
RCN Policy Unit

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



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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



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



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).

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

Care Quality Commission	http://www.cqc.org.uk/	<p>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.</p> <p>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."</p>
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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

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/gnic.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