This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

Common law

**National law database**

*Language:* English  
*Link:* [www.legislation.gov.uk](http://www.legislation.gov.uk)  
*Nature:* Official law database  
*Organisation responsible for the website:* The national archives on behalf of the government  

**Legal UHC start date**

1948

**Source:** [http://www.euro.who.int/__data/assets/pdf_file/0011/96419/E68283.pdf](http://www.euro.who.int/__data/assets/pdf_file/0011/96419/E68283.pdf)

**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to:  
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Regulation

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Regulation

United Kingdom - England
HIT: 2011 - Boyle S
HSPM Members: The King's Fund
HSPM Contributors: Mundle C, Cylus J
United Kingdom - England: Regulation

4. Regulation and planning

This chapter provides an account of the main regulatory mechanisms in the English health care system, as well as a description of the way that health services are planned. It concludes with some discussion of the organization of health care information, and the contribution of health-related R&D in England.

4.1 Regulation

This section reviews the governance and regulation of:

- third-party payers and their role as purchasers of health care
- the purchasing process
- providers of health care
- health care professionals.

Regulation can take place in a number of ways, including self-regulation, regulation by parliament or local authorities, regulation through courts and tribunals, regulation by central government departments and regulation by regulatory agencies (Baldwin & Cave 1999). In the health care sector, much of what is observed is independent regulation through a range of bodies (Table 4.1). NHS hospitals are in the process of attaining greater autonomy from the Department of Health (see the discussion relating to FTs in section 4.1.3), although they remain subject to a system of external audit and inspection that has been developed and extended since 1999. PCTs still operate within a target-based framework, reflecting their responsibility for the use of public funds to meet the health needs of their local populations. Health care professionals had retained a significant degree of autonomy in regulating their practice, although there have been significant changes in recent years; these are discussed in section 4.1.4.

Table 4.1: Decentralization of functions and regulatory institutions in England

<table>
<thead>
<tr>
<th>Function</th>
<th>Type of decentralization</th>
<th>Regulatory institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set standards</td>
<td>Centralization</td>
<td>Department of Health</td>
</tr>
<tr>
<td></td>
<td>Delegation</td>
<td>NICE</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Delegation</td>
<td>CGC, Audit Commission, NAO, NPSA, Monitor</td>
</tr>
<tr>
<td></td>
<td>Deconcentration</td>
<td>SHAs</td>
</tr>
<tr>
<td></td>
<td>Devolution</td>
<td>Local government overview and scrutiny committees</td>
</tr>
<tr>
<td>Enforce regulation</td>
<td>Privatization</td>
<td>GMC, General Dental Council (GDC), Nursing and Midwifery Council, General Pharmaceutical Council, General Optical Council, General Chiropractic Council, General Osteopathic Council, Health Professions Council</td>
</tr>
<tr>
<td></td>
<td>Delegation</td>
<td>CGC, General Social Care Council, Monitor</td>
</tr>
<tr>
<td></td>
<td>Deconcentration</td>
<td>NHS trusts</td>
</tr>
</tbody>
</table>

Source: Adapted from a categorization in Baldwin & Cave 1999.

The King's Fund finds that NHS performance frameworks need to be simplified
By Sarah Gregory

The approach to performance assessment in the NHS requires radical simplification and alignment in future, a review by The King’s Fund finds. This should include a consolidation of the three national outcomes frameworks into a single framework covering the NHS, public health and social care.

The review of how to assess the performance of local health systems, commissioned by the Department of Health, finds that the number of national bodies involved in assessing performance results in duplication of effort and unnecessary complexity. It also recommends a rationalisation of the disparate public-facing websites to provide the public with an integrated view of services in an area.


Monitor and NHS Trust Development Authority to create a new regulator
By Sarah Gregory

Monitor and NHS Trust Development Authority will be brought together to create a new provider regulator called NHS Improvement. The new body, which will also take responsibility for patient safety, will be in force from April 2016.

Governance and accountability following the Health and Social Care Act 2012
By Sarah Gregory

Following the Health and Social Care Act of 2012 for the first time in the history of the NHS, there is now a statutory divide between the NHS as a commissioner/allocator of resources (NHS England) and ministers and the Department of Health. The Department is now a far smaller organisation than it was and the number of permanent staff employed fell by 31 per cent between 2011 and 2014 (Department of Health 2014 Annual report and accounts 2013–14. p 189), while NHS England has exceeded the vision for a ‘lean’ body with a staff of 15,291 (National Health Service Commissioning Board annual report and accounts 2013–14)

The Act intended to bring about a situation whereby the Secretary of State was not involved in the day-to-day running of the NHS, with the annual mandate (from the Department of Health to NHS England) being the limit of their direction of the service. The mandate itself is structured around an outcomes framework which embodies the Conservative pre-election pledge that process targets – which measure, for example, how long a patient waited rather than the success of their treatment would be replaced by measurement of health outcomes. This was intended to improve survival rates from cancer, stroke and lung disease.

In spite of the coalition government’s initial objections to process targets, they have remained an important part of accountability within the NHS, partly because of the difficulties in holding service providers to account against the high-level outcomes framework. In fact, in 2013, the government introduced a new target under which trusts are fined for every patient who waits more than a year from referral to treatment (NHS England 2013. Everyone counts: planning for patients 2014/15 to 2018/19.). The legally binding pledges in the NHS Constitution and the targets (or standards) in the mandate are now collated and published by NHS England rather than the Department of Health. The contradiction in how the Secretary of State could be ultimately accountable to parliament for the performance of the health service while only setting outcome measures became apparent in 2013 when it was reported that the recently appointed Jeremy Hunt had been contacting chief executives of trusts that were failing to meet accident and emergency targets (Hunt demands explanations from A&E underperformers’. Health Service Journal, 22 November 2013).

Source: Ham et al The NHS under the coalition government, The King’s Fund (2015)
Changes to the regulation of the quality of care

By Sarah Gregory

The coalition government has significantly altered the policy and legislative framework for quality regulation. This was partly in response to the findings of the Francis Inquiry into failures of care at Mid Staffordshire NHS Foundation Trust which called for a change of direction from an emphasis on planned, routine reviews, to more focused reviews that are triggered by and responsive to concerns based on risk and non-compliance with standards. In 2014, the Care Act introduced new fundamental standards of care, including a statutory duty of candour that requires providers to be open and transparent when things have gone wrong.

The new regulatory model requires the CQC to investigate whether the care that is being provided is safe, effective, caring, responsive to people’s needs, and well led.

Other changes include:

• a new form of ‘intelligent monitoring’ of providers to assess ongoing risks to the quality of care, thereby anticipating services at risk of failing before they do so.

• greater use of qualitative data drawing on the experience and expertise of clinicians, patients and carers

• specialist inspections under the auspices of ‘chief inspectors’ (for hospitals, general practice and adult social care), with visits by large teams of experts

• a new form of ‘Ofsted-style’ performance ratings for individual services and the trust as a whole, from ‘outstanding’ to ‘inadequate’

• a new inspection and regulatory model for general practice as a whole.

Following on from the Keogh review recommendations, a ‘special measures’ regime was also introduced to help trusts improve their services, affecting 11 trusts by July 2014. The measures involve close scrutiny from Monitor (for foundation trusts) or the NHS Trust Development Authority (for NHS trusts), the appointment of an improvement director, and linking with a partner (or ‘buddy’) trust that is performing well in those areas where improvement is needed. In some cases it has also involved changes at board level. In July 2014, the Secretary of State announced plans to extend the special measures regime to GP practices and providers of adult social care.


4.1.1 Governance and regulation of PCTs (third-party payers)

In England, the majority of health care expenditure is provided by government.\textsuperscript{37} Funds are allocated to PCTs who are then responsible for the commissioning of health care for their geographically defined populations, as well as, in some cases, providing services themselves (mainly community health care such as district nursing). In addition to commissioning acute and community health services, their responsibility includes contracting for PMS, primary dental services, primary ophthalmic services and pharmaceutical services. PCT performance is monitored and where appropriate managed by their local SHAs, although ultimately PCTs are responsible to the Secretary of State for Health.

PCTs are a part of the NHS and have a board with a majority of non-executive members.\textsuperscript{38} The chairman and non-executive members of the PCT are currently appointed by the Appointments Commission, a non-departmental public body to whom the Secretary of State for Health has delegated this power. The board has a maximum of 14 members excluding the chairman, of whom a maximum of seven can be non-executive members and a maximum of seven executive members, but the number of executive members
must not exceed the number of non-executive members. Executive members must include the chief executive, the director of finance, the chairman of the “professional executive committee” (see below for a description of this committee) and the director of public health. In addition, there should be at least one person, but not more than three, appointed by the chairman of the PCT following nomination by the professional executive committee. There may also be other executive members of the PCT appointed by the chairman and non-executive members of the PCT (Department of Health 2006h).

Each PCT has a professional executive committee whose role is to assist the PCT in the exercise of its functions, in developing strategy and policy and in developing and monitoring clinical governance and quality standards. The PCT appoints the membership of the professional executive committee, with a maximum of 18 members and including at least one GP, one nurse and one other person who is a health professional. Members must include the chief executive and the director of finance, one or two people employed by a relevant local social services authority, at least one public health member and professional members, who should be in the majority (Department of Health 2003c).

Finance

The Department of Health allocates over 80% of the total NHS budget directly to PCTs, which are responsible for commissioning services to meet the needs of their local populations (see section 3.4). PCTs are expected, through a series of negotiations with local service providers, to ensure the availability of health care to meet the needs of their populations within this fixed budget. Resources are also made available to PCTs for capital purposes, although the majority of capital investment funding is the responsibility of the NHS provider organizations.

Commissioning

PCTs set local priorities in consultation with their local communities and partner organizations (i.e. NHS and independent-sector providers, and local authorities). A PCT is able to set its own strategic framework for commissioning and providing services so long as this fits within the overall operating framework of the Department of Health (see section 4.2.1 for more detailed discussion of the planning process). Financial allocations from government are not usually provided for particular services or purposes – although they can be ring-fenced. PCTs have a statutory obligation to fund clinical decisions within recommendations from NICE contained in Technology Appraisal Guidance. They are also expected to implement NSF. The financial implications of NSF are taken into account in the allocations to PCTs and hence PCTs are expected to ensure adequate provision in their budgets.

The Department of Health, through the SHAs, monitors the work of the PCTs. In addition, the Healthcare Commission provided annual measures of the performance of PCTs against standards set by the Department of Health both on services that the PCT provides and those that it commissions, including ways of improving public health. In April 2009, the CQC took over responsibility from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission for the regulation of all health and social care in England, whether provided by the NHS, local authorities, the private sector or the voluntary sector. The CQC now assesses provider and commissioner performance using indicators of quality agreed nationally with the Department of Health based on core standards, world class commissioning, and other national commitments known as “vital signs” (see section 4.2.1 below) (Department of Health 2008h).

PCTs also provide some health services directly. However, by April 2009, PCT provider services were required to be in a contractual relationship with their PCT commissioning function based on the same business and financial rules as applied to all other providers and using the national contract for community health services in order to separate out the commissioning role from the providing role, and hence avoid potential conflicts of interest (Department of Health 2008h). PCTs were not required to divest themselves of the provision of local community health services, but if a PCT continues to provide services there must be clear arm’s-length separation between its provider role and commissioning role. A range of different forms of community health service provision are now in place, including direct arm’s-length provision PCTs, community FTs, NHS-contracted arrangements with existing FTs, social enterprises (e.g. Industrial and Provident Community Benefit Society) and commercial organizations (Department of Health 2009f).

Some very specialized services with low numbers of users are either commissioned regionally by 10 Specialized Commissioning Groups or, where the degree of specialization requires, nationally by the
National Commissioning Group. These groups provide access to treatment or investigation of a very specialized nature or for patients who have rare conditions. In some cases where physical resources are not available in England, the National Commissioning Group commissions services in other countries. In 2007–2008, the National Commissioning Group spent a total of £261.2 million and covered 38 services including heart and lung transplantation, liver transplantation and craniofacial surgery; in the same year, the Specialized Commissioning Groups as a whole spent £3.2 billion on specialized services (National Specialised Commissioning Group 2008).

4.1.2 Governance and regulation of the purchasing process

PCTs now use standard national contracts to commission acute services from providers (see section 3.5 for more detail). These contracts create legally binding agreements between PCTs and NHS trusts, FTs, private-sector providers and voluntary-sector providers. The acute contract should include a payment framework requiring a proportion of providers’ income to be made conditional on quality and innovation – this is known as a Commissioning for Quality and Innovation Framework. Since April 2009, for certain operative procedures, providers were also expected to report on “patient-reported outcome measures” (PROMs) (Department of Health 2008j).

PCTs must also ensure that the procurement of clinical services is undertaken fairly, transparently and non-discriminatory and using the official portal for advertising and contracting known as Supply2Health. Where complaints about alleged breaches of the Department of Health’s Principles and Rules of Co-operation and Competition (official guidance on contract governance) cannot be resolved through a local disputes process, they may be referred to SHAs and – if not resolved by them – to the independent Co-operation and Competition Panel (Department of Health 2008g, 2010n).

New standard contracts have also been established for mental health and learning disabilities, community health services and ambulance services (Department of Health 2010j). As part of community health services contracting, PCTs must describe services in terms other than professional groups. Initially the following terms were to be used:

- health and well-being
- children and families
- acute care provided in the community
- long-term conditions
- rehabilitation
- end-of-life care.

PCTs are responsible for ensuring the provision of the whole range of primary care services for their populations. The contractual arrangements are described in some detail in section 3.6.2. Services provided by individual professionals – GPs, dentists, pharmacists – are governed by nationally negotiated contracts.

PMI

Most companies who provide PMI also sell a range of other types of insurance. As discussed in section 3.3.2 above, the market for PMI in the United Kingdom differs from some other European countries in that there is no regulation of the product or of pricing. However, recently, more formal regulation of insurance sales and administration has been introduced. In January 2005, regulation of insurance sales became the responsibility of the Financial Services Authority, which makes stringent demands regarding the provision of information and advice at the point of sale and also ensures that insurers have adequate finances in place and appropriate systems of financial control (Laing & Buisson 2007).
New Competition and Markets Authority makes its first ruling

By Sarah Gregory

In April 2014 the Office of Fair Trading and the Competition Commission merged to create the Competition and Markets Authority (CMA). The CMA is responsible for promoting competition in the interests of consumers across all sectors, including health. The CMA recently approved a takeover of one foundation trust (Heatherwood and Wrexham Park Hospitals NHS Foundation Trust) by another (Frimley Park Hospital NHS Foundation Trust). The CMA found that a merger would not be detrimental to the interest of local patients as there are several other strong hospitals in the area. Competition and Markets Authority

4.1.3 Governance and regulation of providers

The provision of publicly funded health care is discussed extensively in Chapters 5 and 6. Hospital-based care is mainly provided through NHS trusts or FTs. The former are publicly owned and directly accountable to the Secretary of State for Health. They have a similar governance structure to that of PCTs with a board consisting of a non-executive chairman and at least five non-executive members, all currently appointed by the Appointments Commission, and up to five executive members, including the chief executive, the finance director and the medical director (NHS Appointments Commission 2003). Similarly, FTs are managed by a board of directors. However, they have a board of governors, the majority of whom are elected by members – a member can be anyone who lives in the local area, works for the FT or has been a patient or service user. FTs are regulated by an independent body known as Monitor (see below).

Most primary care is provided by independent GP contractors, dental contractors, ophthalmic contractors and pharmacists. Chapters 5 and 6 have more detailed discussion of the organization of these services; section 4.1.4 below discusses the regulation of the professionals involved in the delivery of these services.

Key regulatory bodies

Providers of NHS services are regulated by a number of bodies\(^4^0\) in a range of ways to ensure quality and efficiency of provision. Organizations currently involved include:

**CQC**

- Audit Commission

**NAO NICE NPSA**

- Monitor
- Department of Health
- SHAs.

These organizations were described in section 2.3; here the focus is on their regulatory role.

**CQC**

The inspection, monitoring and performance rating of the quality and financial efficiency of NHS services has passed through several hands since the introduction in 1999 of CHI the first independent body assigned these tasks. CHI was reinvented as the Commission for Healthcare Improvement in 2004 becoming known as the Healthcare Commission. In April 2009, it was superseded by the CQC, which is now responsible for regulation and inspection of all health care providers (NHS, private sector and voluntary sector). Since April 2010, a common set of regulations has applied across all providers in England under the Health and Social Care Act 2008. Until then, for most purposes, all providers were registered under the Care Standards Act 2000. Now the CQC has a responsibility to license all health and social care providers to ensure they are meeting some essential common quality standards.

Thus, the CQC is responsible for licensing, monitoring and inspection of all health and adult social care, and has enforcement powers (e.g. fines, public warnings, suspension or cancellation of registration and
prosecutions) that may be invoked if the legal requirements of registration, including quality standards, are not met. The CQC has also continued the work of the Healthcare Commission in monitoring the quality and safety of service provision, undertaking special reviews of particular services, pathways of care or themes where there are general concerns about quality, as well as investigating where there may be serious or urgent causes for concern. The CQC publishes an annual report on the quality of health and adult social care services in England (CQC 2010b).

**Audit Commission**

The Audit Commission is concerned with the financial health and probity of NHS bodies. It aims to improve public services, promote good practice and help public services to achieve better outcomes. It does this through independent audit on the basis of quality and cost-effectiveness of the financial management of NHS bodies as well as of the work of local government in the health and social care sector. It also undertakes comprehensive performance assessment of local bodies in various parts of the public sector, publishes national performance indicators and carries out national value-for-money studies.

**NAO**

The NAO is concerned with the economy, efficiency and effectiveness with which all government bodies use public funds. It is also responsible for auditing the accounts of all government departments and agencies and reporting the results to parliament.

**NICE**

NICE has operated within the NHS since 1999 and is responsible for bringing together knowledge and providing guidance on the promotion of good health and the prevention and treatment of ill health. It does this by developing guidelines in three areas of health:

- health technologies: guidance on the use of new and existing medicines, treatments and procedures within the NHS;
- clinical practice: guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS; and
- public health: guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector.

The key role of NICE is in the determination of whether interventions provided within the NHS (drugs and other technologies, procedures, clinical guidelines, and to some extent, systemic interventions) are safe, effective and cost-effective. Since 2000, NICE has published several hundred such reports. NHS service providers are required to implement NICE guidance and findings. NICE was given a new role in April 2009 to assist in improving quality in the NHS by setting quality standards and advising on indicators for the QOF under which general practice operates (see section 3.6.2 for discussion of this framework).

**NPSA**

Established in 2001, the NPSA is not a regulator as such. Rather, it promotes a culture of reporting, analysing and learning from things that go wrong in the patient experience, and it manages a national reporting system. It has evolved over time and currently there are three divisions:

- the National Clinical Assessment Service
- the National Reporting and Learning Service
- the National Research Ethics Service.

The National Clinical Assessment Service works with health bodies and individual practitioners where there is concern about the performance of a dentist, a doctor or a pharmacist. The employer, the contracting body or an individual practitioner can contact the Service for help in clarifying concerns, understanding how they arise and supporting their resolution. The National Clinical Assessment Service is an advisory body not a regulator; the referrer retains responsibility for handling the case throughout the process (NPSA 2007).

The National Reporting and Learning Service is a national patient safety reporting system linked to local provider risk-management systems and provides national trends to the NHS and the public. Submission is voluntary though widespread; the NPSA does not investigate incidents or involve itself with disciplinary procedures. The role of the National Research Ethics Service is to protect the rights, safety, dignity and
well-being of research participants and to facilitate ethical research that is of potential benefit to participants, science and society. It does this through a system of ethical review of research by its NHS research ethics committees combined with provision of guidance, training and a quality assurance framework for research ethics (National Research Ethics Service 2009).

**Monitor**

There is an additional element in the regulatory process that was specifically created for FTs. The Independent Regulator of NHS Foundation Trusts, known commonly as Monitor, was set up in 2004 to authorize and regulate FTs with an aim of ensuring that they are financially strong and well managed. Monitor is an executive, non-departmental public body appointed to oversee FTs and consists of up to five members appointed by the Secretary of State for Health. It is independent of the Secretary of State but must behave in a way that is consistent with the duties of that office. It is accountable to parliament, reporting on an annual basis (Boyle 2005b).

Monitor is responsible for authorizing the creation of FTs. This is a form of licence, setting out the conditions under which the FT will operate which relate to:

- governance arrangements for the trust, including constitution of membership, board of governors and board of directors;
- authorized services: the goods and services that the trust will be expected to deliver as agreed by the regulator;
- the limits on the amount of money that the trust is allowed to borrow: the trust can borrow from private sources but must be within a “prudential borrowing limit” as defined by the regulator; and
- the limits on the assets which the trust is allowed to sell: the trust can sell assets and use the income to develop its service provision, but this is subject to some assets being “protected” from such sale, as agreed with the regulator.

Monitor may intervene where an FT is in significant breach of the terms of its authorization, or is at risk of failing to meet national standards and targets, to stop such a breach. This may involve the removal of any or all directors or members of the board of governors and appointment of interim directors and members of the board. Monitor will also intervene where an FT is in financial difficulty (Monitor 2008a). These powers have been used, though sparingly.

**Department of Health**

The Department of Health continues to play a role in the regulation and monitoring of the provision of health care. In particular, the Department introduced NSFs, starting with mental health in 1999, which set standards for NHS bodies to attain. Since then NSFs have been issued in the following areas: mental health, older people, coronary heart disease, children, young people and maternity services, diabetes, long-term neurological conditions and renal services. NSFs are designed to provide a consensus around good practice in various areas of care and hence reduce variation in the quality of services provided. Providers are expected to work within these NSFs and targets are set which providers are required to attain.

As part of an increased focus on quality within the NHS (Department of Health 2009g), the Health Act 2009 required from April 2010 all health care providers who deliver services for the NHS to publish “quality accounts” that provide a picture of the quality of performance of that provider. The final form for these accounts was laid out in statutory regulations (National Health Service (Quality Accounts) Regulations 2010, S.I. 279). The accounts should include three parts:

- a statement on the quality of care offered by the organization;
- a statement of the degree of compliance with national and regulatory priorities, and a description of at least three future priorities for quality improvement, and how these will be monitored;
- a third part which will be determined locally based on consultation with stakeholders.

The first sets of accounts covering the period 2009–2010 are available on the NHS Choices web site.

**SHAs**
SHAs continue to play a role in the oversight of local health economies as discussed in section 4.1.1 above and also in relation to planning (see section 4.2.1 below). They are a key link between the Department of Health and the NHS, responsible for:

- developing plans for improving health services in their local area;
- making sure local health services are of a high quality and are performing well;
- increasing the capacity of local health services so they can provide more services; and
- making sure national priorities (e.g. programmes for improving cancer services) are integrated into local health service plans.

Notes:
40 The Conservative and Liberal Democrat Coalition Government elected in May 2010 has stated its intention to abolish some of the current regulatory bodies, although their functions are expected to be retained in one form or another (section 7.3 discusses this in more detail).

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**Competition in the NHS - extending the role of the regulator**

By Beccy Ashton

Competition has been a feature of NHS policy since the 1990s and the Health and Social Care Act 2012 further signalled the extent to which competition is a feature of health policy in England. The Act extended the role of Monitor, which had previously been the regulator for foundation trusts. It is now the sector’s economic regulator for all health services. Specifically in relation to protecting choice and preventing anti-competitive behaviour it has powers to:

- apply and enforce sections of the provider licence related to integrated care and choice and competition
- apply and enforce the Procurement, Patient Choice and Competition Regulations
- apply and enforce provisions of the Competition Act 1998 and the Treaty on the Functioning of the European Union
- make market investigation references to the Competition Commission
- provide the Office of Fair Trading (OFT) with advice on matters relating to mergers involving foundation trusts.

Monitor also has a specific duty to encourage integration which is intended to guard against competition impeding joined-up services for patients.

The Health and Social Care Act 2012 confirmed that competition law (and specifically the Enterprise Act 2002) applies to mergers involving foundation trusts. Any relevant merger will be reviewed by the OFT to assess the impact on competition. Monitor, as the sector regulator, advises the OFT on the patient benefits of any proposed merger. The OFT can then refer cases to the Competition Commission.

During 2013, various high-profile cases suggested that the regulators are having a profound impact on health services and this is generating media and political interest. Cases include the rejection of a hospital merger in the south of England by the Competition Commission on the grounds that the merger would significantly reduce patient choice in a variety of specialties. Of particular note in this case was that one of the key counterfactuals provided by the organisations was that one of the hospitals would fail financially were it not to merge. This was rejected by the Competition Commission, mainly on the grounds that governments have not allowed hospitals to fail in the past and that commissioners or central government could choose to give the hospital more money. Also of note is a case in the north of England where centralisation of some specialist cancer services, in response to clinical guidance, has been challenged on competition grounds by an NHS provider who lost out in the process. While not yet concluded, this case raises issues about the extent to which the desire for choice and competition can be balanced by centralisation of specialist expertise.

4.1.4 Regulation of health care professionals

The majority of health care professionals are regulated by professionally led statutory bodies. These regulators protect and promote the safety of the public by setting standards of behaviour, education and ethics that health professionals must meet, and by dealing with concerns about professionals who are unfit to practise owing to poor health, misconduct or poor performance. Regulators register health care professionals who are fit to practise in the United Kingdom and can remove professionals from the register and prevent them from practising where they consider this to be in the best interests of public safety.

The regulators maintain a register of individuals who meet standards of training and who are, therefore, permitted to use a protected professional title; they set standards of training and education, including in many cases requirements for continuing professional development (CPD). They also establish standards of practice or codes of conduct and they monitor and enforce standards of practice by taking action against professionals who are not fit to practise.

There are eight professional self-regulatory bodies in England:

- General Chiropractic Council, regulating chiropractors;
- GDC, regulating dentists, dental nurses, dental technicians, dental hygienists, dental therapists, clinical dental technicians and orthodontic therapists;
- GMC, which was established in 1858 and regulates doctors;
- General Optical Council, regulating optometrists, dispensing opticians, student opticians and optical businesses;
- General Osteopathic Council, regulating osteopaths;
- Health Professions Council, regulating the members of 13 health professions: arts therapists, biomedical scientists, chiroprists/podiatrists, clinical scientists, dieticians, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, prosthodontists, radiographers, and speech and language therapists;
- Nursing and Midwifery Council (formerly the United Kingdom Central Council for Nursing, Midwifery and Health Visiting), regulating nurses, midwives and health visitors; and
- General Pharmaceutical Council, regulating pharmacists and pharmacy technicians and registering pharmacy premises in England, Wales and Scotland.

These bodies maintain lists of professionals who are allowed to practise in the name of their particular professions, and also consider allegations of misconduct or unfitness to practise owing to ill health. In addition, there may be other professional bodies or associations that perform roles complementary to that of the regulating bodies. In 2003, the Council for the Regulation of Health Care Professionals (known as the CHRE) was established with the power to:

- monitor how the health professions regulators perform their functions;
- carry out an annual performance review of each regulator; and
- refer cases to court where decisions are considered too lenient and, in particular, investigate and where necessary refer the final-stage decisions of regulators on the fitness to practise of professionals to the High Court (the Court of Sessions for Scotland or the High Court of Justice for Northern Ireland).

However, the system of statutory professional regulation had been called into question by a number of high-profile failures (see the report of the Bristol Royal Infirmary Inquiry into deaths of children undergoing cardiac surgery (Kennedy 2001); the Fifth Report of the Shipman Inquiry Safeguarding Patients: Lessons from the Past – Proposals for the Future (Smith 2004), which dealt with the criminal actions of Dr Harold Shipman; and the inquiries into the conduct of Richard Neale (Matthews 2004), Clifford Ayling (Pauffley 2004), and Michael Haslam and William Kerr (HM Government 2005)). As a result, the government set out to reassure the public by reforming the system of regulation in the health care sector. In 2007, Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century (Secretary of State for Health 2007), laid out a series of reforms of the regulation of health care professionals designed to address key areas of concern, particularly the independence of the regulators and the need for revalidation of all professionals. The independence of the regulators was to be enhanced by including
equal numbers of lay and professional membership on bodies and by introducing more accountability to parliament.

Changes to regulation were implemented in the Health and Social Care Act 2008. This Act, among other measures, created a new independent body for adjudication of cases of fitness of purpose for the health professions, the Office of the Health Professions Adjudicator, which is an independent statutory body charged with the hearing of cases, thereby separating adjudication of fitness of purpose from investigation and prosecution. This applies to the eight regulators listed above as well as the General Social Care Council.\textsuperscript{42}

The Act also set the standard of proof across all health and social care regulators; this is to be the civil standard of proof as this is regarded as most appropriate for a protective jurisdiction such as professional regulation. The Act made it mandatory for regulators to be composed of at least an equal number of lay members as professionals. In addition, the Act required designated bodies to appoint “responsible officers” who would have responsibilities relating to the regulation of doctors. Designated bodies are defined for this purpose as bodies that provide, or arrange for the provision of, health care, or employ, or contract with, doctors. Therefore, senior doctors will be appointed as responsible officers to monitor the conduct and performance of local doctors and to take whatever immediate action is needed to safeguard patients, and to provide a link to the national processes of the GMC.

In addition, the CHRE, which oversees the eight professional self-regulatory bodies in England,\textsuperscript{43} was given enhanced powers to scrutinize the handling of fitness-to-practise cases by regulators (Secretary of State for Health 2007). In particular, CHRE is expected to develop common protocols for local investigations across all the regulators, with guidance to employers on when such cases should be referred to the national regulator.

**Revalidation**

All statutorily regulated health professions are required to have in place arrangements for the revalidation of their professional registration through which members can periodically demonstrate their continued fitness to practise.

For doctors, revalidation will have two core components: relicensure and specialist recertification. For relicensure, all doctors have a licence to practise that must be renewed every five years and that enables them to remain on the medical register. Moreover, to ensure objectivity, the appraisal process will include “summative” elements which confirm that a doctor has objectively met the standards expected. Specialist recertification will apply to all specialist doctors, including GPs, requiring them to demonstrate that they meet the standards that apply to their particular medical specialty. These standards will be set and assessed by the medical Royal Colleges and their specialist societies, and approved by the GMC. Revalidation will be applied to all practising doctors, not just those working in the NHS.

Other health care professionals in England fall into one of three groups for revalidation purposes.

- **Employees of an approved body**, for example nurses or paramedics working in an NHS organization or a licensed private-sector or independent-sector provider. The evidence to support revalidation will be provided as part of the normal staff management and clinical governance systems, with employers providing recommendations to the professional regulators.

- **People, including self-employed contractors, performing services commissioned by NHS primary care organizations**, for example dentists. The revalidation processes will be carried out under the supervision of either the NHS commissioning organization or, particularly where it is necessary to take an overview of both NHS and private work, the regulatory body, but in either case with appropriate collaboration between the two bodies.

- **All others**, for example, osteopaths. The relevant regulatory bodies will develop direct revalidation arrangements.

For doctors, the government had determined that there should be a separation of investigation and prosecution from adjudication so as to ensure public and professional confidence in the independence of the decisions made by the adjudicator. Hence, in January 2010, the government established the
independent body created by the 2008 Act, the Office of the Health Professions Adjudicator, to adjudicate on fitness-to-practise cases involving the medical profession, and eventually other health professionals.\footnote{44}{The General Pharmaceutical Council took over this role from the Royal Pharmaceutical Society of Great Britain in September 2010. The leadership role of the Royal Pharmaceutical Society will also be provided by a new body, which at the time of writing was under development.} It was intended that doctors and the GMC would have a right of appeal to the High Court against the decision of the independent body. For all the other regulators, the new independent body was also charged with establishing a central list of people, vetted and approved for all adjudication panels, chosen by the Appointments Commission for their expertise and specifically trained to undertake these duties in a fair and impartial manner. Regulatory bodies would be able to draw on this list in order to conduct independent adjudication panels within their own organizations.

\footnote{42}{The General Social Care Council, established in 2001, is a non-departmental public body whose members are chosen by the Appointments Commission; it has responsibility for registering social care workers and regulating their conduct, training and education.}

\footnote{43}{It is also responsible for oversight of the Pharmaceutical Society of Northern Ireland, which regulates pharmacists in Northern Ireland.}

\footnote{44}{The Office of the Health Professions Adjudicator was to become operational in April 2011 but this is now subject to further consultation.}

4.1.5 Other regulatory bodies

There are other regulatory bodies whose responsibilities extend to health care and public health issues.\footnote{45}{These include the following, which are discussed briefly:}

**MHRA**

- NHS Business Services Authority

**NHSLA**

- Human Fertilisation and Embryology Authority
- Human Tissue Authority
- National Institute for Biological Standards and Control
- Food Standards Agency.

**Mhra**

The MHRA is an executive agency of the Department of Health and is responsible for regulation of medicines, medical devices, blood and therapeutic products and services derived from tissue engineering; it ensures standards of safety, quality, performance and effectiveness (see section 6.6.1 for more detailed discussion of the way it operates). The MHRA works closely with the European Medicines Agency (EMEA), which is responsible for the evaluation of medicinal products and for granting marketing authorizations at an EU-wide level.

**NHS Business Services Authority**

The NHS Business Services Authority combines services previously provided by the Dental Practice Board, the NHS Counter Fraud & Security Management Service, NHS Logistics Authority, NHS Pensions Agency and the Prescriptions Pricing Authority. It is the main processing facility for payment, reimbursement and remuneration for NHS patients, employees and affiliated parties, and it also investigates and prosecutes fraudulent acts.

**NHSLA**

The primary responsibility of the NHSLA is to handle negligence claims against NHS bodies in England; it is also responsible for handling family health services appeals dealing with the resolution of disputes between primary care practitioners and their PCTs, and for coordinating equal pay claims on behalf of the NHS. It also monitors human rights case law for the NHS.

**Human Fertilisation and Embryology Authority**
The Human Fertilisation and Embryology Authority is an executive non-departmental public body that acts as the regulator for the United Kingdom overseeing the use of gametes and embryos in fertility treatment and research. It licenses fertility clinics and centres carrying out in vitro fertilization, other assisted conception procedures and human embryo research. It sets the Code of Practice standards for United Kingdom centres providing fertility treatment and carrying out human embryo research, and it also provides guidance on how centres can meet these standards. This Code contains specifications for compliance with the law (including the European Tissues and Cells Directives) and with standards of good professional practice. It inspects licensed centres to assess compliance with the Code of Practice.

**Human Tissue Authority**

The Human Tissue Authority is an executive non-departmental public body that regulates the removal, storage, use and disposal of human bodies, organs and tissue from the living and the deceased for a number of purposes including research, transplantation, education and training, as set out in the Human Tissue Act 2004. The Human Tissue Authority is also responsible for approving donation of solid organs and bone marrow from living donors. It is the competent authority under the EU Tissue and Cells Directive for regulating human application establishments.

**National Institute for Biological Standards and Control**

The National Institute for Biological Standards and Control is a centre of the HPA, a non-departmental public body. It is responsible for the standardization and control of biological medicines such as vaccines and products made from blood and tissues, ensuring they are safe and effective. The National Institute for Biological Standards and Control provides testing of biological medicines to ensure compliance with product specifications, operating as an Official Medicines Control Laboratory of the EU for release of medicines on to the EU market.

**Food Standards Agency**

The Food Standards Agency is a non-ministerial government department set up under the Food Standards Act 1999 to protect public health in relation to food. It reports annually to parliament. It is responsible for food safety, nutrition, diet and food standards through the enforcement of EU and national food legislation and other United Kingdom legislation covering the composition and labelling of foods, chemical safety, food hygiene, control of foodstuffs, and trading and marketing standards. The Agency works with local authority food law enforcement officers to make sure that food law is applied appropriately and it sets out the rights and responsibilities of enforcement authorities and food businesses; it also helps to ensure that food safety and legal requirements are maintained and monitored. It audits local authority monitoring of food businesses and collates data on local authority enforcement activity.

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46 The review of arm’s length bodies that reported in late 2010 may result in the abolition of some of these and the transfer of their functions to other bodies or government departments over the subsequent four years. However, at the time of writing, these organizations continue to carry out the roles described here.

46 Until April 2009, the National Institute for Biological Standards and Control was managed through the National Biological Standards Board, which was abolished under the Health and Social Care Act 2008.