

**WP2: Description of the Benefit Catalogue
England**

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Acronyms and Glossary

Act	Primary legislation produced by Parliament
ALBs	Arm's Length Bodies: independent organisations, sponsored by the DH to undertake its executive functions
Audit Commission	An independent public body responsible for ensuring that public money is spent economically, efficiently, and effectively
Clinical governance	A system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment to encourage clinical excellence
CPMP	Committee for Proprietary Medicinal Products, part of EMEA
CSD	Committee on Safety of Drugs (now known as the Committee on Safety of Medicines, CSM)
Department of Health (DH)	The government headquarters of the NHS, led by the Secretary of State for Health and responsible for a strategic direction, securing resources and setting national standards
DES	Direct Enhanced Services, part of the 2004 GMS contract
EMEA	European Medicines Agency, decentralised body of the European Union
FCE	Finished Consultant Episode, the denominator for Reference Costs
Foundation Trust	Established in 2003, Foundation Trusts are independent public benefit corporations, a type of NHS hospital run by local managers, staff and members of the public.
GDS	General dental services
GMC	General Medical Council
GMS	General medical services
GOS	General ophthalmic services
GP	General (medical) practitioner; primary care physician
GPS	General pharmaceutical services
Health Authority	Established in 1995, the 100 Health Authorities in England were dissolved in 2002 (see SHA)
Healthcare Commission	The independent inspection body for NHS, private and voluntary healthcare organisations, an ALB
HRG	Health care Resource Group
HSC	Health Service Circular (a type of Department of Health guidance)
ICHA	International Classification for Health Accounts
IVF	In vitro fertilisation
LAC	Local Authority Circular
MHRA	Medicines and Health care products Regulatory Agency, an ALB
NHS	National Health Service
NHS Direct	A 24-hour telephone service staffed by nurses
NHS Plan	Published in 2000, the Plan outlines the government's intentions for investment in and reform of the NHS
NHS Trust	A group of NHS hospitals that operates as a single legal entity
NICE	National Institute for Health and Clinical Excellence, a Special Health Authority (type of ALB)
NSF	National Service Framework: a document that set national standards for disease management
Optometrist	Ophthalmic optician
PCT	Primary Care Trusts are local health authorities that manage around 75% of the NHS budget. The 303 PCTs in England are accountable to their local SHA for planning, securing and improving primary and community health care services for their local populations.
PMS	Personal Medical Services are a local alternative to the national GMS contract, aiming to provide greater freedom for primary care professionals to address the needs of patients
PPA	Prescription Pricing Authority, an ALB
PPRS	Pharmaceutical Price Regulation Scheme
QOF	Quality and Outcomes Framework, part of the 2004 GMS contract
RNCC	Registered Nursing Contribution to Care
SDR	Statement of Dental Remuneration
Statutory Instrument	Secondary legislation, made by UK government departments and other Public Authorities which have powers to make such instruments (e.g. Department of Health)
SHA	Strategic Health Authority: created in 2002 to manage the local NHS on behalf of the Secretary of State. There are 28 SHAs responsible for improving local health services (quality and capacity) and ensuring that national priorities are integrated into local health service plans. ¹
Special Health Authority	Health authorities which provide a health service to the whole of England; they are independent, but can be subject to ministerial direction
White paper	A paper presented to Parliament by a government minister, providing a statement of government policy

¹ <http://www.nhs.uk/England/AuthoritiesTrusts/Sha/Default.aspx>, accessed 08/03/05

I Overview of benefit basket in England

The legal framework, within which the National Health Service (NHS) operates, impacts on all six categories of the International Classification for Health Accounts (ICHA). However, duties and powers given by the law are not absolute, but tempered by powers of discretion and by the right to take resource availability into account. For example, the duty to provide services is subject to the Secretary of State's judgement of what is necessary to meet 'all reasonable requirements' (Secretary of State for Health, 1977);(s. 3). Strictly speaking, this means that patients have no entitlement to specific services.

Case law has established that NHS organisations may not operate a 'blanket ban' on the provision of services (such as particular health technologies or interventions), with the possible exception of treatments where "the clinical evidence of its inefficacy is overwhelming" (Newdick, 2005b);(pp 105-107). *R v NW Lancashire Health Authority, ex p A, D and G* made it illegal for health authorities to impose a blanket ban on services they consider to be 'low priorities'. Instead, they must adopt a fair and consistent policy for decision-making that adequately assesses exceptional cases by considering each request for treatment on its individual merits (Newdick, 2005b);(page 101). This means that there are few services that are explicitly excluded from all NHS patients; where exclusions exist, they are principally in the domains of medicines and screening.

The NHS therefore produces a situation where patients have no specific entitlements to services, but also where little is explicitly excluded. This means that the internal quality control mechanisms of the NHS are important to ensure that citizens' rights to health care under international law are honoured (Montgomery, 2003). National guidelines, decisions by the National Institute for Clinical Excellence and standards employed by regulators in their assessments of NHS performance all contribute to what may be considered as 'reasonable requirements' for health care provision. They also help to specify the conditions under which patients may be eligible.

Another way in which patient 'entitlement' to services might be inferred is by the existence of charges or payments. For example, most patients receiving NHS dental services make co-payments in line with a Schedule of Dental Remuneration, with the government paying the remainder of the dental fee. This *suggests* that these services are those that the government endorses as those that, in some sense, should be provided. Equally, the new tariff system of payments for hospital services, whilst in no way guaranteeing provision, highlights services that should be accessible on the NHS.

The NHS embodies the statutory package of health care services and is subject to a considerable quantity of legislation, regulation and guidance. We provide an overview of the benefit basket in England, clarifying the actors and decision making framework involved by describing the principles underpinning the NHS, legislation on and the regulatory framework for health care, the regulation of clinicians and the key health care policies that impact upon patient 'entitlement' to services. We also describe services excluded from the basket. A table summarising the findings is presented in the Appendix (Table 9).

Principles underpinning the National Health Service (NHS)

The core principles outlined in the NHS Plan (Department of Health, 2000b) define the desired characteristics of the National Health Service to which the government, health care professional bodies and trade unions aspire and include the provisions of a 'comprehensive range of services' (Box 1).

Box 1: Core Principles of the NHS

1. The NHS will provide a universal service for all based on clinical need, not ability to pay.
2. The NHS will provide a comprehensive range of services
3. The NHS will shape its services around the needs and preferences of individual patients, their families and their carers
4. The NHS will respond to different needs of different populations
5. The NHS will work continuously to improve quality services and to minimise errors
6. The NHS will support and value its staff
7. Public funds for health care will be devoted solely to NHS patients.
8. The NHS will work together with others to ensure a seamless service for patients.
9. The NHS will help keep people healthy and work to reduce health inequalities
10. The NHS will respect the confidentiality of individual patients and provide open access to information about services, treatment and performance

Source: Department of Health (2000). "The NHS Plan: a plan for investment, a plan for reform." HMSO, London.

The NHS Plan clarifies the meaning of the second principle:

The NHS will provide access to a comprehensive range of services throughout primary and community health care, intermediate care and hospital based care. The NHS will also provide information services and support to individuals in relation to health promotion, disease prevention, self-care, rehabilitation and after care. The NHS will continue to provide clinically appropriate cost-effective services (Department of Health, 2000b).

Firstly, it should be noted that 'comprehensive' describes the *range* of services and these are listed. The NHS Plan does not therefore promise that the NHS will provide all possible health care services. Furthermore, there is a commitment to provide those services that are 'clinically appropriate' and 'cost-effective', implying that there is no guarantee that those services that do not meet these criteria will be provided. Lastly, there is an emphasis on the provision of preventative services, aiming to reduce the demand for curative services.

The fundamental principles stated in the NHS Plan are important because they guarantee to British citizens that their right to health care will be honoured (Montgomery, 2003);(page 52). Legislation directs that Primary Care Trusts and Strategic Health Authorities must 'have regard' to the NHS Plan when exercising their functions (Secretary of State for Health, 2002);(reg. 3(4)). However, citizens' rights are not generally enforceable through the legal system, but are recognised through the managerial structure of the NHS. Nevertheless, health care law plays an important role in signalling the broad categories of service provided by the NHS, as well as conferring particular duties on the Secretary of State for Health and on the local health care organisations that implement the law and deliver the services.

An overview of the legal and quasi-legal framework defining benefits for England is given in Table 1. For details of benefit-defining documents listed by ICHA category, see Appendix (Table 9).

Table 1: Documents defining Benefit Basket, England April 2005

Catalogue: type of document, actors and contents												
Type of Document	Acts of Parliament	Statutory Instruments (SI)	Directions	National Service Frameworks	NICE technology appraisals	NICE clinical guidelines	NICE interventional procedures	Contracts	Waiting time guarantees ²	HRG tariffs	Devices tariff	Fee schedules
Legally Binding	Y	Y	Y	N	Y ³	N	N	Y	N	N	N	N
Decision makers	Parliament	Parliament	Secretary of State for Health SHAs Monitor	Department of Health External reference group (multidisciplinary)	Department of Health Appraisal Committee	National Collaborating Centres Guideline Development Group Stakeholders	Interventional procedures Advisory Committee	Department of Health Professional bodies / associations	Department of Health	Department of Health	Secretary of State for Health PPA	Department of Health Professional bodies / associations
(Original) purpose, e.g. entitlements, reimbursement, target-setting	Establishes duties and powers for broad categories of care	Clarify / amend primary legislation	Direct NHS organisations to undertake action	Improve quality / decrease variations in service	Improve quality / decrease variations in service	Improve quality / decrease variations in service	Quality /safety assurance	Reimbursement	Improve quality / decrease variations in service	Reimbursement	Reimbursement	Reimbursement
Positive/ negative definition of benefits	P	P/N	P	P	P/N	P	P/N	P	P	P	P	P
Degree of explicitness⁴	1	1 to 3	2	2 or 3	3	2 or 3	3	1 to 3	2	2 or 3	3	3
If itemised: goods/ procedures only; linked to indications		Goods Procedures		Goods Procedures	Goods Procedures	Goods Procedures	Procedures	Procedures	Procedures	Procedures	Goods	Procedures
Updating	Irregular Amended by further Acts of	Irregular Amended / revoked by	No	Unclear	Every 4 years	Every 4 to 6 years	Unclear	Infrequent – although small amendments more frequent	Irregular	Still evolving	Monthly	Annually (at least)

² The dominant instrument for securing these are performance ratings prepared by the Healthcare Commission

³ The statutory duty is upon PCTs to ensure funding is available to facilitate implementation, not upon doctors to adopt the approved technology.

⁴ 'Explicit' is subdivided as 1 : all necessary"; 2: areas of care; 3: items

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Catalogue: type of document, actors and contents												
Type of Document	Acts of Parliament	Statutory Instruments (SI)	Directions	National Service Frameworks	NICE technology appraisals	NICE clinical guidelines	NICE interventional procedures	Contracts	Waiting time guarantees ²	HRG tariffs	Devices tariff	Fee schedules
	Parliament or by Statutory Instrument	further Statutory Instrument and/or directions										
Criteria used for defining benefits												
Need	√	√	√	√				√	√			√
Costs					√	√				√	√	
Effectiveness		√	√	√	√	√	√		√			
Cost-effectiveness		√			√	√					√	
Budget		√	√					√		√	√	√
Other	As the Secretary of State judges 'necessary to meet all reasonable requirements'	Safety					Safety				Safety, quality, appropriateness	

Sources: (Montgomery, 2003, Department of Health, 2000b, Newdick, 2005b); DH website (<http://www.dh.gov.uk/Home/fs/en>); HMSO website (<http://www.hmso.gov.uk/>); expert advice (see Acknowledgements)

Legislation on Health Care

Within the NHS, legal and quasi-legal rights 'mainly take the form of general statutory duties rather than individual entitlements' (Montgomery, 2003);(page 80). The NHS was created under the National Health Service Act 1946 (chapter 81):

'to provide for the establishment of a comprehensive health service for England and Wales and ... to provide or secure the effective provision of services in accordance with [the provisions of the Act].'

Section 3 of the 1946 Act specifies the provision of hospital accommodation; medical, nursing or other service required at or for the purposes of the hospitals and service of specialists. Section 19 of the 1946 Act describes the health services to be provided by local health authorities (in 2005, local health authorities are known as Primary Care Trusts, or PCTs). Local health authorities must provide 'health centres' (s. 21(1)) to facilitate the provision of the services they must or may secure through arrangements with local practitioners. These services include general medical and dental services, pharmaceutical services, ophthalmic services and any other specialist outpatient services (ss. 31-48). There are also duties on local health authorities to provide care for mothers and children (ss. 22-24), home nursing (s. 25), vaccinations and immunisations (s. 26) and ambulance services (s. 27).

The 1977 NHS Act (c. 49) consolidated health care legislation published since 1946. Under the 1977 Act, the Secretary of State for Health (the politician in charge of health care) has a duty (Secretary of State for Health, 1977);(s.1(1)):

..to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement –
(a) in the physical and mental health of the people of those countries, and
(b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with this Act.'

The 1977 NHS Act lists broad categories of service, such as hospital accommodation, including high security psychiatric services (s. 3(1)(a)), medical, dental, nursing and ambulance services (s. 3(1)(c)), 'such other services as are required for the diagnosis & treatment of illness' (s. 3(1)(f)) and family planning services (s. 5(1)(b)) (Secretary of State for Health, 1977). However, the Secretary of State is obliged to provide these '...to such extent as he considers necessary to meet all reasonable requirements' (Secretary of State for Health, 1977);(s. 3). Importantly, the 1977 NHS Act does not impose an absolute duty on the Secretary of State to provide specified services; the courts have established that he may also take economic factors into account (Newdick, 2005a):

' a comprehensive service may never, for human, financial and other resource reasons, be achievable.... ...The [1977 NHS] Act does not impose an absolute duty to provide the specified services. The Secretary of State is entitled to have regard to the resources made available to him under current government economic policy (*R v. North & East Devon Health Authority, ex p. Coughlan* 16th July 1999).

The exercise of discretion is therefore at the heart of the statutory duties (Montgomery, 2003);(page 64). Strictly speaking, this means that *patients have no entitlement to specific services*. Moreover, the Secretary of State's duties are delegated to Strategic Health Authorities (who now carry the duty to promote a comprehensive health service) and to Primary Care Trusts (PCTs) (Newdick, 2005a).⁵ The burden of prioritising service provision falls to PCTs, and these organisations are also subject to an obligation to keep within their financial allocation (Secretary of State for Health, 1977);(s. 97(c)).

⁵ The relevant statutory instruments are: S.I. 1989/51; S.I. 1996/654; S.I. 1996/708; S.I. 2000/89; S.I. 2000/695; S.I. 2001/747; S.I. 2002/2375

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There are two ways in which patients may attempt to use the law to enforce duties. Firstly, patients may claim that the NHS has failed to perform its statutory duties. This process uses judicial review and is a public law matter (see Box 2). The court may overturn the decision by an NHS body to refuse treatment, but it is unlikely that judges will order treatment to be offered. However, such actions are seldom successful, although they may improve services as a result of bringing adverse publicity to current provision (Montgomery, 2003);(page 68). Secondly, patients may appeal to the civil law obligations of the NHS to perform its functions properly. This may result in the patient receiving compensation for his or her loss and that future service provision will be different in order to avoid further claims.

Attempts to use the law to enforce legal duties have generally proved frustrating for litigants (Montgomery, 2003);(page 67). This means that the internal quality control mechanisms of the NHS – a constitutional structure for planning, purchasing and providing care – are important to ensure that citizens' rights to health care under international law are honoured. However, there are also rules that govern practice, principles that people are bound to follow, even if they are unenforceable.

Legal rules in a strict sense, as developed by Parliament and the courts, are not the only type of binding norm that is relevant to health care law (Montgomery, 2003);(page 4).

Apart from legislation that operates within the UK (Box 2), there are also Human Rights established by European Law. The European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) assigns citizens political rights. The European Social Charter (1996) grants social and economic rights, including disease prevention and health promotion. Nevertheless, the Convention does cover public health (Articles 8 to 11) and the right to access to health services. There is also a right to found a family (Article 12) (Montgomery, 2003);(page 13). The United Nations' International Covenant on Economic, Social and Cultural Rights recognises in Article 12 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.⁶

The UK Human Rights Act (1998) ruled that courts must interpret the law to comply with the Convention (Secretary of State for Health, 1998). If an existing law incompatible with Convention, then there must be a '*declaration of incompatibility*' (s. 4). An example of this relates to the part of the Mental Health Act 1983 that put the onus patients to demonstrate that there was no longer justification for their detention. The Act was found to be incompatible with the Convention (Articles 4 and 5), and a Statutory Instrument was written to amend sections 72(1) and 73(1) of the Mental Health Act 1983 thereby removing the incompatibility of those provisions with a Convention right (Newdick, 2005a, Montgomery, 2003). As it is unlawful for public authority – this includes NHS bodies – to act in a way that is incompatible with a Convention right (Secretary of State for Health, 1998);(s. 6), victims may sue (s. 7). EC Treaties and regulations are binding on Member States (Montgomery, 2003);(page 13).

The law also makes provision for overseas visitors to receive NHS treatment. Under the 1977 NHS Act, 'persons not ordinarily resident in Great Britain' may be charged for services received (Secretary of State for Health, 1977);(s. 121) and 1989 Regulations place health authorities under a duty to recover costs.⁷ Some services are exempt (e.g. emergency care);(S.I. 1989/306);(reg.3) as are certain overseas visitors (reg. 4) and nationals of member states, refugees and stateless persons whose need arose during their visit (reg. 5). Treatment of 'temporary residents' is also covered by legislation. A person is a temporary resident if 'when he arrives ... he intends to stay there for more than 24 hours but not more than three months' (Secretary of State for Health, 2004a);(reg. 16(2)). Temporary residents are eligible for free primary and emergency NHS care, but may be charged for hospital care if they are not 'ordinarily resident' in the UK.⁸

⁶ http://www.unhcr.ch/html/menu3/b/a_ceschr.htm, accessed 24/02/05

⁷ http://www.legislation.hmso.gov.uk/si/si1989/Uksi_19890306_en_1.htm, accessed 18/04/05

⁸ <http://www.dh.gov.uk/PolicyAndGuidance/International/OverseasVisitors/fs/en>, accessed 19/04/05

Box 2: Overview of Legislation relating to Health Care		
Type of Law	Derivation	Types
General law	<p><i>Statute law</i> comes from the legislative work of Parliament and includes: Primary legislation (Acts of Parliament). These establish duties and powers to provide broad categories of service provision. Acts are divided into sections (abbreviated as 'ss') and subsections.</p> <p>Secondary legislation (Statutory Instruments; directions) clarifies, amends, updates or enforces existing primary legislation. <i>Statutory Instruments</i> are divided into regulations (abbreviated as 'reg'). SIs may be negative or positive procedures. Under negative procedures, the SI is laid before Parliament and comes into force unless Parliament prevents it. Under positive procedures, the SI needs a positive decision by Parliament in order to come into force. A Secretary of State may issue <i>directions</i> to other bodies (e.g. health authorities) to act on his behalf under the NHS Act 1977 (ss. 13-17). Failure to comply may result in use of default powers (s. 85). Directions, unlike SIs, may be subject to judicial review.</p> <p><i>Case law</i> is law that has been established from cases tried in the courts. The outcome of the test case creates a precedent by which future cases are judged. The court cannot take decisions on behalf of NHS bodies, but can refer cases back for reconsideration. It is rare for patients to pursue their rights through the courts, but successful court cases may be very important in determining patient entitlement.</p> <p><i>Common law</i> is a part of English Law that has not come from Parliament. It consists of rules of law that have developed from customs or judgements made in courts over hundreds of years.</p>	<p>There are three types of general law:</p> <ol style="list-style-type: none"> 1. Civil law deals with relationships between citizens 2. Criminal law deals with the relationship between wrongdoer and society 3. Public law deals with the relationship between citizens and the state (e.g. limits of power for Department of Health)
Quasi Law	<p>The term 'quasi-law' covers rules that are not usually legally binding, although they may have some legal force, but which will in practice determine the way in which people act.</p>	<p>Professional Law</p> <p>Entrance to professional register</p> <p>Conditions upon continuing registration – for example, the General Medical Council describes doctors' duties, guidance on good practice and can remove doctors' right to practise⁹</p> <p>Guidance from the Department of Health, such as Health Service Circulars¹⁰ and National Service Frameworks</p> <p>Guidance on clinical practice or codes of practice from professional bodies, such as Royal Colleges</p>

Sources: (Montgomery, 2003, House of Commons Information Office, 2002, Newdick, 2005b)

The NHS Regulatory Framework

Since regulation and policy play such an important role in determining which services are available within the NHS, we describe below the key aspects of the English regulatory health care framework. Many of these concepts¹¹ were introduced by the Labour government in its White Paper of 1997, 'The New NHS: modern, dependable' (Department of Health, 1997). Concerns over issues of fairness and consistency within the NHS underpinned the White Paper (§ 7.1) with the availability of services to be determined by issues of effectiveness and cost-effectiveness (§7.5). The practicalities of implementation and delivery were provided in the NHS Plan of 2000 (Department of Health, 2000b). Important components of the regulation include National service Frameworks; the work of the National Institute for Clinical Excellence (NICE); and guidance from the Department of Health.

⁹ <http://www.gmc-uk.org/standards/default.htm>, accessed 24/02/05

¹⁰ Health Service Circulars may sometimes take the form of directions from the Secretary of State for Health and so impose statutory obligations upon the organisations they address

¹¹ Some regulations, such as those relating to nursing home care, predate the 1997 White Paper

I. NHS Plan

The government's 1997 White Paper proposed far reaching structural changes across the NHS (Department of Health, 1997). The NHS Plan implemented those changes, outlining a 10-year process of reform to transform the manner in which NHS meets its obligations (Department of Health, 2000b, Montgomery, 2003);(page 61). Published in 2000, 'the NHS Plan: a plan for investment, a plan for reform' described a new delivery system for the NHS as well as changes between health and social services, and changes for NHS doctors, for nurses, midwives, therapists and other NHS staff (Department of Health, 2000b). The Plan also documented changes for patients and in the relationship between the NHS and the private sector.

The central tenet of the NHS Plan is that there is a shortfall between what the NHS is and what patients and staff would like it to be. In order to modernise it for the twenty-first century, the Plan specifies three principal goals, derived from a public consultation:

1. More and better paid staff using new ways of working
2. Reduced waiting times and high quality care centred on patients
3. Improvements in local hospitals and surgeries

Recognising that chronic underfunding was partly responsible for the failings of the NHS, the government pledged to increase NHS funding by one-third in real terms over a five-year period. New hospitals, equipment and more investment in the recruitment and retention of staff, increasing their skills and enabling them to extend their roles, were planned. Reforms would ensure that the extra money was translated into better care. The Plan describes a dynamic and emerging set of changes that will have implications for many years. These changes include the introduction of Patient Choice, new contracts for NHS staff, national standards and inspection, diversification of providers through the introduction of NHS Foundation Trusts and private providers and the devolution of the main responsibility for planning services, and the money to go with it, to Primary Care Trusts (PCTs). These changes seek to make the NHS more responsive to local needs and individual patients, while treating everyone fairly. The aim is to make NHS organisations more accountable locally, less reliant on central intervention and top-down performance management and more subject to checks and balances within the system. However, this internal regulation is subject to 'effective external regulation' (Audit Commission, 2004b). In practice, the balance of power may simply have shifted to intermediate regulators, such as Strategic Health Authorities, the Healthcare Commission and Monitor (Newdick, 2005b);(page 77).

Until recently, there was no *guarantee* on quality of care. Principle 5 of the NHS Plan states that the NHS will work continuously to improve quality services and to minimise errors (Department of Health, 2000b):

The NHS will ensure that services are driven by a cycle of continuous quality improvement. Quality will not just be restricted to the clinical aspects of care, but include quality of life and the entire patient experience. Healthcare organisations and professions will establish ways to identify procedures that should be modified or abandoned and new practices that will lead to improved patient care. All those providing care will work to make it ever safer, and support a culture where we can learn from and effectively reduce mistakes. The NHS will continuously improve its efficiency, productivity and performance.

Under the NHS Plan, waiting lists for hospital appointments and admission were to be abolished and replaced with booking systems, aiming to give all patients a choice of a convenient time within a guaranteed maximum waiting time (Department of Health, 2000b):

- Access to a primary care professional within 24 hours, and to a general practitioner (GP) within 48 hours (§12.6)
- Maximum wait of no more than four hours in accident and emergency from arrival to admission, transfer or discharge (§12.10)
- Maximum waiting time for a routine outpatient appointment of three months (§16.6)
- Maximum wait for inpatient treatment of six months (§16.6)

- Maximum wait for any stage of treatment to three months (long term goal) (§12.21)

Some of these targets represent agreements between the Department of Health and the Treasury. Further details of the 'Public Service Agreements' are given in the section on Patient Choice.

National Service Frameworks (NSFs), introduced in the 1997 White Paper, embodied new approach to rationing: by specifying national standards, they encourage the selection and adoption of some treatments and approaches, whilst rejecting others (Montgomery, 2003);(page 61). However, waiting times remain the main rationing mechanism. Private health care acts as a valve for releasing pressure within the NHS: patients' use of private health care reflects the disutility of waiting rather than dissatisfaction with the quality of care (Yates, 1995);(pp. 20-21).

The treatment of cancer, heart disease and mental health services receives special attention in the NHS Plan. This includes the expansion of cancer screening programmes and broadening the availability of cancer drugs; the introduction of rapid access chest pain clinics, intermediate care services for the mentally ill and the elderly; and free nursing care for people in nursing homes. The Plan also states the government's commitment to enable access to NHS dentists for all who want it by September 2001, supported by NHS Direct (a 24 hour telephone service staffed by nurses), additional funding for more dental access centres and improvements to dental practices and improved rewards for NHS dentists (Department of Health, 2000b). At the time of writing (April 2005), this commitment is still to be realised.

II. National service frameworks (NSFs)

National Service Frameworks (NSFs)¹² form one of a range of measures that seek to raise quality and decrease variations in service. NSFs were introduced in the government's 1997 White Paper and consultation document on quality (Department of Health, 1997, Department of Health, 1998). They set national standards, identify key interventions for a defined service or care group that should be available, establish strategies to support implementation and outline ways to ensure progress within an agreed time scale (Department of Health, 1997). Essentially, NSFs provide positive guidance and do not explicitly stipulate interventions that should not be undertaken. They are modelled on an existing framework on cancer services (Calman and The Expert Advisory Group On Cancer, 1995), and cover a range of disease areas (Table 2).

¹²http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthAndSocialCareArticle/fs/en?CONTENT_ID=4070951&chk=W3ar/W, accessed 24/02/05

Table 2: Published National Service Frameworks, April 2005

Topic	Date of Launch	Comments
Paediatric intensive care	July 1997	The Paediatric Intensive Care NSF aims to ensure appropriate levels of care for sick children. The National Co-ordinating Group on the provision of paediatric intensive care was set up in June 1996. Its report, 'Paediatric Intensive Care: A Framework for the Future' put in place a policy framework for developing the service and the standards which should be met in all hospitals providing paediatric intensive care.
Mental health	September 1999	The NSF for Mental Health is a statement on how mental health services will be planned, delivered and monitored until 2009. The NSF lists seven standards that set targets for the mental health care of adults aged up to 65. These standards span five areas: health promotion and stigma, primary care and access to specialist services, needs of those with severe and enduring mental illness, carers' needs, and suicide reduction.
Coronary heart disease	March 2000	The NSF for Coronary Heart Disease sets 12 standards for improved prevention, diagnosis and treatment, and goals to secure fair access to high quality services. The standards are to be implemented over a 10-year period.
Cancer	September 2000	The Calman Hine report set out a framework for cancer care provision in 1995 (Calman and The Expert Advisory Group On Cancer, 1995). The NHS Cancer Plan provides a statement of the government's comprehensive national programme for investment and reform of cancer services in England.
Older people	March 2001	The NSF for Older People seeks to set new national standards and service models of care across health and social services for all older people whether they live at home, in residential care or are being cared for in hospital.
Diabetes	December 2001	1.3 million people in England suffer from diabetes, and the number is increasing. The diabetes NSF aims to ensure these people, wherever they live, receive the same high standard of care. Embodied in the NSF is the central value of the NHS Plan—that good service is the outcome of genuine partnership between the patient and the provider. The NSF seeks to substantially reduce the suffering caused by diabetes.
Renal	January 2004	The Renal Services NSF aims to raise standards, reduce variations in services and improve health care for kidney patients. The National Service Framework sets five standards and identifies 30 markers of good practice to try to help the NHS and its partners manage demand, increase fairness of access and improve choice and quality in dialysis and kidney transplant services.
Children, Young People, Maternity	October 2004	The Children's NSF is a 10-year programme intended to stimulate long-term and sustained improvement in children's health. Setting standards for health and social services for children, young people and pregnant women, the NSF aims to ensure fair, high quality and integrated health and social care from pregnancy, right through to adulthood.
Long term conditions	March 2005	The National Service Framework for long-term conditions aims to improve the lives of the many people who live with neurological and other long-term conditions by providing them with better health and social care services. Key themes are independent living, care planned around the needs and choices of the individual, easier, timely access to services and joint working across all agencies and disciplines involved.

Source: Department of Health Website¹²

The rolling programme of NSFs, launched in April 1998, usually produces only one new framework a year. Each NSF is developed with the assistance of an external reference group (ERG), which seeks to engage a full range of views by bringing together health professionals, service users and carers, health service managers, partner agencies, and other advocates. However, the economic input into NSFs is sometimes weak. The Department of Health supports the ERGs and manages the overall process. It is unclear how NSFs are to be updated to reflect changes in the evidence base that underpins them.

There is no statutory obligation on health care organisations to implement NSF standards. However, the Health And Social Care (Community Health And Standards) Act 2003 gave the Secretary of State powers to publish standards for health care (s. 46(1)) that NHS bodies are bound to take into account (s. 46(4)); NSFs could inform these standards (Secretary of State for Health, 2003). Furthermore, in April 2004 the Healthcare Commission began reviewing health care organisations' implementation of the NSFs for Coronary Heart Disease and for Older People, reinforcing the quasi-legislative nature of NSF guidance (see The Healthcare Commission). Guidance contained within each NSF covers many of the International Classification for Health Accounts (ICHA) categories (Table 3).

Table 3: ICHA categories covered by selected NSFs

ICHA Category	National Service Framework					
	Children	CHD	Diabetes	Mental Health	Older People	Renal
HC.1 Services of curative care	Guidance on hospital-based services for children (standard 7) and on community-based care (standard 3)	Standard 7 NHS Trusts to provide appropriate investigations and treatments for patients with suspected or confirmed CHD	Standard 7 NHS to provide rapid and effective treatment for diabetic emergencies	Inpatient hospital beds including intensive care beds for people needing a short period of intensive intervention and observation	Standard 4 Need for appropriate specialist care Standard 7 Effective diagnosis, treatment and support for those with mental health problems	Quality requirement 2 Timely, appropriate and effective investigation, treatment and follow-up for those with chronic kidney disease Standard 5 All likely to benefit from a kidney transplant to receive a high quality service which supports them in managing their transplant NA
HC.2 Services of rehabilitative care	Standard 7 Guidance on hospital services for children includes recommendations covering rehabilitation	Standard 12 NHS Trusts to offer patients cardiac rehabilitation	NA	Standard 5 All users with severe mental health needing rehabilitation have timely access to an appropriate 'mental health place'	Standard 3 Intermediate care to include effective rehabilitation services	NA
HC.3 Services of long-term nursing care	Standard 8 Care for disabled children, young people and those with complex health needs Standard 6 Care for children with long-term conditions	NA	NA	Standards 4 & 5 Care of people with severe mental illness	Standard 4 At discharge from hospital, access to long term nursing care is one of three options listed in the NSF	Quality requirement 4 Jointly agreed palliative care plan for those with renal failure
HC.4 Ancillary services to health care	Standard 7 Services to be available for children in hospital include dietetics, physiotherapy, occupational therapy, speech and language therapy, and psychological support services.	Standard 12 Patients with CHD invited to participate in multidisciplinary programme for secondary prevention	Standard 12 All people with diabetes requiring multi-agency support will receive integrated health and social care	Standard 3 Access to psychological therapies is a performance measure listed in the NSF	Standard 4 Hospital-based care should include access to audiology, ophthalmology, podiatry and orthotics services Standard 6 Stroke patients to have access, as indicated, to physiotherapy, speech therapy and occupational therapy services	Standard 1 Access to a multi-skilled renal team whose members have the appropriate training, experience and skills.
HC.5 Medical goods dispensed to out-patients	Standard 10 Children and Young People should have access to safe and effective medicines prescribed on the basis of the best available evidence.	Standard 11 Patients with heart failure to be offered treatments most likely to both relieve their symptoms and reduce their risk of death	Standard 4 All adults with diabetes to receive high quality care throughout their lifetime	Standards 2-5 One of the NSF milestones is that all service users should be assessed for and receive new antipsychotics where indicated	A Medicines Management booklet accompanies the NSF	A Medicines Management booklet accompanies the NSF
HC.6 Prevention and public health services	Standard 1 Child Health Promotion Programme Standard 11 Maternity services	Standards 1 & 2: NHS and partner agencies to work to reduce heart disease in the population	Standard 1 NHS to reduce the risk of developing Type 2 diabetes in the population	Standard 7 To reduce the death rate from suicide and undetermined injury by at least a fifth ¹³	Prevention of stroke (standard 5), falls (standard 6) and promotion of active healthy living (standard 8)	Part 2 of the NSF deals with the prevention of established renal failure

Sources: (Department of Health, 2004h, Department of Health, 2004g, Department of Health, 2000a, Department of Health, 2002a, Department of Health, 1999, Department of Health, 2001b)

¹³ This target was set in the government document 'Saving lives: Our Healthier Nation' (1999)

III. NICE guidance

The National Institute for Clinical Excellence (NICE) was introduced in April 1999 to promote clinical excellence within the NHS by reducing the variations in uptake of new technologies (Secretary of State for Health, 1999c, Newdick, 2005a). In August 1999, the law was amended¹⁴ to ensure that cost effectiveness considerations were included in the Institute's decisions:

(2) In article 3 (functions of the Institute) after the words 'promotion of clinical excellence' there are inserted the words 'and of the effective use of available resources' (Secretary of State for Health, 1999b).

NICE produces three types of guidance, which may ensure the availability of treatment in any category in the International Classification for Health Accounts (ICHA).

1. **Technology appraisals:** guidance on the use of new and existing treatments within the NHS. To date (April 2005), 88 technology appraisals have been published. Technologies may include:
 - a. Medicines
 - b. Medical devices (e.g. inhalers)
 - c. Diagnostic techniques (e.g. cervical cytology)
 - d. Surgical procedures (e.g. use of coronary artery stents)
 - e. Health promotion activities (e.g. ways of helping people with diabetes manage their condition).

The NICE Appraisal Committee is an independent advisory body constituted of individuals drawn from a range of professional backgrounds. The Committee considers the evidence from an academic assessment group and from company submissions. Clinical specialists and 'expert patients' are also present to give their views, though are asked to leave when the Committee discusses the Appraisal Consultation Document. This Document then goes out to consultation. The Final Appraisal Determination is then developed, approved by the NICE Guidance Executive put out again for consultation. Following an appeal process, the guidance is published (National Institute for Clinical Excellence, 2004). All guidance is reviewed at regular intervals and recommendations reconsidered in the light of any new evidence. It should be noted that the overwhelming majority of technologies used in the NHS are *not* the subject of recommendations by the NICE Appraisal Committee.

2. **Clinical guidelines:** these offer guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS (Table 4). Clinical guidelines are based on the best available evidence and are intended to help health care professionals in their work, but do not replace their knowledge and skills. Topics include the management of chronic heart disease, dyspepsia and hypertension. Settings covered include primary, secondary and tertiary care. There are currently (April 2005) 39 guidelines, of which 14 were previously commissioned guidelines 'inherited' by NICE. The clinical guidelines interpret, and provide detail about how to implement, the National Service Frameworks. For example, the NICE guideline on the 'Management of Type 2 Diabetes' describes the treatment of renal disease, for which the broad aims of management are identified in the National Service Framework on Diabetes (Table 2). National Collaborating Centres support NICE by managing and publishing the guideline.¹⁵ To develop a guideline, the National Collaborating Centre establishes a Guideline Development Group, with members capable of appraising evidence from systematic reviews of the research evidence, examining clinical - and cost-effectiveness issues, integrating clinical understanding and considering the views of patients and carers. An extensive consultation with stakeholders also informs the guideline.

¹⁴ The National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 1999 (S.I. 1999/2219)

¹⁵ http://www.nice.org.uk/pdf/GDP_An_Overview_for_Stakeholders_the_Public_and_the_NHS.pdf, accessed 18/03/05

3. **Interventional procedures:** guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in the NHS. These generally cover new procedures, although existing procedures may be reviewed if there are safety concerns. Topics include radiotherapy for age-related macular degeneration and dynamic cardiac monitoring. Settings include primary, secondary and community care and the Department of Health has provided guidance on the registration of new procedures in a Health Service Circular (HSC 2003/011). To date (April 2005), guidance on 114 interventional procedures has been issued, with 10 additional topics completed, but no guidance issued.¹⁶ The Interventional procedures Advisory Committee, an independent body of 24 members with a range of expertise, considers procedures only in terms of safety and efficacy; it does not examine clinical or cost effectiveness.¹⁷ The Committee produces a Consultation Document and published guidance reflects comments received over the 4-week consultation period.

Although health promotion is within the remit of NICE, the Health Development Agency is the body with principal responsibility for producing evidence-based guidance on public health issues.¹⁸ The rationalisation of Arms Length Bodies saw the two institutions joining forces, with NICE taking over the functions of the Health Development Agency from 1st April 2005 (Table 5).

NICE guidance generally acts like a quasi law, but one aspect of guidance on technology appraisals is supported by statute. If NICE produces guidance on a technology appraisal to say that a new medicine should be made available to NHS patients who meet particular criteria, then the NHS bodies responsible for providing funding for that treatment are under a statutory obligation to ensure that the technology:

...is, from a date not later than three months from the date of that Technology Appraisal Guidance, normally available (Secretary of State for Health, 2001b).

The Department of Health sometimes extends this deadline (e.g. Appraisal No. 68 on macular degeneration). However, although funding bodies are obliged by law to ensure there are adequate resources to *facilitate* the implementation of NICE guidance, the guidance is not binding on individual clinicians, who must assess whether the technology is appropriate for patients under their care (Newdick, 2005a).

¹⁶ <http://www.nice.org.uk/ipsearch.aspx?o=interventionalprocedures.home>, accessed 15/04/05

¹⁷ <http://www.nice.org.uk/pdf/ip/IPProgrammeManual.pdf>, accessed 18/03/05

¹⁸ <http://www.hda-online.org.uk/>, accessed 08/03/05

Table 4: NICE Clinical Guidelines, April 2005

CODE	Title	Wave	Publication	Review
CG6	Antenatal care	6	Oct 2003	
CG22	Anxiety	6th wave	Dec 2004	Dec 2008
CSG	Breast (CSG)	Inherited	Aug 2002	
CG13	Caesarean section	2nd programme	Apr 2004	Apr 2008
CG5	Chronic heart failure	2nd Programme	Jul 2003	Jul 2007
CG12	Chronic obstructive pulmonary disease	6th Wave	Feb 2004	Feb 2008
CSG	Colorectal (CSG)	Inherited	Jun 2004	
CG19	Dental recall	7th wave	Oct 2004	Oct 2008
CG23	Depression	2nd programme	Dec 2004	Dec 2008
CG17	Dyspepsia	1st programme	Aug 2004	Aug 2008
CG9	Eating disorders	2nd programme	Jan 2004	Jan 2008
C	Electronic fetal monitoring	Inherited	May 2001	May 2005
CG20	Epilepsy	6th wave	Oct 2004	Oct 2008
CG21	Falls	6th wave	Nov 2004	Nov 2008
CG14	Familial breast cancer	6th wave	May 2004	May 2008
CG11	Fertility	6th wave	Feb 2004	Feb 2008
CSG	Haemato-oncology (CSG)	Inherited	Oct 2003	
CSG	Head and neck (CSG)	Inherited	Nov 2004	
CG4	Head injury	2nd programme	Jun 2003	Jun 2007
CG18	Hypertension	1st Programme	Aug 2004	Aug 2008
D	Induction of labour	Inherited	Jun 2001	Jun 2005
CG2	Infection control	2nd programme	Jun 2003	Jun 2007
CG24	Lung cancer	6th wave	Feb 2005	Feb 2009
CG8	Multiple sclerosis	1st Programme	Nov 2003	Nov 2007
A	Post MI	Inherited	Apr 2001	Apr 2003
CG26	Post-traumatic stress disorder (PTSD)	6th wave	Mar 2005	Mar 2009
CG3	Preoperative tests	1st Programme	Jun 2003	Jun 2007
CG7	Pressure relieving devices	6th wave	Oct 2003	Oct 2007
B	Pressure ulcers	Inherited	Apr 2001	Apr 2005
CG1	Schizophrenia	1st programme	Dec 2002	Dec 2006
CG16	Self-harm	6th wave	Jul 2004	Jul 2008
CSG	Supportive and palliative care for people with cancer (CSG)	Inherited	Mar 2004	
CG15	Type 1 diabetes	2nd programme	Jul 2004	Jul 2008
G	Type 2 diabetes - blood glucose	Inherited	Sep 2002	Sep 2005
CG10	Type 2 diabetes - footcare	1st update	Jan 2004	Jan 2008
H	Type 2 diabetes - management of blood pressure and blood lipids	Inherited	Oct 2002	Oct 2005
F	Type 2 diabetes - renal disease	Inherited	Feb 2002	Mar 2005
E	Type 2 diabetes - retinopathy	Inherited	Feb 2002	Mar 2005
CSG	Urological (CSG)	Inherited	Sep 2002	
CG25	Violence	6th wave	Feb 2005	Feb 2009

Compliance with clinical guidelines remains at the discretion of local planners (Primary Care Trusts, or PCTs). There is, however, evidence of political 'encouragement' to adhere to these guidelines. For example, the NICE clinical guideline on fertility treatments (National Collaborating Centre for Women's and Children's Health, 2004) recommended that the NHS should provide 3 cycles of in vitro fertilisation (IVF) treatment for suitable patients in England and Wales. Commenting on geographical variations in the availability of in vitro fertilisation (IVF), the Secretary of State, John Reid, observed in February 2004:

I am glad that NICE itself recognises that the NHS cannot reasonably make this expansion overnight. Our immediate priority must be to ensure a national level of provision of IVF is available wherever people live. As a first step, by April next year I want all PCTs, including those who at present provide no IVF treatment, to offer at least one full cycle of treatment to all those eligible. In the longer term I

would expect the NHS to make progress towards full implementation of the NICE guidance (Department of Health, 2004c).

In addition to the priority criteria recommended by NICE, the Health Secretary stated that couples with a child/children from the current or previous relationship should not have access to NHS treatment.

Although NICE and NSFs play a part in rationing health care, the principal rationing mechanism is the waiting list (Montgomery, 2003);(page 62). The legal mechanisms needed to enforce and challenge these new rationing processes are as yet largely untested (Montgomery, 2003). Private health care acts as a safety valve for cases where demand exceeds NHS supply, with patients relying either on insurance cover or self-payments (see above, NHS Plan).

IV. Department of Health Guidance

The NHS is a centrally planned organisation, whose management is facilitated by the 'constant stream of communication' from the Department of Health to NHS organisations (Montgomery, 2003);(page 15).

Guidance in the form of Health Service Circulars (HSCs) is the main type of communication. HSCs are formal communications, primarily to NHS chief executives. They usually contain a requirement for significant or urgent specific action. Some HSCs are issued jointly with a local authority circular (LAC) where the topic is relevant to a joint health and local authority audience.¹⁹ Many are quasi-legislative. This means that they are rules that are not usually legally binding, and therefore carry no legal sanctions, but which in practice determine the way that people behave (Montgomery, 2003);(page 16). However, sometimes circulars can take the form of directions from the Secretary of State and are therefore legally binding.¹⁰ HSCs may address any of the ICHA categories of health care provision. An example an HSC addressing curative care (ICHA 1) is the 'National Guidance on the Safe Administration of Intrathecal Chemotherapy' (HSC 2003/010), which specified action to be taken by Chief Executives of Strategic health Authorities and NHS Trusts. An example of the Health Secretary issuing directions in the form of a Health Service Circular is HSC 2003/006, which addresses long-term nursing care (ICHA 3) (see HC3 Services of long-term).

Guidance to PCTs and NHS Trusts may also come from Strategic Health Authorities (SHAs). SHAs are regional organisations accountable to the Secretary of State that manage performance of NHS bodies at the local level (Newdick, 2005b);(page 77). Specifically, SHAs have a duty to support and monitor PCTs and manage their performance in exercising their functions, with a view to improving the quality of health care provided to individuals in their area (Secretary of State for Health, 2002);(reg. 3(2(b))). SHAs are also charged with the duty to promote a comprehensive health service, can give (statutory) directions²⁰ to NHS Trusts about any of their functions and can request the fluoridation of water supplies (Secretary of State for Health, 2002);(regs. 3(3), 5). The 1999 Health Act legislation places SHAs, NHS Trusts and PCTs under a duty to co-operate with each other (Secretary of State for Health, 1999a);(s. 26).

Key Regulatory Bodies

Department of Health 'Arm's Length Bodies' and the Healthcare Commission have important regulatory roles in the NHS. Although the Audit Commission pre-existed the 1997 Labour government reforms, it continues to be influential in the regulation of health care, particularly in its relation to the Healthcare Commission. 'Monitor', the watchdog responsible for overseeing financial management in Foundation Trusts, is also described. Lastly, some of the key actors in the regulation of medicines and devices are outlined.

¹⁹ <http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/fs/en>, accessed 18/02/05

²⁰ PCTs are not empowered to issue directions on behalf of the Secretary of State S.I. 2002/2375;reg. 5(2)

I. Arm's Length Bodies

The UK government has a range of Arm's Length Bodies (ALBs) that service the NHS. With a view to rationalising overlapping and duplicated functions and removing 'unnecessary' activities, the government aims to reduce ALBs from 38 to 20 and see a 25% reduction in staff working in the sector by 2008 (Department of Health, 2004o). The implementation framework groups the ALBs into four categories that designate their function (Table 5)(Department of Health, 2004f).

Table 5: Department of Health's Arm's Length Bodies (ALBs), England 2004

Function	Long Term ALBs	ALBs whose functions will be taken on by other ALBs or removed from the ALB sector	
Regulation	1 Healthcare Commission	Mental Health Act Commission	
	2 Independent Regulator of NHS Foundation Trusts ('Monitor')		
	3 Commission for Social Care Inspection		
	4 Regulatory Authority for Fertility and Tissue	Human Fertilisation and Embryology Authority Human Tissue Authority	
	5 Council for Regulation of Health Care Professionals		
	6 General Social Care Council		
	7 Postgraduate Medical Education and Training Board	Dental Vocational Training Authority	
	8 Medicines and Health care products Regulatory Agency		
Standards	9 National Institute for Clinical Excellence	Health Development Agency	
Public Welfare	10 National Patient Safety Agency	National Clinical Assessment Authority NB: to continue as a division of the NPSA, supporting five-year re-licensing by the General Medical Council ('revalidation').	
	11 Health Protection Agency	Commission for Patient and Public Involvement in Health	
	12 National Treatment Agency for Substance Misuse	Public Health Laboratory Service	
		National Radiological Protection Board National Biological Standards Board	
Central services	13 Blood and Transplant Authority	National Blood Authority UK Transplant	
	14 NHS Litigation Authority	Family Health Services Appeal Authority (Special Health Authority)	
	15 NHS Appointments Commission	NHS Modernisation Agency	
	16 NHS Institute for Learning, Skills and Innovation (NILSI)	NHS University Leadership Centre	
	17 Health and Social Care Information Centre	NHS Information Authority DH statistical services	
	18 National Programme for IT		
	19 NHS Business Services Authority	Prescription Pricing Authority Dental Practice Board NHS Pensions Agency NHS Counter Fraud and Security Management Service	
	20 NHS Purchasing and Supply Agency	NHS Logistics Authority NHS Estates	
	Removed from ALB sector	NHS Direct NHS Professionals ²¹	Transfer to independent status in 2-3 years

Sources: (Department of Health, 2004m, Department of Health, 2004f)

Arm's Length Bodies that have an important impact on patient entitlement to NHS services are described in further detail below.

II. The Healthcare Commission

Established under the Health and Social Care (Community Health and Standards) Act 2003, the Healthcare Commission is the independent inspection body for healthcare organisations

²¹ NHS Professionals is the in-house flexible staffing service run by the NHS for the NHS

HealthBASKET

(Secretary of State for Health, 2003). Regulation of both NHS and independent (private and voluntary) health care organisations is within the Commission's remit. The Healthcare Commission has a wide range of functions, of which the main ones are listed below.²²

- To independently assess the performance of the health services from patients' perspectives, using standards set out by the Department of Health; this is a statutory duty for the Commission
- To co-ordinate NHS inspections with a range of other health care organisations in order to minimise disruption to health care staff
- To identify how effectively public funds are used within health care – particularly whether tax payers are getting good value for money
- To develop an independent second stage for complaints about the NHS which can not be resolved locally
- To investigate serious failures in health care services
- To publish regular ratings of NHS hospitals and trusts, and an annual report on health care

Regulation by the Healthcare Commission includes assessments of compliance with standards. Currently, every NHS organisation is assessed annually and awarded a 'star rating', ranging from zero (lowest level of performance) to three stars (highest). There are four elements to the star rating. Firstly, key targets are set, which vary by type of organisation – so Ambulance Trusts have different targets to those set for hospital Trusts²³ – and performance against these targets contributes to the organisation's star rating. For example, key targets for hospital Trusts comprise of various waiting time indicators, hospital cleanliness, cancelled operations, the financial state of the Trust and a demonstrated commitment to improve working conditions. For most Trusts, there are also three sets of subsidiary indicators, comprising of those with a *clinical focus* (such as emergency re-admission rates); a *patient focus* (such as the resolution of written complaints); and those with a *staff focus* (such as junior doctors' hours). Trusts with a 'balanced scorecard' – good or high performance in all four areas – are then awarded two or three stars respectively (Kaplan and Norton, 1992).

The Healthcare Commission is currently developing a new approach to assessing the performance of organisations that provide healthcare in the NHS and independent (private and voluntary) sectors. Regulation will take place through licensing, annual ratings and annual inspections. Aiming to make regulation more helpful to patients and users and less burdensome to providers,²⁴ the Commission seeks to shift the focus of the assessment towards the *quality of care* provided to patients and towards the *capacity* of the organisations to deliver services of high quality. Major revisions to the assessment system planned for 2005/06. Covering seven quality domains,²⁵ the government's report 'National Standards, Local Action' outlines a set of 24 'core' standards, supported by 13 'developmental' standards. The core standards seek to integrate existing standards that 'service users have a right to expect', whilst the developmental standards aim to facilitate continuous improvement (Department of Health, 2004i). The intention is that *all* health care organisations will be judged by the same standards:

The standards apply with immediate effect to services provided under the NHS, whether within NHS bodies or within the independent or voluntary sector. As foreshadowed in the consultation document, there will be an appropriate phasing in of the applications of these standards to cover other services provided entirely by the independent sector (Department of Health, 2004q); (§31).

²² <http://www.healthcarecommission.org.uk/Homepage/fs/en>, accessed 01/11/04

²³ 'Hospital trusts', or 'NHS Trusts', are groups of hospitals that operate as a single legal entity

²⁴ <http://www.healthcarecommission.org.uk/assetRoot/04/00/00/20/04000020.pdf>, accessed 08/11/04

²⁵ The seven quality domains are: safety; clinical and cost effectiveness; governance; patient focus; accessible and responsive care; care environment and amenities; and public health.

The Commission is concerned with both treatment and prevention, such as the quality of services that help people to stop smoking. Organisations' performance will be judged not just by national targets, but also by whether high quality care is delivered across a range of areas. These include NSFs (core standard C23; developmental standard D2) and NICE appraisal guidance (core standard C5a) and NICE guidance more generally, including NICE clinical guidelines (developmental standard D2).²⁶ The expectation is that 'inspection will be a powerful lever for ensuring that the changes outlined in [the NFSs] happen' (Department of Health, 2004g);(Standard for Hospital Services). In addition, organisations will be able to set their own targets to tackle local priorities. Although summary assessments for health care organisations will continue, the Commission proposes to disband star ratings (Healthcare Commission, 2004). Instead the performance ratings for the 'annual health check' will include two four-point scales: firstly, core standards and existing standards will be assessed on a scale ranging from 'fully met' to 'not met'; and secondly, a scale ranging from 'excellent' to 'weak' will be used for all other components and also serve as an overall rating (Healthcare Commission, 2005).

Health care organisations need to ensure that clinicians participate in regular clinical audit and reviews of clinical services in order to meet the core standards. Clinical audit is defined as:

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against specific criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in health care delivery (Department of Health, 2004i).

A range of disease areas and procedures are currently covered by clinical audits, some of which are specified by National Service Frameworks (e.g. the NSF for Coronary Heart Disease). However, questions over how the national strategy will develop remain: in particular, it is unclear whether participation will be mandatory; how large and comprehensive the programme will be and how necessary action will be enforced; and how the programme will be managed. Currently, the National Clinical Audit Support Programme manages some clinical audits on behalf of the Healthcare Commission.²⁷

III. The Audit Commission

Although the Audit Commission pre-existed the 1997 Labour government reforms, it continues to play an important role in the regulation of health care, particularly in its relation to the Healthcare Commission. Formally known as the Audit Commission for Local Authorities and the National Health Service in England and Wales, the Audit Commission is an independent public body 'responsible for ensuring that public money is spent economically, efficiently, and effectively in the areas of local government, housing, health, criminal justice and fire and rescue services'.²⁸ Whilst the Audit Commission assesses financial management and value for money at the *local* level, the Healthcare Commission assesses value for money at the *national* level. The Health and Social Care (Community Health and Standards) Act 2003 places a duty on the two organisations to co-operate with each other (Secretary of State for Health, 2003);(s. 65).

Aiming to promote the delivery of high-quality public services, and underpinned by a robust evidence base, the Audit Commission works with the Department of Health, the National Assembly of Wales and the Healthcare Commission. The Audit Commission inspects and reports on the performance of local authorities, which includes public health issues such as the provision of leisure and sports facilities. Primarily, the Audit Commission is concerned with the quality of financial management in the NHS. It produces national reports on topics such

²⁶ <http://www.parliament.the-stationery-office.co.uk/pa/cm200405/cmhansrd/cm050110/text/50110w26.htm>, accessed 07/03/05

²⁷ <http://www.nhsia.nhs.uk/ncasp/pages/default.asp>, accessed 07/03/05

²⁸ <http://www.audit-commission.gov.uk/aboutus/index.asp>, accessed 12/02/05

as the implications of the new NHS funding system (Audit Commission, 2004b), drug misuse (Audit Commission, 2004a), services for older people (Audit Commission, 2004c), acute (Audit Commission, 2003) and primary care (Audit Commission, 2004d).

IV. Monitor

Monitor is an independent public body established under the Health and Social Care Act 2003 (Secretary of State for Health, 2003). Its formal name is the 'Independent Regulator for NHS Foundation Trusts'. Monitor takes over duties from the Secretary of State, such as the duty to promote a comprehensive health service and to provide clinical facilities to universities with medical or dental schools (Secretary of State for Health, 2003)(s. 3). Foundation Trusts are subject to the direction of Monitor, not to the Secretary of State.

Monitor is responsible for ensuring the financial sustainability of NHS Foundation Trusts, through authorisation, monitoring and regulation. The Healthcare Commission undertakes performance management of these organisations. Foundation Trusts, also established by the 2003 Health and Social Care Act, differ from ordinary NHS Trusts in three ways:²⁹

- Freedom to decide locally how to meet their obligations
- Accountable to local people, who can become members and Governors
- Authorised and monitored by Monitor, rather than by the Healthcare Commission

In authorising Foundation Trusts, Monitor specifies the goods and services that may be provided and the information required to facilitate monitoring. In addition, the Healthcare Commission inspects the performance of a Foundation Trust against healthcare standards and Monitor receives a copy of the inspection report. Like the Healthcare Commission for NHS Trusts, Monitor has powers to intervene in the running of a Foundation Trust if it fails in its healthcare standards or other aspects of its activities, when this amounts to a significant breach in the terms of its authorisation. Since Foundation Trusts are not subject to directions by the Secretary of State for Health, the contracts they enter with Primary Care Trusts are not NHS contracts – the type that operates between 'ordinary' NHS Trusts and PCTs – but legal contracts which are enforceable through the courts (Newdick, 2005b);(page 86).

V. Medicines and Health care products Regulatory Agency

The Medicines and Health care products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) on 1 April 2003. As an executive agency of the Department of Health, the MHRA seeks to protect and promote public health and patient safety by ensuring that medicines, health care products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.³⁰

MHRA activities include:³¹

- Assessing the safety, quality and efficacy of medicines sold or supplied in the UK for human use
- Authorising medicines
- Overseeing the organisations that audit device manufacturers
- Operating post-marketing surveillance and other systems for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices and taking any necessary action to safeguard public health, for example through safety warnings, removing or restricting the availability of products or improving designs
- Operating a quality surveillance system to sample and test medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines

²⁹ http://www.monitor-nhsft.gov.uk/register_nhsft.php, accessed 18/02/05

³⁰ <http://www.mhra.gov.uk/>, accessed 18/10/04

³¹ <http://www.mhra.gov.uk/aboutmhra/aboutmhra.htm>, accessed 22/01/05

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- Regulating clinical trials of medicines and medical devices
- Monitoring and ensuring compliance with statutory obligations relating to medicines and devices through inspection, taking enforcement action where necessary
- Promoting good practice in the safe use of medicines and devices
- Managing the General Practice Research Database, the British Pharmacopoeia and the Device Evaluation Service, and helping to develop performance standards for medical devices

VI. Pharmaceutical Price Regulation Scheme

Whilst the MHRA authorises the medicines and devices that are available within the UK, the Pharmaceutical Price Regulation Scheme (PPRS) deals with the pricing of pharmaceuticals. Although not strictly a regulatory body, the PPRS has an important, albeit unintentional, impact: by influencing the price of pharmaceuticals, the PPRS affects NICE technology appraisals, which consider the costs and benefits of pharmaceuticals in order to make recommendations for their use within the NHS (see NICE guidance).

Jointly agreed between the UK Health Departments and the Association of the British Pharmaceutical Industry, the PPRS seeks to ensure that the NHS has access to good quality branded medicines at reasonable prices, and aims to promote a healthy, competitive pharmaceutical industry.

The 2005 Pharmaceutical Price Regulation Scheme is an agreement for the purposes of Section 33 of the Health Act 1999, which gives the Secretary of State for Health powers to manage the scheme (Secretary of State for Health, 1999a). The stated objectives of the scheme are that it should continue to:

- (a) Secure the provision of safe and effective medicines for the NHS at reasonable prices
- (b) Promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines
- (c) Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in the UK and other countries.

The PPRS restricts the rate of return that pharmaceutical companies are allowed to earn from their sales of branded medicines to the NHS; permits freedom of pricing for new active substances on market entry but prevents subsequent price increases unless the producing company's rate of return falls below a specified (low) threshold level. It also covers notification of product discontinuations and describes some other informational requirements (Department of Health, 2004a). In addition, under the 2005 Scheme, the prices of medicines covered by the PPRS were reduced by 7% from 1 January 2005, with no price increases permissible until 31st December 2005. As an alternative to an across the board price reduction, scheme members may modulate the list price of their PPRS products by reductions that *equate* to an overall level of 7% (known as cost-neutral modulation) (Department of Health, 2004a).

VII. Prescribing Prescription Authority

The Prescription Pricing Authority (PPA) is concerned with the payment and budget management of health care professionals. The PPA prescribing information services seek to improve patient care through facilitating performance management of the primary care sector. The PPA processes over 600 million prescription items annually, manage payments to more than 10,000 pharmacy contractors and also calculate the payments due to approximately 4,400 dispensing doctors in England.

The main functions of the PPA are:³²

³² http://www.ppa.org.uk/ppa/ppa_main.htm, accessed 21/03/05

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- to calculate and make payments for amounts due to pharmacists and appliance contractors, and calculate amounts due to general practitioners, for supplying drugs and appliances prescribed under the NHS
- to produce information for General Practitioners (GPs), Nurses, Primary Care Trusts (PCTs) and other NHS stakeholders about prescribing volumes, trends and costs
- to manage a range of health benefits including the NHS Low Income Scheme, Medical and Maternity Exemption Certificates, Prescription Pre-payment Certificates and Tax Credit exemptions
- to produce the Drug Tariff containing the reimbursement prices of a range of prescribable items and remuneration rules

Each month, the Pharmaceutical Directorate of the PPA produces the Drug Tariff for the Secretary of State under regulation 18(1) of the National Health Service (Pharmaceutical Services) Regulations 1992 (Secretary of State for Health, 1992b).³³ The Drug Tariff for England and Wales is supplied primarily to pharmacists, doctors' surgeries and (twice yearly) to nurse prescribers (Prescription Pricing Authority, 2005). It provides guidance on dispensing, the schedule of fees and allowances and prices of drugs and appliances. The Drug Tariff also contains lists for dental and nurse prescribing and for drugs that may not be prescribed on the NHS under any circumstances (black list drugs) or that may be prescribed under special circumstances (grey list drugs). Although Part IX of the Drug Tariff provides a positive list of appliances that may be prescribed on the NHS, there is no equivalent 'positive list' for drugs. Instead, Part VIII exists to facilitate the generic prescribing of drugs and also to help control the NHS Drugs Bill.³⁴

Regulation of Health Care Professionals

There is a wide range of self-regulators within the health care profession. The Council for the Regulation of Health Care Professionals, an independent body that seeks to make the framework of professional self-regulation more transparent and accountable to Parliament, now oversees these bodies. Of the regulators overseen by the Council, the General Medical Council (GMC) is perhaps the most prominent in setting standards for health care.

The contracts that physicians sign when undertaking work for the NHS may specify – or encourage – particular services. The new General Medical Services (GMS) and consultants' (secondary care physicians') contracts are described and the services they promote are outlined. Guidance from Royal Colleges may also affect the availability of services and these are considered below. General dental services and general ophthalmic services for which patients may be charged a fee provide an indication of services to which patients may assume an entitlement.

I. Council for the Regulation of Health Care Professionals

Established in 2003, the Council for the Regulation of Health Care Professionals is an independent body that oversees the work of bodies that regulate health care professionals, and seeks to integrate approaches for standard setting, performance monitoring, inspection and validation. The NHS Plan highlighted the need for formal co-ordination of regulators (Department of Health, 2000b); (§10.15), and was echoed by recommendation 39 in the Kennedy Report on the Bristol tragedy (Kennedy *et al.*, 2001).

Existing regulators that the Council oversees include (Department of Health, 2003a):

- General Medical Council
- General Dental Council
- General Optical Council
- Royal Pharmaceutical Society
- Health Professions Council

³³ Now in regulation 56 of the 2005 Regulations (S.I. 2005/641)

³⁴ http://www.ppa.org.uk/ppa/drug_tariff_guidance_notes.htm, accessed 21/03/05

- Nursing and Midwifery Council
- General Osteopathic Council
- General Chiropractic Council
- Pharmaceutical Society of Northern Ireland

II. The General Medical Council

The General Medical Council (GMC) was established under the Medical Act of 1858.³⁵ It has legal powers designed to maintain the standards the public have a right to expect of doctors:

The main objective of the General Council in exercising their functions is to protect, promote and maintain the health and safety of the public (Medical Act 1983; part 1(1)(a))

Public confidence in the medical profession's ability to protect the interest of patients was undermined by a series of cases, of which the serial murders by Harold Shipman and the misconduct charges brought at the Bristol Royal Infirmary were the most serious. The Bristol tragedy revealed systemic failures of existing forms of self-regulation and audit processes, placing the GMC under heavy criticism and eroding public trust in the medical profession more generally (Davies and Shields, 1999). The Shipman Inquiry precipitated a review of the GMC's system by which medical competence is monitored and regulated. Plans to introduce a new licensing and revalidation system for doctors have been postponed, following the latest report from the Shipman Inquiry and the recommendations contained in the report will be help to inform the proposed system.

III. Royal Colleges and Societies

Medical Royal Colleges have direct responsibility for postgraduate medical education and continuing medical education. They also set standards of medical practice. The word 'College' is slightly misleading because Colleges have no students, and give no lectures in the normal sense of the word. Medical Colleges are networks of doctors who are committed to improving patient care, developing their own skills and developing their 'specialty'. The Colleges have no role in disciplinary actions or processing complaints from patients – these are the responsibility of the General Medical Council.

The Medical Colleges seek to promote high standards of care through provision of continuing education, establishment of training standards, setting and running of examinations and supporting of research, giving them considerable influence over service provision. As well as managing the development of national government guidelines, many Colleges produce their own clinical guidelines. For example, the Royal College of Physicians has produced a guideline on 'Stroke in Childhood', covering diagnosis, management and rehabilitation.³⁶ In addition, Colleges seek to support their members, educate the public and advise the Department of Health, NHS organisations and other professional bodies.

There are also Royal Colleges for other clinicians or paramedical professionals, such as the Royal College of Nursing, the Royal College of Midwives and the Royal College of Speech and Language Therapists. Other physician organisations include the British Societies, such as the British Society of Haematology and Royal Societies, such as the Royal Pharmaceutical Society of Great Britain for pharmacists. These organisations may also produce guidelines to promote high standards of care. Where these guidelines are national, the Healthcare Commission may enforce compliance with their recommendations for service provision as part of their core standard assessments (Department of Health, 2004i). Otherwise, the impact of the guidance is unclear, but may be expected to vary.

IV. Agenda for Change

Agenda for Change claims to be the most radical shake up of the NHS pay system since the NHS began in 1948. It applies to over a million NHS staff with the exception of doctors,

³⁵ <http://www.gmc-uk.org/about/default.htm>, accessed 18/02/05

³⁶ <http://www.rcplondon.ac.uk/pubs/books/childstroke/>, accessed 09/03/05

dentists and senior managers.³⁷ The new pay scales are based on the findings of job evaluation, so that salaries reflect skills, responsibilities, knowledge, effort and working conditions. However, unlike the new General Medical Services (GMS) contract, there are no incentives linked to the provision of specific services.

V. The General Medical Services (GMS) Contract

The General Medical Services (GMS) contract was introduced on 1st April 2004, following negotiations between the NHS Confederation and the General Practitioners Committee of the British Medical Association. Primary Care Trusts now have a new duty to secure the provision of primary medical services (Department of Health, 2003c). Under this contract, there are three levels of service that general (medical) practitioners (GPs) must or may provide to their patients (Box 3).

Box 3: Service categories in the 2004 GMS contract		
Category of service	Status for General Practitioner provision	Services included
Essential services	Mandatory Core hours: weekdays, from 8:00 to 18:30	Immediate and necessary emergency treatment Management of registered patients and temporary residents with terminal illness, chronic disease or conditions from which recovery is generally expected Home visits where GP considers this to be medically necessary Annual health checks offered to patients aged over 75 Health checks offered to patients not seen within three years Health checks offered to newly registered patients
Additional services	Practices will have a preferential right to provide additional services and will normally do so but they will have an ability to opt out within set rules Right to opt out of out-of-hours care from 01/01/05	Cervical screening Contraceptive services Vaccinations and immunisations Childhood vaccinations and immunisations Child health surveillance (under 5s) Maternity services Minor surgery
Direct Enhanced services (DES)	Optional	PCTs must commission (plan for and buy) 6 DESs <ol style="list-style-type: none"> 1. Preparing patient information ready for computerisation 2. Improved access 3. The childhood immunisation programme 4. Minor surgery 5. Protection of GPs, their staff and other patients from violent patients 6. Influenza protection for the over-65s and at-risk patients Other services are commissioned at PCT discretion

Source: (Department of Health, 2003c)

PCTs can now also contract with non-NHS bodies such as voluntary or commercial sector providers to supply primary medical services.³⁸ Out-of-hours care is optional for GPs, but PCTs are expected to negotiate suitable alternative arrangements so that all patients can continue to access these services (Department of Health, 2004d); there is a statutory requirement on PCTs to do this (Secretary of State for Health, 2004a),(sch. 6, §70). Practices receive payments from the 'global sum' that funds the provision of essential, additional and out-of-hours services and is based on patient need and practice costs.³⁹ Practices can earn additional income by contracting with the PCT to provide enhanced services. There is also the opportunity for practices to substantially increase practice income by participating in the

³⁷ http://www.modern.nhs.uk/scripts/default.asp?site_id=48, accessed 25/02/05

³⁸ <http://www.natpact.nhs.uk/primarycarecontracting/68.php>, accessed 08/03/05

³⁹ This represents a departure from the previous contract, in which payment was made to doctors (rather than to practices), based on unadjusted list size. This meant that payment levels took no account of the needs of registered patients.

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Quality and Outcomes Framework (QOF) (Box 4) (Department of Health, 2004i). This framework lists evidence-based best practices in health care provision, including the treatment of patients with chronic conditions. Some (but not all) of the areas covered by the quality framework overlap with Direct Enhanced Services. For example, influenza immunisation for at-risk patients is a DES and is included in the QOF for patients with diabetes, chronic obstructive pulmonary disorder, asthma, coronary heart disease and stroke. However, the DES does not cover medicines management, which is part of the quality framework, and the QOF does not address minor surgery.

Box 4: Quality and Outcomes Framework (QOF)		
	Total points	%
Secondary Prevention in Coronary Heart Disease	121	11.5%
Stroke or transient ischaemic attacks	31	3.0%
Hypertension	105	10.0%
Diabetes Mellitus (Diabetes)	99	9.4%
Chronic Obstructive Pulmonary Disease (COPD)	45	4.3%
Epilepsy	16	1.5%
Hypothyroidism	8	0.8%
Cancer	12	1.1%
Mental Health	41	3.9%
Asthma	72	6.9%
A. Records and information about patients	85	8.1%
B. Patient communication	8	0.8%
C. Education and training	29	2.8%
D. Practice Management	20	1.9%
E. Medicines Management	42	4.0%
Patient experience	100	9.5%
Additional Services ⁴⁰	36	3.4%
Holistic Care	100	9.5%
Quality Practice	30	2.9%
Access Bonus	50	4.8%
TOTAL	1050	100%

Source: (Department of Health, 2004i)

Before the beginning of each financial year, practices agree with PCTs the level of quality points that they aspire to achieve by the end of that financial year and receive aspiration payments. During the financial year practices and PCTs will review the level of achievement under the quality framework. After the end of the financial year, practices will receive their achievement payment, reflecting their full achievement, minus the aspiration payment that they have already received. In the first year, practices will receive an average of £75 (€108)⁴¹ per quality point, however this will be adjusted for list size to reflect workload. There will be a further workload adjustment to take account of disease prevalence (Department of Health, 2004j).

The Personal Medical Services (PMS) contract is the local alternative to the new national General Medical Services (GMS) contract.⁴² Whereas the GMS contract is national, but has local flexibilities, the PMS contract is a locally agreed contract between Primary Care Trusts and PMS providers, such as a GP practice, a salaried GP, nurses or other primary care professionals. PMS offers GPs a salaried contract and facilitates an enhanced role for nurses and when the new GMS contract was introduced in April 2004, over 40% of GPs in England were working under PMS contracts (Department of Health, 2004r). The services to be provided under PMS *must* be specified in the contract (S.I. 2004/627);(reg. 11(1)(a)) and these *may* include essential services (reg. 12(1)). Since PMS is a more flexible contract than

⁴⁰ i.e. cervical screening, child health surveillance, maternity services and contraceptive services

⁴¹ Currency conversions performed on 18/03/05 using rate of 1 GBP = 1.43978 EUR

⁴² <http://www.natpact.nhs.uk/primarycarecontracting/4.php>, accessed 08/03/05

GMS, PMS providers may elect to offer a less comprehensive service. In this case, the PCTs bear responsibility for arranging supplementary services from other providers (Newdick, 2005b);(page 90).

There are two other forms of primary care service provision. Firstly, Primary Care Trusts may provide services themselves, by employing their own staff or by independently contracting practitioners (Newdick, 2005b);(pp. 90 - 91). This is known as *Primary Care Trust Medical Services*, a form of service provision designed to enable PCTs to 'plug the gaps' in areas that do not attract GMS or PMS providers. Under these arrangements, it is the PCT – rather than the prescriber – given the duty to ensure that prescribing is in accordance with clinical need. Under *Alternative Provider Medical Services*, private companies, not-for-profit organisations, NHS Trusts and Foundation Trusts may provide primary care services (Newdick, 2005b);(page 91). The rationale behind this arrangement is to facilitate provision of services in areas of historic underprovision. Importantly, the contract must exclude the possibility of financial advantage for the provider. The duty to prescribe according to clinical need is preserved.

VI. *The Consultant*⁴³ *Contract*

Concern over the 'issue of consultant's private practice' underpinned the government's promise to 'fundamentally overhaul' the national consultant contract of 1948 (Department of Health, 2000b);(§§ 8.19, 8.20). The new consultant contract was implemented in April 2004 (Maynard and Bloor, 2004). It applies to all new practitioners, but is optional for existing consultants. Under the new contract, consultants agree a 'Job Plan' with their clinical manager, setting out the main responsibilities and duties. 'Programmed Activities' are agreed; these normally describe a four-hour period and include a number of duties. Each consultant will undertake up to ten Programmed Activities each week, although there is scope for flexibility (Department of Health, 2003b). On average, 7½ Programmed Activities will be devoted to direct clinical care: for example, clinical diagnostic work, predictable emergency duties, specialty ward rounds, outpatient clinics and clinically related administration.⁴⁴ This leave 2½ Programmed Activities for 'Supporting Professional Activities', such as training and research. Consultants are paid according to the number of Programmed Activities performed. Clearly, individual contracts will specify particular services that must be provided and these will vary. However, paragraph 6.1 of the contract specifies that Job Plans must contribute to 'the efficient and effective use of NHS resources'.

The NHS Plan had proposed that newly qualified consultants would have to work exclusively for seven years before undertaking any private work (Department of Health, 2000b);(§8.24). Even then, it was envisaged that the right to undertake private practice would depend on fulfilling job plan and NHS service requirements (ibid). However, these conditions form no part of the new contract. Instead, the contract specifies that privately paid work or fee-for-service work may not *generally* be undertaken during the time scheduled for Programmed Activities (Department of Health, 2003b);(§§ 11.2, 11.3). The code of conduct for private practice, which provides guidance on the contract, states that 'NHS consultants and NHS employing organisations should work on a partnership basis to prevent any conflict of interest between private practice and NHS work' and that 'the provision of services for private patients should not prejudice the interest of NHS patients or disrupt NHS services.'⁴⁵ Therefore, service provision agreed in the contract should not be jeopardised by consultants' private work.

VII. *Dental, Ophthalmic and Pharmacist contracts*

Unlike the regulations governing general medical practitioners, there is no statutory duty upon dental medical practitioners, or ophthalmic opticians to provide general dental or general ophthalmic services respectively. Instead, Primary Care Trusts are charged with the duty of ensuring that these services are provided (Secretary of State for Health, 2002);(reg. 3(1)). However, the 1977 NHS Act introduced the facility for payments to be made for the provision

⁴³ Consultants are medical or surgical specialists

⁴⁴ <http://www.modern.nhs.uk/consultants/briefing2003.ppt>, accessed 01/04/05

⁴⁵ <http://www.modern.nhs.uk/consultants/14680/Code.pdf>, accessed 08/03/05

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of dental and ophthalmic services, acting as an incentive to encourage potential providers and signal that these services are those patients should be able to access on the NHS.

For dental practitioners, the National Health Service (General Dental Services) Regulations 1992 (S.I. 1992/661) make provision for the Secretary of State for Health to determine dentists' remuneration, including a 'scale of fees' for providing particular services (reg. 19(1)). The Statement of Dental Remuneration⁴⁶ describes the services covered by these fees, including clinical examinations and treatment planning, diagnostic procedures, such as radiographic examinations, preventative, periodontal, conservation and surgical treatments and the supply of prostheses. Patients treated under general dental services make a co-payment for treatment, with the government reimbursing the balance. For example, the current fee for a clinical examination is £7.30 (€10.51),⁴¹ for which the patient is charged £5.84 (€8.41). School and college students and women who are pregnant or who have a child under 12 months of age are exempt from co-payment (Secretary of State for Health, 2005c, Secretary of State for Health, 2004b). Patients pay 80% of the charge, up to a maximum of £384 (€553).

Similarly, the National Health Service (General Ophthalmic Services) Regulations 1986 (S.I. 1986/975) make provision for opticians and ophthalmic medical practitioners and opticians to make charges for sight tests and for optical appliances (Secretary of State for Health, 1986);(reg. 10). Currently (April 2005), the charge for a sight test is £18.39 (€26.48).⁴⁷ For certain patients, vouchers are available that reduce or remove the charge incurred by patients. Eligibility for general ophthalmic services, outlined in the Health and Medicines Act 1988 (s. 13), is determined by age, disease (or risk of disease) or income (S.I. 2004/642).

The Optician Act of 1958 imposes a duty on opticians (and on general and ophthalmic medical practitioners) who test the sight of patients to examine the patient's eyes for any sign of abnormality, disease or injury (section 20B).⁴⁸ Findings must be reported to the patient and appropriate referrals made with patient consent (S.I. 1986/975; schedule 1, reg. 10(2)). For patients with diabetes or glaucoma, sight test results *must* be reported to the physician, irrespective of patient consent (reg. 10(3)).

The new pharmacist contract came into effect on 1st April 2005 (Secretary of State for Health, 2005b). Like the GMS contract for primary care doctors, the pharmacist regulations define 'essential services' (S.I. 2005/641);(regs. 3 to 21). These cover the dispensing services (including dispensing of electronic prescriptions), disposal services, the promotion of healthy lifestyles and support for self care. Other services include 'prescription linked intervention' (reg. 16), public health campaigns (reg. 17) and signposting (reg. 18). Under 'prescription linked intervention' services, the pharmacist has a duty to provide appropriate advice to patients who want to have their prescription dispensed and who appear to the pharmacist to be suffering from diabetes, to be at risk of coronary heart disease or who appear overweight or who appear to be smokers. The pharmacist must record any advice given in a way that will facilitate audit and follow up care. Where pharmacists are unable to provide advice, they must provide the patient with contact details of relevant health or social care services; this is known as 'signposting'. Pharmacists are also under a duty to co-operate with a request from PCTs to participate in up to six public health campaigns annually. 'Directed services', are additional pharmaceutical services provided in accordance with a direction under section 41A(a) of the 1977 NHS Act. These essentially cover the supply of 'proper and sufficient drugs and medicines and listed appliances'. Reimbursement for directed services is determined by the Secretary of State for Health (Secretary of State for Health, 2005a).

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http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Dental/DentalDocumentsArticle/fs/en?CONTENT_ID=4002195&chk=IPT5CG, accessed 28/02/04

⁴⁷ <http://www.dh.gov.uk/assetRoot/04/10/70/47/04107047.pdf>, accessed 25/04/05

⁴⁸ Section 20(B) was added to the Opticians Act 1958 by the Health and Medicines Act 1988 (c. 49)(section 14)

Key Health Care Policies

I. Patient Choice

Giving patients more choice about how, when and where they receive treatment is one cornerstone of the government's health strategy, as outlined in the NHS Plan. Another is giving members of the public more influence in shaping local care systems. As such, choice is a characteristic of the 'basket' of health care services.

Government research highlighted shorter waiting times as a top priority for patients. In response, the Public Service Agreements, which specify national goals within the public sector, outline waiting time targets for the NHS (HM Treasury, 2004):

- By the end of 2005, patients will wait a maximum of six months for inpatient admission and no more than 13 weeks for an outpatient appointment
- By the end of 2008 the maximum wait from general practitioner (GP) referral to hospital treatment will be 18 weeks

Targets that should already be achieved, and henceforth maintained, include the 4-hour maximum wait for emergency care⁴⁹ and the 24/48 target for accessing primary care.⁵⁰ From December 2005, 'choose and book' system should be operational, whereby patients needing elective treatment will be offered a choice of four or five hospitals once their GP has decided that a referral is required. These could be NHS Trusts, Foundation Trusts, treatment centres, private hospitals or practitioners with a special interest operating within primary care. As well as choosing *where* they go, patients should be able to choose *when*, thanks to a national electronic booking programme. Appointments can be made at the practice surgery, by calling a contact centre, online and eventually via digital television.

II. Payment by Results

'Payment by Results' is a case payments system, similar to many DRG (Diagnostic Related Group) payment mechanisms. First proposed in 2002, Payment by Results seeks to radically change the NHS funding mechanism and requires higher standards of financial management in Primary Care Trusts, NHS Trusts and Foundation Trusts (Department of Health, 2002b). It was introduced ostensibly as a means of delivering the NHS Plan, but Payment by Results could also stimulate non-price competition between the NHS and private sector, as tariffs include HRGs critical to waiting time targets (Street and AbdulHussain, 2004). The system offers major opportunities and incentives, but it also carries 'major risks, which if not well managed will lead to financial instability and service difficulties' (Audit Commission, 2004b).

Previously, funding of services was based mainly on block contracts between purchasers and providers, allowing local circumstances and marginal costs to be taken into account. 'Payment by Results' aims to facilitate and support NHS modernisation by paying hospitals for the work they do, rewarding efficiency and quality. It does this through a nationally fixed price or tariff for each procedure. Tariffs are classified by Health care Resource Group (HRG), defined by diagnosis and complexity, and are based on an average of all hospital costs for that procedure (known as 'reference costs'). Therefore, a procedure that can be offered as either a day case or inpatient case receives a single tariff, based on a weighted average of the day case and inpatient reference costs. Adjustments are made for wage and price inflation, as well as the impact of NICE and NSF guidance.

The Payment by Results system was first piloted in Foundation Trusts in April 2004 and covered all types of care. Tariffs are still evolving and are not yet fully formed. For the rest of the NHS, tariffs currently cover only elective care involving 48 HRGs (Street and AbdulHussain, 2004). Earlier plans to roll out tariffs to include non-elective and outpatient activity from April 2005 have been postponed, but the expectation remains that national tariff

⁴⁹ The 4-hour wait target is that patients should spend no more than 4 hours in an Accident and Emergency hospital department from arrival to admission, transfer or discharge

⁵⁰ The 24/48 target is that patients will be able to see a general practitioner within two working days or another primary care professional within one working day.

prices will apply to 90% of specialities by 2008/09.⁵¹ Local price negotiations will not take place for work covered by the tariff, except where service changes result in significant efficiency gains. Unavoidable regional cost differences are to be funded nationally. All contracts between PCTs and NHS Trusts will be 'cost and volume' with payment linked directly to the actual work done. Therefore, if an operation is cancelled and the hospital fails to offer a new appointment date, the money allocated for that operation would move to a new provider.⁵² Increases or reductions in activity will be charged at full rather than marginal cost.

A recent study of Foundation Trusts' activity under the Payment by Results system showed that there had been an increase in short-stay inpatient admissions through Accident and Emergency, compared with non-Foundation NHS Trusts (Rogers *et al.*, 2005). This raises the concern that providers may reclassify patients into more complex (and more expensive) HRGs in order to increase revenue.

The tariff system of payments for hospital services, whilst in no way guaranteeing provision, place an NHS price on particular services, thereby 'suggesting' a basket of services.

Services or Technologies Excluded from NHS Provision

Historically, treatments appear to have been excluded on the basis of culture or tradition. However, NHS Trust purchasing contracts made explicit exclusions at the local level, covering various forms of cosmetic surgery (tattoo removal, buttock lift, breast augmentation and procedures for pinning back ears). The reversal of sterilisation and of vasectomy also featured frequently in the contracts, as did in vitro fertilisation (Klein, 1997).

Case law has established that NHS organisations may not operate a 'blanket ban' on service provision, with the possible exception of treatments where "the clinical evidence of its inefficacy is overwhelming" (Newdick, 2005b);(pp 105-107). *R v NW Lancashire Health Authority, ex p A, D and G* made it illegal for health authorities to impose a blanket ban on services they consider to be 'low priorities'. Instead, they must adopt a fair and consistent policy for decision-making that adequately assesses exceptional cases by considering each request for treatment on its individual merits (Newdick, 2005b);(page 101). This means that there are few services that are explicitly excluded from all NHS patients; where exclusions exist, they are principally in the domains of medicines and screening.

The law imposes certain restrictions on general practitioners' (GPs) prescribing. Some drugs must not be prescribed at all on the NHS (the so-called 'black list'), whilst others may be prescribed only for 'specified patients and specified purposes' (the Selected List Scheme, or 'grey list'). These restrictions are outlined under section 28U of the Health and Social Care (Community Health and Standards) Act 2003 and specified under S.I. 2004/629. The black list includes thousands of items, covering a bizarre range of products from 4711 Cologne, Barkoff Cough Syrup, Cow & Gate Premium Baby Food, Elizabeth Arden Flawless Finish, Gale's Honey, Heinz Weight Watcher Baked Beans and Ribena! The 'grey list' in S.I. 2004/629 is much shorter and contains products that can be prescribed on the NHS only under specific circumstances; drugs for the treatment of erectile dysfunction are an example of those included on the grey list and two influenza drugs have recently been added (S.I. 2004/3215). However, 'black' or 'grey' listed products may still be prescribed privately (Secretary of State for Health, 2004a);(sch. 6, §42(2)).

Of the 88 NICE technology appraisals published to date (April 2005), only a few have received 'negative' decisions regarding NHS provision (Table 6). Still fewer of these appraisals have been entirely negative; for example, guidance No. 8 on hearing aids did not recommend digital aids but did encourage the NHS to make full use of the analogue aids available.

⁵¹ <http://www.dh.gov.uk/assetRoot/04/10/09/34/04100934.pdf>, accessed 15/04/05

⁵² http://news.bbc.co.uk/1/hi/uk_politics/4323749.stm, accessed 07/03/05

Table 6: 'Negative' Decisions from NICE technology appraisals, April 2005

Topic (Guidance No)	Drug/Device	Summary of guidance
Wisdom teeth - removal (No. 1)	Procedure	The practice of prophylactic removal of pathology-free impacted third molars should be discontinued in the NHS.
Hearing disability - new advances in hearing aid technology (No. 8)	Device	Nationwide introduction of digital hearing aids not recommended. Guidance withdrawn three years later following successful pilots and the subsequent widespread availability of digital aids.
Colorectal cancer - laparoscopic surgery (No. 17)	Procedure	Open rather than laparoscopic surgery should be used for the treatment of colorectal cancer and laparoscopic surgery should be restricted to randomised controlled clinical trials.
Colorectal cancer (advanced) - irinotecan, oxaliplatin & raltitrexed (No. 33)	Drug	Irinotecan or oxaliplatin in combination with 5-fluorouracil and folinic acid not recommended for routine first-line therapy for advanced colorectal cancer. Raltitrexed not recommended for the treatment of advanced colorectal cancer.
Lymphoma (follicular non-Hodgkin's) - rituximab (No. 37)	Drug	Permitted only for last-line treatment, in the context of a prospective case series.
Ultrasound locating devices for placing central venous catheters (No. 49)	Device	Audio-guided Doppler ultrasound is not recommended for inserting central venous catheters.
Flu - zanamivir (review), amantadine and oseltamivir (No. 58)	Drug	Amantadine is not recommended for the treatment (No. 58) or prevention (No. 67) of influenza.
Flu - (prophylaxis) amantadine and oseltamivir (No. 67) (review)		
ECT - Electroconvulsive therapy (No. 59)	Procedure	ECT is not recommended as a maintenance therapy in depressive illness. ⁵³
Rheumatoid arthritis - anakinra (No. 72)	Drug	Anakinra not recommended for the treatment of rheumatoid arthritis, except in the context of a controlled, long-term clinical study.

There are also some examples of technologies that received negative decisions on their first appraisal, but subsequent appraisals that considered additional evidence produced positive decisions. Examples of these were NICE appraisals of laparoscopic surgery for hernia (Appraisal Nos. 18 and 83), zanamivir for influenza⁵⁴ (Appraisal Nos. 15 and 58) and of liquid-based cytology for cervical cancer (Appraisal Nos. 5 and 69). However, most of the 'positive' appraisals include caveats on eligibility (i.e. negative decisions for certain patient groups, tantamount to a partial rejection). For instance, Appraisal No. 23 (Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer)) endorses the use of the drug on the NHS for patients who have failed first-line chemotherapy treatment with other agents, but excludes NHS provision for patients who have failed primary therapy (surgery and/or radiotherapy), except in the context of a randomised controlled trial against a standard-treatment comparator.⁵⁵ Equally, Appraisal No. 57 (Guidance on the use of continuous subcutaneous insulin infusion for diabetes) recommended the use of insulin pumps for patients with type I, but not for type II, diabetes.⁵⁶ Lastly, NICE has recently proposed – a final decision is awaited – that the NHS ceases to fund anti-dementia drugs, although patients already receiving treatment will continue to do so. This has precipitated hostile responses from the press and from patient groups (Kmietowicz, 2005).

Some dental treatments are not available on the NHS. For example, the most recent Statement of Dental Remuneration implicitly excludes cosmetic treatments such as teeth whitening (Secretary of State for Health, 2005c).

The UK National Screening Committee, an advisory body to UK Health Ministers, has recommended that certain types of screening be excluded from current public NHS provision. The Committee uses research evidence to identify programmes that do more good than harm, then makes policy recommendations about those programmes that will do more good than harm at a reasonable cost (UK National Screening Committee, 2004). Current exclusions include but are not limited to:

- Screening for prostate cancer for any age or gender group⁷⁰

⁵³ However, short-term ECT is available on the NHS for a narrowly-defined group of patients

⁵⁴ However, S.I.2004/3215 added zanamivir to the Selected List Scheme ('grey list' drugs)

⁵⁵ <http://www.nice.org.uk/page.aspx?o=16566>, accessed 15/03/05

⁵⁶ http://www.nice.org.uk/pdf/57_Insulin_pumps_fullguidance.pdf, accessed 15/03/05

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- For pregnant women, routine tests are not recommended for Chlamydia,⁵⁷ cystic fibrosis and hepatitis C, diabetes
- For newborn babies, routine tests are not recommended for Duchenne muscular dystrophy, neonatal alloimmune thrombocytopenia and neuroblastoma
- For children, screening is not recommended for autism, hypertension, speech and language delay, iron deficiency anaemia, lead poisoning, obesity and vision defects
- For adults, screening is not recommended for Alzheimer's disease; anal, bladder, lung, oral, ovarian cancers; depression; hepatitis C; and osteoporosis

Other exclusions from NHS provision include single vaccines for measles, mumps and rubella (Montgomery, 2003);(page 34) and the smallpox vaccine.⁵⁸

⁵⁷

http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SexualHealth/SexualHealthGeneralInformation/SexualHealthGeneralArticle/fs/en?CONTENT_ID=4084098&chk=CSLxsK, accessed 02/03/05

⁵⁸ <http://www.homeoffice.gov.uk/terrorism/threat/faq/>, accessed 17/03/05

II. Definitions of entitlements and benefits by sector

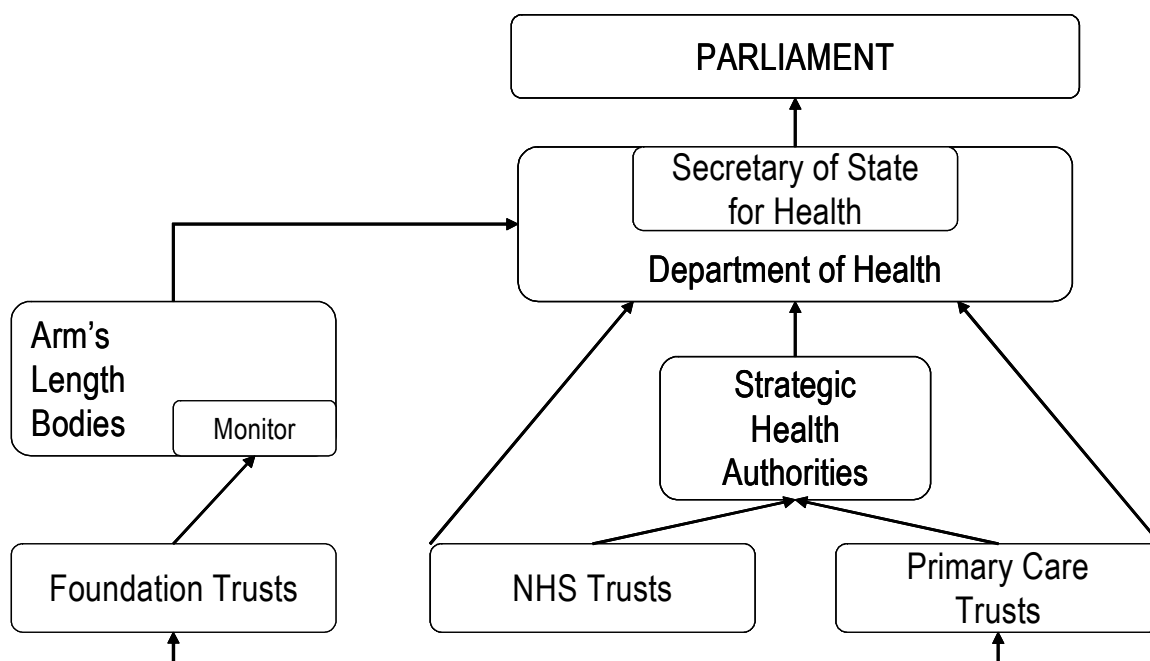
Under the OECD classification of personal health care services and goods, there are six categories of service known as the International Classification for Health Accounts (ICHA). NHS provision covers all six categories. A description of the benefits that are provided within the English health care system is given below, covering the legislative and regulatory frameworks and the role of central government and other actors. Further details are presented in the Appendix (Table 9).

All services are defined implicitly, in the sense that there are no positive lists of treatments to which patients are entitled. Although PCTs may interpret national policy differently, there is only one payer, the government, to whom this applies.

An overview of statutory accountability within the NHS is given in Figure 1. The duty placed on the Secretary of State for Health to promote a comprehensive health services has been delegated to Strategic Health Authorities, who may issue directions on behalf of the Secretary of State to both NHS Trusts and to PCTs. Foundation Trusts are not accountable to the Secretary of State for Health, but to the independent regulator, Monitor, who also carries a duty to promote a comprehensive health services.

PCTs are responsible for providing, or arranging the provision of services, stipulated under sections 3, 4 and 5 of the 1977 NHS Act. To do this, they must contract with NHS Trusts. However, these NHS contracts are not legally binding. In contrast, the contracts between Foundation Trusts and PCTs are legally binding. Section 26 of the 1999 Health Act placed duty on NHS organisations to co-operate with each other; the Health and Social Care (Community Health and Standards) Act 2003 extended this duty to explicitly include Foundation Trusts (Secretary of State for Health, 2003);(s. 29).

Figure 1: Statutory Accountability within the NHS, England 2005



HC1 Services of curative care

This includes care where the principal medical intent is to relieve symptoms or reduce severity or protect against exacerbation or complication of illness or injury. Care may be delivered in inpatient, day case or outpatient settings, including ambulatory care.

I. Summary of legal entitlement

The National Health Service Act 1946 (c. 81) and the National Health Service Act 1977 (c. 49) address the establishment and promotion of 'a comprehensive health service' and require the Secretary of State for Health (the 'Minister for Health' in the 1946 Act) 'to provide or secure the effective provision of services'. However, discretion is at the heart of these duties and the politician in charge of health care is entitled to take into account the resources available to him.

The 1977 NHS Act specifies that the Secretary of State for Health has a *duty* to provide 'to such extent as he considers necessary to meet all reasonable requirements' (Secretary of State for Health, 1977):

- Hospital accommodation (s. 3(1(a))), including high security psychiatric services (s. 4)
- Other accommodation necessary for the purpose of any other services required by the Act (s. 3(1(b)))
- Medical, dental and nursing services (s. 3(1(c)))
- Such other services as are required for the treatment of illness (s. 3(1(f)))

The 1977 Act defines 'medical' as including 'surgical' and 'illness as including a mental disorder and any injury or disability requiring medical or dental treatment or nursing (Secretary of State for Health, 1977);(s. 128(1)).

Facilities and services that the Secretary of State for Health has *powers* to provide 'as he considers appropriate' include facilities for the care of persons suffering from illness (s. 3(1(e))). Following secondary legislation,⁵ the responsibility for providing these services has passed to the local health authorities, which in the current organisational structure are known as Primary Care Trusts (PCTs).

The 1977 NHS Act places a duty on Primary Care Trusts ('Area Health Authorities', in the original terminology) to provide general medical services (s. 29), general dental services (s. 35), pharmaceutical services (s. 41) and general ophthalmic services (s. 38).

As well as the primary legislation embodied by the 1946 and 1977 Acts, there is also a considerable quantity of relevant secondary legislation. Most recently, the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291) provide details of the terms of service for general practitioners (GPs) (Secretary of State for Health, 2004a). This Statutory Instrument legislates for the provision of curative (and other) services by GP practices. For example, 'essential services' must be provided, covering emergency treatment and treatment for patients with chronic, terminal and self-limiting disease (reg. 15(3)(5)(6)(8)). However, the provision of other services is incentivised under the voluntary Quality and Outcomes Framework (Department of Health, 2004). For example, payments are awarded to practices for ensuring that a given proportion of patients with coronary heart disease receive regular blood pressure checks and lipid tests.

In case law, *R v NW Lancashire Health Authority, ex p A, D and G* examined the case of three applicants suffering from 'gender identity dysphoria' (Newdick, 2005b);(page 101). The Health Authority had identified this illness as amongst the bottom 10% in terms of need⁵⁹ and so transsexual surgery would be provided only in cases of 'overriding clinical need'. The court acknowledged the need for priority setting in which issues of effectiveness, the seriousness of the condition and cost were taken into account. However, the court found that the Health Authority had in practice adopted a 'blanket ban' and recommended the authorities introduced a fair and consistent policy for decision-making that adequately assessed exceptional cases by considering each request for treatment on its individual merits. The case therefore made it illegal for Health Authorities to impose a blanket ban on gender reassignment surgery and other 'low priority' services.

⁵⁹ Also included in the bottom 10% were cosmetic surgery, reversal of sterilisation, correction of myopia and most 'alternative' medicines.

II. Regulatory regimes / Quasi law

The Department of Health issues National Service Frameworks (NSFs) that cover some services of curative care. For example, the NSF for renal diseases aims to increase fairness of access and improve choice and quality in dialysis, which comes under the ICHA classification of 'day cases of curative care' (Department of Health, 2004h). The ICHA category 'outpatient curative care' is addressed by the NSF for Mental Health, which sets the standard that patients should have 24-hour access to an approved duty doctor and to an approved social worker (Department of Health, 1999).

Clinical guidelines by the National Institute for Clinical Excellence (NICE) cover the management of various conditions and may include recommendations for curative treatment. For example, the NICE guidelines on Dyspepsia (CG18) and Post Myocardial Infarction (an 'inherited' guideline that predated the establishment of NICE) recommend lifestyle advice and appropriate medication as secondary preventative measures. The guideline on Head Injury (CG4) specifies treatment pathways covering emergency, outpatient and inpatient care.

III. Role of central government and other actors

Under current legislation, the two types of NHS body primarily responsible for the provision of curative services are Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs). The Secretary of State for Health can delegate his functions directly to Primary Care Trusts (Secretary of State for Health, 2002);(reg. 3(2(a))). SHAs have to support PCTs and manage their performance in exercising these functions (reg. 3(2(b))). Previous legislation places PCTs and SHAs under a duty to co-operate (Secretary of State for Health, 1999a);(s. 26). Therefore, the provision of curative services, such as hospital accommodation and other facilities or treatments for the care of the sick, is now the responsibility of PCTs.

Some functions may not be exercised by PCTs, but these do not include any curative services. However, the provision of high security psychiatric services by PCTs were conditional upon joint provision with an NHS Trust and with the approval of the Secretary of State (Secretary of State for Health, 2002);(reg. 8(1)(a))).

The functions of NHS Trusts are outlined in the National Health Service and Community Care Act (Secretary of State for Health, 1990) and the Health Act 1999 (Secretary of State for Health, 1999a). The 1990 Act describes NHS Trusts' broad *financial* functions (duties and powers), which are to be carried out 'effectively, efficiently and economically' (sch. 2, 6(1)) and makes provision for secondary legislation to establish and specify particular functions for individual NHS Trusts (sch. 2, 1-4). The 1990 Act confers considerable freedoms on NHS Trusts, summarised in the 'power to do anything which appears to it to be necessary or expedient for the purpose of or in connection with the discharge of its functions'. This includes particular power to acquire and dispose of land and other property, to enter into such contracts as seem to the Trust to be appropriate, to accept gifts of money, land or other property, including money, land or other property to be held on Trust, either for the general or any specific purposes of the NHS Trust or for all or any purposes relating to the health service; and to employ staff on such terms as the Trust thinks fit (Secretary of State for Health, 1990);(sch. 2, 16). Primary Care Trusts enter contracts ('NHS contracts, or local service agreements) with NHS Trusts to provide services, but NHS Trusts are accountable to the Secretary of State. This creates a tension, because PCTs are bound to arrange the provision of services, but have no statutory power over providers.

NHS Foundation Trusts were established by the Health and Social Care (Community Health and Standards) Act 2003 (Secretary of State for Health, 2003). The principal purpose of the trust is the provision of goods and services for the purposes of the health service in England (s. 14(2)), and, like NHS Trusts, Foundation Trusts must execute their duties 'effectively, efficiently and economically' (s. 39). However, Foundation Trusts are not subject to the direction of the Secretary of State, but to the direction of an independent regulator (s. 3);(see Monitor). They have greater financial and management freedoms than NHS Trusts, including freedoms to retain surpluses and to invest in delivery of new services (s. 14(3)). These 'new services' are not specified, but must support the principal purpose. As Foundation Trusts are not subject to direction by the Secretary of State, the contracts they enter with PCTs are legal contracts – enforceable by law – rather than NHS contracts.

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The 1999 Health Act amends the legislative framework for NHS Trusts, extending the powers of the Secretary of State to direct all their functions. Subject to Secretary of State approval, the 1999 Act also gave NHS Trusts powers to provide high security psychiatric services (Secretary of State for Health, 1999a);(s. 41).

The National Institute for Clinical Excellence (NICE) produces guidance on the use of some curative technologies. For example, guidance on interventional procedures is given by an independent body asked by NICE to examine the evidence in terms of safety and efficacy; it does not examine clinical or cost effectiveness.¹⁷ NICE also oversees the production of clinical guidelines that may include recommendations about curative care services (e.g. Head Injury, CG4) and undertakes appraisals of new and existing technologies, such as the removal of wisdom teeth (Appraisal No. 1).

PCTs are under a statutory duty to provide general medical, ophthalmic and dental services by negotiating contracts with doctors, optometrists and dentists (Secretary of State for Health, 2002, Secretary of State for Health, 2003);(ss.170,174). Although general medical practitioners (GPs) are bound by the conditions of their contract to provide general (medical) services or personal (medical) services, the same is not true of optometrists and dentists. There is currently a shortage of dentists providing general dental services for the NHS. Private practice has grown rapidly since 1992, following a 7% cut in fees that was intended to counteract previous overpayments (Department of Health, 2004k, Oliver, 2002). The lack of access to NHS dentists has triggered an urgent review of the regulations governing the dentists' terms of service and a recent cash injection of over £350 (€504)⁴¹ million, aimed at increasing the number of dentists working for the NHS (Department of Health, 2004n).

Perhaps the most important actors in determining whether patients can access curative services are the physicians. Their terms of service grant them considerable freedom to deliver services as they perceive appropriate to meet clinical need. Although specific services are required from general practitioners who work under the GMS contract (see The General Medical Services (GMS) Contract), the decision of who to treat, when and how are at a GP's discretion (Newdick, 2005b);(page 22).

HC2 Services of rehabilitative care

This includes medical and paramedical services delivered to patients during an episode of rehabilitative care, where the emphasis is on improving functional levels.

I. Summary of legal entitlement

The 1977 NHS Act specifies that the Secretary of State for Health has a *duty* to provide 'to such extent as he considers necessary to meet all reasonable requirements' and 'as he considers are appropriate' (Secretary of State for Health, 1977):

- facilities for 'the aftercare of persons who have suffered from illness' (s. 3(1(e)))

Following secondary legislation,⁵ the responsibility for providing these services has passed to the local health authorities, which in the current organisational structure are known as PCTs. The definition of 'illness' includes mental disorder as defined in the 1983 Mental Health Act and any disability or injury that requires medical or dental treatment or nursing (Montgomery, 2003);(page 54). In the 1977 Act, the word 'hospital' specifically includes 'any institution for the reception and treatment of persons during convalescence or persons requiring medical rehabilitation' (Secretary of State for Health, 1977);(s. 128(1)). Under section 117 of the Mental Health Act 1983, health authorities and local social services have a legal duty to provide after-care for patients who have been detained in accordance with the Act, but who have left hospital. There is no power to charge for section 117 after-care.

II. Regulatory regimes / Quasi law

Some services of rehabilitation are specified in National Service Frameworks (Table 3). The NHS Plan announced new intermediate care services for older people and those with mental health problems (Department of Health, 2000b). The NSF for Older People reflects this in standard 3:

Older people will have access to a new range of intermediate care services at home or in designated care settings, to promote their independence by providing enhanced services from the NHS and councils to prevent unnecessary hospital admission and effective rehabilitation services to enable early discharge from hospital and to prevent premature or unnecessary admission to long-term residential care (Department of Health, 2001b).

The NSF for Mental Health includes requirement that all users with severe mental health needing rehabilitation have timely access to an appropriate hospital bed or alternative bed or 'mental health place' (standard 5)(Department of Health, 1999). The NSF on Coronary Heart Disease specifies services that should be available for cardiac rehabilitation, including lifestyle advice, effective medicines, exercise sessions and referral to specialist cardiac, behavioural (e.g. exercise, smoking cessation) or psychological services as clinically indicated ;(standard 12). Health care organisations' compliance with NSFs is now monitored by the Healthcare Commission, as part of the new assessment framework (see The Healthcare Commission).

Clinical guidelines may also act as quasi law, specifying service patterns and treatment pathways that represent best clinical practice. For example, the Royal College of Physicians has produced a guideline on 'Stroke in Childhood', covering diagnosis, management and rehabilitation.⁶⁰ The NICE clinical guideline on Supportive and palliative care services for adults with cancer states that those responsible for providing care should 'ensure that patients' needs for rehabilitation are recognised and that comprehensive rehabilitation services and suitable equipment are available to patients in all care locations' (CSG, Recommendation 16).⁶⁰

III. Role of central government and other actors

See entry under HC2.

HC3 Services of long-term nursing care

This includes ongoing health and nursing care for patients who need assistance on a continuing basis due to chronic impairments and reduced independence and activities of daily living. The category includes respite care, hospice care, palliative care, but excludes social care.

In 1942, the Beveridge Report recommended separating responsibility for provision of health care from social care, a distinction reflected in the 1946 NHS Act and the 1948 National Assistance Act. Whilst the 1946 Act gave the Secretary of State for Health duties over the provision of (generally free) health care services, the 1948 Act gave local social services authorities duties over social care provision, for which patients may be charged (Newdick, 2005b);(page 114). Since then, there has been an ongoing debate over the boundaries between social and health care, essentially trying to decide the circumstances governing when a 'patient' becomes a 'client' or 'resident'. Services of long-term nursing care are one area where this debate is evident. Legislation has been introduced to attempt to clarify the responsibilities of health and social care organisations.

I. Summary of legal entitlement

Under the 1977 NHS Act, the Secretary of State has a duty promote a comprehensive health service (1(1)) and to provide nursing care (Secretary of State for Health, 1977);(s. 3(1(c))). However, the courts have determined that this duty is not absolute:

' a comprehensive service may never, for human, financial and other resource reasons, be achievable.... ...The [1977 NHS] Act does not impose an absolute duty to provide the specified services. The Secretary of State is entitled to have regard to the resources made available to him under current government economic policy (*R v. North & East Devon Health Authority, ex p. Coughlan* 16th July 1999).

⁶⁰ <http://www.nice.org.uk/pdf/csgspexecsummary.pdf>, accessed 17/03/05

The case of *Ex parte Coughlan* concerned a woman who had been in a serious car accident and was severely disabled and living in a care home. The Health Authority proposed to move the residents of a care home into a different home, thereby transferring caring responsibility for the residents from the NHS to the local social services authority. This meant that residents could now be charged for their care depending on their income and other forms of wealth (Newdick, 2005b);(pp. 95 ff). The Court of Appeal found this proposal to be illegal: the NHS was entitled, under the 1977 Act, to decide which long-term residents were eligible for NHS care, but was not empowered to transfer its duties across to local authorities. However, the Court of Appeal also noted that 'the Secretary can exclude some nursing services from the services provided by the NHS. Such services can then be provided as a social or care service, rather than a health service' (cited in (Newdick, 2005b); page 117).

The National Health Service Act 1977 gives power to local social services authorities to provide residential and nursing accommodation for those in need of care and attention, where these are not otherwise available and need exists by reason of age, illness, or disability (Secretary of State for Health, 1977);(s. 21). A 1993 Local Authority Circular (LAC 93/10) converts this power into a duty for some client groups, such as persons who are suffering from, or who have suffered from a mental disorder. However, this duty is upon local social service authorities, rather than upon health authorities. Local authorities can either provide the services themselves or purchase them from other providers on behalf of clients (Montgomery, 2003);(page 86).

Whether patients are eligible for *institutional* nursing care, such as that provided in a nursing home, is determined by section 47 of the NHS and Community Care Act 1990 (Secretary of State for Health, 1990). The 1990 Act outlines whether individuals have care needs that call for the provision of community care services; and if so, whether individuals have need for care and attention that is not otherwise available to them under section 21 of the National Assistance Act 1948 (Department of Health, 2003d). Definitions of 'nursing care' are given in the Health and Social Care Act 2001 (Secretary of State for Health, 2001a);(s.49(2)):

..."nursing care by a registered nurse" means any services provided by a registered nurse and involving-

- (a) the provision of care, or
 - (b) the planning, supervision or delegation of the provision of care,
- other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a registered nurse.

There is a separate system for assessing eligibility for another type of long-term NHS care, known as NHS continuing care. This type of care is for people who do not need care in an acute hospital, but who require a high degree of ongoing health care.⁶¹ Most people who qualify for NHS continuing care are elderly (House of Commons Health Committee, 2005).

On 1 October 2001, the commitment set out in the NHS Plan to bring in free care nursing care from a registered nurse for those people paying all the costs of their care – so-called 'self-funders' – was realised, affecting approximately 42,000 individuals (Secretary of State for Health, 2001a);(s. 49), (Department of Health, 2001a). Further changes were introduced in April 2003 by directions from the Secretary of State for Health. The funding of the nursing care was transferred from local authorities to the NHS, affecting around 88,000 residents of care homes who were receiving care from a registered nurse (Department of Health, 2003d).

II. Regulatory regimes / Quasi law

The report by the Royal Commission on Long Term Care was published in 1999 (Sutherland, 1999). One of the main recommendations was that the costs of long-term care should be divided between living costs, housing costs and personal care. Personal care should be available after assessment, according to need and paid for from general taxation: the rest

⁶¹ Also known as 'continuing NHS care' (see S.I. 2003/2277)

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should be subject to a co-payment according to means. The Commission defined 'personal care' as the care needs, often intimate, which give rise to the major additional costs of frailty or disability associated with old age. It was to include support from skilled professionals.

The government's response to the Commission's recommendations was set out in the NHS Plan (2000) (Department of Health, 2000b). Acknowledging that the existing system of funding was 'confusing, complicated and anomalous' (§15.7), the government proposed:

- To change the way in which the value of an individual's own home was taken into account when assessing patient payments for nursing or residential homes
- To change the law to reduce 'unacceptable variations in charges for home care'
- To make nursing care provided in nursing homes fully funded by the NHS
- To invest a further £360 million to help people meet the costs of their residential and nursing home care.

The government therefore declined to implement fund *personal care*, but took steps to ensure the NHS would fund all *nursing care*. The NHS now aspires to meet the costs of registered nurse time spent on providing, delegating or supervising care in all settings, addressing the anomaly of people having to pay for care in a nursing home that would be provided free in residential accommodation or at home.⁶²

The National Service Frameworks affect the provision of long-term nursing care insofar as they recommend particular services. For example, the NSF for Mental Health addresses the care of working aged adults with severe mental illness, and highlights the need for 'community mental health teams' to include nursing care. These teams provide care for people in their own homes and work across the primary/secondary care interface (Department of Health, 1999). The NSF states that home-based services "should be available at weekends and in evenings as well as during office hours" (Department of Health, 1999);(page 132). The NSFs for Children also contains recommendations about long-term nursing care (Table 3).

III. Role of central government and other actors

The central government has been instrumental in ushering in changes to the way long-term nursing care is funded. Under the 2001 Health and Social Care Act, local authorities were divested of their powers to provide or arrange nursing care (Department of Health, 2001a). Instead, the powers and duties to provide nursing care given to the NHS under the 1977 NHS Act were revitalised. In practice, this means that Primary Care Trusts are now responsible for funding long-term nursing care (Secretary of State for Health, 2002). However, many agencies, including the NHS, specialist hospices, the voluntary sector and social care and education services (for children), currently provide palliative care services that may involve long term nursing care (Department of Health, 2004g).

The Department of Health worked with the Royal College of Nursing and other key stakeholders to develop an assessment tool for determining who is eligible for free nursing care provided by a registered nurse.

For all adults who were moving into a nursing home, a 'Registered Nursing Contribution to Care' (RNCC) framework was developed (Department of Health, 2001c). Informed by a Single Assessment Process⁶³ of a person's needs and the resulting Care Plan, the RNCC framework was intended to standardise the assessment process, whilst enabling registered nursing input to be determined on an individual basis (Department of Health, 2001c);(page 12):

The tool should not be used in a mechanistic or bureaucratic manner, but should reflect the principles that underpin the entire assessment process, i.e. it focuses

⁶²http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/IntegratedCare/NHSFundedNursingCare/NHSFundedNursingCareArticle/fs/en?CONTENT_ID=4070915&chk=IK/bDy, accessed 24/01/05

⁶³ The Single Assessment Process was introduced in 2000 as part of the NSF for Older People

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on the person as an individual, looks at their needs in the round, follows a standardised approach, and is outcome-centred.

The Single Assessment Process collects information about the person's self-reported problems and expectations, clinical background, disease prevention (e.g. whether they take regular exercise), personal care needs, sensory loss and mental health. In addition, information about the person's social network, personal safety and environment is documented. The RNCC framework builds on this information. The nurse assessor begins by checking that all opportunities for rehabilitation have been taken (i.e. a nursing home is the appropriate setting) and then allocates the person to one of three bands:

- *High*: for people with complex/ unstable / unpredictable needs involving frequent registered nursing intervention over 24 hours
- *Medium*: for people with stable / predictable needs involving daily intervention by a registered nurse, but who may need access to a nurse at any time
- *Low*: for people who have chosen to go into a nursing home although care could be provided in another setting

The bands correspond to different funding levels (in April 2005 these were £40 (€58), £80 (€115) and £129 (€186) ⁴¹ per week) (Department of Health, 2004e). The nurse assessor also provides a rationale for the decision and sets a date for review. Where a person's needs are significantly greater than those covered by the high band, the assessor redirects the person to be assessed for *NHS continuing care* so that they can receive regular and specialist supervision.

Eligibility criteria for NHS continuing care were drawn up in 1995. These criteria were based on the complexity, intensity or unpredictability of a person's health care needs, where the person required regular supervision was by a hospital physician, specialist nurse or other member of the NHS multidisciplinary team (House of Commons Health Committee, 2005). Within this framework, each Health Authority was to develop local policies and eligibility criteria (at the time of writing this report (April 2005), this responsibility falls to Strategic Health Authorities). This meant that central guidance on the criteria for eligibility for funding was interpreted locally. Whilst nursing staff carried out the initial assessment of a patient's eligibility, in practice, the final decision was often made by a panel. This panel met infrequently and had responsibility for a large caseload.

If eligible for NHS continuing health care, a patient's care should be fully funded by the NHS, however the lack of uniformity in the eligibility criteria has meant that access to funding is extremely fragmented, and has resulted in many patients being wrongly denied funding. In 2003 the Health Service Ombudsman's report into NHS funding for long term care found that many people had been wrongly denied funding (Abraham, 2003); (§33):

Given the freedom to decide their own eligibility criteria within the loose national framework, health authorities have adopted a range of approaches, both to the criteria themselves and to procedures and guidance underlying them. Looking at most of the sets of criteria we have seen, it is fairly easy to identify a group of people who would definitely not be eligible for funding, and a very small group of people who definitely would be eligible (many of whom would not be well enough to leave hospital). But there is a large number of people in the group in between.

It recommended that Strategic Health Authorities in England conduct a review of cases and reimburse those who had been unfairly treated. By the end of March 2004 over 6,000 cases had been reviewed resulting in more than £180 (€259)⁴¹ million in compensation. Although the problem has been highlighted, it has yet to be resolved with many people still not receiving the funding to which they are entitled.

Consequently, there was a clear need for centrally supported learning and development materials for all staff involved in decisions regarding the provision of funding and subsequent

service provision, for patients who require NHS continuing health care. In December 2004, the Department of Health announced its intention to introduce national eligibility criteria for continuing health care funding. In 2005, the Department of Health is working with Strategic Health Authorities and other stakeholders to draft new criteria to assess patients eligible for fully funded NHS continuing care (Department of Health, 2004e). At the time of writing (April 2005), the new criteria have not been published.

HC4 Ancillary services to health care

This includes a variety of services performed by paramedical or medical technical personnel, such as laboratory services, diagnostic imaging and patient transportation.

I. Summary of legal entitlement

The 1946 NHS Act (c. 81) gives the Secretary of State ('Minister for Health') powers – but does not place a duty on him – to 'provide a bacteriological service, which may include the provision of laboratories, for the control of the spread of infectious diseases' (s. 17). The 1977 NHS Act (c. 49) the wording is similar, but refers to a 'microbiological service' (Secretary of State for Health, 1977);(s. 2(c)).

Under section 27 of the 1946 Act, local health authorities (PCTs in today's NHS) are given the duty of providing ambulance services 'for the conveyance of persons suffering from illness or mental defectiveness or expectant or nursing mothers from places in their area to places in or outside their area.' In the 1977 Act, the responsibility for ambulance services was transferred to the Secretary of State for Health (Secretary of State for Health, 1977);(s. 3(c)), but was subsequently passed back to the local health authorities, which in the current organisational structure are known as PCTs.⁵

In the 1946 Act, there is an *implicit* duty upon the Secretary of State to provide hospital-based diagnostic or other paramedical services, which could be considered to come under the category 'other services required at or for the purposes of hospitals' (s. 3(b)). The 1977 NHS Act is more explicit, stating that the Secretary of State has a duty to provide 'such other services as are required for the diagnosis and treatment of illness' (s. 3(f)). Although this is still subject to the proviso 'to such an extent as he considers necessary to meet all reasonable requirements', these services are no longer limited to hospital-based care and the diagnostic services are explicitly mentioned. As medical, dental, nursing services are mentioned separately (s. 3(c)), section 3(f) effectively enables the Secretary of State to provide paramedical services. Once again, these duties are now transferred to local health authorities, Primary Care Trusts.⁵

II. Regulatory regimes / Quasi law

There appears to be little quasi-law relating to ancillary services. The National Service Framework for Coronary Heart Disease recommends the use of defibrillators for people with symptoms of a possible heart attack:

People with symptoms of a possible heart attack should receive help from an individual equipped with and appropriately trained in the use of a defibrillator within 8 minutes of calling for help, to maximise the benefits of resuscitation should it be necessary (Department of Health, 2000a);(standard 5).

This implies that ambulance staff, appropriately trained to use defibrillators, should be available. The NSF also recommends that complex electrophysiology, including implantable defibrillators should be available for the investigation and management of patients with complex arrhythmia (Department of Health, 2000a);(§3.32).

NICE technology appraisals have covered some relevant topics (e.g. ultrasound locating devices for placing central venous catheters, Appraisal No. 49).

III. Role of central government and other actors

All the duties upon the Secretary of State to provide, or to ensure the provision of, ancillary services have been delegated to Primary Care Trusts. However, NHS Trusts and Foundation

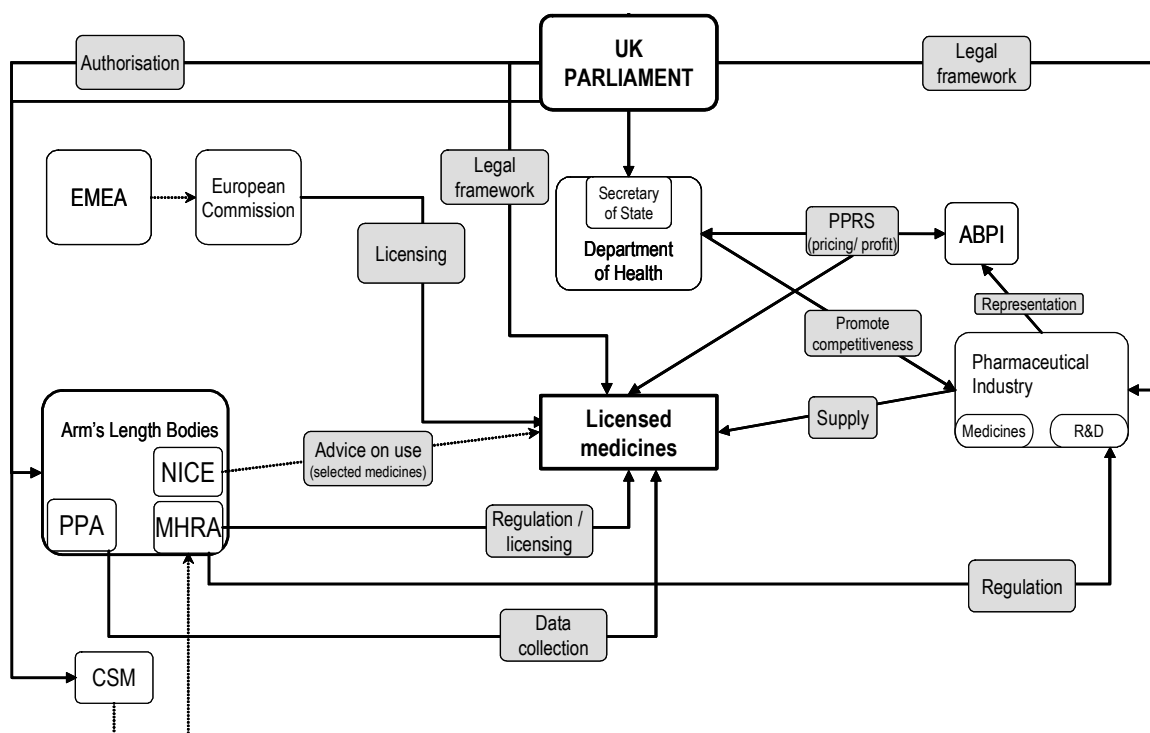
Trusts are responsible for purchasing decisions on diagnostic equipment. NHS and Foundation Trusts are largely self-governing, but Strategic Health Authorities are responsible for the performance management of NHS Trusts and may direct them to provide particular services. Ambulance Trusts are other actors in the provision of ancillary services. There are 33 Ambulance Trusts in England, responsible for the provision of emergency access to health care, although they also provide non-emergency patient transport.

NICE and the Department of Health, through National Service Frameworks, may also help to determine which ancillary services are provided. The Healthcare Commission reinforces these messages through its regulation of NHS bodies (see The Healthcare Commission).

HC5 Medical goods dispensed to out-patients

This includes services of pharmacies, opticians and chemists, including mail, telephone and web shopping. Prescribed and over-the-counter medicines are included in this category. Therapeutic appliances and devices such as prosthetics, wheelchairs, hearing aids and glasses are also included. An overview of the regulatory structure for medicines dispensed to outpatients is given in Figure 2. Advisory relationships are denoted by a dotted line.

Figure 2: Regulatory Structure of Outpatient Medicines: England, April 2005



I. Summary of legal entitlement

The 1968 Medicines Act regulates the development, manufacturing, distribution and importation of medicines (Montgomery, 2003);(page 215). The 1968 Act established a statutory advisory body called the Medicines Commission to give advice on matters specified in the Act relating to medicinal products.⁶⁴ In granting a product licence, the licensing agency (currently the MHRA) must take account of safety, quality and efficacy (s. 19), but may not consider relative effectiveness or price (s. 20 (3)). Licences cannot be refused without consulting the Committee of Safety of Medicines or the Medicines Commission (Montgomery, 2003);(page 217). The Act classifies medicines as prescription only (s. 58),⁶⁵ 'pharmacy only' medicines that can only be supplied by a pharmacist, but can be dispensed without a prescription (s. 60); and general sales list medicines (s. 51).

⁶⁴ <http://www.mca.gov.uk/> accessed 18/10/04

⁶⁵ The Prescription Only Medicines (Human Use) Order 1997 (S.I. 1997/1830) brought classification into line with EC marketing authorisations.

Exemptions are listed in section 12 and include the manufacture and supply of unlicensed relevant medicinal products for individual patients ('specials'); the importation and supply of unlicensed relevant medicinal products for individual patients; and the herbal remedies exemption (Montgomery, 2003);(page 220). Section 12(1) allows a person to make, sell and supply a herbal remedy during the course of their business provided the remedy is manufactured or assembled on the premises and that it is supplied as a consequence of a consultation between the person and their patient. Section 12(2) allows the manufacture, sale or supply of herbal remedies, under specific conditions.

European Community (EC) legislation now takes precedence over the Medicines Act, its Instruments and Orders, which are amended from time to time to align with new EC requirements. 1995 saw a new European system for authorising medicines, enabling a medicine that is marketed in one EC country to be made available in other EC countries, subject to the same conditions. There are two procedures: the 'centralised' procedure and the mutual recognition (decentralised) procedure.

The centralised procedure is compulsory for biotechnologies and optional for other innovative new medicines. Applications are submitted to the European Medicines Agency (EMA) to be evaluated by the Committee for Proprietary Medicinal Products (CPMP). The CPMP contracts out assessments to experts in one of the member states ('rapporteur'), taking the applicant's preference into account. The EMA then makes a decision (opinion), which it forwards to the European Commission. The Commission then makes the final decision about marketing authorisation. An EC authorisation is valid throughout the EU and is usually given for five years.⁶⁶ The mutual recognition procedure is based on the existing multi-state procedure: EU Member States recognise each other's national marketing authorisations.

However, prescribing by general practitioners in England is governed by two factors. Firstly, doctors have a legal duty to prescribe according to perceived medical need (Secretary of State for Health, 2004a);(sch. 6, §39(1)):

... a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form or a repeatable prescription and such a prescription form or repeatable prescription shall not be used in any other circumstances.

These regulations apply to general medical services, but identical regulations exist for personal medical services (S.I. 2004/627; sch. 5, §38(1)). Secondly, the law imposes certain restrictions on doctors' prescribing. Some drugs must not be prescribed under the contract (the so-called 'black list'), or may be prescribed only for 'specified patients and specified purposes' (the Selected List Scheme or 'grey list'). These restrictions are outlined under section 28U of the Health and Social Care (Community Health and Standards) Act 2003 (Secretary of State for Health, 2003). The right to prescribe does not operate on the basis of a specific list of treatments available on the NHS: there is no 'white list' (Newdick, 2005b);(page 113). However, prescribers may, subject to certain conditions, 'prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement' (Secretary of State for Health, 2004a);(sch. 6, §42(2)).

Charges for drugs, medicines or appliances were introduced in the 1977 NHS Act (s. 77) and are updated regularly. Charges for dental and optical appliances (s. 78) and for dental treatment (s. 79) were also introduced (Secretary of State for Health, 1977).

Optometrists and dentists already have limited prescribing rights: optometrists may prescribe, under certain circumstances, drugs listed by the General Optical Council (Opticians Act 1989);(s. 31(1(c))), whilst dentists may also supply listed drugs under their terms of service (Secretary of State for Health, 1992a);(sch. 1(22)). Furthermore, under 'patient group directions', nurses or pharmacists may 'prescribe' drugs from a limited formulary; nurses are more likely to have prescribing rights than are pharmacists (Cooke *et al.*, 2005). The Crown Report reviewed the options widening for prescribing rights to clinicians other than doctors (Crown, 1999). Subsequently, the Health and Social Care Act 2001 amended the 1968

⁶⁶ <http://www.mca.gov.uk/ourwork/licensingmeds/european/europelic.htm> accessed 18/10/04

Medicines Act by extending prescribing rights to a range of health care practitioners, including osteopaths, chiropractors and pharmacists (Secretary of State for Health, 2001a);(s. 63).

II. Regulatory regimes / Quasi law

The control of medicines by officials in the United Kingdom dates back to the reign of King Henry VIII (1491-1547), when the Royal College of Physicians of London had the power to inspect apothecaries' products in the London area and destroy defective stock.⁶⁷ The first 'London Pharmacopoeia', was published in 1618. The need for further legislation was under discussion in the early 1960s when the thalidomide tragedy occurred. In June 1963 the Committee on Safety of Drugs (CSD) was set up. The CSD consisted of a group of independent experts in the fields of medicine, pharmacy, toxicology, pharmacology and statistics. The pharmaceutical industry agreed to submit data on their products to the CSD and abide by its advice. The CSD advice was concerned with the 'reasonable safety for its intended purpose'. Evaluation of efficacy alone was not included. The CSD became the core of the Committee for Safety of Medicines (CSM) in 1971, which continues to advise on licensing issues and monitors the safety of licensed medicines (pharmacovigilance).⁶⁷

For new medicines and devices, guidance from the National Institute for Clinical Excellence (NICE) is key in determining whether technologies are available on the NHS and, if so, to which patient groups and under what circumstances. Although there is a statutory obligation on PCTs to fund NICE appraisal guidance, the implementation of that guidance remains at the discretion of the treating clinician (see NICE guidance). Nevertheless, the so-called 'negative' appraisal decisions evoke strong feelings amongst the public who perceive their rights to access effective medicines to be threatened by NICE decisions (Table 6). For example, NICE has recently proposed – a final decision is awaited – that the NHS ceases to fund anti-dementia drugs, although patients already receiving treatment will continue to do so. This has precipitated hostile responses from the press and from patient groups (Kmietowicz, 2005).

Older (post-patent) medicines are not generally subject to NICE scrutiny, except where they are compared with newer technologies in the assessment process. However, NICE makes no recommendation on the use of these older technologies and cannot, for example, advise disinvestment (Maynard *et al.*, 2004). The availability of existing drugs is determined by whether they are listed in the British National Formulary, although there is no 'white list' that specifies drugs to which patients are entitled (Newdick, 2005b);(page 113).

The provision of some medicines is incentivised under the Quality and Outcomes Framework, which is part of the new contract for general practitioners (Department of Health, 2004). For example, payments are awarded to practices for ensuring that a given proportion of patients with coronary heart disease receive appropriate medication, such as beta-blockers, ACE inhibitors and anti-platelet therapy.

III. Role of central government and other actors

Subject to Parliamentary approval, the Secretary of State for Health is responsible for secondary legislation that dictates the contents of the 'black' and 'grey' lists of medicines that are, respectively, not available at all on the NHS or that are available only to very narrowly defined patient groups and under special circumstances. The black list dates back to 1985, when the government issued a list of preparations not to be prescribed on the NHS, comprising of products that were duplications, or were too expensive, not necessary, or that had no medicinal use.⁶⁸ The grey list contains far fewer products than the 'black list', comprising chiefly of products for which there are budgetary or clinical safety concerns (Newdick, 2005b);(page 113). The Prescription Pricing Authority produces a monthly 'Drug Tariff' that lists generic drugs, those available for nurse or dentist prescribing and specifies which appliances and devices may be prescribed on the NHS (see Prescribing Prescription Authority).

⁶⁷ <http://www.mca.gov.uk/>, accessed 18/10/04

⁶⁸ http://www.ppa.org.uk/ppa/drug_tariff_guidance.htm#link9, accessed 21/03/05

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The Medicines and Health care products Regulatory Agency (MHRA) authorises (licenses) medicines and devices on behalf of the government (veterinary products are outside its remit). However, it may not take account of relative efficacy or price, but bases its decision upon safety, quality and efficacy (Medicines Act 1968; ss. 19, 20). Licences cannot be refused without consulting the Committee of Safety of Medicines (Montgomery, 2003);(page 217). Appeals can be made to the Medicines Commission.

The National Institute for Clinical Excellence also plays an important role in deciding upon which (generally) new technologies – drugs and devices – are available for use by the NHS, as part of its technology appraisals. NICE clinical guidelines, though without any mandatory backing, may also recommend the use of particular drugs and devices, such as appropriate use of endoscopy and proton pump inhibitors for dyspepsia (CG17). National Service Frameworks may also contain recommendations for the use of particular drugs, such as statins for coronary heart disease (Department of Health, 2000a).

NHS Trusts also produce their own local formularies and often have committees to assess the impact of new medicines on their own budget as well as on primary care (Cooke et al., 2005).

Whilst the MHRA authorises the medicines and devices that are available within the UK, the Pharmaceutical Price Regulation Scheme (PPRS) deals with the pricing of pharmaceuticals. Although not strictly a regulatory body, the PPRS has an important, albeit unintentional, impact: by influencing the price of pharmaceuticals, the PPRS affects NICE technology appraisals, which consider the costs and benefits of pharmaceuticals in order to make recommendations for their use within the NHS (see NICE guidance).

HC6 Prevention and public health services

This includes maternal and child health, family planning services, school health services, the prevention of communicable and non-communicable diseases, occupational health care and 'all other miscellaneous public health services'.

I. Summary of legal entitlement

The Ministry of Health Act 1919 gave the Secretary of State responsibility for 'securing preparation, carrying out and co-ordination of measures conducive to public health'. This duty has now passed to Primary Care Trusts (Secretary of State for Health, 2002);(sch. 1).

The 1946 NHS Act gave local health authorities the *duty* to provide care of mothers and young children, including dental care for children under 5 (ss. 22-23). In the 1977 NHS Act, this responsibility was transferred to the Secretary of State, who was no longer *bound* to provide the services, but was instead given *powers* to provide 'as he considers appropriate ... facilities for the care of expectant and nursing mothers and young children' (s. 3(d)). However, additional duties given to the Secretary of State under the 1977 NHS Act includes:

- Medical and dental inspection at appropriate intervals of pupils in schools maintained by the local education authorities (s. 5(1)(a))
- Family planning advice (s. 5(1)(b))

The 1977 NHS Act specifies that the Secretary of State for Health has a duty to provide these 'to such extent as he considers necessary to meet all reasonable requirements' (Secretary of State for Health, 1977)(s. 3(1)). The 1988 Education Reform Act widened the responsibility to include grant maintained schools. Provision of medical and dental inspections in schools is now again the responsibility of local health authorities, Primary Care Trusts (Secretary of State for Health, 2002).

The 1946 NHS Act gave local health authorities the duty to provide for the prevention of illness (s. 28). The responsibility for providing facilities for preventative services transferred to the Secretary of State for Health under the 1977 NHS Act (s. 3(e)), and was tempered by the clause 'as he considers appropriate as part of the health service'. Therefore, no preventative

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services are mandated by the 1977 Act, rather the Secretary of State has a duty to make appropriate provision of *facilities* to accommodate such services.

The Public Health (Control of Diseases) Act 1984 consolidated earlier legislation to give 'drastic powers of entry and investigation', including compulsory medical examination where notifiable disease⁶⁹ is suspected (Montgomery, 2003);(page 31). Local authorities are the only bodies with powers over public health, but in practice local authorities usually appoint employees of the health authority to exercise these powers (page 27). The 1984 Act may breach of human rights law (page 34).

Other relevant legislation includes the Food Safety Act 1990; the Environmental Protection Act 1990; the Health and Safety at Work Act 1974; the Human Rights Act 1998; the Health & Social Care Act 2001;and the Health Protection Act 2004.

The Public Health (Infectious Diseases) Regulations 1988 provide for free vaccination and immunisation, but only for those who want it (Montgomery, 2003);(page 33).

The recent GMS contract has placed a greater emphasis on preventative care, obliging primary care physicians to offer (Secretary of State for Health, 2004a):

- Annual health checks to registered patients aged over 75
- A health check to newly registered patients
- A health check to existing patients on the register not seen within three years

Payments are also made for giving smoking cessation advice to patients with diabetes, COPD, coronary heart disease, asthma, hypertension and stroke sufferers. The Quality and Outcomes Framework (QOF) also offers payments for primary care physicians to comply with local guidelines on antenatal screening and child development (Department of Health, 2004). There are also incentives in the QOF to offer vaccinations and immunisations to older people and to those 'at risk' of influenza (Department of Health, 2004).

The 2005 Pharmacist contract places a duty on pharmacists to participate in up to six public health campaigns annually, when requested to do so by their local PCT (Secretary of State for Health, 2005b);(reg. 17) and to promote healthy lifestyles (reg. 15).

II. Regulatory regimes / Quasi law

The NHS Plan included a commitment to improving the prevention of ill health and providing screening programmes when they are effective (Department of Health, 2000b).

The Healthcare Commission is concerned with both treatment and prevention, such as the quality of services that help people to stop smoking. Therefore, inspections also look at how well health services protect and improve public health.²⁴

Some NICE clinical guidelines include screening advice, such as the guidelines on familial breast cancer (CG14), the management of type II diabetes (which addresses screening for diabetic retinopathy - a guideline NICE has inherited), or the Routine Antenatal Care guideline (CG6). A number of tests may be offered to pregnant women, including tests for HIV, Down's syndrome, rubella immunity and spina bifida (UK National Screening Committee, 2004).

National service frameworks may include advice on screening for particular disease areas, such as coronary heart disease (Department of Health, 2000a) or cancer (Calman and The Expert Advisory Group On Cancer, 1995). The recent NSF for Children, Young People And Maternity also deals with preventative services over the course of childhood, including immunisations; screening for hearing and for diseases such as hepatitis B, sickle cell disease

⁶⁹ Notifiable diseases include amongst others AIDS, meningitis, diphtheria, dysentery, typhoid fever, rabies, tuberculosis and malaria

and cystic fibrosis; developmental and needs assessments; and health promotion. Other NSFs also address public health issues (Table 3).

The NHS Plan announced an expansion of cancer screening (Department of Health, 2000b). The NHS Breast Screening Programme provides free breast screening every three years for all women in the UK aged 50 to 64, although this is being extended to include women aged up to 70 (Department of Health, 2001b). There is a national programme for cervical cancer screening⁷⁰ and all women between the ages of 25 and 64 are entitled to a test at three or five yearly intervals depending on their age and the results of previous tests. There are plans to introduce a national screening programme for colorectal cancer in April 2006 (Department of Health, 2004p). There are no plans to introduce prostate cancer screening unless evidence shows that the benefits outweigh the risks.

Although there is no statutory obligation on PCTs to provide sexual health services, nor a National Service Framework on the topic, the Minister for Public Health has recently said that 'there will be more fierce forms of monitoring and performance management ... there will be a demand that [PCTs] deliver on sexual health' (Martin, 2005). The National Strategy for Sexual Health included the recommendation that opportunistic screening for Chlamydia infection is offered to women and men under 25 years of age,⁵⁷ and this is set to become a national programme by 2007 (Department of Health, 2004b).

Prior to legislation, the government can introduce statements of its policy in a White Paper. The recent White Paper 'Choosing Health' listed some 'overarching priorities' (Department of Health, 2004b):

- Reducing the numbers of people who smoke
- Reducing obesity and improving diet and nutrition
- Increasing exercise
- Encouraging and supporting sensible drinking
- Improving sexual health
- Improving mental health

The 2004 White Paper contained a wide range of proposals to promote public health that recognised that co-ordinated multi-sector approaches – by the NHS, industry, communities, schools and workplaces – were needed to tackle public health issues. Proposals included: that all enclosed public places and workplaces be smoke free by 2008; access to high-quality NHS Stop Smoking Services in all areas; an expansion of school nursing services by 2010; access to an NHS-accredited health trainer; and accessible sexual health services delivered in both community and hospital settings (Department of Health, 2004b).

III. Role of central government and other actors

The government establishes policy through its White Papers, Health Service Circulars and secondary legislation. Primary legislation requires Parliamentary approval, so other political parties influence whether or not legislation is enacted.

Strategic Health Authorities (SHAs) are alone responsible for requesting water fluoridation (Secretary of State for Health, 2002);(reg. 5). Together with PCTs, Strategic Health Authorities are responsible for 'securing preparation, carrying out and co-ordination of measures conducive to public health', including the provisions of care for mothers and young children, family planning advice, the medical inspection and treatment of pupils, their dental inspection and treatment and their education in dental health (Secretary of State for Health, 2002);(reg. 3(2)).

Primary Care Trusts may prepare and implement population screening programmes, provided that the appropriate Strategic Health Authority approves the arrangements for providing or

⁷⁰ <http://cancerscreening.org.uk>, accessed 02/03/05

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securing the provision of such services (Secretary of State for Health, 2002);(reg. 8(4(b))). The same condition applies also to PCT provision of services for sexual transmitted diseases (reg. 8(5)).

The National Institute for Clinical Excellence is an NHS body that commissions (i.e. pays other bodies to produce) clinical guidelines. These may include Royal Colleges, academic institutions and patient groups (see above, NICE guidance).

The Department of Health produces National Service Frameworks (NSFs) that address a range of public health issues (Table 3). For example, the NSF for Mental Health includes the target of reducing the death rate from suicide and undetermined injury by at least a fifth by 2010 (Department of Health, 1999);(standard 7).

The Medicines and Health care products Regulatory Agency (MHRA) oversees the safety of medicines and devices and thereby promotes public health. The Patient Safety Agency, the General Medical Council and the Council for the Regulation of Health Care Professionals are all charged with the duty of promoting patient safety.

The UK National Screening Committee is an advisory body to UK Health Ministers. The Committee makes recommendations that certain types of screening be included or excluded from current public NHS provision. The Committee is informed by research evidence on effectiveness, risk (or safety) and cost (UK National Screening Committee, 2004).

Until April 2005, the Health Development Agency was the national authority for providing evidence-based guidance on public health issues to improve people's health and reduce health inequalities.⁷¹ Thus, the Agency evaluated public health interventions, mirroring the appraisals National Institute for Clinical Excellence (NICE) conducts of health technologies. The rationalisation of Arms Length Bodies saw the two institutions joining forces, with NICE taking over the functions of the Health Development Agency (Table 5). Concerns have been expressed about the appropriateness of applying methodologies, designed to appraise to health technologies, to public health interventions (Kelly *et al.*, 2003). NICE has launched a public consultation on how public health guidance will be produced; the intention is to review both effectiveness and cost-effectiveness evidence, using methods that 'build upon existing NICE methods, with appropriate modifications to reflect the evidence available in public health.'⁷¹

⁷¹ <http://www.nice.org.uk/page.aspx?o=248187>, accessed 25/04/05

III. Description of benefit catalogues, involved actors and decision criteria

There are few specific and detailed benefit documents relating to the NHS. These can be grouped into professional contracts; NICE technology appraisal guidance; device lists; fee schedules; waiting time guarantees; and screening programmes.

Professional contracts

An important example of a detailed benefit document is the 2004 contract for general medical services (GMS) (Secretary of State for Health, 2004a). The Statutory Instrument defines 'essential services' that a general medical practitioner must provide under the GMS contract (Box 3). Essential services are described in S.I. 2004/291);(reg. 15(3)(5)(6)(8) and documented in Table 7.

Table 7: Eligibility for primary care 'essential services' under the 2004 GMS Contract

Type of Essential Service	Eligibility for Treatment
Immediate and necessary emergency treatment	'Any person to whom the contractor has been requested to provide treatment ... at any place in its practice area' (reg.15(6))
Management of terminal illness	Registered patients and temporary residents
Treatment of conditions from which recovery is generally expected	Registered patients and temporary residents
Treatment of chronic disease	Registered patients and temporary residents
Advice in connection with the patient's health, including relevant health promotion advice;	Registered patients and temporary residents
Referral of the patient for other services under the [1977] Act	Registered patients and temporary residents
Home visits	Where contractor considers it inappropriate, because of a patient's medical condition, for the patient to attend the practice premises
Annual health checks	Patients aged over 75
Health checks	Patients not seen within three years Newly registered patients

Source: (Department of Health, 2003c)

Essential services must be provided between the 'core hours' of 8:00 and 18:30 hours, and this includes 'immediate and necessary emergency treatment'. However, general medical practitioners operating under the Personal Medical Services (PMS) contract are not bound to provide essential services. Therefore, patients registered with these practices employing PMS GPs have no entitlement to essential services.

The new contract for pharmacists came into effect on 1st April 2005 (Secretary of State for Health, 2005b). Like the GMS contract for primary care doctors, the pharmacist regulations define 'essential services' (S.I. 2005/641);(regs. 3 to 21). These cover the dispensing services (including dispensing of electronic prescriptions), disposal services, the promotion of healthy lifestyles and support for self care. Other services include 'prescription linked intervention' (reg. 16), public health campaigns (reg. 17) and signposting (reg. 18). Under 'prescription linked intervention' services, the pharmacist has a duty to provide appropriate advice to patients who want to have their prescription dispensed and who appear to the pharmacist to be suffering from diabetes, to be at risk of coronary heart disease or who appear overweight or who appear to be smokers. The pharmacist must record any advice given in a way that will facilitate audit and follow up care. Where pharmacists are unable to provide advice, they must provide the patient with contact details of relevant health or social care services; this is known as 'signposting'. Pharmacists are also under a duty to co-operate with a request from PCTs to participate in up to six public health campaigns annually (Secretary of State for Health, 2005b).

NICE technology appraisal guidance

Another example of a 'benefit catalogue' is the technology appraisal guidance produced by NICE. NICE guidance generally acts like a quasi law, but one aspect of guidance on

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technology appraisals is supported by statute: if NICE produces guidance on a technology appraisal to say that a new medicine should be made available to NHS patients who meet particular criteria, then the NHS bodies responsible for providing funding for that treatment are under a statutory obligation to ensure that the technology:

...is, from a date not later than three months from the date of that Technology Appraisal Guidance, normally available (Secretary of State for Health, 2001b).

The Department of Health sometimes extends this deadline (e.g. Appraisal No. 68 on macular degeneration). However, although funding bodies are obliged by law to ensure there are adequate resources to *facilitate* the implementation of NICE guidance, the guidance is not binding on individual clinicians, who must assess whether the technology is appropriate for patients under their care (Newdick, 2005a).

Technology appraisals include guidance on the use of new and existing treatments within the NHS. To date (April 2005), 88 technology appraisals have been published. Technologies may include:

- a. Medicines
- b. Medical devices (e.g. inhalers)
- c. Diagnostic techniques (e.g. cervical cytology)
- d. Surgical procedures (e.g. use of coronary artery stents)
- e. Health promotion activities (e.g. ways of helping people with diabetes manage their condition)

The NICE Appraisal Committee is an independent advisory body constituted of individuals drawn from a range of professional backgrounds. The Committee considers the evidence from an academic assessment group and from company submissions. Clinical specialists and 'expert patients' are also present to give their views, though are asked to leave when the Committee discusses the Appraisal Consultation Document. This Document then goes out to consultation. The Final Appraisal Determination is then developed, approved by the NICE Guidance Executive put out again for consultation. Following an appeal process, the guidance is published (National Institute for Clinical Excellence, 2004). All guidance is reviewed at regular intervals and recommendations reconsidered in the light of any new evidence. It should be noted that the overwhelming majority of technologies used in the NHS are *not* the subject of recommendations by the NICE Appraisal Committee.

Device lists

Although there is no comprehensive 'positive list' for pharmaceuticals, there is such a list of appliances available in primary care. The National Health Service (Pharmaceutical Services) Regulations 1992 (reg. 18) provides that the Secretary of State shall compile and publish a statement, referred to as the Drug Tariff, which shall include, among other things, the list of appliances and chemical reagents approved by the Secretary of State for the supply to persons under Section 41 of the NHS Act 1977.⁷² The Secretary of State authorises the Prescription Pricing Authority (PPA) to deal with applications on his behalf. This list - Part IX of the Drug Tariff - is of the appliances and chemical reagents which general practitioners are able to prescribe on the NHS. The four sections covered are dressings, bandages and certain other appliances; incontinence appliances; stoma appliances; and chemical reagents. The Drug Tariff is updated monthly. To be included in the list, appliances must be safe and of good quality; appropriate for primary care prescribing (including nurse prescribing, if applicable); and cost effective.⁷² Safety and quality are determined in accordance with EC directives, such that any product bearing a CE mark is deemed to be acceptable. Appropriateness for GP or nurse prescribing is determined by factors such as whether community use is appropriate, whether the product could be loaned (instead of prescribed) and whether self-administration is likely. Depending on whether similar products (or alternative regimens) have been listed before, the PPA judges cost effectiveness by absolute (and relative) costs and absolute (and relative) effectiveness. Manufacturers may be asked to submit evidence to support their application – particularly if similar products have not been

⁷² http://www.ppa.org.uk/ppa/drug_tariff_part_ix_2004a.pdf, accessed 25/04/05

listed before, or if the price requested is higher than that of existing alternatives – and may appeal in the event of a negative listing decision.

Fee schedules

Where fee schedules exist for NHS care, patient 'entitlement' to services might be inferred. For example, most patients receiving NHS dental services make co-payments in line with a Statement of Dental Remuneration; the government pays the remainder of the dental fee. This *suggests* that these services are those that the government endorses as those that, in some sense, should be provided.

For dental practitioners, the National Health Service (General Dental Services) Regulations 1992 (S.I. 1992/661) make provision for the Secretary of State for Health to determine dentists' remuneration, including a 'scale of fees' for providing particular services (reg. 19(1)). The Statement of Dental Remuneration⁴⁶ (SDR) is a document that describes over 400 services covered by the fees, including clinical examinations and treatment planning, diagnostic procedures, such as radiographic examinations, preventative, periodontal, conservation and surgical treatments and the supply of prostheses. The Statement of Dental Remuneration is updated at least annually; the current (April 2005) SDR is Amendment 93. Patients treated under general dental services make a co-payment for treatment, with the government reimbursing the balance. For example, the current (April 2005) fee for a clinical examination is £7.31 (€10.51),⁴¹ for which the patient is charged £5.84 (€8.41). School and college students and women who are pregnant or who have a child under 12 months of age are exempt from co-payment (Secretary of State for Health, 2005c). Patients pay 80% of the charge, up to a maximum of £384 (€553). The Doctors and Dentists Review Body reviews existing fee scales and makes recommendations regarding uplift. The Department of Health then considers these recommendations and the Chief Dental Officer for England notifies SHAs, PCTs, NHS Trusts and all general dental practitioners of the updated fee scales.⁷³

Similarly, the National Health Service (General Ophthalmic Services) Regulations 1986 (S.I. 1986/975) make provision for opticians and ophthalmic medical practitioners and opticians to make charges for sight tests and for optical appliances (Secretary of State for Health, 1986). Currently, the charge for a sight test is £18.39 (€26.48).⁴¹ Charges are determined by the Secretary of State in consultation with professional bodies, updated at least annually and amended by Statutory Instrument.⁴⁷ For certain patients, vouchers are available that reduce or remove the charge incurred by patients. Eligibility for general ophthalmic services, outlined in the Health and Medicines Act 1988 (s. 13), is determined by age, disease (or risk of disease) or income. Voucher values are updated at least annually by secondary legislation (S.I. 2005/483).

Equally, the new national tariff system of payments for hospital services, whilst in no way guaranteeing provision, 'suggests' services that should be accessible on the NHS. The national tariff system provides a national price schedule for patient services, classified by Health care Resource Group (HRG). A range of clinical procedures, treatments and diagnoses are covered. Tariffs are derived⁷⁵ from Reference Costs, which contain details of unit cost, length of stay and activity levels for a wide range of hospital services, enabling those providing and purchasing services to review and examine comparative costs.⁷⁶ The tariff system is 'spell-based', meaning that each tariff covers an entire spell of hospital care from admission to discharge for individual patients. This contrasts with Reference Costs, which are based on Finished Consultant Episodes (FCE); there may be multiple FCEs in one 'spell'. For each provider, the tariff is adjusted by a Market Forces Factor to take account of the unavoidable costs faced in different geographic areas. Table 8 shows the 48 HRGs covered by the 'payment by results' tariff system for elective inpatient care for 2004/05; these are unchanged for 2005/06.

⁷³ <http://www.dh.gov.uk/assetRoot/04/10/69/32/04106932.pdf>, accessed 25/04/05

⁷⁵ An uplift is applied to Reference Costs to take account of changes in the underlying cost of delivering care in each HRG

⁷⁶ <http://www.dh.gov.uk/assetRoot/04/07/01/09/04070109.pdf>, accessed 25/04/05

Table 8: Admitted Patient Care: subset of 48 designated HRGs, England 2004/5

HRG	HRG name	Elective spell-based tariff (£)	Elective spell-based tariff (€) ⁴¹
B02	Phakoemulsification Cataract Extraction with Lens Implant	£786	€ 1,132
B03	Other Cataract Extraction with Lens Implant	£876	€ 1,261
E03	Cardiac Valve Procedures	£10,199	€ 14,684
E04	Coronary Bypass	£8,080	€ 11,633
E13	Cardiac Catheterisation with Complications	£866	€ 1,247
E14	Cardiac Catheterisation without Complications	£895	€ 1,289
E15	Percutaneous Transluminal Coronary Angioplasty (PTCA)	£3,326	€ 4,789
E16	Other Percutaneous Cardiac Procedures	£2,470	€ 3,556
F71	Abdominal Hernia Procedures >69 or w cc	£2,304	€ 3,317
F72	Abdominal Hernia Procedures <70 w/o cc	£1,495	€ 2,152
F73	Inguinal Umbilical or Femoral Hernia Repairs >69 or w cc	£1,363	€ 1,962
F74	Inguinal Umbilical or Femoral Hernia Repairs <70 w/o cc	£1,016	€ 1,463
F75	Herniotomy Procedures	£956	€ 1,376
G11	Biliary Tract - Complex Procedures	£5,885	€ 8,473
G12	Biliary Tract - Very Major Procedures	£2,948	€ 4,244
G13	Biliary Tract - Major Procedures >69 or w cc	£2,509	€ 3,612
G14	Biliary Tract - Major Procedures <70 w/o cc	£1,857	€ 2,674
H01	Bilateral Px Hip Replacement	£7,319	€ 10,538
H02	Primary Hip Replacement	£5,568	€ 8,017
H03	Bilateral Px Knee Replacement	£7,776	€ 11,196
H04	Primary Knee Replacement	£6,182	€ 8,901
H09	Anterior Cruciate Ligament Reconstruct	£2,223	€ 3,201
H10	Arthroscopies	£1,033	€ 1,487
H11	Foot Procedures - Category 1	£1,025	€ 1,476
H12	Foot Procedures - Category 2	£1,392	€ 2,004
H13	Hand Procedures - Category 1	£752	€ 1,083
H14	Hand Procedures - Category 2	£1,360	€ 1,958
H15	Hand Procedures - Category 3	£1,746	€ 2,514
H16	Soft Tissue or Other Bone Procedures - Category 1 >69 or w cc	£1,275	€ 1,836
H17	Soft Tissue or Other Bone Procedures - Category 1 <70 w/o cc	£1,159	€ 1,669
H18	Soft Tissue or Other Bone Procedures - Category 2 >69 or w cc	£2,830	€ 4,075
H19	Soft Tissue or Other Bone Procedures - Category 2 <70 w/o cc	£1,934	€ 2,785
H20	Muscle, Tendon or Ligament Procedures - Category 1	£1,045	€ 1,505
H21	Muscle, Tendon or Ligament Procedures - Category 2	£1,925	€ 2,772
H22	Minor Procedures to the Musculoskeletal System	£632	€ 910
J02	Major Breast Surgery including Plastic Procedures >49 or w cc	£2,386	€ 3,435
J03	Major Breast Surgery including Plastic Procedures <50 w/o cc	£2,308	€ 3,323
J04	Intermediate Breast Surgery >49 or w cc	£1,083	€ 1,559
J05	Intermediate Breast Surgery <50 w/o cc	£898	€ 1,293
L27	Prostate Transurethral Resection Procedure >69 or w cc	£2,088	€ 3,006
L28	Prostate Transurethral Resection Procedure <70 w/o cc	£1,819	€ 2,619
L29	Prostate or Bladder Neck Intermediate Endoscopic Procedure (Male and Female)	£1,243	€ 1,790
L30	Prostate or Bladder Neck Minor Endoscopic Procedure (Male and Female)	£439	€ 632
M01	Lower Genital Tract Minor Procedures	£515	€ 741
M02	Lower Genital Tract Intermediate Procedures	£649	€ 934
M03	Lower Genital Tract Major Procedures	£2,098	€ 3,021
M04	Lower Genital Tract Complex Major Procedures	£5,681	€ 8,179
Q11	Varicose Vein Procedures	£1,063	€ 1,530

Source: <http://www.dh.gov.uk/assetRoot/04/07/01/21/04070121.xls>, accessed 25/04/05

Note: w cc / w/o cc: with /without comorbidity or complications

Waiting time guarantees

Government research highlighted shorter waiting times as a top priority for patients. In response, the Public Service Agreements, which specify national goals within the public sector, outline waiting time targets (or 'guarantees') for the NHS (HM Treasury, 2004):

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- By the end of 2005, patients will wait a maximum of six months for inpatient admission and no more than 13 weeks for an outpatient appointment
- By the end of 2008 the maximum wait from general practitioner (GP) referral to hospital treatment will be 18 weeks

Targets that should already be achieved, and henceforth maintained, include the 4-hour maximum wait for emergency care⁴⁹ and the 24/48 target for accessing primary care.⁵⁰ From December 2005, the 'choose and book' system should be operational, whereby patients needing elective treatment will be offered a choice of four or five hospitals once their GP has decided that a referral is required. These could be NHS Trusts, Foundation Trusts, treatment centres, private hospitals or practitioners with a special interest operating within primary care. As well as choosing *where* they go, patients should be able to choose *when*, thanks to a national electronic booking programme. Appointments can be made at the practice surgery, by calling a contact centre, online and eventually via digital television.

Screening programmes

There are currently two major screening programmes constituting a type of 'entitlement'. The NHS Plan announced an expansion of cancer screening (Department of Health, 2000b). The NHS Breast Screening Programme provides free breast screening every three years for all women in the UK aged 50 to 64, although this is being extended to include women aged up to 70 (Department of Health, 2001b). There is a national programme for cervical cancer screening⁷⁰ and all women between the ages of 25 and 64 are entitled to a test at three or five yearly intervals depending on their age and the results of previous tests. PCTs are encouraged to implement the cervical screening programme through the 2004/05 Star Ratings system. In addition, the Ratings support a government target that by 2006 a minimum of 80% of people with diabetes to be offered screening for the early detection (and treatment if needed) of diabetic retinopathy. This is to form part of a systematic programme that meets national standards, rising to 100% coverage of those at risk of retinopathy by the end of 2007. The 'balanced scorecard' of the 2004/05 Star Ratings contains an indicator to reflect this target.⁷⁷

⁷⁷ http://ratings.healthcarecommission.org.uk/Indicators_2005/Trust/Indicator/indicators.asp?trustType=4, accessed 25/04/05

IV. Discussion

The NHS is a highly developed, heavily regulated health care system in which the roles of actors are in general clearly defined. However, such clarity of roles does not necessarily lead to clarity about the services to which citizens are entitled. Indeed, the lack of explicitness in the definition of the health basket and the lack of a strong legal framework has led to a great deal of uncertainty.

The fact that the provision of a particular service stipulated in statute does not necessarily guarantee patient access. For example, the 1977 NHS Act obliges PCTs to provide, or to arrange for the provision of, general dental services (Secretary of State for Health, 1977);(s. 35). However, a large proportion of the population is unable to access general dental services within the NHS because of a shortage of dentists willing to provide these services for the NHS. The problem is due not a shortage of dentists, but rather to the rapid growth of private practice since 1992. This appears to have been precipitated by a 7% cut in fees, which was designed to redress the perceived excessive income (Department of Health, 2004k, Oliver, 2002). The problem of access to NHS dentists has triggered an urgent review of the regulations governing the dentists' terms of service and a recent cash injection of over £350 (€504)⁴¹ million, aimed at increasing the number of dentists working for the NHS (Department of Health, 2004n). The Healthcare Commission's Star Ratings contain a target to encourage PCTs to increase NHS dental activity. The British Dental Association is in negotiations with the Department of Health to develop a new contract which is expected in April 2006.⁷⁸

The National Service Framework for Coronary Heart Disease (CHD) takes account of the whole spectrum of CHD including diagnosis, presentation in primary care, secondary care, emergency admissions and transport issues (Department of Health, 2000a). Within that spectrum, 'a very small number of CHD service elements' were identified for 'definite commissioning' (i.e. 'purchasing and providing') under the arrangements for specialised services. These include:

- Cardiothoracic transplantation, for those with end-stage heart failure.
- Complex electrophysiology, including *implantable defibrillators*, for the investigation and management of patients with complex arrhythmia

Health care organisations' compliance with NSFs is now monitored by the Healthcare Commission, as part of the new assessment framework (see The Healthcare Commission). Furthermore, the National Institute for Clinical excellence has recommended the use of defibrillators in this patient group (NICE Appraisal No. 11). The NICE recommendation carries with it the statutory duty upon Primary Care Trusts to ensure funding is available to facilitate provision (see NICE guidance). However, a recent study of the use of implantable defibrillators in England found evidence that uptake was inequitable and that an inverse care law⁷⁹ appeared to be operating, despite recommendations in the NSF, supported by monitoring by the Healthcare Commission and reinforced further by NICE guidance (Parkes et al., 2005). Barriers to implementation of guidance reported in the study included identification and referral of eligible patients to implanting centres; staff capacity; and funding constraints.

A national evaluation NHS Trusts' or Primary Care Trusts' compliance with NICE guidance found variable implementation. Looking at rates of prescribing and use of procedures and medical devices, the time series analysis found that significantly increased prescribing of some taxanes for cancer and orlistat for obesity in line with guidance. Although prescribing of drugs for Alzheimer's disease and removal of wisdom teeth showed trends consistent with NICE guidance, the changes could not be reliably attributed to the guidance. Often, prescribing practice appeared to have little relation to detailed guidance. No change was apparent in the period following NICE guidance regarding the use of hearing aids, hip

⁷⁸ http://specialistdentalaccountants.co.uk/new_nhs_dental_contract_delayed.htm, accessed 25/04/05

⁷⁹ The inverse care law predicts that access to good quality services in more deprived areas will be less than that in affluent areas

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prostheses, implantable defibrillators, laparoscopic hernia repair, and laparoscopic colorectal cancer surgery (Sheldon *et al.*, 2004).

The evidence suggests that the English system is heading towards a more formal statement of benefits and entitlements. NICE guidance on new and existing technologies is in effect establishing a 'positive list' of technologies that the NHS should fund; National Service Frameworks describe interventions that should be implemented to achieve standards of care. The Payment by Results system will be rolled out to cover non-elective care and the Healthcare Commission will increasingly encourage NICE and NSF implementation, reinforcing standards through its new 'annual health check' (Healthcare Commission, 2005). In addition to the new legal contracts for general medical and general pharmaceutical services, legal contracts specifying service provision between NHS Trusts and PCTs will become more common as NHS Trusts take on Foundation Trust status. These factors together take the NHS forward towards defining a more explicit health basket for England.

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Appendix

Table 9: International Classification for Health Accounts (ICHA) categories: The National Health Service (England)

ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
HC.1 Services of curative care	HC.1.1 In-patient curative care		Yes	Acts: 1 NHS plan: 2 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1946 (c. 81) ss. 3(1)(a)-(c), 4 National Health Service Act 1977 (c. 49) ss. 3(1)(a)-(c), 4 <i>R v NW Lancashire Health Authority, ex p A, D and G</i> , made it illegal for health authorities to impose a blanket ban on gender reassignment surgery or any other 'low priority' areas ⁸¹	The NHS Plan (2000) announced guaranteed waiting times, refined by the Public Service Agreements, 2004 Some services covered by NSFs, e.g. NSF Paediatric Intensive Care (1997); NSF Mental Health (1999), NSF for renal services (2004); (transplantation) NICE guidance on interventional procedures NICE clinical guidelines (e.g. Head Injury, CG4)	Secretary of State for Health – functions delegated to PCTs Department of Health sets standards through NSFs NICE NHS Trusts / Foundation Trusts SHAs Physicians	None
	HC.1.2 Day cases of curative care		Yes	Implicit	See HC1.1 (no explicit reference to day care)	The NHS Plan (2000) announced guaranteed waiting times, refined by the Public Service Agreements, 2004 Some services covered by NSFs, NSF for renal services (2004) aims to increase fairness of access and improve choice and quality in dialysis and provides guidance on day surgery. NICE guidance on interventional procedures	See HC1.1 (no explicit reference to day care)	None

⁸⁰ In addition, almost all legislation is subject to Parliamentary approval, either explicitly or implicitly.

⁸¹ "Unless the clinical evidence of its inefficacy is overwhelming" Newdick, C. (2005b) "Who should we treat? Rights, Rationing and Resources in the NHS", Oxford University Press, Oxford. ;(page 107)

ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
						NICE appraisal No 48 recommends that all suitable patients be offered the choice between home haemodialysis or haemodialysis in a hospital/satellite unit.		
	HC.1.3 Out-patient care	HC.1.3.1 Basic medical and diagnostic services	Yes	Acts: 1 SIs: 1 to 3 NHS plan: 2 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1946 (c. 81) ss. 33-34 National Health Service Act 1977 (c. 49) ss. 3(1)(c), 15(1) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), reg. 15(3)(5)(6)(8)(essential services) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), r. 17, 30-32, Sch.3, Sch 6(10-13, 70), Sch 7 (out of hours care)	NICE clinical guidelines (e.g. Head Injury, CG4) The NHS Plan (2000) announced guaranteed waiting times, refined by the Public Service Agreements, 2004 NSF for Mental Health (1999) specifies. 24 hr access to duty doctor (section 12 approved) and approved social worker NICE guidance on interventional procedures NICE clinical guidelines (e.g. Head Injury, CG4)	Secretary of State for Health – functions delegated to PCTs Department of Health NHS Confederation British Medical Association NHS Trusts / Foundation Trusts General Medical Practitioners	None
		HC.1.3.2 Out-patient dental care	Yes	Acts: 1 SIs: 1 to 3 NHS plan: 2 NICE guidance: 2 or 3	National Health Service Act 1946 (c. 81) s. 22 (1), 40 National Health Service Act 1977 (c. 49) ss. 3(1)(c), 15 (1), 35-37 National Health Service (General Dental Services) Regulations 1992 (S.I. 1992/661)	The NHS Plan (2000) announced the government's commitment to ensure universal access to NHS dentists for all who want it NICE clinical guidelines (e.g. Dental recall, CG19)	Secretary of State for Health – functions delegated to PCTs Department of Health Doctors and Dentists Review Body	Some cosmetic treatments, such as teeth whitening ⁸² implicitly excluded

⁸² <http://www.dentalhealth.org.uk/faqs/leafletdetail.php?LeafletID=30>, accessed 17/03/05

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
					Statement of Dental Remuneration, Amendment 93 to S.I. 1992/661		General Dental Practitioners	
		HC.1.3.3 All other specialised health care	Yes	Acts: 1 SIs: 1 to 3 NHS plan: 2 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1946 (c. 81), s. 3(c) specialist services in hospital, outpatient clinic and home Mental Health Act 1983 (c. 20) National Health Service (General Medical Services) Regulations 1992 (S.I. 1992/635), s. 32-33 (minor surgery) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), Sch. 2(8) (minor surgery)	NHS Plan (2000) announced 'general practitioners with special interests' (ch 12, §7); PCT must ensure that there is evidence that the GP has the necessary competencies for the role, using guidelines from the relevant Royal Colleges NSFs cover some specialist outpatient care, e.g. the NSF for Children (Mental Health and Psychological Wellbeing) outlines specialised services for more severe, complex or persistent disorders. Some relevant topics covered by NICE technology appraisals (e.g. atypical antipsychotics), NICE clinical guidelines (e.g. Eating Disorders CG9)	Secretary of State for Health – functions delegated to PCTs Department of Health NICE Royal Colleges Physicians	None
		HC.1.3.9 All other out-patient curative care	Yes	Acts: 1 NSFs: 2 or 3	National Health Service Act 1946 (c. 81), s. 23 (midwives), s. 24 (health visitors), s. 25 (home nurses) National Health Service Act 1977 (c. 49) s. 15 (1), 38-40 (ophthalmic services) Health and Social Care Act 2001 (c. 15), s. 63 (extension of prescribing rights to other practitioners)	NSFs cover some paramedical services, e.g. the NSF for Cancer (2000) recommends that physiotherapy, dietetics, speech therapy and occupational therapy services should be easily available.	Secretary of State for Health – functions delegated to PCTs	None
	HC.1.4 Services of curative home care		Yes	Acts: 1 SI: 1 NSFs: 2 or 3	National Health Service Act 1946 (c. 81), s. 23 (midwives), s. 24 (health visitors), s. 25 (home nurses) Nurses, Midwives and Health Visitors Act 1979 (c. 36)	NSFs cover some home-based care, e.g. the NSF for Renal services (2004)	Secretary of State for Health – functions delegated to PCTs Department of Health	None

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
					Nurses, Midwives and Health Visitors Act 1997 (c. 24)			
					The Nursing and Midwifery Order 2001 (S.I. 2002/253)			
HC.2 Services of rehabilitative care	HC.2.1 In-patient rehabilitative care		Yes	Acts: 1 NHS plan: 2 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1977 (c. 49) s. 3(1)(e)	The NHS Plan (2000) announces new intermediate care services, reflected in the NSF for Older People (2001);(standard 3) NSF for Mental Health (1999) includes requirement that all users needing rehabilitation have access (standard 5) NICE clinical guideline on Supportive and Palliative Care (CSG) recommends access to 'comprehensive rehabilitation services' in all settings	Secretary of State for Health – functions delegated to PCTs Department of Health sets standards through NSFs NHS Trusts / Foundation Trusts	None
	HC.2.2 Day cases of rehabilitative care		Yes	Implicit	See HC2.1 (no explicit reference to day care)	See HC2.1	See HC2.1	
	HC.2.3 Out-patient rehabilitative care		Yes	Acts: 1 SIs: 1 to 3 NSFs: 2 or 3	National Health Service Act 1946 (c. 81), s. 28 (optional) Mental Health Act 1983 (c. 20), s. 117 See also HC2.1	NSF for Coronary Heart Disease (2000) recommends that NHS Trusts offer patients cardiac rehabilitation programmes (standard 12) See also HC2.1	Secretary of State for Health – functions delegated to PCTs NHS Trusts / Foundation Trusts	None
	HC.2.4 Services of rehabilitative home care		Yes	See HC2.3	See HC2.3	See HC2.1	Secretary of State for Health – functions delegated to PCTs	None
HC.3 Services of long-term nursing care	HC.3.1 In-patient long-term nursing care			Acts: 1 HSCs: 3 NSFs: 2 or	National Health Service Act 1946 (c. 81) s. 3(1)(a)-(c), 4 National Health Service Act 1977, (c. 49) ss. 3(1)(a)-(c), 4	NSF cancer plan (1995) states that palliative care and symptom control should be available at all stages of a patient's illness and that hospitals, primary care, social services and the voluntary sector should all be involved.	Secretary of State for Health – functions delegated to PCTs Local authorities	None

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
				3	National Health Service Act 1977, (c. 49) s. 21 Community Care (Delayed Discharges etc.) Act 2003 (c.5) SI 2003/2277 (The Delayed Discharges (England) Regulations 2003) HSC2001/17: LAC(2001)26 (Direction) Guidance on free nursing care in nursing homes HSC2003/006 (Direction) Guidance on NHS funded nursing care			
	HC.3.2 Day cases of long-term nursing care		See HC3.1	See HC3.1	See HC3.1			None
	HC.3.3 Long-term nursing care: home care		Acts: 1 SIs: 1 to 3 NHS plan: 2	Acts: 1 SIs: 1 to 3 NHS plan: 2 See also HC3.1	Community Care (Delayed Discharges etc.) Act 2003 (c.5) SI 2003/2277 (The Delayed Discharges (England) Regulations 2003) See also HC3.1	The NHS Plan (2000) announces free nursing home care, reflected in the NSF for Older People. Eligibility criteria for NHS continuing care currently under review (April 2005)	Department of Health SHAs Ombudsman	None
HC.4 Ancillary services to health care	HC.4.1 Clinical laboratory		Optional	Acts: 1 SIs: 1 to 3	NHS Act1946 (s. 17) (bacteriological service, optional) National Health Service Act 1977 (c. 49), s. 5 (2)(c) (microbiological service; optional) Microbiological Research Authority Regulations 1994 (S.I. 1994/602)		Secretary of State for Health, delegated to PCTs	None

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
	HC.4.2 Diagnostic imaging			Acts: 1 NICE guidance: 2 or 3	National Health Service Act 1977 (c. 49) s. 3(f)	NICE technology appraisals have covered some relevant topics (e.g. ultrasound locating devices for placing central venous catheters)	Secretary of State for Health, delegated to PCTs NHS Trusts / Foundation Trusts	None
	HC.4.3 Patient transport and emergency rescue		Yes	Acts: 1	National Health Service Act 1946 (c. 81), s. 27 National Health Service Act 1977 (c. 49) s. 3(1)(c) Health and Social Care (Community Health and Standards) Act 2003 (c. 43), s. 167 (payments)		Secretary of State for Health, delegated to PCTs Ambulance Trusts	None
	HC.4.9 All other miscellaneous services							
HC.5 Medical goods dispensed to out-patients	HC.5.1 Pharmaceuticals and other medical non- durables	HC.5.1.1 Prescribed medicines	Yes	Acts: 1 SIs: 1 to 3 NHS plan: 2 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1946 (c. 81) ss. 38, 39 Medicines Act 1968 (c. 67), (ss. 51, 58, 60) National Health Service Act 1977 (c. 49) ss 15(1), .41 Health and Medicines Act 1988 (c. 49) Prescription Only Medicines (Human Use) Order, 1997 (S.I. 1997/1830) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), §38-	The NHS Plan (2000) seeks to end the postcode lottery for cancer drugs NICE technology appraisals of new and existing treatments contain recommendations for NHS use. NICE clinical guidelines NSFs include recommendations for the use of some drugs, such as the NSF for Mental Health (1999), which sets the target that all service users should be assessed for, and receive where indicated, new antipsychotic drugs.	European Commission and EMA Secretary of State for Health ('black' and 'grey' lists) MHRA (licensing) Medicines Commission, Committee on Safety of Medicines (advisory) PPRS	Black and grey listed drugs explicitly excluded (3) Drugs and devices receiving negative appraisal by NICE are explicitly excluded (3)

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
					52 (note: excess prescribing unlawful, volume or cost)		PPA	
					National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641)		General medical practitioners	
		HC.5.1.2 Over-the-counter medicines	Yes	Acts: 1	Medicines Act 1968 (c. 67), s. 12 (herbal medicines)		MHRA	
							Advisory Board on the Registration of Homoeopathic Products	
	HC.5.2 Therapeutic appliances and other medical durables	HC.5.2.1 Glasses and vision products	Yes	Acts: 1 SIs: 1 to 3	National Health Service Act 1946 (c. 81), ss. 41, Opticians Act 1958 (c. 44) National Health Service Act 1977 (c. 49) ss. 15(1), 38-40 (ophthalmic services), 77-79 (charges) Health and Medicines Act 1988 (c. 49), ss. 13-14 The National Health Service (Optical Charges and Payments) and (General Ophthalmic Services) Amendment Regulations 2004 (S.I. 2004/642)		Primary Care Trusts NHS Trusts Ophthalmic opticians	NHS glasses and vouchers are not available to working age adults, with some age- or income-related exceptions (explicitly excluded, 3).
		HC.5.2.2 Orthopaedic appliances and other prosthetics					Some relevant NICE technology appraisals, e.g. Hip disease - replacement prostheses (No. 2)(2000)	None
		HC.5.2.3 Hearing aids					NICE guidance No.8 (2000) recommended use of the full range of <i>analogue</i> hearing aids, but did not recommend a national introduction	None

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
						of digital hearing aids –guidance withdrawn three years later following widespread adoption of digital aids		
		HC.5.2.4 Medico-technical devices, incl. wheelchairs	Yes	Acts: 1	National Health Service Act 1977 (c. 49), s. 5 (2)(a) (optional)		Secretary of State for Health – functions delegated to PCTs	None
		HC.5.2.9 All other miscellaneous medical durables						
HC.6 Prevention and public health services	HC.6.1 Maternal and child health; family planning and counselling		Yes	Acts: 1 SIs: 1 to 3 NHS plan: 2 NSFs: 2 or 3	<i>Maternal and child health:</i> National Health Service Act 1946 (c. 81), s. 22 National Health Service Act 1977 (c. 49), s. 3(d) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), Sch. 2(5-7)	The NHS Plan (2000) announces an expansion of cancer screening, reflected in the NSF for Older People NSF for Children, Young People and Maternity Services	Secretary of State for Health – functions delegated to PCTs General Medical Practitioners	Some routine tests for pregnant women, neonates and children explicitly excluded (3) Screening children for a range of diseases explicitly excluded (3)
			Yes	Acts: 1 SIs: 1 to 3 NICE guidance: 2 or 3 NSF: 2 or 3	<i>Family planning:</i> National Health Service Act 1977 (c. 49), s. 5(1)(b) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), Sch.2 (3)	Some relevant topics covered by NICE technology appraisals (e.g. routine anti-D prophylaxis), NICE clinical guidelines (e.g. induction of labour, fertility) and NICE guidance in interventional procedures (e.g. hysteroscopic sterilisation) NSF for Children, Young People and Maternity Services	Secretary of State for Health – functions delegated to PCTs General Medical Practitioners	
				Acts: 1 SIs: 1 to 3	Abortion Act 1967 (c. 87) Abortion Regulations 1991 (S.I.	NSF for Children, Young People and Maternity Services states that “young women [should] have early and easy access to free pregnancy testing, unbiased advice and		

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
				NSFs: 2 or 3	1991/499) Abortion (Amendment) (England) Regulations 2002 (S.I. 2002/887)	speedy referral for NHS funded abortion or ante-natal care.”		
	HC.6.2 School health services		Yes	Acts: 1	National Health Service Act 1977 (c. 49), s. 5 (1)(a) Health and Medicines Act 1988 (c. 49), ss. 10(1) (school dental provision no longer mandatory)		Secretary of State for Health – functions delegated to PCTs	
	HC.6.3 Prevention of communicable diseases		Yes	Acts: 1 SIs: 1 to 3 NICE guidance: 2 or 3 NSF: 2 or 3	National Health Service Act 1946 (c. 81), ss. 1(1)(b) (general prevention), s. 17 (bacteriological service, optional), 26 (vaccination / immunisation), 28 (prevention of illness, optional) National Health Service Act 1977 (c. 49), ss. 1(1)(b) (general prevention), 5 (2)(c) (microbiological service; optional), 5(4) (Public Health Laboratory Board) Public Health (Control of Diseases) Act 1984 (c. 22) Public Health (Infectious Diseases) Regulations 1988 (S.I. 1988/1564) National Health Service (General Medical Services) Regulations 1992 (S.I. 1992/635), r.3(2), Sch. 2 (12)(2)(c) (vaccination / immunisation) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), Sch 2 (4-5) (vaccination / immunisation)	NICE technology appraisals include preventative technologies (e.g. appraisal No. 67, amantadine and oseltamivir for the prevention of influenza). NSF for Children, Young People and Maternity Services states that “young people [should be] informed of the risks of unprotected sexual activity, and of sexually transmitted infections and the potential consequences of teenage pregnancy”...with “rapid access to testing and treatment”	Secretary of State for Health – functions delegated to PCTs Local authorities	Single vaccines for measles, mumps and rubella Smallpox vaccination

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
					Health Protection Act 2004 (c. 17), s. 2(b)			
	HC.6.4 Prevention of non-communicable diseases		Yes	Acts: 1 SIs: 1 to 3 NSFs: 2 or 3 NICE guidance: 2 or 3	National Health Service Act 1977 (c. 49), s. 1(b) National Health Service (General Medical Services) Regulations 1992 (S.I. 1992/635), r.3(2) Sch. 2 (15)(1) (consultations, adults under 75); Sch. 2 (16) (consultations, adults 75 and over) National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), Sch.2 (2)(Cervical screening), Sch 6 (4-6) (annual health checks)	NICE clinical guidelines may include screening advice (e.g. familial breast cancer, CG14). National service frameworks may include advice on screening for particular disease areas (e.g. NSF for coronary heart disease; NSF for Mental Health)	Secretary of State for Health – functions delegated to PCTs Local authorities UK National Screening Committee General practitioner	Screening for some cancers, Alzheimer's and depression (amongst others)
	HC.6.5 Occupational health care			Act: 1	National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641), regs. 15, 17 Health and Safety at Work Act 1974		Local authorities	
	HC.6.9 All other miscellaneous public health services			Acts: 1 SIs: 1 to 3	Ministry of Health Act 1919 (c. 21) Food Safety Act 1990 (c. 16) Environmental Protection Act 1990 (c. 43) Human Rights Act 1998 (c. 42) Health and Social Care Act 2001 (c. 15) Health Protection Agency Act 2004 (c. 17)		Secretary of State for Health – functions delegated to SHAs (water fluoridation) Local authorities	

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ICHA-HC 1 digit level	ICHA-HC 2 digit level	ICHA-HC 3 digit level	Included	Implicit/ explicit ⁴ inclusion	Legislation	Regulation	Actors (decision makers) ⁸⁰	Implicit / explicit ⁴ exclusion
					Blood Safety and Quality Regulations 2005 (S.I. 2005/50)			