



Royal College
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RCN Policy Unit

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The Regulatory Landscape in Health and Social Care in England in 2009

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Royal College of Nursing
Policy Unit – Room 209
20 Cavendish Square
London
W1G 0RN

Telephone 020 7647 3754
Fax 020 7647 3498
Email policycontacts@rcn.org.uk

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Introduction and context

Health and social care in England is undergoing major changes to system regulation. In particular, the Care Quality Commission (CQC) began its work to regulate health and social care from the 1st April 2009. CQC has taken over the work of 3 previous regulators; the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission. This was part of the Government's goal of streamlining regulation.

This briefing sets out the range and scope of 'regulators' in the health and social care sector in England. Its aim is to outline who does what in regulating, inspecting, auditing and contributing to setting standards in health and social care in the new regulatory landscape. We include both system regulators (such as the CQC) and professional regulators (such as the Nursing and Midwifery Council) because it is important that system regulation and professional regulation is complementary; high quality safe care needs both professionals who can deliver care and the systems to support them in that delivery. We also include other agencies and organisations who may inspect or visit providers, audit providers and/or set standards. For example, LINks, who can choose to visit providers as part of their role as organisations which aim to provide citizens a stronger voice in how their health and social care services are delivered. Most organisations we include in this briefing will require information from providers.

Regulation is becoming increasingly important in the context of an NHS and social care system in England with:

- *Commissioning*, either undertaken by Primary Care Trusts (PCTs) or commissioning outsourced to independent sector providers deciding what to buy and from whom;
- *Patient choice and voice* allowing patients' choice over their provider and more consultation and engagement with patients. In addition, the potential for greater scope of personal or individual budgets for some individuals in both health and social care to purchase those services which best meet their needs;
- *Plurality of providers* including Foundation Trusts, the independent sector and the third sector (including for example, charities and social enterprises);
- A renewed *focus on quality* as part of the Next Stage Review; and
- A new *NHS constitution*.

Regulators therefore need to respond to a more diverse provider base. If the number and type of providers is increasing, it is important to ensure that they operate in ways that deliver high quality, safe care. The CQC (and others) have a role to play in setting standards and monitoring providers. In particular, the CQC has a number of enforcement powers ranging from fines through to closing a provider down; the CQC therefore can bring to bear strong incentives for providers to ensure that they deliver high quality safe care. The CQC is part of a continuum of performance management undertaken by PCTs, SHAs, Monitor, and DH. The CQC has particular powers which mark it out as a key regulator.

What is regulation?

The term regulation is often used but rarely clearly defined. According to the Library of Liberty and Economics, “*regulation consists of requirements the government imposes on private firms and individuals to achieve government’s purposes*”.¹

The King’s Fund notes that:

*“[Regulation] in essence involves the creation of mechanisms that allow governments, directly or indirectly, to shape the behaviour of providers or funders of goods and services that they do not own to ensure that governmental objectives (such as efficiency and consumer safety) are achieved in the face of potential significant market failures.”*²

In addition, some industries decide to put in place self regulation; where they set out their own mechanisms to ensure the quality of their goods and services.

Why have regulation?

Regulation can be put in place for various reasons. For many it is linked to economic concepts; to help solve market failures. What this means is that there might be reasons why individuals might need to have greater protection than they otherwise would; perhaps because they will not have all the information that they need to make an informed decision. Government can then step in to require that certain information is provided to individuals or put in place checks and balances to make sure those providing goods or services do not mislead individuals.

In the health and social care context the CQC acts as an inspector and monitors providers. Where there are concerns that care is poor (either through the CQC's own monitoring or because another party has raised a concern about a provider with the CQC) the CQC can investigate and require providers to make changes. In the most extreme case, providers could be closed down. In the case of very

¹ <http://www.econlib.org/library/Enc/Regulation.html>

² http://www.kingsfund.org.uk/research/publications/how_to_regulate.html

poor quality the involvement of a regulator can be the catalyst for change as occurred in the tragic example of Mid Staffordshire Trust.³

Who regulates?

There are a vast number of agencies who can be considered broadly involved in regulating, inspecting, auditing or setting standards in health and social care. The agencies change over time; as do their remit and activities. Table 1 provides an overview of the main agencies as they stand in 2009.⁴

In addition there is a central government drive to consider the appropriate balance of regulation under the remit of the Better Regulation Executive, within the Department for Business Enterprise and Regulatory Reform (BERR).⁵ The aims are:

- to work with departments to improve the design of new regulations and how they are communicated;
- to work with departments and regulators to simplify and modernise existing regulations; and
- to work with regulators (including local authorities) and departments to change attitudes and approaches to regulation to become more risk-based.

'Good' regulation

It's difficult to set out what makes 'good' regulation. The government has however set out five principles which it believes must underpin good regulation.⁶ The principles state that any regulation should be:

- transparent
- accountable
- proportionate
- consistent
- targeted – only at cases where action is needed

These can be seen as underpinning the desire to make regulation 'light touch', including an element of self assessment and a risk based approach. This should minimise the burden of regulation, but if implemented appropriately, still ensure

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http://www.cqc.org.uk/db/documents/Investigation_into_Mid_Staffordshire_NHS_Foundation_Trust.pdf

⁴ This list was informed by the NHS Confederation's work in 2007 (see <http://www.timesonline.co.uk/tol/news/uk/health/article1484971.ece>) and has been updated via website searches.

⁵ <http://www.berr.gov.uk/whatwedo/bre/index.html>

⁶ <http://www.berr.gov.uk/whatwedo/bre/>

minimum standards. This is by focusing upon the activities which are most likely to cause significant harm and where regulation is the appropriate way to solve the problem.

So what?

The opportunity is significant; intelligent regulation of health and social care could lead to better health and social care for patients/users.

However, there are inevitably pitfalls; the regulators will need to work together in order to ensure that there are no regulatory 'gaps' (and to help to reduce duplication and the burden on providers since administration detracts from front line delivery).⁷

⁷ See for a recent discussion of bureaucracy: <http://www.nursingtimes.net/comment/opinion/frances-blunden-on-the-burden-of-nhs-bureaucracy/5000525.article> and; IHAS and NHS Confederation, What's it all for? Removing unnecessary bureaucracy in regulation, June 2009 http://www.nhsconfed.org/Publications/Documents/Whats_it_all_for.pdf

Table 1: Regulators, agencies that can visit providers and quality improvement agencies in health and social care in England

Agency	Website	Responsibilities
Human Fertilisation & Embryology Authority	http://www.hfea.gov.uk/	The Human Fertilisation & Embryology Authority (HEFA) licenses fertility clinics and centres carrying out in vitro fertilisation (IVF), other assisted conception procedures and human embryo research.
Human Tissue Authority	http://www.hta.gov.uk/	The Human Tissue Authority (HTA) licenses premises across five diverse sectors: human application, research, post mortem, anatomy and public display.
Medicines and Healthcare Products Regulatory Agency	http://www.mhra.gov.uk/index.htm	The Medicines and Healthcare Products Regulatory Agency (MHRA) licences new medicines. They “enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe”.
Monitor – Independent Regulator of NHS Foundation Trusts	http://www.monitor-nhsft.gov.uk/	Monitor authorises and regulates NHS foundation trusts. Monitor is independent of central government and directly accountable to Parliament.
Environment Agency	http://www.environment-agency.gov.uk/	The Environment Agency is a public agency with a remit to protect and improve the environment in England and Wales. Their job is to “make sure that air, land and water are looked after by everyone in today’s society, so that tomorrow’s generations inherit a cleaner, healthier world.”
Fire authorities e.g. London Fire Brigade	http://www.london-fire.gov.uk/	Fire authorities can provide provide advice and information to assist employers about workplace fire safety training and fire risk assessment.
Health and Safety Executive	http://www.hse.gov.uk/	The Health and Safety Executive’s (HSE) mission is to ‘prevent death, injury and ill health in Great Britain’s workplaces’ via research, information and advice, promoting training, new or revised regulations and codes of practice, inspection, investigation and enforcement.
Information Commissioner	http://www.ico.gov.uk/	The Information Commissioner’s Office is the UK’s independent authority set up to promote access to official information and to protect personal information.
National Audit Office	http://www.nao.org.uk/	The National Audit Office audits the accounts of all central government departments and agencies, as well as a wide range of other public bodies, and reports to Parliament on the economy, efficiency and effectiveness with which they have used public money.
Local authority environmental health departments		Local authority environmental health departments have responsibilities for health and safety in workplaces, including care homes amongst other premises.
Audit Commission	http://www.audit-commission.gov.uk/	The Audit Commission has the “aim to improve the quality of financial management in the NHS and encourage continual improvement in public services.” The Audit Commission audits NHS trusts, Primary Care Trusts (PCT) and strategic health authorities to review the quality of

		their financial systems and also works with foundation trusts. They publish independent reports which highlight risks and good practice to improve the quality of financial management in the health service and encourage continual improvement in public services including in the field of public health and health inequalities.
Care Quality Commission	http://www.cqc.org.uk/	The Care Quality Commission (CQC) is the independent regulator of health and social care in England. Their aim is to "make sure better care is provided for everyone, whether that's in hospital, in care homes, in people's own homes, or elsewhere." CQC regulate health and adult social care services, whether provided by the NHS, local authorities, private companies or voluntary organisations. In addition, they protect the rights of people detained under the Mental Health Act. In the future, the CQC will also licence providers in primary care.
Overview and scrutiny committees of local authorities	http://www.dh.gov.uk/en/Managingyourorganisation/PatientAndPublicinvolvement/DH_4093409	OSCs take on the role of scrutiny of the NHS, including the ongoing operation and planning of services. The intention is to "bring democratic accountability into healthcare decisions and make the NHS more publicly accountable and responsive to local communities."
LINKs	http://www.dh.gov.uk/en/Managingyourorganisation/PatientAndPublicinvolvement/DH_076366	Local Involvement Networks (LINKs) aim to "give citizens a stronger voice in how their health and social care services are delivered." LINKs are run by local individuals and groups and independently supported. Their role is to "find out what people want, monitor local services and to use their powers to hold them to account."
General Social Care Council	http://www.gsc.org.uk/Home/	Registers Social Workers and regulates their conduct and training.
Council for Healthcare Regulatory Excellence	http://www.chre.org.uk/	The Council for Healthcare Regulatory Excellence is an independent body accountable to Parliament. Their purpose is to "promote the health, safety and well-being of patients and other members of the public." CHRE scrutinises and oversees the health professions regulators, working with them in identifying and promoting good practice in regulation, carrying out research, developing policy and giving advice.
General Chiropractic Council	http://www.gcc-uk.org/page.cfm	The General Chiropractic Council was established by parliament to "regulate and develop the chiropractic profession"
General Dental Council	http://www.gdc-uk.org/	The General Dental Council is the organisation which regulates dental professionals in the UK
General Medical Council	http://www.gmc-uk.org/	The General Medical Council registers doctors to practise medicine in the UK. Their purpose is to "protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine."
General Optical Council	http://www.optical.org/	The General Optical Council's purpose is to "protect the public by promoting high standards of education, conduct and performance amongst opticians."

General Osteopathic Council	http://www.osteopathy.org.uk/	The General Osteopathic Council registers qualified professionals, sets standards of osteopathic practice and conduct, assures the quality of osteopathic education, ensures Continuing Professional Development and helps patients with complaints about an osteopath.
Health Professions Council	http://www.hpc-uk.org/	The Health Professions Council was set up to protect the public. The Council does this via a register of health professionals who meet their standards for their training, professional skills, behaviour and health
British Association for Counselling and Psychotherapy	http://www.bacp.co.uk/about_bacp/profile_history.php	BACP ensures that it meets its remit of public protection
Nursing and Midwifery Council	http://www.nmc-uk.org/	The Nursing and Midwifery Council “safeguards the health and wellbeing of the public.” They do this via registering all nurses and midwives and ensure that they are properly qualified and competent to work in the UK. They also set the standards of education, training and conduct that nurses and midwives need to deliver high quality healthcare consistently throughout their careers.
Royal Pharmaceutical Society of Great Britain	http://www.rpsgb.org.uk/	The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. The primary objectives of the Society are to “lead, regulate, develop and represent the profession of pharmacy.”
Health Protection Agency	http://www.hpa.org.uk/	The Health Protection Agency provides independent testing and support services to many groups and organisations. These include government agencies and departments, the NHS, local authorities, health professionals, national and international bodies, industry, and universities.
National Patient Safety Agency	http://www.npsa.nhs.uk/	The National Patient Safety Agency “leads and contributes to improved, safe patient care by informing, supporting and influencing organisations and people working in the health sector.”
National Treatment Agency for Substance Misuse	http://www.nta.nhs.uk/	The National Treatment Agency for Substance Misuse (NTA) is a special health authority within the NHS to “improve the availability, capacity and effectiveness of treatment for drug misuse in England.”
National Institute for Innovation and Improvement	http://www.institute.nhs.uk/	The NHS Institute for Innovation and Improvement “supports the NHS to transform healthcare for patients and the public by rapidly developing and spreading new ways of working, new technology and world-class leadership.”
National Institute for Health and Clinical Excellence	http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp http://www.nice.org.uk/aboutnice/qof/qof.jsp	NICE has a role in terms of quality standards, and in the Quality and Outcomes Framework, which will impact upon information requirements from primary care in the future.
Connecting for Health: Information Governance Toolkit	http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/igsoc/faqs/igt?searchterm=information+gover	Information Governance ensures necessary safeguards for, and appropriate use of, patient and personal information.

	nance+toolkit	
NHS Business Services Authority	http://www.nhsbsa.nhs.uk/	NHS Business Services Authority has a "vision to be the organisation of choice to provide business solutions that deliver service excellence and value for money for the NHS."
NHS Security Management Service	http://www.nhsbsa.nhs.uk/security	The aim of the NHS Security Management Service is "to protect the NHS so that it can better protect the public's health."
NHS Prescription Services	http://www.nhsbsa.nhs.uk/prescriptions	NHS Prescription Services remunerate and reimburse dispensing contractors across England. They also provide the NHS with a range of financial, prescribing and drug information
NHS Litigation Authority	http://www.nhsla.com/home.htm	The NHSLA is a Special Health Authority (part of the NHS), responsible for handling negligence claims made against NHS bodies in England. In addition to dealing with claims when they arise, we have an active risk management programme to help raise standards of care in the NHS and hence reduce the number of incidents leading to claims. We also monitor human rights case-law on behalf of the NHS through our Human Rights Act Information Service. Since April 2005 we have been responsible for handling family health services appeals and in August 2005 we acquired the further function of co-ordinating equal pay claims on behalf of the NHS.
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Postgraduate Medical Education and Training Board	http://www.pmetb.org.uk/	PMETB is the independent regulatory body responsible for postgraduate medical education and training. We ensure that postgraduate training for doctors is of the highest standard
Skills for Health	http://www.skillsforhealth.org.uk	Skills for Health is the Sector Skills Council (SSC) for the UK health sector. We help the whole sector develop solutions that deliver a skilled and flexible UK workforce in order to improve health and healthcare
Cancer Peer Review	http://www.cquins.nhs.uk/	The Cancer Peer Review is a national quality assurance programme for NHS cancer services. The programme involves both self-assessment by cancer service teams and external reviews of teams conducted by professional peers, against nationally agreed "quality measures".
Peer Review of Cancer Registries	http://82.110.76.19/peerreview/	The National Cancer Peer Review Programme is "an integral part of the NHS Cancer Plan and modernisation of cancer services. The Programme supports quality assurance of cancer services and enables quality improvement."
Cancer Screening quality assessment	http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp19.html http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp15.html	External quality assessment schemes for specific cancer screening programmes.

NHS Estates	http://www.dh.gov.uk/en/Managingyourorganisation/Estatesandfacilitiesmanagement/DH_302	NHS Estates provide “strategic development of a flexible and responsive environment for health and social care, delivering improved health outcomes through innovative estates and facilities solutions which enable high quality, safe patient care.”
Health Information Accreditation Scheme	http://www.dh.gov.uk/en/Healthcare/PatientChoice/BetterInformationChoice/Health/Informationaccreditation/DH_076505	The information accreditation scheme “has a pivotal role in improving patient experience in that it will ‘kite mark’ information producers in order to make it easier for people to make their own judgements about the quality of information to make decisions about their health, health care and social care.”
Accreditation scheme for tissue banks	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006116	This Code of Practice applies to tissue banks in the public sector supplying human tissues for therapeutic purposes to the health service.
Accreditation for acute inpatient mental health services	http://www.rcpsych.ac.uk/clinicalservicestandards/centreforqualityimprovement/aims.aspx	Accreditation for Inpatient Mental Health Services (AIMS) is an initiative from the Royal College of Psychiatrists' Centre for Quality Improvement which identifies and acknowledges wards that have high standards of organisation and patient care, and supports and enables others to achieve these.
A Quality Network for Inpatient Child and Adolescent Psychiatry	http://www.rcpsych.ac.uk/clinicalservicestandards/centreforqualityimprovement/qnic.aspx	The network aims to “demonstrate and improve the quality of in-patient child and adolescent psychiatric in-patient care through a system of review against the QNIC service standards. This process follows a clinical audit cycle with self-review and peer-review.”
Investors in People	http://www.investorsinpeople.co.uk/Pages/Home.aspx	Investors in People provide “straightforward, proven frameworks for delivering business improvement through people.”
Clinical Pathology Accreditation Ltd	http://www.cpa-uk.co.uk/	CPA provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA). This includes an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review.
Health Quality Services	http://www.hqs.org.uk/	The Health Quality Service Is a health accreditation service with the aim of improving the quality of patient care through consultancy services and the development of health care standards and assessment processes.
Standards for Health Promotion in Hospitals	http://www.euro.who.int/document/e8	WHO has set out five core standards applicable to all hospitals.

	2490.pdf	
Ofsted	http://www.ofsted.gov.uk/	Ofsted "inspects and regulate to achieve excellence in the care of children and young people, and in education and skills for learners of all ages."

Note: We have listed organisations where a key website can be found.

RCN View

The RCN has made clear in several recent Consultation responses and briefings the importance of system regulation. The RCN calls for a truly effective regulatory regime given the increase in providers involved in the delivery of health and social care. This includes sufficient levels of monitoring, investigation, and inspections, appropriate indicators and timely intervention by the CQC where quality is poor. This means a regulator with teeth. By that we mean a regulator who proactively monitors providers via regular intelligence gathering and analysis, who acts swiftly when there is likely to be/harm, and uses powers to require changes and in extreme cases, closes providers down.

The RCN is also calling for 'intelligent' regulation. This means avoiding a box ticking approach but rather allowing for the use of professional judgement. It also requires investment in leadership by the CQC. This can be achieved by providing continuing training and support to assessors and inspectors and allowing standards to be measured through a mix of questions and indicators.

The RCN also notes that this absolutely requires investment in leadership; not just at CQC, but within every organisation in the NHS and social care (from commissioners to providers). The Healthcare Commission has repeatedly documented the importance of leadership and culture and appropriate staffing and training when it has investigated serious incidents. This is also backed up by various other evidence on the link between staffing levels, the role of nurses and patient outcomes.⁸ It is now well known that there need to be sufficient nurses with an appropriate skill mix, able to perform their roles, to avoid negative impacts upon patients. This evidence of the link between these must not be ignored and the new integrated regulator has a real opportunity to champion long term sustainable safe and high quality care.

⁸ Not least the latest report of the Healthcare Commission on Mid Staffordshire Trust, http://www.cqc.org.uk/db/documents/Investigation_into_Mid_Staffordshire_NHS_Foundation_Trust.pdf Other examples include: research by Dr Veena Rayleigh of the Healthcare Commission examined the Patient experience survey and staff survey and found a correlation between positive patient experiences and good HR and health and safety practice.

<http://www.nhsemployers.org/EmploymentPolicyAndPractice/staff-engagement/Pages/Healthcare-Commission-research.aspx>

See Healthcare Commission Investigation into outbreaks of Clostridium difficile at Maidstone and Tunbridge Wells NHS Trust (October 2007)

http://www.healthcarecommission.org.uk/db/documents/Maidstone_and_Tunbridge_Wells_investigation_report_Oct_2007.pdf

See also Nurses in society: starting the debate (15th October 2008)

<https://clearingatkins.org/schools/nursing/nru/reviews/nis.html> and State of the art metrics for

nursing: a rapid appraisal (15th October 2008)

<https://clearingatkins.org/schools/nursing/nru/reviews/metrics.html> and Manley, K., Organisational culture and consultant nurse outcomes: Part 1 organisational culture. Nursing Standard 2000; 14:34-38, and Manley, K., Organisational culture and consultant nurse outcomes: Part 2 consultant nurse outcomes. Nursing Standard 2000; 14:34-39.

It also requires alignment and effective working across the many agencies that are involved in contributing to setting standards, monitoring, auditing and inspecting providers.

Additional RCN resources on CQC

If you want to find out more about what the RCN has said about the CQC you can find out more using the following links:

http://www.rcn.org.uk/_data/assets/pdf_file/0008/240398/Looking_back_to_look_forward_FINAL.pdf

http://www.rcn.org.uk/_data/assets/pdf_file/0016/203533/15-2008_The_Care_Quality_Commission_CQC_in_England.pdf

http://www.rcn.org.uk/_data/assets/pdf_file/0006/236715/CQC_Statement_of_Involvement_response.pdf

http://www.rcn.org.uk/_data/assets/pdf_file/0015/235131/Consultation_on_CQC_reviews.pdf

http://www.rcn.org.uk/_data/assets/pdf_file/0018/206163/Consultation_on_CQC_enforcement_policy_FINAL.pdf

http://www.rcn.org.uk/_data/assets/pdf_file/0008/30995/the_future_regulation_of_health_and_adult_social_care.pdf

Tell us what you think

This briefing is intended as backgrounder on regulation in health and social care in England and the Policy Unit would like to receive comments/feedback from as many members as possible on this important issue. Please email: policycontacts@rcn.org.uk .

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