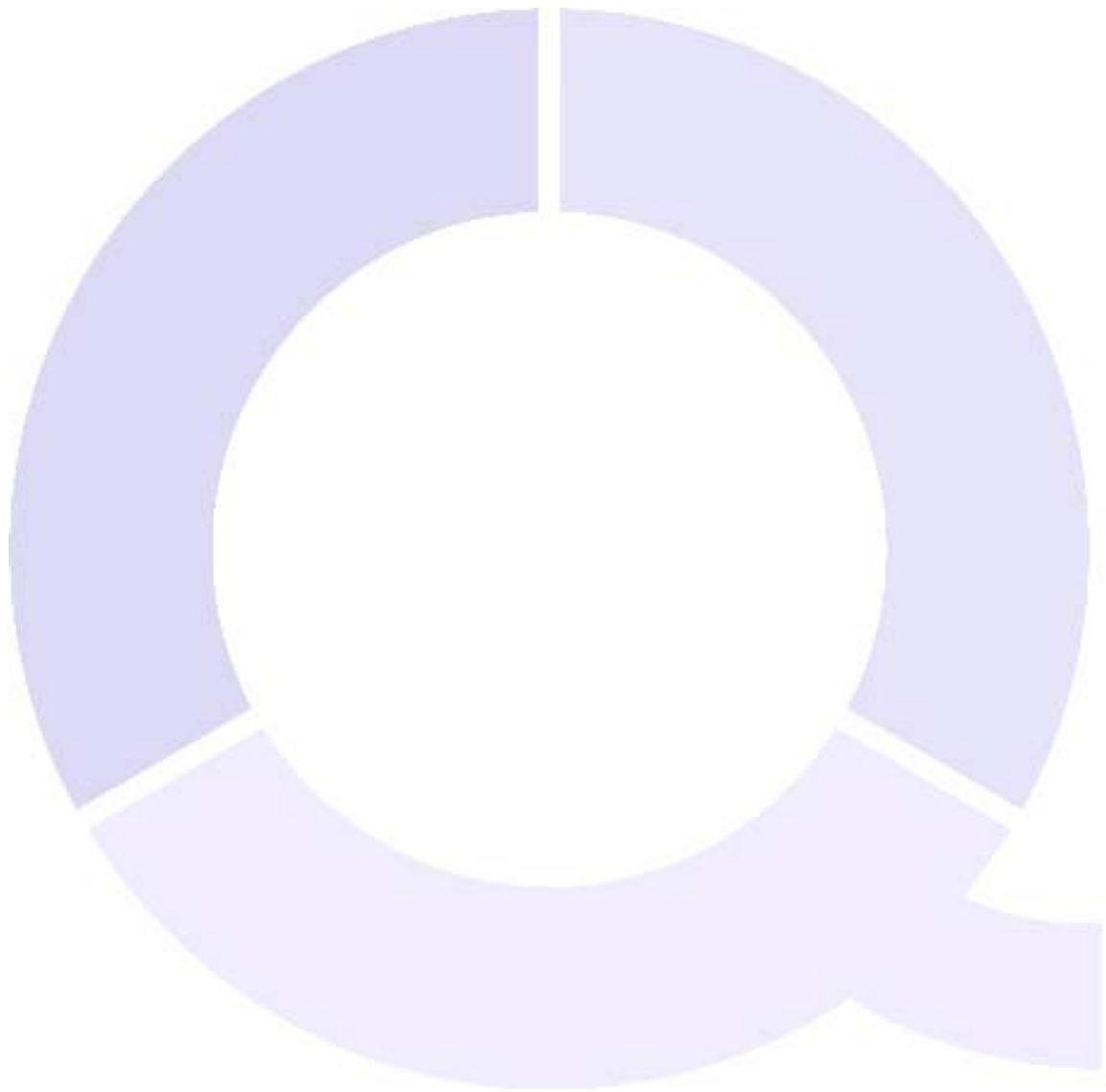
The review team will present its findings to a reference group at key points in the review process, including finalising proposals for consultation, and drafting amendments to the regulations.

The Director of Financial Planning and Allocations will be responsible for signing off proposals for consultation, the consultation response, draft amendments to the regulations and the related impact assessments before they are put to Ministers for final clearance.

Any amendments to the regulations will go through the affirmative Parliamentary process.

Timetable

The intention is to develop proposals for consultation before the end of 2012/13, and to make any necessary amendments to the regulations before April 2014.

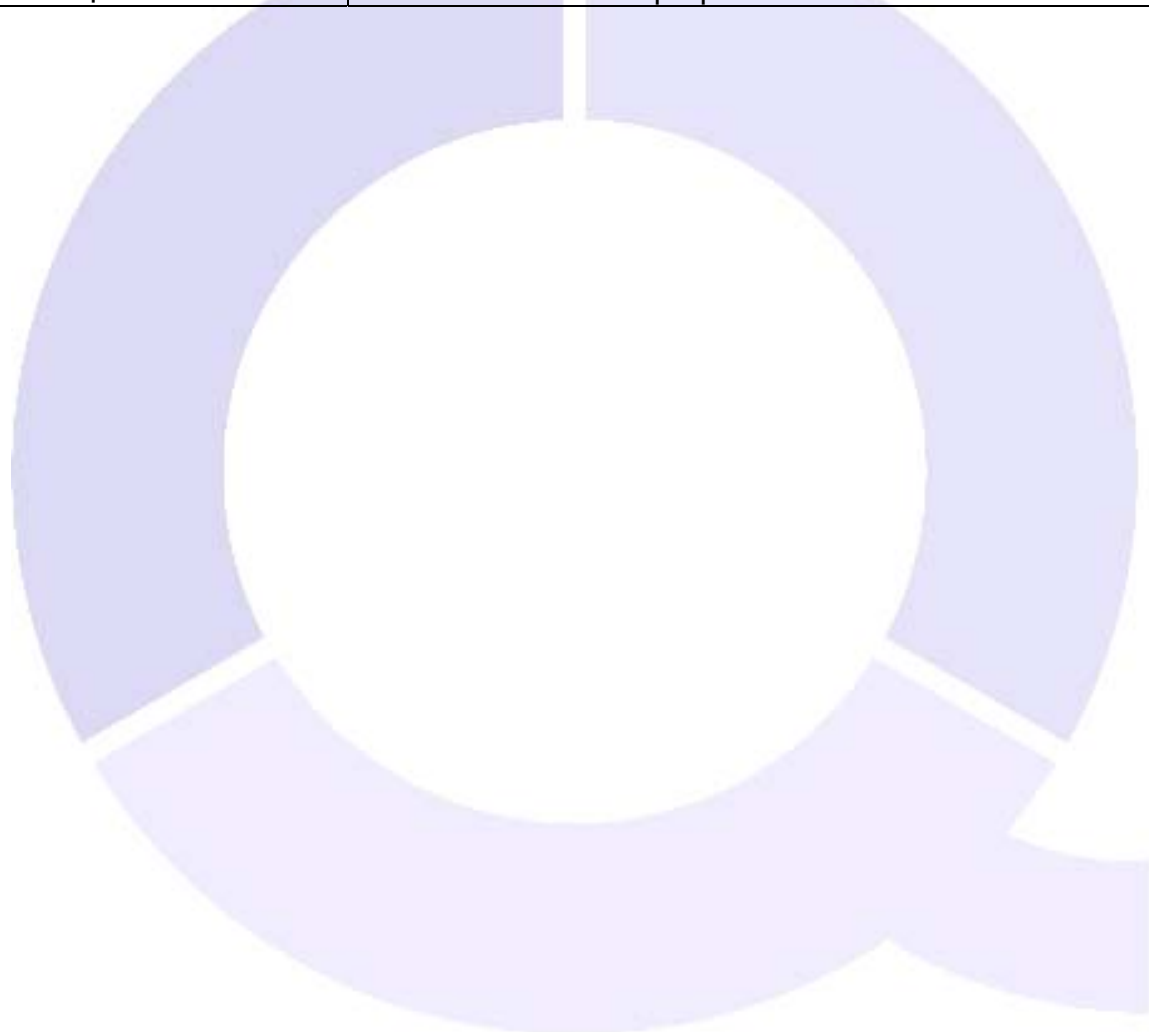


Annex C: Full list of issues currently identified for consideration in the review

Issue	Description
Nursing care	<ul style="list-style-type: none"> • Reviewing the definition in the regulations
Personal care	<ul style="list-style-type: none"> • Reviewing the definition in the regulations • Consideration of whether day care should be within the scope of registration • Reviewing the position with regards to domiciliary care agencies • Reviewing arrangements for personal care away from home and in prison
Ancillary services	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and in practice
Services in slimming clinics	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and in practice
Further education for young adults with personal care needs	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and in practice
Surgical procedures	<ul style="list-style-type: none"> • Reviewing the scope of regulation, in relation to the level of risk of harm
Telemedicine	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and whether it appropriately reflects current practice
Termination of pregnancy	<ul style="list-style-type: none"> • Considering extending regulations that only apply to private sector, to cover NHS providers and therefore make the playing field more level
Family planning services	<ul style="list-style-type: none"> • Reviewing the scope of regulation, in relation to the level of risk of harm
Working with OFSTED	<ul style="list-style-type: none"> • Looking at whether there are any obstacles caused by the regulations that can be resolved
Transport services	<ul style="list-style-type: none"> • Reviewing the wording of the regulations, in particular in relation to air ambulance services and repatriation issues
Controlled drugs review	<ul style="list-style-type: none"> • Considering any implications for CQC that may require changes to the regulations
Human Rights Act issues	<ul style="list-style-type: none"> • Reviewing the interlinks between the HRA and the 2008 Act, including in relation to domiciliary care
Criminal records checks and safeguarding	<ul style="list-style-type: none"> • Considering any implications for CQC that may require changes to the regulations
Community drug and alcohol services	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and whether it appropriately reflects current practice
Exemption for clinicians that work for a regulated provider, but also have private practice	<ul style="list-style-type: none"> • Reviewing the definition in the regulations and whether it appropriately reflects current practice
Anaesthesia	<ul style="list-style-type: none"> • Looking at whether this should be a regulated activity

Cosmetic procedures	<ul style="list-style-type: none"> • Reviewing the coverage of these procedures in the regulations and whether it is appropriate
Care arranged by people themselves	<ul style="list-style-type: none"> • Reviewing whether there should be exemptions for care or treatment that people arrange for themselves
Temporary services solely existing during sporting or cultural events	<ul style="list-style-type: none"> • Considering extending the current exemption for the services set up solely for the duration of the Olympics to cover a wider range of events
Sole traders/small businesses	<ul style="list-style-type: none"> • Looking at a range of issues to do with small providers • Chiropractors carrying out x-rays • Physiotherapists carrying out ultrasound • Micro businesses/groups of individuals • Sole providers
Treatment of disease, disorder or injury	<ul style="list-style-type: none"> • Reviewing a number of issues around the definition in the regulations, including: <ul style="list-style-type: none"> • Pharmacy • Dentistry • Mental health services • Review of the list of healthcare professionals that trigger registration
Diagnostics and screening services	<ul style="list-style-type: none"> • Reviewing the definition in the regulations
Dual registration of providers	<ul style="list-style-type: none"> • Looking at the interface between, eg MHRA and HTA with CQC
Social Care White Paper issues	<ul style="list-style-type: none"> • Enforcement of disclosure • Serious case reviews
Sustainability	<ul style="list-style-type: none"> • Looking at whether there should be a requirement on providers to reduce carbon emissions etc
Duty of candour	<ul style="list-style-type: none"> • Considering whether there should be a duty of candour requirement for providers
Registration requirement protecting people from financial abuse	<ul style="list-style-type: none"> • Considering whether the registration requirements around safeguarding from abuse needs to be revised
Statement of purpose	<ul style="list-style-type: none"> • Reviewing the use of the Statement of Purpose
Implications of: Health and Social Care Act 2012; Francis Inquiry; Capability Review; PAC/HSC hearings	<ul style="list-style-type: none"> • Considering all recommendations from the Act and each of these reviews to see if they have any implications for the regulations
Enforcement and offences issues	<ul style="list-style-type: none"> • Reviewing the effectiveness of the regulations that set out offences and enforcement
Financial oversight of social care providers	<ul style="list-style-type: none"> • Considering whether there is a stronger role for CQC in financial oversight of big social care providers
Standard setting (eg staff numbers/ratios)	<ul style="list-style-type: none"> • Considering whether CQC regulations should set staffing ratios for providers
Statutory notifications	<ul style="list-style-type: none"> • Reviewing the burden and justification for each of the

	statutory notifications providers are required to make to CQC
Registered managers	<ul style="list-style-type: none"> • Reviewing the registered manager regulations to see if it can be more flexible and less burdensome
Whistleblowing	<ul style="list-style-type: none"> • Considering CQC's handling of whistleblowing concerns and whether there needs to be some requirements on providers
Government Department exemption	<ul style="list-style-type: none"> • Reviewing the current exemption for care and treatment carried out by a Government department, to ensure it is fit for purpose



Annex D: Issues currently identified for consideration in the review: in detail

Enforcement

1. At present CQC is only able to prosecute a provider for failing to comply with the registration requirements that set the essential levels of safety and quality where it has previously issued a warning notice. In effect this makes it impossible for CQC to prosecute a provider for a one-off episode of non-compliance, regardless of how serious the consequences are for patients and service users. The review will consider whether there are possible alternative arrangements that will enable CQC to prosecute a provider for non-compliance with the registration requirements that has serious consequences for service users, even where the incident is entirely in the past.

The *treatment of disease, disorder or injury* regulated activity

2. The regulated activity of *Treatment of disease, disorder or injury* (TDDI) brings most NHS bodies into the scope of CQC registration. The activity is defined as the provision of TDDI, where it is provided by, or under the supervision of, a listed healthcare professional (or in the case of mental health care, a social worker). Therefore, the presence of a particular kind of healthcare professional (including: doctors, dentists, nurses, midwives, paramedics and radiographers) in a team is effectively a trigger for the requirement to register with CQC. There are clearly flaws in the approach (for example, a team that did not include a listed healthcare professional could be carrying out the same care as one that did, without having to register with CQC), but DH has so far been unable to find an alternative approach.
3. The review will consider whether there is a better way to reflect the level of risk than using the 'healthcare professional' proxy. Failing that, DH will review the list of healthcare professionals to ensure there is the most appropriate list in relation to the potential risk of harm to people using services.

The *diagnostics and screening procedures* regulated activity

4. The *diagnostics and screening procedures* regulated activity brings procedures such as x-rays, ultrasound, MRI, endoscopy, removal of bodily tissues for biopsy, and the use of equipment to measure physiological data into the scope of registration. There is a broad spectrum of diagnostic procedures and services, ranging from those that can be done at home by the individual through to those that require specialist equipment and trained specialists. The current wording of the regulated activity relies on definitions of specific activities that are either within the scope of registration or outside. The review will consider whether there is a better way to define those activities that better reflects the risk to people who use services.

The definition of personal care and the *personal care and accommodation for persons who require nursing or personal care* regulated activities

5. The regulations include a definition of personal care, which covers: physical assistance (or prompting with supervision) with eating or drinking, toileting, washing or bathing, dressing, oral care or the care of skin, hair and nails. The review will look at whether that definition is fit for purpose.
6. The *personal care* regulated activity brings domiciliary care into regulation where it is provided by an agency, or commissioned by an NHS body or local authority. The *accommodation for persons who require nursing or personal care* brings care homes into regulation. The review will consider issues around the provision of personal care in other circumstances, such as day care, and care provided to people while on holiday.
7. There are also some minor issues that the Board may be interested in. These include:

Issues around whistleblowing

8. DH is intending to look at whether there is a role for CQC regulation in managing whistleblowing concerns, for example, whether there should be a registration requirement that requires providers to have a whistleblowing procedure in place.

Statutory notifications that providers must make to CQC

9. The regulations set out a number of instances where providers are required to notify CQC of events or issues. DH is intending to consider whether the notifications are appropriate and justified.

Issues around the Statement of Purpose

10. All registered providers are required to give CQC a Statement of Purpose, setting out specified information, for example: the kinds of service being carried out; the name and address of the service provider; and locations where the activity is being carried out. As this information is collected by CQC as part of the registration process, DH is looking at whether there are changes that should be made to the regulations to remove the burden or amend the information required.