NHS Confederation evidence to Health Select Committee’s scrutiny of the regulators Care Quality Commission (CQC) and Monitor
22 June 2011

About the NHS Confederation
The NHS Confederation is the only body to bring together the full range of organisations that make up the modern NHS to help improve the health of patients and the public. We are an independent membership organisation representing all types of providers and commissioners of NHS services. The NHS Confederation includes the NHS Employers organisation, which represents NHS organisations in England on workforce issues and has particular expertise of professional regulation.

Our response complements that of the NHS Confederation’s Partners Network, which represents independent sector providers of NHS care, and of the Foundation Trust Network, which reflects the particular perspective of NHS foundation trusts.

1. Executive summary
- Our submission covers general points on regulation, including the contribution of professional regulation and commissioning, but concentrates on the operation of the CQC and Monitor.
- Effective regulation is fundamental to maintaining public confidence in services and ensuring patients receive safe, effective care.
- Clear, realistic expectations are needed of what regulation can achieve in terms of standards of care: the NHS Confederation believes regulation should only be responsible for minimum standards of entry either to a profession or for organisations to the market.
- CQC, Monitor, GMC and NMC regulation are just part of NHS regulatory and oversight mechanisms. There is a complex range of requirements that result in overlap and duplication, but potentially also failure to act on issues of poor quality care because of confusion about responsibilities. Better alignment of the different types of regulation and processes is needed.
- The legislative framework and associated regulations have provided an unduly onerous framework for CQC registration, which has been hampered in its operation by insufficient CQC resources.
- The trust or organisation-level unit of registration is too large to provide the public with meaningful assurances of care standards care in particular units or facilities.
- Our members have particular concerns about the operation of the CQC and question whether it is fit for purpose including:
  - The CQC is insufficiently risk-based or proportionate in its approach.
  - It is insufficiently independent of government.
  - CQC’s model of regulation and inspection is:
    - Too generic and takes insufficient account of the particular considerations for different types of service
Insufficiently flexible to respond to emerging models of care or service changes readily
Inconsistent with variations of approach between regional offices and inspectors
Not sufficiently effective in influencing standards of care provision and does not represent value for money.
  o Registration processes are cumbersome, bureaucratic and poorly administered and subject to significant delays.
  o CQC information, advice and guidance have been inadequate and not available sufficiently early in processes.

We recommend the CQC:
  o Develops a constructive relationship with our members to determine a more effective regulatory model and approach
  o Adopts a more-tailored approach to regulating the different types of services
  o Provides named CQC contacts to give consistency and continuity for providers
  o Reviews the use of ‘location’ as a key concept for registration as this has been difficult to apply meaningfully in some services.

The costs of regulating health and social care are significant and primarily met by providers, including the costs of administrative and management processes to comply with regulatory requirements. For public-funded services, this can divert resources from front-line care.

Economic and quality regulation should remain separate but closely-aligned. Monitor and CQC must be held accountable for how they discharge their duties to cooperate.

Setting the legislative framework for Monitor’s new role will be crucial to its effective operation as sector regulator. However, it will be essential to learn and develop future policy from its operation. This would be aided by setting out how it conducts its role in secondary legislation which could be more-easily amended if unintended consequences occur.

We would like to see a clearer statement of intent at the outset about how the procurement and competition regimes will operate and how Monitor will balance its competing duties.

We welcome proposed amendments to the Health and Social Care Bill that would allow the Secretary of State (SoS) to report on national organisations, and we expect the SoS to assess regularly how Monitor fulfils its role and duties in the interest of patients and taxpayers.

When considering our evidence, we urge the Committee to bear in mind the following points on the overall regulatory system:
  o Member concerns about the bureaucratic nature of many requirements
  o The need for the government to take a systematic and longer-term approach to regulation, which should be informed by the findings of the public inquiry into Mid Staffordshire NHS Foundation Trust.
  o The need to clarify the role of commissioners in promoting and assuring quality.
2. Introduction
2.1 The NHS Confederation supports strong, effective regulation. This is fundamental to reinforcing public trust in both the individuals and organisations providing care, and to helping safeguard patients and ensure they receive high-quality and safe care provided by well-run organisations.

2.2 As organisations working in the public interest, regulators must be accountable for their performance and practice. We therefore welcome this opportunity to submit evidence to inform the Health Select Committee’s scrutiny of the CQC and Monitor. Our members have direct experience of the requirements and operation of these regulators on a daily-basis and are well-placed to make observations about their effectiveness.

2.3 Our submission draws extensively on member feedback and intelligence, as both providers and commissioners of care, and employers of healthcare professionals. It also draws on NHS Confederation seminars held in winter 2010-11, which considered how economic and quality regulation should operate and included participants from patient groups, other interested parties and NHSC members.

2.4 Our submission covers:
• The proper role and operation of regulation
• The extensive regulatory and oversight structures for healthcare, and their inter-relationships, including between regulation and commissioning
• CQC’s role as a quality regulator, including detailed comments about its operation and registration
• Bureaucracy and the costs of regulation
• Monitor’s future role
• Coordination of quality and economic regulation.

3. The proper role of regulation
3.1 The NHS Confederation believes that it is essential all regulators have clear objectives and understanding of their role (and how this relates to other regulators), which underpins their operation. Our recent regulation seminars identified five key elements as the proper focus of regulation:
• Protecting people from harm, especially the most vulnerable in society
• Protecting and promoting the patient interest
• Assuring the quality of services and delivery of good outcomes for patients
• Ensuring access to essential services
• Changing behaviours and internalising good practice to achieve the desired objectives.

3.2 All regulation should be consistent with better regulation principles, i.e. risk-based, proportionate, consistent, targeted, transparent and accountable. However, we question whether current healthcare regulation consistently adheres to these principles.
3.3 We suggest there is a need for much greater honesty with the public about what both professional and service regulation can deliver. A realistic understanding is needed of what regulators can actually achieve, and the likely costs of different regulatory approaches, which should inform their practical operation. We believe regulators should be responsible for setting minimum standards that guarantee entry to a profession or allow organisations to provide care. Responsibility for improving quality lies elsewhere, not least with providers themselves.

3.4 Recent debate has questioned whether existing regulatory structures can prevent failures in care, often advocating a more inspection-based approach. However, inspection-based regulation can only give assurance that things were right at a particular time and location, although inspections (including unannounced inspections) should be an important tool for any regulator. No regulatory system can ever prevent all failures of care, and designing a system that seeks to do so is likely to be unsustainable financially and overly-disruptive to delivering care.

3.5 The NHS Confederation believes primary responsibility for delivering safe and high-quality care and ensuring organisations are well-run and financially viable lies with the Board and frontline clinicians. The regulator’s role should be to encourage providers to develop more robust systems for monitoring and delivering quality, and to reinforce that with an effective enforcement regime.

4. Current regulatory framework for healthcare

4.1 While important, the GMC, NMC, CQC and Monitor are not the only regulators with oversight for healthcare standards. In the joint NHS Confederation/Independent Healthcare Advisory Services report *What’s it all for?*,¹ we identified over 69 bodies with oversight of healthcare providers, including powers of regulation and inspection. These include the Health and Safety Executive, other professional regulators (such as the Health Professions Council), the Medicines and Healthcare products Regulatory Agency, and many others. Additionally, commissioners have an important role in assuring quality.

4.2 We are concerned there is a tendency to view individual regulators in isolation, without recognising the interconnectivity of their roles and impact on healthcare provision. Often responsibilities overlap and there is insufficient clarity about respective roles and functions. This can not only result in duplication, but also cause things to slip through the cracks, as there is insufficient clarity about who is responsible for taking action. Effective regulation requires all regulators to find ways of managing their respective roles and inter-relationships, and any potential tensions between their different roles and objectives (such as between quality and access, competition and safeguarding services) to deliver over-riding benefits for patients.

¹ NHS Confederation and Independent Healthcare Advisory Services (2009) *What’s it all for?*
4.3 Despite the many bodies with oversight of the quality and safety of healthcare, high-profile failures of care continue to raise significant questions about the effectiveness of current regulatory structures. This undermines public confidence in the regulators’ ability to prevent unacceptable standards of care/safeguard those using services. Recent events have particularly called into question the CQC’s effectiveness, and its ability to safeguard vulnerable individuals.

4.4 Each high-profile failure of care tends to result in ad hoc regulatory responses, and the incremental growth of regulatory and oversight processes. These are often costly, burdensome, duplicative and bureaucratic, and add little to guaranteeing quality, safety and access for patients.

4.5 A more systematic approach is needed, and we hope the public inquiry into Mid Staffordshire NHS Foundation Trust will result in a sensible and considered approach to the respective roles and functions of the different parts of the regulatory and oversight structures. This should avoid another costly and radical revision of regulatory structures. Such an approach is particularly important given current proposals for Monitor to take on the role of sector regulator for health and social care, particularly to clarify how it should operate and work with the CQC in discharging its responsibilities.

4.6 A significant gap in the current structures is how to deal effectively with service failure and closure of services, particularly where they are uneconomic or (as in the case of Southern Cross) are provided by financially unsound organisations where the market seems unable to develop an acceptable solution of its own accord. This issue must be addressed before the proposed health reforms begin to take effect.

5. **Professional regulation**

5.1 Professional regulation should set the standards for education and training, competence and conduct for individual professionals, which help to create a culture and guide individual professionals to act in patients’ interests. These apply and be enforced whether individuals work as clinicians or as managers.

5.2 The NHS Confederation has supported the revalidation of doctors and NHS Employers has worked to develop appropriate processes to achieve its implementation. Revalidation can provide useful checks of individual professionals’ competence, but these should be part of a wider system of appraisal and performance assessment by employers. Employers must have appropriate systems in place, and it is their responsibility to pick up early indications of a failure to deliver appropriate care and take action.
5.3 It is also important that professional regulators and the CQC are clear about their reciprocal responsibilities in the quest to maintain quality and ensure that information is shared readily and appropriately with each other.

6. Regulation and Commissioning

6.1 Commissioning can play an important role in driving quality and access, but there is currently no agreement about the role of commissioners as part of NHS regulatory and oversight structures.

6.2 The Health and Social Care Bill is clear that clinical commissioning groups will have a duty to seek to secure continuous improvements in the quality of services and health outcomes. While agreeing these are core functions for commissioning organisations, our members have warned against loading responsibilities for quality monitoring and service improvement on commissioners in a way that is inappropriate and undeliverable.

6.3 A distinction should be drawn between these commissioning responsibilities and the responsibility of all organisations providing NHS services to ensure their quality, safety and effectiveness. A more realistic view of commissioners' responsibility and scope in the new system should include:

- assuring themselves only registered providers are added to local service directories
- gathering patient and public feedback of their experiences of using services
- monitoring trends in reported experience and outcomes, complaints and serious incidents
- making this information available to the public and to individual referrers in accessible formats
- taking prompt, appropriate action if any information received gives cause for concern or further scrutiny.

6.4 In practice, the 'right' approach will depend on factors such as the number of providers a commissioner relates to, their quality and safety record and the local priorities for health and service improvement, but no approach will be comprehensive or fail-safe.

6.5 The NHS Confederation believes agreement is needed on what is a reasonable and appropriate role for commissioners in assuring and promoting quality, and their responsibility to quality regulators. It will be especially important that the new clinical commissioning groups and NHS Commissioning Board do not develop additional regulatory-type requirements for providers that duplicate CQC requirements or act as barriers to entry for new providers.
7. CQC’S ROLE AS A QUALITY REGULATOR

Strategic concerns about the CQC

7.1 Many of our members, both NHS and independent sector providers, have considerable concerns about the operation of CQC, the current registration system and its model for monitoring quality. They question whether the CQC is sufficiently risk-based or proportionate in its approach and model of regulation is well suited to current and emerging models of care, particularly its ability to assess quality across patient pathways.

7.2 Fundamentally, there is insufficient clarity about whether CQC’s focus should be “quality” regulation or assuring minimum standards. We suggest CQC can only set and enforce the minimum standards of safety and quality all providers must meet in order to provide care. While these standards may rise over time, operating these minimum requirements for entry to the market effectively must be CQC’s core role, particularly given proposals to encourage new providers of NHS services.

7.3 We suggest the CQC lacks sufficient independence from government, making it difficult for them to be an objective advocate of quality, particularly at a time of significant public expenditure constraints. This raises questions about whether the CQC should speak out about the impact of funding constraints on its capability to discharge its functions and, more generally, the impact on quality for publicly funded health and social care services.

7.4 We are concerned the CQC is being expected to do more, including taking on regulatory functions from other bodies, but with limited resources and when the efficacy of its current approach is being fundamentally questioned. Pressure on CQC resources has resulted in the demise of positive initiatives to promote active information sharing with other regulators and co-ordination of activity (planned collaborative reviews) and the end of service reviews looking across pathways.

7.5 We also suggest that the CQC is insufficiently accountable for the cost-effectiveness of its operation and quality and performance of its regulatory approach. Feedback from our members continues to question CQC’s effectiveness and its actual impact on quality and safety standards. We believe the CQC should consult regulated providers to help determine its regulatory model and approach, which would be consistent with better regulation principles.

Concerns about the CQC’s approach to registration:

7.6 These include:

- Their generic model underpinning registration means that sometimes guidance does not make sense in the context of the particular service being inspected or inspectors do not understand the services they are inspecting adequately. This is a particular concern for providers of mental health, ambulance and community
services, who often state that the CQC’s approach is too acute and social care focused. For example, it took significant time to resolve issues for the registration of air ambulances.

- CQC’s approach lacks sufficient flexibility to accommodate new service models or rapid service changes readily. At a time of major service change in the NHS, this presents particular problems for maintaining service continuity while changes to registration are made.
- The unit of registration (the NHS trust or group in the case of independent sector healthcare and social care providers) is too large to provide a meaningful assessment of quality for users of services. This will be increasingly important as NHS trusts amalgamate and provide a range of services in different settings.
- Some service providers have found the key concept of “location” difficult to apply meaningfully to their registration, particularly ambulance services and services provided in the community and people’s homes.
- CQC’s apparent failure to coordinate activity and share information internally, e.g. between those undertaking assessments of mental health providers under the Mental Health Act and more general inspections.

*Use of Quality Risk Profiles*

7.7 Our members have several concerns about the CQC’s Quality Risk Profiles (QRP) and CQC’s reliance on QRPs to pick up early indications of poor quality care and provide the basis for action. These include:

- the accuracy of some information contained in their QRP
- whether QRPs take sufficient account of the intrinsic risks associated with certain procedures and types of care or the vulnerability of service users.

7.8 Members of our Mental Health Network have particularly questioned the CQC’s understanding of risk in a mental health context.

*CQC processes*

7.9 Members have found CQC processes often cumbersome, bureaucratic and poorly administered, with delays in responses. This results partly from the current legislative framework, which requires providers to notify the CQC of detailed service changes. This imposes significant burden on providers and the CQC, which has apparently not had sufficient resources to deal with these applications quickly and effectively. Examples include:

- Providers must notify any change in registered manager, even if the registered manager held this position at another of the provider’s locations
- Providers must submit a new Statement of Purpose with each registration application and variation
- Delays in providing submission references for forms submitted electronically making it difficult for providers with multiple CQC applications
- Delays in issuing certificates and processing variations to registration.
7.10 Our members indicate that CQC advice and information has not been sufficiently consistent, clear or timely. In particular:

- ambulance trusts, mental health trusts, community and independent sector providers report inconsistent advice and approaches by different regional offices
- the CQC website is poor with limited availability of online forms and inadequate guidance to support their completion
- CQC helpline staff do not appear to have the necessary knowledge to provide the clarification of guidance required.

7.11 The requirements of registration and ongoing compliance are complex, and organisations need practical, detailed information to help navigate them. Our members suggest that registration should be underpinned by a better understanding of how different types of service are provided in the NHS, with more tailored guidance for different types of service, including using specialist inspectors. They would like to see named CQC contacts to provide continuity and consistency, and improve the quality of advice. This should contribute to a more effective and tailored approach to quality regulation that is better able to pick up early indications of poor quality care.

**Bureaucracy and the costs of regulation**

7.12 The costs of operating the CQC and associated administration in providers to monitor and demonstrate compliance are significant. Preparing for registration and on-going compliance are immensely bureaucratic processes demanding significant resources. Our members continue to question whether this provides value for money, particularly its impact on quality and safety standards.

7.13 All providers, including the NHS, pay fees to cover CQC’s costs of operating registration, and are on a trajectory to cover these costs fully. Despite initial promises that registration would be cost-neutral to the NHS, NHS organisations pay significant fees to the CQC. Some providers have faced considerable increase in this year’s fees, which have been difficult to fund in the current financial climate, and in some cases, diverted funding from frontline services.

7.14 NHS Confederation members continue to highlight the significant, on-going costs, processes and functions associated with CQC registration. Given current government commitments to reduce bureaucracy and red-tape, we find it surprising the statutory regulatory systems are major drivers of this. Many members believe more could be done to simplify CQC’s burden on providers without undermining its effectiveness. This should yield administrative cost savings for providers and result in reduced fees.
7.15 The NHS Confederation believes the CQC should be more transparent in setting its fees, particularly explaining how these relate to the costs of regulating different sectors, and the CQC fee structure should include incentives for providers to improve their quality. We are concerned that the latest scandals may result in a significant shift to the CQC adopting a more direct/inspection-based approach, with all providers having to bear the full extent of these costs irrespective of their quality and safety standards. We suggest that if a level of regulation and scrutiny is required in the public interest, these costs should be borne centrally by the public purse rather than diverting resources from front-line patient care.

8. Developing the role of Monitor
8.1 NHS Confederation members are familiar with Monitor’s risk-based operation as regulator of NHS foundation trusts, which has helped to drive up financial and governance standards.

8.2 Current health reforms propose a new role for Monitor as sector regulator for health and social care. This has caused significant concerns, particularly the rigid application of economic regulation and competition principles to the English health market, which is relatively undeveloped and has some peculiarities, such as commissioners as third-party payers.

8.3 The NHS Confederation believes creation of an appropriate economic regulation regime and regulator is an essential part of the new system. However, this must be:
- based on a primary duty to protect and promote the interests of people who use healthcare services and taxpayers by promoting the economic, efficient and effective provision of NHS services
- tailored and able to be applied flexibly to different types of service and locality.

8.4 We welcome the government’s recognition that the Health and Social Care Bill should place an additional duty on Monitor to promote co-operation and integration where appropriate, alongside its duty to promote competition.

8.5 A clearer statement of intent at the outset about how the procurement and competition regimes will operate and how Monitor will balance its competing duties would provide some reassurance. It is important to be clear that Monitor’s role is to provide a framework to support local commissioners rather than make local decisions, but that where local commissioning decisions are challenged, Monitor will judge the appropriateness of them.

8.6 Careful consideration is needed in setting the legislative framework for Monitor’s new role as sector regulator to avoid creating perverse incentives and unintended consequences. These might be overcome by setting out Monitor’s high-level duties in
primary legislation, with detail of how it conducts its role expressed in secondary legislation, which can be amended if unintended consequences emerge.

8.7 There will undoubtedly be a period of learning and it will be important to ensure there is an opportunity to learn and develop policy and carry out proper evaluation. We believe that the Secretary of State for Health could be responsible for regularly assessing how Monitor is fulfilling its role and duties in the interests of patients and taxpayers.

9. **Coordination of economic and quality regulation**
9.1 Ensuring close integration and alignment between economic, service and professional regulation is vital, in theory and in practice, for effective regulation and to minimise duplication and overlap, and ensure the adequate provision of safe care. For example, some elements of CQC registration already relate to the financial viability of organisations.

9.2 Recent evidence sessions at the Mid Staffordshire public inquiry have highlighted the benefits of a single economic and quality regulator for health and social care. While this could lead to better co-ordinated economic and quality regulation, we are concerned there is a danger quality will be continually trumped by economic considerations.

9.3 On balance, the NHS Confederation believes separate economic and quality regulators are more appropriate. However, Monitor and CQC must be held accountable for how they discharge their duties to cooperate and practically work together to safeguard and promote patients’ interests effectively. We also suggest better alignment of financial incentives and quality objectives is essential to ensure better coordination of approach.