These notes refer to the Health and Social Care Act 2001 (c.15) which received Royal Assent on 11 May 2001

HEALTH AND SOCIAL CARE ACT 2001

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health and Social Care Act 2001 which received Royal Assent on 11 May 2001. They have been prepared by the Department of Health, with assistance from the Wales Office, in order to assist the reader of the Act. They do not form part of the Act and have not been endorsed by Parliament.

2. These notes need to be read in conjunction with the Act. They are not, and are not meant to be, a comprehensive description of the Act, so where a section or part of a section does not seem to require any explanation or comment, none is given.

SUMMARY

3. In July 2000 the Government published *The NHS Plan, A plan for investment, A plan for reform* (Cm 4818-1) and *The NHS Plan, The Government's response to the Royal Commission on Long Term Care* (Cm 4818 – II). In September 2000 the Government published *Pharmacy in the Future – Implementing the NHS Plan.* Action has been taken to implement many of the proposals set out in these documents. In October 2000 the Scottish Executive published the *Response to the Royal Commission on Long Term Care* and provision is made in the Act for one aspect of this as mentioned below.

4. This Act is intended to deliver many of the aspects of the NHS Plan and the Government's response to the Royal Commission on Long Term Care that require changes to primary legislation. Its purpose is to improve the performance of the NHS, provide better protection for patients through a faster, more effective and fair system for regulating practitioners, provide better protection around the use of patient information, strengthen the way the public and patients are involved in the way the NHS works, modernise pharmacy and prescribing services, extend direct payments for social services users and provide a fairer system of funding for long term care including measures to reduce the need to sell one's home on entering residential care.

THE ACT

5. The Act is in five parts :

Part 1 makes changes to the way the NHS, including family health services, is run and funded in England and Wales.

Part 2 deals with pharmaceutical services in England and Wales and some aspects of such services in Scotland.

Part 3 provides for the establishment of Care Trusts and for the transfer of staff in connection with partnership arrangements.

Part 4makes changes to the way long term care is funded and provided in England and Wales. Provision is also made for Scotland in relation to the ending of preserved rights.

Part 5 deals with the control of patient information and the extension of prescribing rights as well as various miscellaneous and supplementary provisions.

6. **Part 1** of the Act is mainly concerned with implementing those of the proposals set out in the NHS Plan which require primary legislation. This part of the Act therefore makes a number of changes to the framework of the NHS in England and Wales. *Sections 1 to 5* concern the **funding of the NHS**. *Section 1* enables the Secretary of State and the National Assembly for Wales to take into account the level of a Health Authority's non-cash limited allocation in determining its total allocation. *Section 2* deals with payments to Health Authorities in respect of past performance. *Section 3* enables the Secretary of State and the National Assembly for Wales to make additional **supplementary payments** to support new initiatives and to attach conditions to such payments. *Sections 4 and 5* allow for the extension of **public private partnerships** in the NHS.

7. *Section 6* deals with the powers of the Secretary of State to direct certain NHS bodies about the **terms and conditions of employment** of their staff.

8. *Sections 7 to 12* are intended to strengthen arrangements for **public and patient involvement in the NHS**. *Sections 7 to 10* provide for local authority overview and scrutiny committees to scrutinise the NHS and represent local views on the development of local health services. *Section 11* places a duty on NHS organisations to have arrangements for involving patients and the public in decision making about the operation of the NHS. *Section 12* requires independent advocacy services to be established to assist patients in making complaints about the NHS.

9. *Section 13* allows the Secretary of State to **intervene in poorly performing NHSorganisations** .

10. *Sections 14 and 15* provide for new arrangements for Health Authorities to manage the **distribution of General Practitioners.** *Section 17* removes the requirement that remuneration paid to a **General Practitioner** must not, except in special circumstances, consist wholly or mainly of a salary which has no reference to the number of patients to whom the General Practitioner has undertaken to provide general medical services. *Section 18* provides for regulations as to the approval by Health Authorities of providers of **out of hours cover for medical practitioners.**

11. *Sections 19 to 26* introduce new arrangements covering the **regulation of family health service practitioners and those performing personal medical services or personal dental services**. All practitioners undertaking to provide family health services (general medical services, general dental services, general ophthalmic services and pharmaceutical services) must currently have their names included in a list maintained by a Health Authority. In future, Health Authorities will be required to maintain lists covering all practitioners, including deputies and locums for their area. Only practitioners included in such lists will be able to deliver family health services. It is intended that the criteria to be admitted to (and to remain on) a list will include probity and positive evidence of good professional behaviour and practice. It is intended that this will be done through a system of declarations, annual appraisal and participation in clinical audit. *Section 20* provides a power for Health Authorities to refuse to include a practitioner on the relevant **medical, dental, ophthalmic or pharmaceutical list** on the grounds of unsuitability. *Section 21* provides powers to make regulations providing for a person's inclusion in a Health Authority list to be subject to conditions. *Section 22* deals with dental corporations and lists. *Section 23* requires practitioners to declare financial interests and the acceptance of **gifts or other benefits**. *Section 24* provides for Health Authorities to keep **supplementary lists** of deputies and assistants who provide the various family health services (including GPs, dentists and people who provide pharmaceutical and optical services). *Section 25* provides for new arrangements for Health Authorities to suspend and remove practitioners from the relevant lists on the grounds of inefficiency, fraud or unsuitability. *Section 26* introduces new arrangements

to further the Health Authority list system to include those practitioners who may perform personal medical services and personal dental services. *Section 27* creates the **Family Health Services Appeal Authority** as an independent body whose functions will include dealing with appeals by these practitioners against Health Authority decisions. Consequently s*ection 16* provides for the **abolition of the NHS Tribunal**.

12. **Part 2** of the Act concerns **pharmaceutical services.** Chapter 1 provides for new arrangements under which community pharmacy and related services may be provided on a pilot basis. The services provided under these arrangements will be known as local pharmaceutical services. *Section 28* contains introductory provisions about **pilot schemes** for the provision of local pharmaceutical services. *Section 29* and Schedule 2 set out how proposals for a pilot scheme are to be made by a Health Authority and submitted to the relevant authority (the Secretary of State or National Assembly for Wales). *Section 30* provides for the designation of neighbourhoods or premises in connection with pilot schemes. *Section 31* requires the relevant authority to conduct at least one **review of each pilot scheme** and to comply with certain conditions in doing so. *Section 32* gives the relevant authority power to vary or terminate pilot schemes. Health Authorities may vary schemes without referring the matter to the relevant authority only to the extent that they are permitted to do so in directions. *Section 33* allows potential providers of local pharmaceutical services to apply to the relevant authority to become health service bodies. One result will be that certain arrangements they make with other health service bodies will be NHS contracts. This section also allows the courts to enforce a direction for payment given by the relevant authority in respect of obligations under such contracts.

13. *Section 34* permits regulations to be made to allow Health Authorities to **make payments for preparatory work for pilot schemes**, subject to certain conditions. *Section 35* enables **charges corresponding to those for pharmaceutical services** under Part 2 of the National Health Service Act 1977 to be levied for local pharmaceutical services, subject to exemptions. *Section 36* specifies that the provisions of the 1977 Act, including the relevant authority's direction-making powers, apply to functions under Part 2 of this Act as though they were functions under Part 1 of the 1977 Act. *Section 37* permits regulations to be made preventing the provision of pilot scheme services from the same premises as pharmaceutical services under Part 2 of the 1977 Act, except as provided in the regulations. It also permits regulations to make provision about the inclusion, re-inclusion, removal and modification of entries in pharmaceutical lists held under Part 2 of that Act. *Section 38* permits regulations to prescribe the extent to which pilot schemes are to be taken into account when considering applications for inclusion in those lists. *Section 39* provides that the relevant authority may only bring the **permanent regime for local pharmaceutical services** into effect where, having regard to reviews of pilot schemes which have been conducted, they are satisfied that it is in the interests of any part of the health service. *Section 40* inserts new provisions into the 1977 Act to enable Health Authorities to make schemes for the provision of local pharmaceutical services in accordance with regulations. *Section 41* provides a power to make further regulations about both the permanent regime and pilot schemes, which correspond to measures in force in relation to personal medical or personal dental services.

14. Chapter 2 of Part 2 introduces changes to the existing arrangements for the provision of **pharmaceutical services**. *Section 42* substitutes the existing section 41 of the 1977 Act. The new section 41 will require Health Authorities to make arrangements for the supply to persons in their area of those drugs, medicines and listed appliances prescribed for them by medical and other practitioners under the National Health Service. In particular it provides powers for the relevant authority to specify in regulations the categories of person whose prescriptions will be dispensed and any conditions in accordance with which they must prescribe. This section also provides for the arrangements made by Health Authorities to include arrangements for the provision of these pharmaceutical services by remote means.

15. *Section 43* authorises arrangements for the provision of **additional pharmaceutical services by remote means**. The intention is to facilitate, and provide a means to control, the development of internet, mail order, home delivery and other arrangements which may involve dispensing across Health Authority boundaries. This will provide patients with greater flexibility in the way they can present their prescriptions and obtain the drugs or appliances that have been ordered for them. *Section 44* makes provision for items prescribed by certain categories of prescriber to be dispensed as part of NHS community pharmaceutical services in Scotland.

16. **Part 3** of the Act creates new powers to establish **Care Trusts** by building on existing health and local authority powers to forge partnerships and provide integrated care. *Section 45* provides for Care Trusts to be established voluntarily. Where services are failing *section 46* provides for the Secretary of State or the National Assembly for Wales to direct the local partners to enter into partnership arrangements. *Section 48* concerns the transfer of staff in connection with partnership arrangements.

17. **Part 4** of the Act changes the way long term care is funded and provided in England and Wales. *Section 49* excludes nursing care from community care services. *Sections 50 to 52* make local authorities responsible for arranging and meeting the care needs of people who have until now had their **long term care** funded through **preserved rights** to income support and jobseeker's allowance. *Sections 53 to 55* extend the powers of **local authorities to place a charge on an interest in land** as an alternative method of a person financing their long term care. They also provide for regulations to specify when a local authority is required to provide residential accommodation and when additional payments may be made for more expensive accommodation. *Section 56* deals with new arrangements for **cross border placements**. Regulations will give local authorities in England and Wales powers to place people in residential care homes and nursing homes in Scotland, Northern Ireland, the Isle of Man and the Channel Islands. *Sections 57 and 58* give regulation-making powers to the Secretary of State concerning direct payments.

18. **Part 5** deals with the control of patient information and the extension of prescribing rights as well as various miscellaneous and supplementary provisions. *Section 60* concerns the **control of patient information**. It enables the Secretary of State to require or permit patient information to be shared for medical purposes where he considers that this is in the interests of improving patient care or in the public interest. *Section 61* provides for the establishment of a statutory committee that is to be consulted about regulations to be made under *section 60*. *Section 62* requires the Secretary of State to produce **separate annual reports on the development of services for people with mental illness and people with learning disability.** *Section 63* makes provision for the **extension of prescribing rights** to health professionals other than doctors, dentists and certain specified nurses, health visitors and midwives who already have prescribing rights. This part also includes a number of supplementary provisions.

19. Annex A contains an outline of the existing legislation relating to the NHS. Annex B contains an outline of the existing legislation relating to social care. Annex C deals with miscellaneous relevant legislation. In general, functions of the Secretary of State under the existing legislation are exercisable by the National Assembly for Wales in relation to Wales by virtue of a Transfer of Functions Order made in 1999. The Act reflects this when amending existing legislation, i.e. functions are conferred just on the Secretary of State. *Section 68* will ensure that such functions will be exercisable for Wales by the National Assembly for Wales. Many of the functions under this Act are conferred on "the relevant authority", which is defined by *section 66* to mean the Secretary of State in relation to England, the National Assembly for Wales in relation to Wales and the Scottish Ministers in relation to Scotland.

COMMENTARY ON SECTIONS

Part 1: National Health Service

Health Service Funding

Section 1: Determination of allotments to and resource limits for Health Authorities and Primary Care Trusts

20. *Section 1* changes the way in which resources are allocated between Health Authorities ("HAs") by the Secretary of State and between Primary Care Trusts ("PCTs") by HAs.

21. When distributing the resource and cash limited elements the Secretary of State and the National Assembly for Wales (for HAs) and HAs (for PCTs) may take into account how much is being spent on the non-resource and non-cash limited family practitioner services. Those who are spending more than their fair share on these services may get a smaller increase for their other services. Conversely if they are spending less than their fair share they can be given a larger increase. This monetary device will have the effect of supporting action taken to increase the number of GPs in under-doctored areas.

22. *Section 1* provides for changes to the way in which unified allocations – which are cash limited – are made to HAs and PCTs. This provision will allow the Secretary of State and the National Assembly for Wales and HAs to take account of general Part 2 expenditure (non cash limited expenditure on family health services) when making decisions about unified allocations. In the first instance the intention is to take into account only the general Part 2 expenditure on general medical services (GMSNCL). It is envisaged that the power will be exercised so as to make larger increases in the unified allocations of areas which are " under- doctored" than if GMSNCL was not taken into account; and to make smaller increases in the unified allocations of areas which are "over-doctored" than if GMSNCL was not taken into account. It will also provide a financial mechanism for regulating the number of doctors in a Health Authority area (the abolition of the Medical Practices Committee – see *sections 14 and 15* - will mean that HAs will become responsible for declaring GP vacancies).

23. The Department has asked the Advisory Committee on Resource Allocation to devise a new funding formula for GMSNCL expenditure. Using this new formula in conjunction with the existing formula for HA and PCT unified allocations will allow the Department to determine targets, or "fair shares" of available resources for an area covering both unified allocations and GMSNCL. But changes to funding will only be made to unified allocations. Health Authority and Primary Care Trust unified allocations will move towards this overall target level over time (e.g. if the Health Authority is over target it will receive lower funding growth than if it was under target). While these changes will see resources for under doctored areas grow more quickly than the resources for over doctored areas, they will not lead to the cash limiting of Part 2 general expenditure or change the entitlement of primary care practitioners.

24. The statutory provision dealing with the public funding of Health Authorities is section 97 of the National Health Service Act 1977 (the "1977 Act"). Health Authorities are paid money in each year by the Secretary of State under section 97(1) and (3). Section 97(1) concerns the remuneration of persons providing services under Part 2 of the 1977 Act (for example, General Medical Practitioners). Unless such remuneration is excepted from section 97(1), it is not cash limited. The Secretary of State is under a duty to pay each Health Authority the cost of such remuneration, and cannot impose a ceiling on such expenditure (defined as "general Part 2 expenditure" in paragraph 1 of Schedule 12A to the 1977 Act). Section 97(3) provides that the Secretary of State must pay to each Health Authority money not exceeding the amount allotted to it by the Secretary of State. This amount is allotted towards meeting an Authority's "main expenditure" (defined in paragraph 2 of Schedule 12A to the 1977 Act). In the case of a Health Authority this includes all expenditure attributable to the performance of their

functions in relation to the provision of hospital-based and community health services, all their administrative costs, the costs of drugs attributed to them by the Secretary of State and certain other expenditure. The amount allotted constitutes a limit on the cash which may be spent by the Authority.

25. Health Authorities are under similar obligations to provide funds to Primary Care Trusts. Each Primary Care Trust is established for an area contained within the area of a Health Authority. Under section 97C, each year the Health Authority must pay each of its Primary Care Trusts (a) the cost of general Part 2 expenditure incurred by the trust and (b) money not exceeding the amount allotted by the Authority for that year towards meeting main expenditure. As with the allotments to Health Authorities, the amount allotted to each Primary Care Trust covers all expenditure attributable to the performance of their functions in relation to the provision of hospital-based and community health services, all their administrative costs and the costs of drugs attributed to them by the Secretary of State. The amount allotted constitutes a limit on the cash which may be spent by the Authority.

26. *Subsection (2)* inserts a new subsection (3AA) into section 97 of the 1977 Act. This allows the Secretary of State to take account of expenditure attributable to the remuneration paid to Part 2 practitioners in the Health Authority area in determining the amount to be allotted to the Health Authority. Subsection (4) inserts a new subsection (1A) into section 97C of the 1977 Act. This allows a Health Authority to take account of the distribution within their area of expenditure attributable to the remuneration paid to Part 2 practitioners in determining the amount to be allotted to each of its Primary Care Trusts.

27. The Government Resources and Accounts Act 2000 inserts two new sections into the 1977 Act (sections 97AA and 97E). These new sections provide for the setting of resource limits for every Health Authority and Primary Care Trust in addition to cash limits. Section 97AA concerns resource limits for Health Authorities; section 97E concerns resource limits for Primary Care Trusts. Section 97AA(2) provides for general Part 2 expenditure to be excluded from the resource limit.

28. *Subsection (3)* inserts a new subsection (2A) into section 97AA of the 1977 Act. This allows the Secretary of State to take account of general Part 2 expenditure in setting the resource limits for Health Authorities, mirroring the new subsection (3AA) of section 97 which allows the Secretary of State to take account of general Part 2 expenditure in determining the amount to be allotted to a Health Authority.

29. *Subsection (5)* inserts a new subsection (2A) of section 97E into the 1977 Act. This allows a Health Authority to take account of the distribution within their area of general Part II expenditure in setting the resource limits for its Primary Care Trusts, mirroring the new subsection (1A) of section 97C which allows the Health Authority to take account of the distribution within their area of general Part 2 expenditure in determining the amount to be allotted to each of its Primary Care Trusts.

Section 2: Payments relating to past performance

30. *Section 2* amends the existing provisions of section 97 of the 1977 Act which enable the Secretary of State and the National Assembly for Wales to increase the initial allocation each of them makes to a Health Authority, where that Authority has satisfied certain conditions. This enables the Secretary of State to make payments to Health Authorities based on their past performance. The existing section 97(3C) provides that the Secretary of State may make such increases where a Health Authority has in any preceding year satisfied objectives which have been notified to Health Authorities in advance.

31. The new subsection (3C) enables the Secretary of State and the National Assembly for Wales to increase an Authority's allocation not only where it has satisfied objectives, but also where it has performed well against performance criteria. The Secretary of State must notify the Authority of such criteria in advance, although he might not notify

them in advance of the exact method by which performance will be measured. This would enable the Secretary of State to make additional payments to Health Authorities on the basis of their performance relative to other Authorities (against criteria notified to them in advance) in addition to them meeting particular objectives. For example, he may need to wait until he knows how well NHS bodies have performed against specific measures in the previous year before he is able to finalise the best method of measuring their performance in the coming year. However, the Secretary of State would need to inform Authorities in advance of the criteria against which their performance would be measured if he intended to make additional payments to Authorities on this basis.

32. Under the existing section 97(3C), the Secretary of State and the National Assembly for Wales can only make increases to Health Authority allocations based on performance in preceding financial years. The new subsection (3C) enables the Secretary of State to make such increases on the basis of performance over a period which has been notified to the Authority in advance, whether it consists of, or any part of, a preceding year or any part of the current financial year.

33. *Section 2(3)* amends section 97(3D), which provides that a Health Authority is notified of an objective, if the objective is specified or referred to in a notice given to Health Authorities by the Secretary of State. The amendment means that the Secretary of State may specify or refer to objectives, criteria or periods in a notice given to an individual Health Authority, rather than a notice to all Authorities.

34. It is intended that the NHS Performance Fund will be allocated according to a traffic light system to underpin a system of earned autonomy. "Green" organisations will have access to their share of the National Performance Fund as of right. "Yellow" Health Authorities, NHS trusts and Primary Care Groups/Trusts will be required to agree plans, signed off by the regional office, setting out how they will use their share of the fund. "Red" organisations will have their share of the fund held by the new Modernisation Agency. They will get their fair share of extra funds but the Agency will oversee spending.

Section 3: Supplementary payments to NHS trusts and Primary Care Trusts

35. *Section 3* enables the Secretary of State and the National Assembly for Wales to make payments direct to NHS trusts and Primary Care Trusts, outside the existing arrangements for funding such bodies. In particular it enables payments to be made to NHS trusts other than under NHS contracts and to Primary Care Trusts other than under NHS contracts or the provisions of section 97C of the 1977 Act (Health Authority allocations to Primary Care Trusts). This will facilitate direct payments to NHS trusts and Primary Care Trusts.

36. These supplementary payments may be made through Health Authorities rather than direct to trusts. Under section 16C of the 1977 Act (as inserted by section 12 of the Health Act 1999), the Secretary of State may direct Health Authorities to exercise his powers under the new paragraph 5A of Schedule 3 to the 1990 Act (NHS trusts) and/or section 97C(5A) of the 1977 Act (Primary Care Trusts). The Secretary of State would be able to control how Health Authorities made these supplementary payments to trusts by giving directions under section 17 of the 1977 Act.

37. Under current arrangements, the Secretary of State for Health makes allocations to Health Authorities under section 97 of the 1977 Act. He can direct that particular sums must be applied for the purpose of making payments to NHS trusts, but such payments are then made under "service level agreements" (i.e. NHS contracts). In relation to Primary Care Trusts, if the Secretary of State attaches conditions as to how sums are to be spent when allocating an amount to a Health Authority, the Health Authority can attach those conditions when allocating part of that amount to a Primary Care Trust (see section 97C(5) of the 1977 Act).

38. These existing arrangements may not be appropriate for supplementary payments to NHS trusts and Primary Care Trusts, for example where the Secretary of State wishes to make payments to trusts specifically for rewarding their staff performance and/or improving facilities. The section is intended to provide for a more efficient resource allocation route to NHS trusts and Primary Care Trusts for such supplementary payments, that will exist alongside income from NHS contracts or in the case of Primary Care Trusts, Health Authority allocations.

Section 4: Public-Private Partnerships

39. This section will insert a new section 96C into the 1977 Act to provide for the Secretary of State and the National Assembly for Wales to participate in public-private partnerships with companies that provide facilities or services to persons or bodies carrying out NHS functions. As with various other powers of the Secretary of State under the 1977 Act, these new powers could be delegated to Health Authorities, and through them to Primary Care Trusts, and to Special Health Authorities. The intended first use of this new power is the establishment of NHS LIFT (NHS Local Improvement Finance Trust) which will be set up to invest in primary care premises.

40. Subsection (1) of the new section 96C provides for the Secretary of State to form or participate in forming companies to provide facilities or services to:

— any person or body providing services, or exercising functions, under the 1977 Act;

— NHS trusts (which exercise functions under the NHS and Community Care Act 1990).

41. Subsection (2) provides that the Secretary of State may invest in companies providing such facilities or services or provide loans or guarantees or make other financial provision.

42. Subsection (3) provides that the powers are exercisable irrespective of whether the company also provides facilities or services to other persons or bodies or to persons or bodies, for example pharmacists, whose activities are not solely confined to the NHS.

43. Subsection (5) makes it clear that the inclusion of section 96C is without prejudice to any other powers of the Secretary of State.

Section 5: Income Generation

44. The purpose of this section is to enable the Secretary of State and the National Assembly for Wales and other NHS bodies exercising "income generation" powers under section 7 of the Health and Medicines Act 1988 to form, invest in and otherwise make financial provision in relation to companies. Section 7 of the 1988 Act confers powers under which the Secretary of State and the National Assembly for Wales may carry out a wide range of commercial activities, such as the supply of goods and services and the exploitation of intellectual property, in order to increase the funds available for improving the health service . This is subject to the proviso that such activities do not interfere with the performance of any duties under the 1977 Act or operate to the disadvantage of patients. The Secretary of State may authorise bodies established under the 1977 Act to exercise these powers subject to any directions he might give. NHS trusts are given the same income generation powers by virtue of paragraph 15 of Schedule 2 to the NHS and Community Care Act 1990.

45. Subsection (7A) would be inserted into section 7 of the 1988 Act so as to provide for the formation of, investment in and making of financial provision in relation to companies where that was calculated to facilitate, or be conducive, or incidental to, the exercise of income generation powers.

46. Subsection (7B) defines "companies" and makes clear that the inclusion of the new subsection would be without prejudice to any other powers of the Secretary of State.

Terms of employment of health service employees

Section 6: Terms and conditions of employment by certain health service bodies

47. This section provides for the Secretary of State and the National Assembly for Wales to make regulations and give directions to certain health service bodies about the terms and conditions on which they employ staff and generally in connection with matters concerning the employment of staff. The NHS Plan makes a commitment to modernisation of the NHS pay system to deliver better, fairer awards for staff. This new power is designed to ensure that NHS bodies implement changes to terms and conditions of staff approved by the Secretary of State.

48. *Subsection (1)* amends paragraph 10(1) of Schedule 5 to the 1977 Act to provide for Health Authorities and Special Health Authorities to pay their officers such remuneration and allowances, and employ them on such other terms and conditions, as they may determine subject to any regulations made or directions given by the Secretary of State or the National Assembly for Wales. Paragraph 10(1) is also amended to provide for regulations or directions to make provision with respect to any matter connected with the employment of an Authority's officers. *Subsection (2)* replaces paragraphs 8 and 11(2) of Schedule 5A to the 1977 Act to the effect that Primary Care Trusts may pay their officers such remuneration and allowances, and employ them on such other terms and conditions, as they think fit but subject to regulations or directions by the Secretary of State or the National Assembly for Wales about those matters or otherwise in connection with the employment of such officers . Before making any such regulations the Secretary of State or the National Assembly for Wales are required to consult representative bodies. *Subsection (3)* makes similar provision in relation to NHS trusts.

Scrutiny of Health Service provision, Patient and Public involvement and Independent Advocacy – Background

49. The Government believes that patients and the public should have a much greater role in the development and operation of the NHS. Chapter 10 of the NHS Plan set out the Government's proposals for enhancing patient and public influence and for introducing local democratic scrutiny of the NHS through local authority overview and scrutiny committees.

50. *Sections 7 – 12* make provision for this strengthened patient and public consultation and involvement in the operation of the NHS. Local authority overview and scrutiny committees will scrutinise the NHS including decisions on NHS reorganisations and service change. Independent complaint advocacy services will be provided across the country to assist patients in making complaints about health services. NHS bodies will have a statutory duty to make arrangements with a view to securing that the public are involved in and consulted on the planning of NHS services and decisions affecting the operation of those services.

51. The new arrangements are to be complemented by a new non-statutory arrangement, Patient Advocacy and Liaison Services (PALS). PALs will be new trust-based services able to assist and support patients. They will be able to provide information and resolve problems and difficulties. It is intended that they will be situated in or near main reception areas of hospitals and act as a welcoming point for patients and carers. The PALS will also advise patients on how to access independent advocacy to support their complaints.

Local Authority Scrutiny of Health Service Provision

Section 7: Functions of overview and scrutiny committees

52. This section provides for local authority overview and scrutiny committees to exercise new functions in relation to the NHS and NHS bodies. In particular, it enables such a committee to review and scrutinise the operation of the health service in its area.

53. Local authority overview and scrutiny committees (OSCs) are to be established under section 21 of the Local Government Act 2000. These committees are part of the arrangements for local authorities under Part II of that Act. Under these arrangements, local authorities may establish an executive to perform particular functions and to implement the plans and policies approved by the authority. The executive may take one of four forms –

- an elected mayor and cabinet executive consisting of 2 or more councillors;
- a council leader and cabinet executive consisting of 2 or more councillors;
- an elected mayor and an officer of the authority appointed as the council manager;
- such other form as may be prescribed in regulations made by the Secretary of State.

54. An overview and scrutiny committee is a committee of the authority made up of councillors who are not members of the executive. The committee's functions are to review and scrutinise the decisions and other actions of the executive or the authority itself, and to make reports or recommendations to the authority or executive with respect to the discharge of functions by the executive or authority. In addition, the committee may make reports and recommendations to the authority or executive on matters which affect the authority's area or its inhabitants.

55. *Subsection (1)* confers on some of these committees the additional functions of reviewing and scrutinising health service matters and making reports and recommendations to NHS bodies on such matters. These functions will not be conferred on all overview and scrutiny committees; the provisions only apply to committees of county councils, county borough councils in Wales, unitary authorities and London borough councils (see *subsection (2)*). These are the authorities that also hold responsibility for social services. District Councils will be able to contribute to the scrutiny of the NHS through joint arrangements with the authorities set out above (see s*ection 8*).

56. The detail of how the committees are to operate and the matters which they may review and scrutinise are to be set out in regulations under *subsection (3)*. HAs would be required to consult OSCs on major service changes and Chief Executives of local NHS bodies will be required to attend OSC meetings at least twice a year. It is intended that overview and scrutiny committee functions will include referring contested proposals for major service changes to the Secretary of State on the grounds of process and merit. A new Independent Reconfiguration Panel is being established to advise the Secretary of State on proposals referred to him in this way and its membership will include clinicians, patient representatives and NHS managers.

57. OSCs will scrutinise not only health services, but also social care services provided or commissioned by NHS bodies exercising local authority functions under arrangements under section 31 of the Health Act 1999 (*see subsection (5)*). OSCs may scrutinise local authority social services under the existing provisions of the Local Government Act 2000.

Section 8: Joint overview and scrutiny committees etc

58. This section allows the Secretary of State (or, in relation to Wales, the National Assembly for Wales) to make regulations which provide for joint overview and scrutiny

committees of two or more local authorities; it allows for a number of different options. It enables the Secretary of State and the Assembly to make regulations providing for local authorities to form joint OSCs, for a local authority to delegate the NHS functions of their OSC to an OSC of another local authority, and for district council OSC members to be co-opted on to county council OSCs as voting members.

59. *Subsection (2)(a)* allows for two or more authorities, which can include district councils, to form a single overview and scrutiny committee to scrutinise health organisations. Where a district council joins with a county council, the scrutiny is the county council's responsibility, and the county council will therefore remain in the lead. These joint arrangements may also include local authorities operating "alternative arrangements" under regulations under section 32 of the Local Government Act 2000. "Alternative arrangements" do not involve the creation of an executive for the authority, but they will provide for the establishment of a committee to undertake scrutiny functions similar to those carried out by an overview and scrutiny committee under section 21 of the Local Government Act 2000.

60. *Subsection (2)(b)* provides for two or more authorities whose OSCs have responsibility to scrutinise the NHS to give the lead to one OSC so that it exercises the others' functions in relation to health scrutiny. Under this provision, a county council and district council could arrange for the district OSC to undertake the county council OSC's responsibility of scrutinising health services in the district. This approach may be appropriate where a localised service is being considered, for example a particular PCT.

61. *Subsection (2)(c)* provides for a county council to co-opt one or more district council OSC members onto its own OSC; the county council may also co-opt district council OSC members when that county is part of a joint scheme with another OSC.

62. *Subsection (3)* allows regulations relating to the joint arrangements to set out the circumstances and conditions under which joint schemes can be established. District council involvement in the joint scheme arrangements will be set out in regulations; the lead will always be with local social services authorities. Regulations and directions may also under *subsection (4)* provide for the circumstances where authorities will be required to put in place joint scheme arrangements.

63. The regulations that relate to the normal arrangements for scrutiny and review of the NHS by OSCs will also apply to the scrutiny and review of the NHS where there is a joint scheme in operation.

Section 9: Overview and scrutiny committees: exempt information

64. As local authority committees, overview and scrutiny committees are subject to section 100A of the Local Government Act 1972, which provides that councils and their committees must be open to the public except to the extent that they must be excluded under section 100A(2) (where certain confidential information may be disclosed) or may be excluded under section 100A(4) (exclusion by resolution of the council or committee, if certain "exempt information" may be disclosed). The categories of exempt information are set out in Schedule 12A to the 1972 Act. *Section 9(2)* of, and *Schedule 1* to, the Act extend the categories of exempt information, where an overview and scrutiny committee is dealing with NHS matters. As with the categories of exempt information in the 1972 Act, the Secretary of State may add to, or remove provisions or otherwise amend the list by making an order (*section 9(4) and (5)*).

Section 10: Application to the City of London

65. The Local Government Act 2000 does not provide for the Common Council of the City of London (the local authority for the City) to establish an overview and scrutiny committee. This section makes it possible for the Common Council of the City of London to set up a committee which mirrors the functions of the overview and scrutiny

committees in relation to the scrutiny of the NHS. *Subsection (2)* applies sections 7(3) to (5) and 8 and 9 and Schedule 1 to the committee that is set up. *Subsection (3)* of *section 10* applies the provisions of section 21 of the Local Government Act 2000 (overview and scrutiny committees) to a scrutiny committee established by the Common Council, with modifications to reflect the fact that the Common Council will not have an executive under Part 2 of that Act.

Public involvement and consultation

Section 11: Public involvement and consultation.

66. *Section 11* confers on each Health Authority, Primary Care Trust and NHS trust a new statutory duty to make arrangements with the aim of involving patients and the public in the planning and decision making processes of that body, in so far as they affect the operation of the health services for which the body is responsible. In relation to Health Authorities, this would cover both the hospital and community health services for which they are responsible and the family health services provided by practitioners in their area.

Independent advocacy services

Section 12: Independent advocacy services

67. *Section 12* imposes a new duty on the Secretary of State to arrange independent advocacy services for people who wish to complain about the service they or someone they care for has received from the NHS. Advocacy is to be independent, so far as practicable, by being provided by a person or body other than the person or body against which the complaint is being made, or the person or body investigation or adjudicating the complaint (see *subsection (5)*).

68. PALS will play an important role in informing patients of the availability of independent advocacy services and how to access them. However PALS will not control access to independent advocacy, and patients will be able to access them directly. Independent advocacy services in each area could be commissioned and/or provided by the local authority (under section 2 of the Local Government Act 2000) or by other persons or bodies.

69. Under *subsection (2)* independent advocacy services will be made available when a complaint is being made using the hospitals complaints procedures or when complaining to the Health Service Commissioner for England or Health Service Commissioner for Wales. The Secretary of State may by regulations extend the scope of the procedures covered by the advocacy service. A possible extension could be complaints made to one of the regulating professional bodies (e.g. General Medical Council), or which give rise to disciplinary proceedings against a member of staff. *Subsection (4)* allows the Secretary of State to further extend these arrangements as he sees necessary to provide assistance to individuals in connection with complaints about health services.

Intervention powers

Section 13: Intervention orders

70. Management of the NHS will move to a system of earned autonomy. Good performance will be rewarded and failure tackled swiftly and effectively. *Section 2* provides for the performance payments that will help underpin this new system. *Section 13* provides for new intervention powers to provide a sanction against the most serious and persistent failures. Early identification of poor performance through performance management and the new Traffic light system, backed up by support from the NHS Executive

Regional Office and the Modernisation Agency should mean that performance can be improved in most cases without resorting to formal intervention orders.

71. The purpose of this section is to enable the Secretary of State to intervene in an NHS body (Health Authorities, Special Health Authorities, Primary Care Trusts and NHS trusts) where he has concerns about the management of that body, its ability to perform its functions adequately (for example, to deliver health care to the required standard) or where there has been a one off catastrophe . This new power will complement the performance fund in delivering the NHS Plan commitment to drive up performance in the NHS.

72. *Section 13* inserts new sections 84A and 84B into the 1977 Act. Section 84A enables the Secretary of State to make an intervention order in respect of a Health Authority, Special Health Authority, NHS trust or Primary Care Trust. *Subsection (1)* sets out the test that must be satisfied before he may intervene using such an order. The test would enable the Secretary of State to intervene if he was satisfied, for example, that an NHS trust was failing to provide health services to an adequate standard. The Secretary of State would however not be restricted to intervening where there was a failure to provide adequate health services; he might also intervene where the body concerned is not being properly administered or managed. The Secretary of State must also be satisfied that the form of intervention provided for under these new provisions is appropriate; for example, he may be satisfied that temporarily replacing the board of an NHS trust, is the appropriate way to ensure that the body's performance is substantially improved.

73. Section 84B sets out the effect of an intervention order and the different forms the intervention may take. The first form of intervention (*subsections (2) and (3)*) is that members of the body concerned (i.e. the members of Health Authorities, Special Health Authorities and Primary Care Trusts, and the Chairman and directors of NHS trusts) may be suspended or removed from office, and new individuals appointed in their place. The members of a body are responsible for how that body is managed; by replacing existing members with the new members, it will enable changes to be made in the way an individual body is managed. Under these provisions, the Secretary of State has a wide range of options: he may remove all the members, or only some; he may suspend members from all their board duties, or only in respect of some duties.

74. The second form of intervention (*subsection (5)*) will enable the Secretary of State to require an NHS body to make arrangements for some other person or body to perform that NHS body's functions. Alternative expressions of interest will be selected from an approved list. Although the functions were performed by that other person or body, the NHS body would remain legally responsible for that functions – for example, an NHS trust would retain overall responsibility for managing its hospital and providing services. The Secretary of State may also direct how functions are to be performed so as to achieve particular objectives. These two forms of intervention may be combined (see section 84A(3)).

75. Sections 84B(7) and (8) provide that the Secretary of State's intervention order may disapply or modify any legislative provision relating to the membership or procedure of the body subject to intervention. The purpose is to ensure that the intervention can operate effectively where the Secretary of State removes or suspends board members, and substitutes replacements. The replacements need not be the same number as those replaced. The nature of intervention is that it must be prompt and that the Secretary of State must be able to adapt the intervention to the particular local circumstances; it may not be practicable or appropriate to find an identical number of replacements. If the number of members is different, the existing rules which govern the number of members the body must have, or about the numbers of members which must be present at the meetings of the body, may be inconsistent with the new membership arrangements implemented by an intervention order. In addition, as the method of appointing those replacements and the length of time they remain in office are to be determined by the intervention order, the rules about appointment of members and tenure of office may

require modification. The Secretary of State will only be able to disapply or modify provisions about membership or procedure, and will be able to do so only where he considers that it is appropriate (for example, in order to ensure the intervention order operates effectively). The provision for disapplying or modifying provisions will be limited to the particular body concerned and to the period during which the intervention order is in force.

76. Section 84B(9) allows the Secretary of State to include in the order supplementary directions to give full effect to an intervention. He may wish to make more specific directions about how the intervention should work. For example, he may wish to ensure that the body makes staff or other assistance available to the replacement members or the third party to which functions have been delegated. These directions are akin to the directions which the Secretary of State may give to NHS bodies under section 17 of the 1977 Act.

77. *Section 20(2)* provides that intervention orders under these provisions are not statutory instruments.

Abolition of Medical Practices Committee and National Health Service Tribunal

Section 14: Abolition of Medical Practices Committee

78. *Section 14* abolishes the Medical Practices Committee ("MPC"). (*Section 15* transfers the function of declaring GP vacancies to Health Authorities). This section should be considered alongside *section 1*, which provides for Health Authority allocations to be determined with reference to both their general allocations and Part 2 general expenditure in their area. This is intended to provide a new resource based method of control over the distribution of GPs and is intended to ensure that Health Authorities with a shortage of GPs will now be given sufficient allocations to attract more GPs. The result of this is intended to be a more equitable distribution of GPs.

79. The MPC is constituted under sections 7 and 34 of the 1977 Act. Its main function is to control the distribution of the general practitioner workforce in England and Wales. Essentially it controls the numbers of general medical practitioners wishing to provide GMS in Health Authority areas. This function will be taken on by Health Authorities , so *Section 14* provides for the abolition of the MPC. Sections 7 and 34 of the 1977 Act are therefore repealed in Schedule 6 to the Act.

80. *Subsection (2)* provides for the transfer to the Secretary of State of all property, rights and liabilities relating to the MPC including certification regarding the sale of medical practices. This includes certification relating to the sale of goodwill.

Section 15: Vacancies for medical practitioners

81. *Section 15* provides for regulations enabling Health Authorities to determine the existence, and filling, of vacancies in their area for GPs under GMS and requiring them to undertake consultation before making their determinations.

82. *Subsection (3)* provides for a right of appeal against a decision of a Health Authority as to how a vacancy is to be filled to the Family Health Services Appeal Authority. The existing right of appeal is to the Secretary of State.

83. *Section 15* alongside s*ection 1* provides for a new method of controlling the distribution of GPs. Health Authorities will have the power to declare vacancies under GMS, but GMS expenditure within the Health Authority area will be taken into account when determining the allocation of funds to that Health Authority. This is expected to lead to a more equitable distribution of GPs and health resources.

Section 16: Abolition of NHS Tribunal

84. *Sections 20 to 26* introduce a new system whereby all practitioners working in family health services will be required to be on the list of a Health Authority and for decisions about the removal and suspension of such practitioners from these lists to be taken by Health Authorities. The aim is that this will lead to faster and more effective decisions being taken where there are doubts about the ability of a practitioner to practise. Consequentially, the NHS Tribunal will no longer be needed. *Section 16* provides for the NHS Tribunal to be abolished. Sections 46 to 49E of, and Schedule 9 to the 1977 Act (which relate to its constitution and functions) are repealed in Schedule 6 to this Act.

General and personal medical services, general dental services, general ophthalmic services and pharmaceutical services

Section 17: Remuneration of General Medical Practitioners

85. *Section 17* ends the requirement under section 29(4) of the 1977 Act that the remuneration paid to GPs must not, except in special circumstances, consist wholly or mainly of a salary which has no reference to the number of patients to whom the GP has undertaken to provide services under General Medical Services ("GMS").

Section 18: Out of hours medical services

86. GPs undertake 24 hour responsibility for patients. GPs may discharge this in a number of ways: by providing the service personally; in a rota with other practices; by joining a GP co-operative; by employing a commercial deputising service established for the purpose of providing an out-of-hours service for GPs; or a combination of two or more of these.

87. *Section 18* provides powers to regulate the provision of out-of-hours services. The body to be regulated is any person or persons providing out-of-hours cover to GPs that will have to be accredited by a Health Authority. Accreditation is intended to ensure the delivery of out-of-hours GP patient care to consistent high quality standards. This was recommended in the independent Report *Raising Standards for Patients, New Partnerships in Out of Hours Care* which considered how consistent high quality services could be made available across the country. Concern had also been expressed by the Health Services Commissioner (the "Ombudsman") about the quality and responsiveness of out-of-hours services provided in some areas.

88. Regulations may specify those who are to be accredited under the regulations, the procedure for applying for accreditation, any conditions with which accredited bodies must comply and the transfer of liability from the GP to the out of hours service provider. They may also provide for the withdrawal or suspension of approval by Health Authorities as well as the criteria to be used in making decisions under the regulations.

89. Once this section has come into force, existing powers under the 1977 Act and the 1997 Act will be used to effect consequential changes to the Terms and Conditions of Service for GPs and to the Directions for the Implementation of Personal Medical Services to ensure that GPs use only accredited providers of out-of-hours services.

Section 19: Enhanced criminal record certificates

90. Health Authorities are currently required by Part 2 of the 1977 Act to maintain lists of all practitioners who undertake to provide general medical services (GMS), general dental services (GDS), general ophthalmic services (GOS) and pharmaceutical services (PhS) in their area. *Sections 24* and *26* of this Act extend this list system to cover those who assist in the provision of these primary care services (e.g. deputies or locums) as well as those practitioners performing personal medical services (PMS) or personal dental services (PDS). To remain on a list, or be admitted to it, the intention is that persons will have to declare any criminal convictions, bindings-over following a criminal conviction

and cautions. In requiring a practitioner to declare his criminal conviction, Health Authorities will need to take steps to verify the information that they are given. The Home Office's new Criminal Records Bureau (CRB) set up under Part 5 of the Police Act 1977 will assist in the provision of criminal record checks.

91. The policy is that Health Authorities should have the fullest possible report from the CRB to ensure maximum protection for the public. Health Authorities can already be provided with standard criminal conviction or criminal record certificates under section 112 and 113 of the Police Act 1977. *Section 19* amends the Police Act 1997 to also enable Health Authorities to have access to enhanced criminal record certificates under section 115 of that Act. These are certificates, which will involve an extra layer of checking with local police records. Such enhanced disclosures are presently required for posts involving significant contact with children and vulnerable adults.

92. *Subsection (2)* of this section amends the Police Act 1977 to provide that section 115 certificates may be made available for those practitioners identified in new *subsections (6C), (6D)* and *(6E)*.

93. *Subsection (3)* of the section inserts *subsections (6C), (6D) and (6E)* into section 115 of the Police Act 1977. New *subsection (6C)* covers those practitioners included or seeking inclusion in the main GMS, GDS, GOS or PhS lists. *Subsection (6D)* covers directors of bodies corporate included or seeking inclusion in a main GDS or GOS list, members of limited liability partnerships included or seeking inclusion in a GOS list and a member of the body of persons controlling a body corporate included or seeking inclusion in a PhS list.

94. New *subsection (6E)* covers individuals included or seeking inclusion in a supplementary list (of, for example, deputies or locums) or services list (of those who may perform Personal Medical Services/Personal Dental Services). It also covers individuals seeking inclusion in service lists of people providing Local Pharmaceutical Services, should such lists be established by virtue of regulations made under s*ection 41* of this Act.

Section 20: Medical, dental, ophthalmic and pharmaceutical lists etc.

95. As indicated in the notes on s*ection 19*, Health Authorities are already required by Part 2 of the 1977 Act to maintain lists of all practitioners who provide GMS, GDS, GOS and PhS in their area. These are known respectively as the medical, dental, ophthalmic and pharmaceutical lists. *Section 20* provides new powers for Health Authorities to refuse a practitioner admission to the appropriate list on the grounds of unsuitability, prejudice to efficiency or because of previous fraudulent behaviour.

96. *Subsection (2)* amends section 29A of the 1977 Act to provide for regulations requiring practitioners already included in the medical list to provide the Health Authority information of a prescribed description as well as criminal conviction or criminal record certificates under sections 112, 113 or 115 of the Police Act 1977.

97. *Subsection (3)(a)* amends section 29B of the 1977 Act to provide for regulations specifying when Health Authorities may, or must, refuse an application from a medical practitioner to fill a vacancy: for example, because the applicant is considered to be unsuitable to work in the provision of general medical services, because it is considered that the applicant's inclusion in the list would be prejudicial to the efficiency of the service or because of the risk of the applicant's fraudulent behaviour. It further allows regulations to be made specifying the information which an applicant must provide (or arrange to be provided) in support of the application, including the supply of a certificate provided under sections 112, 113 or 115 of the Police Act 1997. Regulations may provide for the disclosure by Health Authorities to prescribed persons of specified information about persons applying for inclusion in the medical list as well as refusals of such applications.

98. *Subsection (3)(b)* provides for the regulations to specify when a Health Authority may defer a decision to nominate or approve a medical practitioner for appointment to fill a vacancy.

99. *Subsection (3)(c)* provides for a right of appeal, by re-determination, to the Family Health Services Appeal Authority (FHSAA) against a decision by a Health Authority under its discretionary powers.

100. *Subsections (4), (5), (6) and (7)* provide for similar regulatory powers in respect of practitioners included, or applying for inclusion in, dental, ophthalmic, pharmaceutical and dispensing doctor lists.

Section 21: Conditional inclusion in medical, dental, ophthalmic and pharmaceutical lists

101. *Section 21* inserts new section 43ZA into the 1977 Act. *Subsection (1)* of the new section provides powers to make regulations providing for a person's inclusion in a GMS, GDS, GOS or PhS list to be subject to conditions determined by the Health Authority; for the Health Authority to vary the conditions or impose new ones and for the consequences of a practitioner failing to comply with a condition, which could include removal from a list.

102. *Subsection (2)* requires that the imposition of conditions must relate to preventing any prejudice to the efficiency of the service or preventing any fraudulent acts.

103. *Subsection (4)(a*) provides that if the regulations provide for a practitioner's removal from a list for breach of condition, the regulations may also prevent the practitioner from withdrawing from the list whilst the Health Authority are investigating in order to see whether there are grounds for removal, or after the Health Authority have made the decision to remove the practitioner but before they have given effect to that decision. *Subsection (4)(b*) requires the regulations to include provision for a practitioner to be given notice of any allegations against him; for him to put his case at a hearing before a Health Authority makes a decision , and for him to be informed of a Health Authority's decision, the reasons for it and his right of appeal.

104. *Subsection (5*) requires the regulations to provide for a right of appeal to the FHSAA against a Health Authority's decision to impose conditions, to vary a condition, to vary terms of service or to remove a person from a list for a breach of a condition. The regulations may provide for a Health Authority decision not to have effect until the FHSAA has determined the appeal (and must do so in relation to a decision to remove the person from a list).

105. *Subsection (7*) provides that regulations may provide for a Health Authority to notify prescribed persons or persons of prescribed descriptions of any decisions they make to conditionally include practitioners in a list or remove such persons from a list for breach of condition. They may also supply any related information.

Section 22: Dental Corporations

106. *Section 22* enables Health Authorities to make arrangements with dental corporate bodies to provide GDS as well as with individual dental practitioners.

107. *Subsection (2)* amends section 35 of the 1977 Act to make provision for Health Authorities to arrange for the provision of GDS by dental corporations as well as dental practitioners. *Subsection (2)(c)* introduces the definition of 'dental corporation' as a body corporate which carries on the business of dentistry within the meaning of section 40 of the Dentists Act 1984 (i.e. to receive payments for providing dental treatment).

108. *Subsection (3)* amends section 36 of the 1977 Act which enables regulations to be made about the delivery of GDS. *Subsection (3)(a)* provides for such regulations to empower

Health Authorities to include dental corporations in their list of those undertaking to provide GDS. *Subsection (3)(b)* confers a right on dental corporations to be included in that list subject to certain conditions. *Subsection (3)(d)* provides for the removal of dental corporations from the Health Authority list in the event that the body never provides, or ceases to provide, GDS in that area.

Section 23: Declaration of financial interests, gifts, etc.

109. *Section 23* introduces new arrangements requiring practitioners providing family health services to declare their financial interests and any gifts or benefits they receive. The aim is to be broadly consistent with other NHS workers. Doctors, and other NHS employees, in the hospital sector are required to agree to local standards of business conduct that normally oblige them to refuse all gifts from patients except those gifts which are of low intrinsic value such as diaries or chocolates.

110. *Subsection (2)* amends section 29 of the 1977 Act to provide that regulations may require practitioners providing general medical services to declare any financial interests, gifts above a prescribed value or other benefits that they may receive in connection with the provision of NHS services. Such regulations will be subject to consultation.

111. *Subsections (3), (4) and (5)* provide for similar regulatory powers requiring persons and organisations providing general dental services, general ophthalmic services and pharmaceutical services to declare any gifts or other benefits that they may receive in connection with the provision of NHS services. Such regulations will also be subject to consultation.

Section 24: Supplementary lists

112. *Section 24* amends the 1977 Act to extend the existing Health Authority list systems to embrace all people who assist in the provision of family health services (i.e. otherwise than as principals in their own right).

113. This section inserts new section 43D into the 1977 Act. *Subsection (1)* of that section provides powers to make regulations providing for the preparation and publication by each Health Authority of lists covering practitioners (locums, deputies, or employees) assisting in the provision of GMS, GDS, GOS and PhS. *Subsection (2)* of the new section provides that such a list is to be referred to as a "supplementary list".

114. New section 43D(3) sets out provisions which (among others) may be included in the regulations about supplementary lists.

115. Paragraph (a) provides powers to prescribe the Health Authority to which an application for inclusion in a supplementary list should be made.

116. Under paragraph (b), the regulations may make provision about the procedure for applying for inclusion in a list. This may include details of the information to be supplied to the Health Authority, either directly by or by arrangement with an applicant, in order for that Authority to assess the applicant's suitability.

117. Paragraph (c) enables provision to be made about the grounds on which a Health Authority may or must refuse an application for inclusion in a list. This includes reasons of unsuitability or other grounds. For example, regulations might require a Health Authority to refuse entry to a list where the applicant has a conviction for murder. Regulations might also require a Health Authority to have regard to, but not be bound by previous decisions by other Health Authorities concerning the applicant's inclusion or otherwise in their lists. The Health Authority would, however, be bound by national disqualification decisions issued by the FHSAA (see section 25). Provision may be made under paragraph (e) as to the grounds on which a Health Authority may, or must suspend or remove a person from a supplementary list and the procedure for doing so.

118. Provisions may be made under paragraph (f) about payments to be made to or in respect of suspended practitioners. Applicants for inclusion in a list and practitioners already included may, under paragraph (g), be required to supply the Health Authority with criminal conviction or criminal record certificates. Paragraph (h) provides that regulations may make provision to prevent a person withdrawing from a Health Authority supplementary list (for example, during any period a practitioner is under investigation which might result in removal or during any period awaiting removal from a list). Under paragraph (k), regulations may provide for the disclosure by Health Authorities to prescribed persons or persons of prescribed descriptions of specified information about applicants applying for inclusion in a supplementary list as well as refusals of such applications and suspensions and removals from lists.

119. Section 43D(4) provides for regulations to make provision for a person's inclusion in a list to be subject to conditions determined by the Health Authority. The Health Authority may vary these conditions or impose different ones. The regulations will also set out the consequences of a person failing to comply with a condition, which could include removal from the list. They may also provide for the Health Authority to review their decisions to conditionally include a person in the list. Section 43D(5) requires that the imposition of conditions must relate to preventing any prejudice to the efficiency of the service or preventing any fraudulent act.

120. Section 43D(6) allows provision to be made about supplementary lists which corresponds to provision which may be made about principal lists under sections 49F to 49N (which are inserted by s*ection 25*).

121. Section 43D(7) requires that, if regulations make provision for a Health Authority to suspend or remove a practitioner from a supplementary list, the regulations must also include provision for a practitioner to be given notice of any allegation against him; for him to put his case at a hearing before the Health Authority makes a decision; and for him to be informed of the Health Authority's decision, the reasons for it and any right of appeal.

122. Section 43D(8) provides that if regulations provide for the removal of a person from a supplementary list, or for refusal to include him in one (other than a compulsory removal or refusal) they must also provide for an appeal, by re-determination, to the FHSAA against the Health Authority's decision to do so.

123. If the regulations make provision under section 43D(4), they must also provide for an appeal, by re-determination, to the FHSAA against any Health Authority decision to impose conditions on a person's inclusion in a supplementary list; to vary a condition, to remove a person from a list for failing to comply with a condition or any review of an earlier decision.

124. Section 43D(10) provides for regulations requiring that practitioners on one of the main lists may not employ or engage a person to assist them in the provision of the respective family health service, unless that person is included in one of the main lists, a supplementary list, or a services list established under s*ection 26* or a similar list in respect of local pharmaceutical services. However, by virtue of section 43D(11), regulations need not require the two people concerned to be on lists held by the same Health Authority, but they may require that someone must be on a relevant list held by an English Health Authority if they are to be engaged to assist in providing services in England, and on a Welsh Health Authority's list to be engaged in Wales. The intention is to help those, such as locum doctors, who work across Health Authority boundaries by normally requiring them to join just one, rather than several, supplementary lists.

Section 25: Suspension and disqualification of practitioners

125. *Section 25* makes provision for Health Authorities to suspend and remove (including contingent removal) practitioners from the relevant principal family health services list .

This will enable Health Authorities to take fast and effective action where concerns arise about a practitioner involved in the provision of these services.

126. New section 49F of the 1977 Act provides powers for a Health Authority to remove practitioners from the relevant principal medical, ophthalmic, dental, pharmaceutical or dispensing doctor list on the grounds of inefficiency, fraud or unsuitability.

127. Section 49G provides powers for a Health Authority in an efficiency or fraud case to contingently remove, rather than remove, a practitioner from a principal list. If a Health Authority makes a contingent removal it must impose conditions on the practitioner with a view to ensuring that the identified risks of "prejudice to the efficiency of the NHS" or preventing further fraud are eliminated. Where a practitioner fails to meet any such conditions, a Health Authority can vary them, impose new ones, or remove the practitioner from the list. For example, a practitioner might be required to submit more detailed information than normal in order to justify claims for fees and allowances. In consequence of its decision to impose conditions, the Authority may vary the individual practitioner's terms of service.

128. Section 49H(1) provides that in a fraud or unsuitability case a Health Authority may take action against a body corporate if the individuals in control of the body corporate themselves meet the criteria for fraud or unsuitability (whether or not they were running the body corporate at the time they first met the criteria) . Section 49H(2) means that a Health Authority may take action against a practitioner in a fraud case, if the fraud was committed by someone providing services on the practitioner's behalf and the practitioner had not taken all reasonable steps to prevent the fraud.

129. Section 49I provides powers for a Health Authority to suspend a practitioner from their list whilst considering whether that person should be removed or contingently removed or while it waits for a decision affecting the practitioner of a Court or a professional regulatory body anywhere in the world. In deciding whether to suspend a practitioner, a Health Authority must be satisfied that it is necessary to do so for the protection of members of the public or is otherwise in the public interest. If a Health Authority suspends a practitioner, it must specify the period of suspension. This may not exceed a maximum period of six months, except in certain cases. One is a case falling within prescribed circumstances. Regulations could, for example, prescribe that such circumstances would include where there is an ongoing criminal investigation, fraud investigation, or an investigation by the professional regulatory body. The Health Authority may also refer the matter to the FHSAA to determine whether the suspension should continue exceptionally for longer than six months. *Subsections (9)* and *(10)* provide that the Secretary of State may make regulations about payments to suspended practitioners. These regulations may include provision about the amount of the payments or the method of calculating the amount, to be determined by the Secretary of State or someone appointed by the Secretary of State.

130. Section 49J provides that, if a Health Authority decides to remove a practitioner from a list, they may also suspend that person pending any appeal to the FHSAA, if they are satisfied that it is necessary to do so for the protection of members of the public or is otherwise in the public interest.

131. Section 49K provides that while a practitioner is suspended, he shall be treated as though he were not on the list, even though his name was still on it.

132. Section 49L provides for a Health Authority to review any decision to contingently remove or suspend a practitioner. A Health Authority will be obliged to review a decision if requested in writing to do so by the practitioner. Following a review a Health Authority may confirm the suspension or contingent removal, end a suspension it has made, or in the case of contingent removal vary the conditions, impose different conditions, remove all conditions or remove the practitioner from a list.

133. Section 49M provides practitioners with a right of appeal, by re-determination, to the FHSAA against any decision the Health Authority may make to remove or contingently remove them from a list, or any decision on a review of a contingent removal by the Health Authority. In addition, a practitioner can appeal to the FHSAA against any further decision to vary or change the conditions imposed on the practitioner pursuant to a contingent removal. An appeal must be lodged in writing to the FHSAA within 28 days of notice of the decision. The FHSAA may make any decision which could have been made by the Health Authority. If the FHSAA decides to remove the practitioner contingently, the Health Authority and the practitioner may each apply to the FHSAA for the conditions imposed on the practitioner to be varied, for different conditions to be imposed or for the contingent removal to be revoked. The Health Authority may remove the practitioner from their list if they determine that he has failed to comply with a condition. A Health Authority decision to remove or contingently remove a practitioner from a list may not take effect until the specified time to lodge an appeal with the FHSAA has passed and no appeal has been lodged, or if an appeal is lodged, until the FHSAA has disposed of the appeal.

134. Section 49N provides for a "national disqualification". A decision by a Health Authority would be 'local' and would remove a practitioner from the list covering its area. *Subsection (1)* provides for the FHSAA to make a decision to nationally disqualify a practitioner from the principal, supplementary and services lists of all Health Authorities or any of these as specified by the FHSAA. *Subsection (3)* provides that the FHSAA may also impose a national disqualification on a practitioner if it dismisses an appeal against a Health Authority's refusal to include that practitioner in a list (or in the case of a medical list, a refusal to nominate or approve that practitioner for inclusion). *Subsection (4)* provides that a Health Authority may apply to the FHSAA for national disqualification to be imposed on a person after removal from, or a refusal to admit to any of its lists (i.e. principal lists, supplementary lists, and services lists). The Health Authority would be required to apply for such disqualification within three months from the date of removal or their refusal. *Subsection (6)* provides that no Health Authority may subsequently include a person upon whom a national disqualification has been imposed in such a list, or if already included in a list, requires the Health Authority to remove the person from it. *Subsection (7)* provides for the FHSAA to review a national disqualification at any time. Following a review the FHSAA may confirm or revoke the disqualification. Subject to *subsection (9)* a person may not request such a review until at least two years from the date of the original national disqualification, or in the case of repeat applications, at least one year from the date of the last decision. *Subsection (9)* provides that, in prescribed circumstances, a person may request a review either before or after these time limits.

135. New section 49O provides for regulations requiring a Health Authority to notify prescribed persons or persons of prescribed descriptions of any decision they make under this group of sections: for example, to suspend, remove or contingently remove a practitioner from a list. They may also supply any related information.

136. In addition, section 49P provides for regulations stating the circumstances in which a practitioner whom a Health Authority are investigating in order to see whether there are grounds for removal, contingent removal or suspension, or in relation to whom a decision to remove or contingently remove has not yet taken effect, or who has been suspended pending an appeal to the FHSAA, may not withdraw from a list.

137. Section 49Q provides for regulations prescribing the procedure to be followed by Health Authorities in making a decision to suspend, remove or contingently remove a practitioner. *Subsection (2)* requires the regulations to include provision for a practitioner to be given notice of any allegation against him; for him to put his case at a hearing before a Health Authority makes a decision, and for him to be informed of a Health Authority's decision, the reasons for it and his right of appeal.

138. Section 49R is intended to provide a mechanism for preventing a practitioner who has been disqualified from a health board list by a NHS tribunal in Scotland or similarly from an equivalent list in Northern Ireland from being included on any list in England and Wales. Specifically, it enables the Secretary of State to make provisions in regulations to recognise the decisions of Scottish and Northern Irish tribunals in England and Wales.

Personal medical services and personal dental services

Section 26: PMS and PDS lists

139. *Section 26* introduces new arrangements further extending the Health Authority list system to include those practitioners who may perform personal medical services "PMS" and personal dental services "PDS". These arrangements are substantially identical to those relating to supplementary lists.

140. *Subsection (1)* inserts new section 28DA into the 1977 Act. *Subsection (1)* of that section provides powers to make regulations providing for the preparation and publication by each Health Authority of lists of medical and dental practitioners who may perform PMS and PDS. *Subsection (2)* of the new section provides that such a list is to be referred to as a "services list".

141. Section 28DA(3) sets out provisions which (among others) may be included in regulations about services lists.

142. Paragraph (a) provides powers to prescribe the Health Authority to which an application for inclusion in a services list should be made.

143. Under paragraph (b), the regulations may make provision for the procedure for applying for inclusion in a list. This may include details of the information to be supplied to the Health Authority, either directly by or arranged by an applicant, in order for that Authority to assess the applicant's suitability.

144. Paragraph (c) enables provision to be made about the grounds on which a Health Authority may or must refuse an application for inclusion in a list. This includes reasons of unsuitability or on other grounds. For example, regulations might require a Health Authority to refuse entry to a list where the applicant has a conviction for murder. Regulations might also require a Health Authority to have regard to, but not be bound by, previous decisions by other Health Authorities concerning the applicant's inclusion or otherwise in their lists. The Health Authority would, however, be bound by national disqualification decisions issued by the FHSAA (see *Section 25*). Provision may be made under paragraph (e) as to the grounds on which a Health Authority may, or must, suspend or remove a person from a services list and the procedure for doing so.

145. Provision may be made under paragraph (f) about payments to be made to or in respect of suspended practitioners. Applicants for inclusion in a list and practitioners already included, may, under paragraph (g), be required to supply the Health Authority with criminal conviction or criminal record certificates. Paragraph (h) provides that regulations may make provision to prevent a person withdrawing from a Health Authority services list (for example, during any period a practitioner is under investigation which might result in removal or during any period awaiting removal from a list). Under paragraph (k), regulations may provide for the disclosure by Health Authorities to prescribed persons or persons of prescribed descriptions of specified information about applicants applying for inclusion in a services list as well as refusals of such applications and suspensions and removals of practitioners from a services list.

146. Section 28DA(4) provides for regulations to make provision for a person's inclusion in a list to be subject to conditions determined by the Health Authority. The Health Authority may vary these conditions or impose different ones. The regulations will also set out the consequences of a practitioner failing to comply with a condition, which

could include removal from the list. They may also provide for the Health Authority to review their decisions to conditionally include a person in the list. Section 28DA(5) requires that the imposition of conditions must relate to preventing any prejudice to the efficiency of the service or preventing any fraudulent act.

147. Regulations under section 28DA(6) may require that no person may perform PMS or PDS unless they are included in either a medical or dental list, a supplementary list or a services list.

148. Section 28DA(7) allows provision to be made about services lists which corresponds to provision which may be made about principal lists under sections 49F to 49N (which are inserted by *section 25*).

149. Section 28DA(8) requires that, if the regulations make provision for a Health Authority to suspend or remove a practitioner from a services list, the regulations must also include provision for a practitioner to be given notice of any allegation against him; for him to put his case at a hearing before the Health Authority makes a decision; and for him to be informed of the Health Authority's decision, the reasons for it and any right of appeal.

150. Section 28DA(9) provides that any regulations providing for the removal of a person from a services list or a refusal to include him in one (other than a compulsory removal or refusal) must also provide for an appeal, by re-determination, to the FHSAA against the Health Authority's decision.

151. If the regulations make provision under section 28DA(4), they must also provide for an appeal, by re-determination, to the FHSAA against any Health Authority decision to impose conditions on a person's inclusion in a services list; to vary a condition, to remove a person from a list for failing to comply with a condition or any review of an earlier decision.

152. *Subsection (2)* inserts a new section 8ZA into the National Health Service (Primary Care) Act 1997 introducing similar provisions in relation to PMS and PDS pilot schemes.

The Family Health Services Appeal Authority

Section 27: The Family Health Services Appeal Authority

153. The NHS Plan set out the Government's intention to abolish the NHS Tribunal and to devolve the power to suspend or remove practitioners from a Health Authority list to Health Authorities. Practitioners will have a right of appeal to the Family Health Services Appeal Authority (FHSAA) against any decision to remove them a list. *Section 16* of this Act abolishes the NHS Tribunal. The intention is to rationalise the functions carried out by the existing Family Health Services Appeal Authority and the NHS Tribunal into one body. In effect the Family Health Services Appeal Authority created by the Act will take over the functions of the Tribunal, adapted to take account of the new powers of Health Authorities to suspend or remove practitioners. The existing Family Health Services Appeal Authority is a Special Health Authority. *Section 27* provides for the creation of the new Authority as an independent body.

154. *Subsection (1)* of *section 27* inserts a new section 49S into the 1977 Act which sets up the Family Health Services Appeal Authority (FHSAA). *Subsection (2)* of the new section provides for the Authority to be constituted in accordance with new Schedule 9A. *Subsection (3)* provides for the functions of the FHSAA to be conferred on it by the 1977 Act or by any other enactment. *Subsection (4)* provides a power for the Secretary of State to direct the FHSAA to exercise any of his functions relating to the determination of appeals (for example, such functions currently exercised by the existing Family Health Services Appeal Authority). *Subsection (5)* provides that such directions must be given by regulations or in writing. *Subsection (6)* permits the Secretary of State to make available to the FHSAA any facilities (or premises) provided

by him or a Special Health Authority or NHS trust as well as the services of any staff employed by him or by a Special Health Authority or NHS trust.

155. *Subsection (4)* (of*section 27*) inserts Schedule 9A into the 1977 Act. Paragraphs 1 to 6 set out the constitution and membership of the FHSAA. The FHSAA will consist of a President, one or more Deputy Presidents, and a number of other members, all to be appointed by the Lord Chancellor on terms to be determined by him. The number of other members will be determined by the Lord Chancellor after consulting the Secretary of State. The membership must include people with a lay background as well as those with relevant professional expertise.

156. Paragraph 7 provides for the FHSAA to determine its own procedure, subject to the requirements of paragraphs 8 to 18 of the Schedule. Paragraph 8 provides that the functions of FHSAA are exercised by panels consisting of one or more members chosen by the President (who may include himself). Paragraph 9 requires that at least one member of a panel (or in the case of a one member panel, that member) must have a seven year legal qualification. Paragraph 10 provides that a three member panel exercising functions under section 49M or 49N of the 1977 Act, as inserted by *section 25*, must comprise one legal member, one professional member and one other.

157. Paragraph 11 requires that where a panel has more than one member, the President shall nominate one of the members to act as chairman; for decisions to be taken by a majority of votes, and if there is a tie for the chairman to have a second vote as a casting vote.

158. The FHSAA will be required to give notice of a panel's decision and the reasons for it to each party to the proceedings; to publish each decision of a panel, and to send a copy of any such decision, and, where appropriate, any information as appears to be relevant, to prescribed persons or persons of prescribed descriptions.

159. Paragraphs 15 to 18 provide for the Lord Chancellor to make rules regarding the composition of the panels and the procedure to be followed. Paragraph 19 provides for the publication of an annual written report about the FHSAA's activities. Paragraph 20 provides that the President must arrange for appropriate training for himself and the other members of the FHSAA.

Part 2: Pharmaceutical Services

Chapter 1: Local Pharmaceutical Services

160. Chapter 1 of Part 2 provides for new arrangements under which community pharmacy and related services may be provided on a piloted basis. At present, pharmaceutical services, including the dispensing of NHS prescriptions, are provided by community pharmacies, appliance contractors and dispensing doctors under arrangements made with Health Authorities in accordance with Part 2 of the 1977 Act, and in particular regulations made under sections 41 and 42 of that Act. These arrangements are referred to below as "Part 2 pharmaceutical services".

161. The new arrangements will be known as Local Pharmaceutical Services and will provide an alternative legal framework for the provision of pharmaceutical services, under locally agreed contracts. Local Pharmaceutical Services will first be provided under pilot schemes, which are intended to develop and demonstrate innovative ways of providing high quality, cost-effective services to patients. They will be similar to PMS and PDS pilot schemes, established under the NHS (Primary Care) Act 1997. Many of the provisions in this Part of the Act (and in particular s*ections 31 to 34)* are modelled on the equivalent provisions in that Act.

Preparation and making of pilot schemes

Section 28: Pilot Schemes

162. *Section 28* deals with the general nature of Local Pharmaceutical Services pilot schemes. *Subsection (2)* provides that a pilot scheme may consist of one or more agreements between a Health Authority and any other person or persons (other than another Health Authority) under which Local Pharmaceutical Services are to be provided. The Health Authority may not itself provide Local Pharmaceutical Services.

163. Unlike Personal Medical and Dental Services pilots, provision of Local Pharmaceutical Services is not to be restricted to particular classes of person (although nothing in these provisions will alter restrictions in the Medicines Act 1968 and other legislation on who may supply medicines). The parties to pilot schemes may therefore include, amongst others, individual pharmacists, retail pharmacy businesses and dispensing appliance contractors. They may also include NHS trusts and Primary Care Trusts, and *subsection (7)* provides that NHS trusts and Primary Care Trusts have the necessary powers to provide services under a pilot scheme.

164. *Subsection (8)* defines Local Pharmaceutical Services as such services prescribed in regulations which are of a kind that may be provided under section 41 or 41A of the NHS Act 1977 (that is, Part 2 pharmaceutical services). However, *subsection (9*) means that Local Pharmaceutical Services may not include the dispensing of drugs, medicines and appliances by doctors or dentists to their own patients.

165. Under section 41 of the NHS Act 1977, Health Authorities have a duty to arrange Part 2 pharmaceutical services for their area. Since Local Pharmaceutical Services pilot schemes will be providing similar services, *subsection (6)* permits Health Authorities to take into account such schemes in determining how to meet their duty under section 41.

166. *Subsection (3)* provides that a pilot scheme may also include health services which are not Local Pharmaceutical Services, but which may be provided under Part 1 of the NHS Act 1977. This could include, for example, diagnostic testing, therapeutic monitoring and health education. It need not be restricted to services normally associated with pharmacies. So it could, for example, include the provision of chiropody or similar services. Pilot schemes may also include the provision of training and education. However, *subsection (4)* provides that schemes may not combine arrangements for Local Pharmaceutical Services with those for Personal Medical or Dental Services.

167. *Subsection (5)* defines piloted services as services provided under a pilot scheme, which therefore include not only Local Pharmaceutical Services but any other services included within a scheme.

Section 29: Making Pilot Schemes

168. *Section 29* introduces Schedule 2, which makes provision about the making of pilot schemes. In particular, that Schedule provides that pilot schemes may only be established with the approval of the Secretary of State or, in relation to Wales, the National Assembly for Wales.

Section 30: Designation of priority neighbourhoods or premises

169. *Section 30* permits the Secretary of State or National Assembly for Wales to make regulations allowing Health Authorities to designate neighbourhoods, particular premises, or particular descriptions of premises for the purposes of Local Pharmaceutical Services pilot schemes. Under *subsection (2)* the regulations may, in particular, make provision about which such places Health Authorities may designate and in what circumstances. The regulations may allow Health Authorities to defer applications to provide Part 2 Pharmaceutical Services relating to designated places. To avoid designations being prolonged inappropriately, regulations may also deal with

the cancellation of designations, and may permit the Secretary of State or the National Assembly for Wales to direct that a designation be cancelled.

Reviews, variation and termination of pilot schemes

Section 31: Reviews of Pilot Schemes

170. *Section 31* deals with the review of pilot schemes. *Subsection (1)* requires that each pilot scheme be reviewed at least once by the Secretary of State or National Assembly for Wales, and *subsection (2)* requires that this be done within three years of services first being provided under the scheme. *Subsection (3)* requires the Secretary of State or National Assembly for Wales to give the relevant Health Authority and the people providing services under each scheme an opportunity to comment as part of the review, but otherwise *subsection (4)* allows the procedure for the review to be at the discretion of the Secretary of State or National Assembly for Wales.

Section 32: Variation and Termination of Pilot Schemes

171. *Section 32* deals with the variation and termination of pilot schemes. In particular *subsection (1)* permits the Secretary of State or National Assembly for Wales to issue directions to Health Authorities giving them a general authority to vary pilot schemes in specified circumstances and subject to specified conditions. The Secretary of State or National Assembly for Wales may also issue directions under *subsection (2)* to require Health Authorities to vary particular schemes. If for any reason the Secretary of State or National Assembly for Wales is satisfied that a pilot scheme is unsatisfactory, *subsection (3)* permits them to issue directions requiring the Health Authority concerned to bring the scheme to an end.

NHS contracts and financial provision

Section 33: NHS Contracts

172. Under s*ection 33*, persons providing pilot services may apply to become a health service body. The effect of such an application being granted is that the contracts entered into between the Health Authority and the health service body will be NHS contracts within the meaning of the National Health Service and Community Care Act 1990, rather than legal contracts.

173. Where a pilot scheme involves a single individual or body corporate, *subsection (1)* provides for that individual or body to apply to become a health service body. Where a pilot scheme involves more than one person, *subsection (2)* permits all the people involved to apply collectively. In both cases, applications must be made in accordance with regulations under *subsection (3)*. Regulations under *subsection (4)* may provide for applications to be granted except in specified cases. If an application is granted, *subsection (5)* requires the Secretary of State or National Assembly for Wales to specify when it is to come into effect.

174. From a specified day following grant of an application, the applicant or applicants are to be treated as a health service body for the purposes of section 4 of the 1990 Act. *Subsection (7)* provides that where an application has been granted to pilot scheme providers collectively, it is the providers in that scheme at any given time who are to be considered the health service body, even if they have changed since the original application. Regulations under *subsection (9)* may provide for people to cease to be health services bodies in specified circumstances.

175. *Subsections (10) and (11)* require the Secretary of State and National Assembly for Wales to maintain and keep up to date a list of pilot scheme providers who have been awarded health service body status, and to publish it in such manner as they consider appropriate.

176. *Subsection (6)* has the effect that contracts between pilot scheme providers which have been granted the status of health service bodies and other health service bodies (including other pilot scheme providers) are to be treated as NHS contracts if they are for the provision of goods or services in connection with the scheme .

177. NHS contracts are not normally enforceable in the courts. Instead, any disputes can be put to the Secretary of State or National Assembly for Wales for resolution. However, because most pilot scheme providers will be rather different from other health service bodies, *subsection (8)* provides that the County Court may enforce directions issued as a result of that dispute resolution procedure in favour of or against a pilot scheme provider.

Section 34: Funding of preparatory work

178. *Section 34* deals with financial support for people developing proposals for pilot schemes and preparing to provide services under them. *Subsection (1)* provides that regulations may make provision for Health Authorities to give people financial assistance in respect of preparatory work, as defined by *subsection (2)*. S*ubsection (3)* sets out matters which may in particular be included in those regulations.

Section 35: Charges, recovery of payments and penalties

179. *Section 35* deals with charges. The Government's policy is that arrangements for prescription charges under Local Pharmaceutical Services will be the same as those which apply in relation to Part 2 Pharmaceutical Services. People who are exempt, or who otherwise are not required to pay prescription charges, will receive free prescriptions whether they use a pilot scheme provider or a Part 2 provider. Similarly, there will be no difference in the level of prescription charges, or in the cost of pre-payment certificates. Such certificates will be valid for both services interchangeably. To that end, *subsection (1)* provides that regulations may be made about the making and recovery of charges for Local Pharmaceutical Services. *Subsection (2)* specifies matters which may in particular be included in regulations, including the application to Local Pharmaceutical Services of sections 122A and 122B of the 1977 Act, which deal with the recovery of certain charges and the imposition of penalty charges in certain cases. *Subsection (3)* requires the regulations to secure that any charges in respect of Local Pharmaceutical Services will be the same as those which would apply had the service been provided under Part 2 of the 1977 Act.

General

Section 36: Effect of the 1977 Act

180. *Section 36* makes general provision about the status of the functions of the Secretary of State, National Assembly for Wales and Health Authorities in respect of Local Pharmaceutical Services pilot schemes. In particular, *subsection (2)* provides that, unless otherwise specified, the 1977 Act applies to services provided under pilot schemes as if the Secretary of State or National Assembly for Wales had directed a Health Authority to arrange those services on his behalf. One effect of this is that Health Authorities may, subject to directions from the Secretary of State or National Assembly for Wales under section 17A of the 1977 Act, delegate their functions in respect of pilot schemes to a Primary Care Trust. (For that reason, references in these explanatory notes to Health Authorities should be read to include Primary Care Trusts unless the context demands otherwise).

Section 37: Premises from which pilot services may be provided

181. *Section 37* deals with the relationship between pilot schemes and pharmaceutical services provided under Part 2 of the NHS Act 1977. S*ection 37(a)* permits regulations to be made preventing the provision of pilot scheme services from the same premises

as pharmaceutical services under Part 2 of the 1977 Act, except as provided in the regulations. *Section 37(b)* permits regulations to make provision about the inclusion, re-inclusion, removal and modification of entries in pharmaceutical lists held under Part 2 of that Act. It is envisaged that such regulations may be used to establish arrangements for determining whether, and to what extent, pilot scheme providers are to have a preferential right to return (or transfer) to Part 2 services in respect of particular premises on ceasing to provide services under a pilot scheme.

Section 38: Control of Entry Regulations

182. Section 42 of the 1977 Act requires regulations to be made about (amongst other things) the preparation and publication by Health Authorities of lists of people who have undertaken to provide Part 2 Pharmaceutical Services. Except as provided for in those regulations, applications by people wishing to join such a list (or to change the services or premises in respect of which they are already entered in the list) are granted only if the Health Authority is satisfied that it is necessary or desirable to do so in order to secure in the neighbourhood in question the provision of adequate pharmaceutical services by people on the list.

183. *Section 38* provides that regulations under section 42 of the 1977 Act may include provision about the extent which services provided under Local Pharmaceutical Services pilot schemes are to be taken into account when determining such applications.

Assessing the result of pilot schemes

Section 39: Assessing pilot schemes

184. *Section 39* provides that the Secretary of State or National Assembly for Wales may not bring into effect *section 40* (which deals with the provision of Local Pharmaceutical Services otherwise than under pilot schemes) unless they are satisfied that pilot schemes have shown that the continued provision of Local Pharmaceutical Services would be in the interests of the health service (or any part of it). The Secretary of State or National Assembly for Wales must have regard, in particular to the results of reviews of pilot schemes required under *section 31*.

Provision for local pharmaceutical schemes

Section 40: Provision for LPS schemes

185. *Section 40* makes provision for Local Pharmaceutical Services schemes which are not pilot schemes by inserting a new section 28J and a new Schedule 8A into the NHS Act 1977. The new Schedule 8A is set out in Schedule 3 to this Act. *Subsection (3)* inserts a new subsection (2A) in section 42 of the 1977 Act, which has the same effect in relation to Local Pharmaceutical Services schemes which are not pilot schemes, as s*ection 38* has in relation to pilot schemes.

Corresponding provision, etc.

Section 41: Corresponding provision and application of enactments

186. *Section 41* provides a power to make regulations in relation to local pharmaceutical services (or the people involved in providing them) whose provisions correspond to equivalent statutory provision in relation to personal medical or dental services (or the people involved in providing them). The provisions may be applied with such modifications as are considered appropriate.

Schedule 2: Pilot Schemes

187. This Schedule deals with arrangements for establishing Local Pharmaceutical Services pilot schemes (see explanatory notes to Chapter 1 of Part 2 of the Act and in particular *section 29*).

188. *Paragraph 1* provides that a pilot scheme may be established on a Health Authority's own initiative or at the request of a person wishing to participate in a scheme. A request from a prospective participant must be made in writing and must conform to any requirements set out in regulations.

189. *Paragraph 2* deals with the preparation of proposals for pilot schemes both for preliminary and final approval. Before establishing a pilot scheme Health Authorities are to be required to prepare proposals for submission to the Secretary of State or National Assembly for Wales, who may issue directions about the issues to be dealt with and the information to be included in such proposals. They may also issue directions requiring Health Authorities to consult on proposals before submitting them (and any such requirement would be in addition to any other obligation to consult imposed by or under any other legislation).

190. In some cases, it may be that Health Authorities will be required to include with proposals a recommendation about whether it should, or should not, be approved. The Secretary of State or National Assembly for Wales is therefore to be able to issue directions specifying the factors that Health Authorities should take into account in making any recommendation and the form in which the recommendation is to be made. Like other directions under this paragraph, such directions may be general, or particular to specific schemes.

191. Health Authorities are not generally to be required to submit proposals at the request of potential participants. However, sub-paragraph (5) will allow the Secretary of State and National Assembly for Wales to direct Health Authorities to submit summaries of such requests, prepared and presented in accordance with the directions, and to specify circumstances in which Health Authorities must submit proposals for consideration.

192. *Paragraph 3* deals with approval. The Secretary of State or National Assembly for Wales will not be able to approve a proposal unless satisfied that there are adequate arrangements for participants (other than the Health Authority) to withdraw. Otherwise, they may approve proposals as submitted, or with modifications, or reject them. They must notify the relevant Health Authority of their decision and the Health Authority must notify the other participants without delay.

193. *Paragraph 4* will permit a Health Authority to apply for preliminary approval for a scheme, before it has identified who the participants are to be. This could be used, for example, by a Health Authority wishing to establish services in an area that is not adequately served either by Local Pharmaceutical Services or Part 2 Pharmaceutical Services. It could first obtain preliminary approval for a scheme, and then invite bids from people to become the pilot scheme provider. As with full proposals, the Secretary of State and National Assembly for Wales will be required either to approve preliminary approvals as they stand or subject to modifications, or else reject them. If the preliminary proposal is approved, Health Authorities may be required to prepare full proposals in accordance with directions from the Secretary of State or National Assembly for Wales. Preliminary approval will not guarantee final approval of the scheme.

194. *Paragraph 5* requires Health Authorities to include in their proposals for pilot schemes an assessment of the likely effect of the schemes on other services. Those other services are pharmaceutical services provided under Part 2 of the 1977 Act, local pharmaceutical services provided under other pilot schemes, general medical services and personal medical services. Where necessary, the Health Authority making the proposals must

consult any other Health Authority whose area may be affected, and that Health Authority must provide an assessment of the effects on services in its area.

195. *Paragraph 6* permits the Secretary of State and National Assembly for Wales to issue guidance about the criteria they are likely to apply when considering both full and preliminary proposals.

196. *Paragraph 7* deals with the establishment of schemes once approved. It will require Health Authorities to implement proposals that have been approved, in accordance with directions from the Secretary of State or National Assembly for Wales. The Health Authority may not withdraw from the scheme before it is established, but any of the other parties may at any time. A pilot scheme may only differ from the proposals as approved if the Secretary of State or National Assembly for Wales agree the particular change, or if the change falls within the scope of any directions they have issued permitting variations. As soon as possible after implementing a scheme, Health Authorities will be required to publish details of the scheme, in accordance with any directions issued by the Secretary of State or National Assembly for Wales.

Schedule 3: Local Pharmaceutical Services

197. Schedule 3 sets out the new Schedule 8A which is inserted into the 1977 Act by *section 40*. The Schedule makes provision for Health Authorities to make arrangements for Local Pharmaceutical Services schemes on a substantive (rather than a pilot basis).

198. *Paragraph 1* makes provision for Local Pharmaceutical Services schemes, equivalent to those in *section 28* for pilot schemes.

199. *Paragraph 2* allows regulations to be made permitting Health Authorities to designate locations in which they may give priority to Local Pharmaceutical Services. The provision is equivalent to that in *section 30* for pilot schemes.

200. *Paragraph 3* provides for the Secretary of State or National Assembly for Wales to make regulations about Local Pharmaceutical Services. Paragraph 3(2) requires that those regulations must include provision for participants in schemes (other than Health Authorities) to withdraw if they wish. Regulations may also impose conditions to be satisfied by people providing Local Pharmaceutical Services. By virtue of paragraph 3(3), regulations may make provision about other matters, including in particular the items specified in sub-paragraphs (a) – (k). Sub-paragraphs (i) and (j) provide for regulations to make arrangements similar to those provided for in respect of pilot schemes by *section 33* (NHS contracts). Sub-paragraph (k) provides for regulations to make provision for payments by Health Authorities of financial assistance in respect of preparatory work, and is similar in effect to *section 34* for pilot schemes.

Chapter 2: Changes to existing arrangements

England and Wales

Section 42: Dispensing of NHS prescriptions and provision of pharmaceutical services

201. *Subsection (1)* of *section 42* substitutes a revised section 41 in the 1977 Act relating to the arrangements for pharmaceutical services.

202. *Subsection (1)(a)* of new section 41 requires Health Authorities, in accordance with regulations, to make arrangements for the supply to persons who are in their area, of drugs, medicines and listed appliances to those people for whom they have been prescribed by medical practitioners under the national health service (including the Scottish and Northern Ireland health services).

203. *Subsections (1)(b) and (c)* require Health Authorities similarly, in accordance with regulations, to make arrangements for the supply to persons who are in their area, of

drugs and medicines to those people for whom they have been prescribed by dental practitioners.

204. *Subsection (1)(d)* makes provision for items prescribed by certain other categories of prescriber also to be dispensed as part of NHS pharmaceutical services. This subsection gives the Secretary of State powers to specify in regulations the categories of person whose prescriptions will be dispensed and any conditions in accordance with which they must prescribe. It also provides the Secretary of State with powers to determine the particular drugs, medicines and appliances which each of them may prescribe for NHS dispensing. In relation to prescription only medicines, this subsection needs to be read in conjunction with *section 63*, which deals with the related issue of extension of the right to prescribe such medicines.

205. *Subsection (1)(e)* allows the Secretary of State to make regulations extending the scope of the services for which Health Authorities are required to make arrangements.

206. *Subsection (2)* of new section 41 defines these services together with the additional pharmaceutical services provided for under section 41A as "pharmaceutical services".

207. *Subsection (3)* of new section 41 provides that the categories of persons under subsection (1)(d) whose prescriptions may be dispensed must be professionals regulated by law. It includes provision to ensure that prescriptions written by health professionals regulated under Scottish and Northern Irish legislation can be dispensed in England and Wales. *Subsection (4)* of new section 41 relates to the Secretary of State's powers to determine the particular drugs, medicines and appliances which each category of prescriber may prescribe for NHS dispensing. It provides that a determination may make different provision for different cases; specify the circumstances or cases in which a drug, medicine or appliance may be prescribed and allow for the dispensing of such items as the prescriber thinks necessary, in the exercise of their discretion.

208. *Subsection (5)* of new section 41 provides that the arrangements made by a Health Authority can include arrangements for the provision of a service by 'remote' means, so that the person receiving the service does so otherwise than at the premises from which it is provided. *Subsection (6)* of new section 41 makes provision to the effect that (subject to any limitations imposed by the Secretary of State in regulations) people with whom a Health Authority has made arrangements may also provide pharmaceutical services to people who are outside the Authority's area. This might happen, for example, where patients send their prescriptions by post to the pharmacy of their choice, or where a pharmacy collects a prescription from a GP's surgery on a patient's behalf and then delivers the dispensed medicine to the patient's home. The intention is to facilitate, and provide a means to control, the development of internet, mail order, home delivery and other arrangements. This will provide patients with greater flexibility in the way they can present their prescriptions and obtain the drugs or appliances that have been ordered for them.

Section 43: Remote provision of pharmaceutical, etc. services

209. Section 41A of the 1977 Act concerns the provision of "additional pharmaceutical services" which are in addition to those required by section 41. *Section 43* amends this section to give the Secretary of State powers to give directions to Health Authorities authorising or requiring them to arrange for the provision of services to any person, whether or not in their area. *Subsection (1)(b)* (of *section 43*) adds a new subsection (1A) to section 41A of the 1977 Act to allow the Secretary of State to authorise or require Health Authorities to arrange for the provision of these services by remote means so that the service is received otherwise than at the premises from which it is provided.

210. Section 42 of the 1977 Act provides powers to make regulations governing the arrangements made by a Health Authority for the provision of pharmaceutical services. In accordance with section 42(2), regulations require all Health Authorities to prepare and publish lists of persons (other than for medical and dental practitioners) who

undertake to provide pharmaceutical services from premises in their area. Applications for inclusion in a pharmaceutical list are only to be granted if the Health Authority is satisfied that it is necessary or desirable to do so to secure the adequate provision of services in the neighbourhood in which the premises are located. *Subsection (3)* provides that regulations may be made exempting people from the 'necessary or desirable' test where they are to provide services solely by remote means.

211. *Subsection (4)* of *section 43* adds new subsections (3A) and (3B) to section 42 of the 1977 Act.

212. New subsection (3B) allows regulations to be made requiring people providing remote services to be approved for that purpose. It also provides a power to prescribe conditions to be imposed on the grant of an application for inclusion in a pharmaceutical list, where the applicant is to provide services by remote means.

213. *Subsection (5)* (of *section 43*) amends section 43(2A) of the 1977 Act, under which regulations are required to provide for the preparation by Health Authorities of lists of medical practitioners who supply drugs, medicines and appliances. The effect is to ensure that such dispensing doctors are included in the list of each Health Authority with whom they have arranged to dispense, even if they dispense from premises in another Health Authority's area.

214. Section 44 of the 1977 Act permits a Health Authority to recognise a Local Pharmaceutical Committee (LPC) which it is satisfied is representative of persons providing pharmaceutical services in its area. S*ubsection (6) (of section 43)* amends section 44 to clarify that notwithstanding that people in the Health Authority's area may receive pharmaceutical services from people whose premises are outside that area, the LPC need only be representative of persons who are included in a Health Authority's own pharmaceutical list, in order to be recognised by it.

Scotland

Section 44: Dispensing of NHS prescriptions

215. *Section 44* amends section 27 of the National Health Service (Scotland) Act 1978 to make provision for items prescribed by certain categories of prescriber to be dispensed as part of NHS community pharmaceutical services in Scotland. This section was requested by the Scottish Executive and approved by the Scottish Parliament on 17th January 2001. Section 27(1)(cc) as amended, gives Scottish Ministers powers to specify in regulations the categories of person whose prescriptions will be dispensed and conditions in accordance with which they must prescribe. Scottish Ministers may also determine the drugs, medicines and appliances which each of them may prescribe for NHS dispensing. Paragraph (cc) applies to persons other than doctors and dentists, for whom separate provision is made at paragraphs (a) to (c) of Section 27.

216. *Subsection (3)* limits the categories of person who may be prescribed in regulations under Section 27(1)(cc) to certain professionals regulated under statute. It includes provision to ensure that prescriptions written by health professionals regulated under legislation in Northern Ireland can be dispensed in Scotland. It also provides that determinations under that section may make different provision for different cases, specify the circumstances or cases in which a given drug, medicine or appliance may be prescribed, and specify types of prescriber who may prescribe such drugs, medicines and listed appliances as they see fit, in the exercise of their discretion.

Part 3: Care Trusts and Partnership Arrangements

Sections 45 -47: Care Trusts and directed partnership arrangements

217. *Section 45* provides for the designation of Primary Care Trusts (PCTs) and NHS trusts as Care Trusts in cases where they have local authority health-related functions

delegated to them by agreement. The Care Trust will then be able to commission and/or provide integrated services covering health, social services and other health-related local authority functions. Designation as a Care Trust will lead to a change in governance arrangements so that local authority interests are duly represented within the governance structures of the Care Trust. Care Trusts are intended to provide for a high level of integration between health and local authority services enabling patients' needs to be addressed holistically, the synergies of joint working to be exploited and patients to benefit from a seamless provision of their care needs.

218. Care Trust status will be conferred where an application is made to the Secretary of State or the National Assembly for Wales jointly by the NHS bodies and local authorities involved. Under *section 46*, partnership arrangements will have to be set up where the Secretary of State or the National Assembly for Wales directs that partnership arrangements are to be entered in to in order to address the inadequate performance of an NHS body or of a local authorities social services functions .

Section 45: Care Trusts where voluntary arrangements

219. *Section 45* provides for the designation of a PCT or NHS trust as a Care Trust following an application to the Secretary of State or the National Assembly for Wales by the partners in the proposed Care Trust.

220. *Subsection (1)* provides that the Secretary of State or the National Assembly for Wales may designate a PCT or NHS trust that is, or is to be, party to local authority delegation arrangements as a Care Trust. *Subsection (1)(b)* requires the Secretary of State or the National Assembly for Wales to be of the opinion that Care Trust status is likely to promote the effective exercise by the trust of any delegated health-related functions of the local authority alongside the trust's existing NHS functions. This reflects the main aim of a Care Trust which is to improve services through effective integration of NHS and local authority services.

221. *Subsection (2)* sets out the voluntary nature of this approach to forming a Care Trust. The Secretary of State or the National Assembly for Wales will only be able to designate a Care Trust following a joint application by the local partners. The NHS partner could be a PCT, NHS trust or Health Authority, where a Care Trust is to be based on an existing Primary Care Group (see paragraph 225 below). Regulations will define the detailed arrangements for the applications. This will enable the arrangements for the different NHS partners to be specified, and allow regulations to be made governing the formation of a Care Trust where more than one local authority or health body has an interest.

222. *Subsection (3)* enables the Secretary of State or the National Assembly for Wales to direct that where a Care Trust is exercising health-related functions of a local authority alongside its NHS functions , it may exercise health-related functions of that local authority in relation to people for whom it does not exercise NHS functions. The intention is that the NHS and local authority health-related functions of the Care Trust should be exercised together as far as possible in order to provide integrated services. This flexibility will be required to cope with the different populations covered by local authorities and health bodies. A Care Trust may have responsibility for only NHS or only local authority health-related functions for some sections of the population.

223. *Subsection (4)* enables the designation of a Care Trust to be revoked by the Secretary of State or the National Assembly for Wales. This may be of the Secretary of State's or National Assembly for Wales's own motion (after consultation) or following an application by one or more of the parties. In the latter case, the Secretary of State or the National Assembly for Wales must revoke the designation at the earliest time considered appropriate having regard to the steps that need to be taken in connection with the revocation.

224. *Subsection (5)* provides for the Secretary of State or the National Assembly for Wales to designate a body as a Care Trust by order, either amending the establishment order of an existing PCT or NHS trust, or by creating a new PCT or NHS trust. A new body will be created where a Care Trust is to be formed from a partnership between a local authority and a Primary Care Group.

225. *Subsection (6)* contains provisions which enable the Secretary of State or the National Assembly for Wales to dissolve existing PCTs or NHS trusts where they think it is appropriate to do so in connection with the designation of another body as a Care Trust. *Subsection (7)* enables the Secretary of State or the National Assembly for Wales to make regulations dealing with matters which are consequential or supplementary to the formation of Care Trusts and the revocation of the designation of such trusts. *Subsection (8)* sets out particular circumstances for which such regulations may make provision. These include:

(a) the process for applying for Care Trust status, the information to be supplied and the criteria to be met; and

((b) the governance arrangements for a Care Trust. The intention is to include local authority members on the boards of Care Trusts and to increase the representation of social services professionals within the governance arrangements for a Care Trust.

226. *Subsection (9)* explains that the designation of a PCT or a NHS trust as a Care Trust will not affect its functions, rights or liabilities as a PCT or NHS trust.

227. *Subsection (10)* provides that where an NHS body is to exercise social services functions as a Care Trust, it must act in accordance with directions and guidance from the Secretary of State or the National Assembly for Wales under certain powers relating to social services functions.

Sections 46 and 47: Directed partnership arrangements and further provisions about directions in connection with such arrangements and Care Trusts.

228. *Section 46* provides a power for the Secretary of State or National Assembly for Wales to require local authorities and NHS bodies to enter into partnership arrangements and/ or pooled funding arrangements.

229. *Subsection (1)* provides the power for the Secretary of State or the National Assembly for Wales to direct local authorities and NHS bodies to enter into delegation arrangements or pooled fund arrangements. The details of the arrangements are to be specified in the direction. *Subsection (1)(a)* limits the use of this power to circumstances where a local authority or NHS body is failing to deliver its functions adequately, and *subsection (1)(b)* further limits the use of the power to circumstances where the Secretary of State or the National Assembly for Wales is of the opinion that a delegation or pooled fund arrangement would be likely to improve the delivery of the failing function .

230. *Subsection (2)* provides that the directed partnership arrangements may cover not only the function which is being delivered inadequately but also other functions exercised by the same body where this would be likely to contribute to an improvement in the delivery of the failing function.

231. *Subsection (3)* sets out that the power to direct bodies to enter into delegation or pooled fund arrangements applies to NHS bodies and local authorities. In the case of local authorities, these powers can only be triggered by a failure to perform their social services functions adequately. As far as the NHS is concerned, the powers of direction relate to functions prescribed for the purposes of partnership arrangements under section 31 of the Health Act 1999 (see the NHS Bodies and Local Authorities Partnership Arrangements Regulations 2000, SI 2000/617).

232. *Subsection (4)* makes it clear that an improvement in the way in which a function is exercised includes improvement of services to individuals.

233. *Section 47* contains further provisions relating to the Secretary of State's and the National Assembly for Wales' powers to give directions given under sections 45 and 46. *Subsection (1)* enables directions under section 46 to deal with matters which are required to be dealt with by virtue of regulations made under section 31 of the Health Act 1999. The partnership arrangements authorised by the Health Act 1999 are first, pooled fund arrangements, whereby NHS bodies and local authorities contribute to a communal pot so that the money is neither health nor local authority money and is used to purchase integrated services; secondly, arrangements whereby a local authority can delegate its health-related functions to an NHS body; and thirdly, arrangements whereby an NHS body can delegate its functions to a local authority. *Subsection (3)* makes it possible for the Secretary of State and the National Assembly for Wales to issue directions to other NHS bodies and local authorities in connection with the principal direction.

234. *Subsection (4)* makes it possible for the Secretary of State or the National Assembly for Wales to give directions requiring bodies to take such steps as are appropriate to enable a decision to be made about whether a direction under s*ection 46* should be made.

235. *Subsections (5) and (6)* make it clear that directions have to be given in writing, that they can be revoked by further directions and that they must be adhered to.

236. *Subsection (7)* provides that where a direction is revoked any arrangements required by the direction may continue.

Section 48: Transfer of staff in connection with partnership arrangements

237. *Section 48* inserts into the Health Act 1999 a new Schedule 2A, set out as *schedule 4* to this Act. The new Schedule makes provision for the transfer of staff where any functions of a body are to be exercised by another body under section 31 of the Health Act (including where Care Trusts are established under section 45 of this Act). The Schedule enables staff transfer orders to be made which make the same provision as the Transfer of Undertakings Regulations 1981 (S.I. 1981/1794) ("the TUPE Regulations"). This is necessary because there is some doubt as whether the TUPE Regulations apply to transfers of functions in the public sector. Currently the TUPE Regulations exclude pensions, although the Acquired Rights Directive (which the TUPE Regulations implement) has just been amended to enable Member States to include pension provision. Orders under the new Schedule include the transfer of pension provision except in so far as the Order makes provision under paragraph 4 of the Schedule. This is so that the flexibility for Member States to make provision about pensions where the Acquired Rights Directive applies is also available in the case of staff transfers arising from partnership arrangements under section 31 of the 1999Act.

Part 4 : Social Care

238. This section of the Act is designed to improve the system of funding long term care, as set out in *The NHS Plan: The Government's Response to the Royal Commission on Long Term Care*. In addition, it will give local authorities powers to place people in residential care homes and nursing homes outside England and Wales, and it will allow regulations to make provision for direct payments so as to extend the scope of the existing direct payments scheme, allowing individuals more choice and control over the services they receive.

Nursing care

Section 49: Exclusion of nursing care from community care services

239. Currently, people in nursing homes may be required to contribute towards the cost of their nursing care. There are two categories of such people. The first are those who make their own arrangements for nursing home accommodation; the second are those for whom local authorities make arrangements (under Part 3 of the National Assistance Act 1948 ("the 1948 Act")) and who may be liable to make contributions under the means testing regime provided for by sections 22 and 26 of that Act . Those who receive nursing care from the NHS, however, receive their nursing care free of charge.

240. *Section 49* removes local authorities' functions to purchase nursing care by a registered nurse under community care legislation. This is intended to strengthen the incentives for the NHS to ensure effective rehabilitation after acute illness or injury. It is estimated that around 35,000 people who are currently paying for their nursing care will receive free nursing care through the NHS.

241. *Subsection (1)* removes the right of a local authority to provide or arrange nursing care by a registered nurse. It is intended that the NHS in pursuance of its powers and duties under the 1977 Act will provide or arrange nursing care by a registered nurse and such care will (in accordance with the 1977 Act) be free of charge. The Department of Health is currently working with the Royal College of Nursing and other key stakeholders to develop a tool to be used across the country for assessing peoples needs as regards nursing care. NHS staff will be trained in the use of this tool in time for the introduction of free nursing care.

242. *Subsection (2)* defines "nursing care by a registered nurse" as services provided by a registered nurse and involving either the provision of care or the planning, supervision or delegation of the provision of care, other than services which do not need to be provided by a registered nurse. In deciding whether services need to be provided by a registered nurse, it is necessary to have regard to the nature of those services and the circumstances in which they are provided. "Registered" in relation to nurses means registered in the register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting by virtue of qualifications in nursing (see Schedule 1 to the Interpretation Act 1978).

Preserved rights

243. *Sections 50 – 52* concern the abolition of preserved rights. Until 1 April 1993, when the community care reforms came into effect, residential care was paid for by the social security benefits that residents received. The community care reforms transferred the responsibility for paying for residential care to local authorities. However, people who were in residential care immediately before 1 April 1993, retained their right to the higher rate of income support that they had been receiving to pay for their care. Responsibility for paying for their care was not transferred to the local authority.

244. Over time, residential care costs have increased at a disproportionate rate to social security benefits, and in some cases social security benefits are not sufficient to cover the cost of the residential care. This has meant that sometimes people have had to leave the care home they have been living in and find alternative accommodation the cost of which is covered by the social security payment.

245. These sections provide for the removal of the entitlement to higher rates of income support or jobseeker's allowance and require local authorities to make appropriate accommodation arrangements, for those people who received those higher rates, in the same way as they are required to do for those who entered residential accommodation on or after 1 April 1993 . They will require the Secretary of State for Social Security to ensure that the special provision made for those with preserved rights ceases. At the request of the Scottish Executive and by the approval of the Scottish Parliament,

which was obtained on 17th January 2001, *section 50* operates on devolved legislation concerning Scotland so that preserved rights can cease across the whole of Great Britain on the same day.

246. These new arrangements will require local authorities to assess (under the 1948 Act or its Scottish equivalent) the care needs of those who have had preserved rights rates of benefits for community care services.

Section 50: Preserved rights: transfer to local authorities of responsibilities as to accommodation

247. *Section 50* provides for the transfer to local authorities of the responsibility for providing community care services for preserved rights recipients. *Subsection (1)(a)* will allow local authorities in England or Wales to provide residential accommodation for persons who were in such accommodation on 31 March 1993 by repealing section 26A of the 1948 Act. The corresponding provision for Scotland is repealed by *subsection (1)(b).*

248. *Subsection (2)* provides that a "qualifying person" for the purposes of this section is a person to whom either of those provisions applies immediately before the appointed day (i.e. the day on which subsection (1) takes effect).

249. *Subsection (3)* requires a local authority to secure community care services for qualifying persons in relation to their accommodation from, or as soon as possible after, the appointed day. Community care services are defined for England and Wales by section 46 of the National Health Service and Community Care Act 1990.

250. *Subsection (4)* places an obligation on local authorities to actively identify people with preserved rights and to carry out appropriate care assessments. Authorities will do this by working with the Department of Social Security, who will be given power to disclose relevant information by s*ection 51*.

251. *Subsection (5)* provides that where a qualifying person is provided with community care services with respect to his accommodation (under subsection (3)), his private arrangements with the residential home will terminate from the date from which he is provided with those community care services.

252. *Subsection (6)* provides that where a local authority has not been able to assess a person's need for community care services before the appointed day, the person's liability to pay for his accommodation becomes the liability of the local authority until the local authority makes the arrangements they consider necessary or where the person notifies the authority that he does not wish to be provided with community care services, the date of the notification. This is to ensure that *Subsection (7)* enables the local authority to recover from the person all or part of such a payment. It is intended that the Secretary of State will make regulations so that the liability of persons to pay during this period mirrors the means testing system provided for under sections 22 and 26 of the 1948 Act.

253. *Subsection (8)* enables regulations to be made so that the provisions of *section 50* do not apply in relation to any person of a prescribed description.

254. *Subsection (9)* allows regulations to be made to define the meaning of "ordinarily resident". It also allows regulations to be made governing the payment which a person is to make in respect of his accommodation before community care services are provided.

Section 51: Preserved rights: disclosure of information

255. This section is concerned with identifying and locating people with preserved rights by using records held by the Department of Social Security.

256. *Section 51* allows the disclosure of relevant information held by the Secretary of State for Social Security about preserved rights recipients to local authorities or to any person providing services to, or authorised to exercise functions of, such authorities. *Subsection (1)* specifies the persons this section applies to. *Subsections (2) to (4)* specify the type of information which may be supplied and for what purposes it may be used or disclosed. *Subsection (5)* provides that the restrictions imposed on the Secretary of State for Social Security relating to the unauthorised disclosure of information held by him (see section 123 of the Social Security Administration Act 1992) will apply to local authorities who receive information under this section as well as to the authorities' officers and employees .

Section 52: Preserved rights: alignment of social security benefits

257. This section provides for the termination of higher rates of income support and jobseeker's allowance. It requires the Secretary of State to exercise his powers under the Social Security Contributions and Benefits Act 1992 and the Jobseeker's Act 1995 so as to secure that the provisions relating to higher rates of income support or jobseeker's allowance payable to or in respect of persons with preserved rights cease to have effect from the appointed day .

Measures to increase availability of Part 3 accommodation

Section 53: Disregarding of resources when determining need for residential accommodation

258. Currently local authorities can only support people in residential accommodation who are in need of care and attention which is '*not otherwise available to them*'. Local authorities may refuse to support a person who has capital in excess of £18,500, (the current amount of money councils are not allowed to take into account when carrying out a means test) and the capacity to make their own arrangements on the grounds that they have care and attention otherwise available to them (the implication is that the £18,500+ capital could be used to meet care costs).

259. *Section 53* enables the Secretary of State to specify in regulations certain capital that is to be ignored by local authorities in determining whether care and attention is '*otherwise available*'.

260. This section will allow regulations to be made in the future which break the link with the capital limit when determining whether care and attention is "otherwise available", so that more people are able to take up the offer of a charge against their home to pay for their accommodation. Charges against homes are dealt with in *section 55*.

Section 54: Funding by resident etc. of more expensive accommodation

261. Currently, people provided with accommodation by local authorities cannot themselves pay the extra required for them to be provided with more expensive accommodation than the local authority will pay for. In other words, people cannot use any assets ignored by the means test to fund a care placement whose cost is greater than the level the local council would usually pay. This is because they will have been assessed for a fair contribution so should not have extra resources to utilise in this way. A third party (for example, a relative) can make up the difference if a more expensive home is chosen.

262. Under the new arrangements – the three month disregard (whereby for the first three months from admission to residential care, the value of the resident's home is disregarded from the means test) and the deferred payments scheme (see *section 55*) – greater numbers of people will be effectively supported by the local authority and many of these people will have some additional resources available .

263. *Section 54* allows for the making of regulations to enable both residents and third parties to make additional payments so that a resident can enter more expensive

accommodation than that which the authority would normally pay for in respect of a person with the same needs. *Subsection (2)* defines additional payments.

Section 55: Power for local authorities to take charges on land instead of contributions

264. The effect of this section is to make it possible for people going into care to defer selling their homes in order to pay for their care. In effect the local authority will make a loan to the resident and recover the money either from the estate when the resident dies or from the resident if he decides to make a full repayment during his lifetime.

265. *Subsection (1)* enables local authorities to enter into deferred payments agreements. *Subsection (2)* allows directions to be made setting out the circumstances in which an authority must enter into these arrangements. *Subsection (3)* sets out the nature of the deferred payment arrangement. In essence it is an agreement whereby during a certain period of time (the exempt period) a resident will not be required to make the payments, or the whole of the payments, he would otherwise have to make under the means testing regime. Instead the resident will grant the authority a charge over land in respect of such payments. *Subsection (4)* defines the exempt period. *Subsection (5)* allows the local authority to determine the provisions of the arrangement subject to any directions given by the Secretary of State or the National Assembly for Wales and provides that the arrangement must allow the resident to terminate the agreement at any time by giving notice and paying the full amount owing .

266. *Subsection (6)* provides that interest is not to be charged during the exempt period but that a local authority may charge interest after that period at a reasonable rate set out in directions given by the Secretary of State or the National Assembly for Wales or, if no such directions are given, at such a rate determined by the local authority .

267. *Subsection (7)* enables regulations to define how much of a resident's contributions in respect of his accommodation is to be subject to a deferred payment agreement. It also ensures that additional payments under section 54 (that is, payments to cover the cost of more expensive accommodation) are regarded as contributions in respect of his accommodation for the purposes of this section.

268. *Subsection (8)* provides that any directions given under the Section are to be given to local authorities generally.

Section 56: Cross-Border Placements

269. The existing legislation does not allow local authorities in England and Wales to make and pay for residential care placements in Scotland, Northern Ireland, the Channel Islands or the Isle of Man. This section will enable regulations to be made to allow this. It is intended to allow people needing residential care to have care closer to their families, for example, where their families have moved away.

270. *Subsection (1)* allows regulations to be made authorising local authorities to make arrangements for a person to be provided with residential accommodation in Scotland, Northern Ireland, the Channel Islands or the Isle of Man.

271. *Subsection (2)* provides that the regulations may, in particular, make provision specifying conditions to be satisfied before a local authority may make such arrangements, and may make provision applying the provisions of the 1948 Act with or without modifications.

Direct payments

272. Direct payments are cash payments given to persons entitled to social services in lieu of services that would otherwise have been arranged for them by social services departments. Social services clients are then expected to arrange their own care.

273. *Sections 57 and 58* enable regulations to be made in connection with making direct payments in respect of services under section 47 of the 1990 Act, section 2(1) of the Carers and Disabled Children Act 2000 and in respect of children. *Section 57* deals with direct payments in respect of adults. *Section 58* deals with direct payments in respect of children.

Section 57: Direct Payments

274. *Section 57* deals with direct payments in respect of adults. Under the current system local authorities are permitted but not required to offer direct payments to people who meet the eligibility criteria.*Subsection (1)* allows regulations to make provision for and in connection with requiring or authorising a local authority to make direct payments to an individual who fulfils the requirements of the scheme and agrees to be part of it.

275. *Subsection (2)* specifies the persons to whom direct payments may be made. These are: a person who the local authority has decided under the 1948 Act needs a particular community care service; and a person for whom the local authority has decided to provide a service under the Carers and Disabled Children Act 2000.

276. *Subsection (3)* gives particular instances of what the regulations may provide. In particular, regulations may specify the situations in which a local authority is not required or authorised to make a direct payments. It does, however, allow for flexibility: for example, regulations could provide that an individual who has previously made mistakes or misspent may still be able to get a direct payments.

277. It also enables regulations to be made that concern: making direct payments either as gross or net payments; determining the payee's means and any contribution they will make; conditions that the local authority may impose in respect of the direct payment; circumstances when the payments may be terminated or required to be repaid ; and authorising direct payments to be paid to a third party on behalf of the payee.

278. The subsection also enables regulations to be made displacing, to such extent as may be prescribed, the functions and obligations of the local authority with respect to the provision of the service for which the direct payment is made. This will enable the effect of section 2 of the Community Care (Direct Payments) Act 1996 to be reproduced.

279. *Subsection (4)* defines gross payments as payments that are made at a rate that the local authority estimates is equivalent to the reasonable cost of securing the service concerned. It also specifies that they may be made subject to the condition that the recipient will reimburse the local authority in respect of part of that cost.

280. *Subsection (5)* defines a net payment as a payment that is made on the basis that the recipient will himself pay a contribution direct to the person providing the service. Thus the payment will be made at a rate below the equivalent to the reasonable cost of securing the provision of the services concerned in order to reflect the contribution made by the recipient.

281. *Subsection (6)* requires regulations to ensure that no contribution may be sought for services which are provided under section 117 of the Mental Health Act 1983 (after care). This is because local authorities are not able to charge for after-care services provided under that section, and therefore no financial contribution can be sought from the client.

282. *Subsection (7)* makes provision for regulations to limit the maximum period for which residential care may be purchased with a direct payment. It will be possible for direct payments to be used to purchase short-term rehabilitation care.

Section 58: Direct payments in respect of children

283. *Section 58* deals with direct payments in respect of children. It substitutes a new section 17A in the Children Act 1989.

284. Within the revised section 17A of the Children Act 1989:*subsection (1)* enables regulations to make provision for and in connection with requiring or authorising a local authority to make a direct payment to an individual who fulfils the requirements of the scheme and agrees to be part of it.

285. *Subsection (2)* specifies the persons to whom a direct payment may be made. These persons are: a person with parental responsibility for a disabled child; a disabled person with parental responsibility for a child; and a disabled 16 or 17 year old. It also specifies that the local authority must have decided for the purposes of section 17 of the Children Act 1989 that the needs of the child in question call for them to provide services.

286. *Subsection (3)* provides that section 57(3) to (5) and (7) of this Act apply in relation to regulations under the revised section 17A.

287. *Subsection (4)* provides that regulations under this section must specify that direct payments to the categories of people that this subsection applies to are to be gross payments with no contribution being required from them (see subsection (5)).

288. *Subsection (5)* specifies the persons from whom a contribution may not be required. They are: a person with parental responsibility for a disabled child, or a disabled person with parental responsibility for a child, where the child is aged 16 or 17; or a person who is in receipt of income support, working families' tax credit or a disabled person's tax credit under Part 7 of the Social Security Contributions and Benefits Act 1992 or of an income-based jobseeker's allowance.

289. *Subsection (6)* defines "disabled" in relation to an adult by reference to the meaning given by section 17(11) of the Children Act 1989 in relation to a child.

Section 59: Interpretation of Part 4

290. *Section 59* defines the terms used throughout Part 4 (sections 49 to 59).

Part 5 : Miscellaneous and Supplementary

Patient information

Section 60: Control of patient information

291. This section enables the Secretary of State to make regulations for and in connection with requiring or regulating the processing of patient information in prescribed circumstances. This will make it possible for patients to receive more information about their clinical care and for confidential patient information to be lawfully processed without informed consent to support prescribed activities such as cancer registries. The Government places importance on the consistent use of informed consent as the basis for handling confidential patient information. The regulation–making power in this section is therefore intended to provide for exceptional situations where essential services cannot, having regard to the present NHS systems and available technology, operate on that basis.

292. In recognition of the inherent difficulties associated with using confidential information the Act builds in a number of safeguards over the use of this power to protect patients' interests. First regulations can only provide for the processing of patient information for medical purposes (defined in subsection (10)) where there is a benefit to patient care or where this is in the public interest. Secondly , regulations can only require the processing of confidential patient information, where there is no reasonably practicable alternative. The Secretary of State can only make regulations under the terms of this section following consultation with bodies representing the interests of those likely to be affected by the regulations and with the new statutory advisory group introduced by *section 61*. Finally any such regulations can only be made under the

affirmative resolution procedure, requiring the consent of both Houses of Parliament (See *section 64(3)*).

293. It is envisaged that the Patient Information Advisory Group (to be established under *section 61*), will consider and advise the Secretary of State as regards each proposed use of the regulation-making power, including as regards the need to use the information and whether consent should be obtained.

294. The Data Protection Act 1998 governs, in broad terms, the processing of information relating to living individuals. This section does not amend that Act. In addition, regulations made under this section will not be capable of derogating from that Act (see note on *subsection (6)* below). Regulations made under this section may provide additional and more specific restrictions on the use of information relating to patients.

295. Information provided in confidence by patients is also subject to common law requirements which, being derived from case law, are difficult for healthcare professionals to apply with certainty in particular circumstances, especially since there has been little case law relating to healthcare settings. Regulations may provide that the processing of patient information under the regulations is lawful despite any common law obligation of confidence (see note on *subsection (2)(c)* below).

296. *Subsection (1)* enables the Secretary of State, subject to limitations imposed by *subsections (3) – (6)*, to make regulations requiring patient information to be processed for medical purposes (as defined in *subsection (10))* and regulating such processing.

297. *Subsection (2)* specifies some of the ways in which the power conferred by *subsection (1)* may be used.

298. *Subsection (2)(a)* enables regulations to be made that require specified communications about patients to be disclosed to them by NHS bodies, in certain circumstances. Such regulations may only provide for these communications to be disclosed to those persons to whom they relate or principally relate or to a prescribed person on their behalf, for example a spouse. Such regulations are intended to support the NHS Plan commitment that clinicians will in the future be required to share information about patients with them.

299. *Subsection (2)(b)* enables regulations to be made which require the disclosure or other processing of specified patient information subject to conditions or the giving of undertakings. This will support public health work and important activities such as cancer registration where it is essential to maximise the patient information available.

300. *Subsection (2)(c*) enables regulations to be made to permit patient information to be processed lawfully where, but for the regulations, this may be prevented by an obligation of confidentiality at common law. This is subject to the limitations imposed by this section (see, for example, the note on *subsection (6))* and human rights requirements.

301. *Subsection (2)(d)* enables regulations to make provision for their enforcement by the creation of criminal offences.

302. *Subsections (3) – (5)* serve to limit the use of the power conferred by *subsection (1)* to make regulations requiring the processing of confidential patient information (as defined in *subsection (9*)).

303. *Subsection (3)* provides that regulations cannot be made under *subsection (1)* if the purpose for which confidential patient information would be used could be achieved in another reasonably practical way, having regard to cost and available technology. In practice this means, for example, that persons cannot be required to disclose confidential patient information where the purpose can be satisfied by use of anonymised information.

304. *Subsection (4)* requires the Secretary of State to carry out an annual review of whether regulations made under *subsection (1)* and requiring the processing of confidential patient information would contravene *subsection (3)*. The review must be conducted within one month of each anniversary of the making of the regulations (*paragraph (a)*) and, if he determines that they would contravene *subsection (3)*, he must vary or revoke them (*paragraph (b)*).

305. *Subsection (5)* provides that regulations may not be made under *subsection (1)* solely or principally for the purpose of determining the care and treatment that is to be provided to individual patients. The care and treatment of individuals should be determined by appropriate professional staff that work with, and are responsive to the preferences of, those in their care.

306. *Subsection (6)* provides that regulations made under this section cannot make provisions for the processing of information which are inconsistent with the provisions of, or the provisions in instruments made under, the Data Protection Act 1998.

307. *Subsection (7)* provides that before the Secretary of State may make regulations under this section, he must consult such bodies as appear to him to represent the interests of those likely to be affected by the regulations as he considers appropriate in the light of the requirements of section 61. The consultation is intended to ensure that the regulations are fair and non-discriminatory.

308. *Subsection (8)* defines patient information as any information that is, or is derived from, information concerning a patient's physical or mental health or condition, the diagnosis of his condition or his care or treatment. In addition to information which directly identifies individuals, this would include information which is either anonymised (e.g. any information that cannot be tracked back to the individual) or coded (e.g. information that can be tracked back to an individual by persons in possession of the key to the code). It includes information recorded in any manner, whether electronically or manually.

309. *Subsection (9)* provides that "confidential patient information" for the purposes of the section is patient information that has been obtained by a person who owes an obligation of confidence to an individual where the identity of that individual is ascertainable from that information or from that information and other information which is in, or is likely to come into, the possession of the person processing the information .

Section 61: Patient Information Advisory Group

310. This section requires the Secretary of State to establish, by regulations, a committee to be known as the Patient Information Advisory Group. The Secretary of State is required to seek and have regard to the views of this Advisory Group prior to laying draft regulations before Parliament under section 60(1) or making regulations under section 60(4)(b).

311. The work of the Advisory Group is intended to provide an additional safeguard for patients as regards use of the power provided by section 60, complementing the safeguards included within that section. Before draft regulations under section 60(1) are laid before Parliament or regulations under section 60(4)(b) are made, the advice of the Advisory Group must be sought. The Secretary of State is required to publish the views of the Advisory Group.

312. In recognition that there may be other issues arising in relation to the processing of patient information, or other information obtained or generated through health service provision, the section also allows the Secretary of State to seek the views of the Advisory Group on these wider matters. It is envisaged that the Advisory Group's views will be sought on a range of issues pertaining to the confidentiality of patient information and standards of processing such information.

313. It is intended that professional and patient groups will be consulted on appointments to the Advisory Group and its proceedings.

314. A detailed commentary on the subsections of section 61 is set out below.

315. *Subsection (1)* requires the Secretary of State to establish by regulations the Patient Information Advisory Group as soon as reasonably practicable after Royal Assent.

316. *Subsection (2)* requires the Secretary of State to seek and have regard to the views of the Advisory Group prior to laying draft regulations before Parliament under section 60(1) or making regulations under section 60(4)(b).

317. *Subsection (3)* gives the Advisory Group the function of providing advice on wider patient and health service information issues at the request of the Secretary of State.

318. *Subsection (4)* specifies particular matters that may be contained in the regulations that establish the Advisory Group.

319. *Subsection (5)* places a duty on the Secretary of State to publish, in an appropriate manner, the advice provided to him by the Advisory Group on proposed regulations.

Services for disabled people

Section 62: Reports to Parliament on services for disabled people

320. *Section 62* amends section 11 of the Disabled Persons (Services, Consultation and Representation) Act 1986 ("the 1986 Act") so that, for England and Wales, the Secretary of State is required to produce annually separate reports on the development of health and social services for people with mental illness and people with learning disability . The reports can include other appropriate information, for example information from other Government Departments about services for which they are responsible. There will is no longer be a statutory requirement to include information on the number of people receiving treatment for mental illness/learning disability as in-patients in hospitals. This section changes the terminology from "mental handicap" to "learning disability" and includes a definition of learning disability for the purposes of Section 11 of the 1986 Act. The law in Scotland remains unchanged.

Prescribing rights

Section 63: Extension of prescribing rights

321. *Section 63* introduces new arrangements for the prescribing of medicines. Currently doctors, dentists and certain specified nurses, health visitors and midwives are authorised to prescribe prescription only medicines for human use. The Review of Prescribing, Supply and Administration of Medicines recommended the extension of prescribing rights to other health professionals.

322. *Section 63* amends section 58 of the Medicines Act 1968 which governs the sale, supply and administration of prescription only medicinal products both privately and within the NHS. New subsection (1)(e) enables new registered professional groups to be designated by order for the purpose of prescribing such medicines for human use. For example, physiotherapists may be given prescribing rights for certain drugs e.g. anti- inflammatories. One of the effects of this policy might be to remove the need for routine visits to the GP for continuing care.

323. *Subsection (3)* provides that the categories of persons who may be granted prescribing rights must be registered health professionals. It includes provision to ensure that health professionals regulated by statute under separate Scottish and Northern Irish legislation will have the same potential right to prescribe.

324. *Subsection (5)* allows Ministers to provide by order that specified descriptions of appropriate practitioner designated under *subsection (1)(e)* of section 58 of the Medicines Act 1968 (or nurses, midwives or health visitors designated under

subsection (1)(d)) must comply with specified conditions relating to the circumstances of prescribing which may apply to appropriate practitioners .

325. *Subsection (7)* makes it an offence for a person to prescribe a medicinal product in contravention of a condition imposed under *subsection (4A)* of section 58 or to prescribe a medicinal product for which he is not an appropriate practitioner.

326. *Subsection (8)* enables the Secretary of State to establish an advisory body under section 4 of the Medicines Act 1968 , to consider whether prescribing rights should be granted to any additional group of health professionals and to advise on any conditions or limitations that should be applied to their prescribing, prior to the Section coming into force.

Section 64: Regulations and orders

327. *Section 64* makes provision about orders and regulations, in particular when they are exercisable by statutory instrument; the parliamentary procedures relating to statutory instruments; and how the powers in question may be exercised.

Section 65: Supplementary and consequential provision etc

328. *Section 65(1)* and *(2)* enable the Secretary of State by regulations to make such supplementary, incidental or consequential provision, or such transitory, transitional or saving provision, as he considers necessary to give full effect to the Act. This includes power to amend or repeal any enactment, instrument or document.

329. *Subsection (3)* provides that such regulations may also be made by the National Assembly for Wales, Scottish Ministers and the First Minister and Deputy First Minister in Northern Ireland in respect of devolved matters.

Section 66: Interpretation

330. This section contains definitions of certain terms used in the Act. In particular, it provides that “regulations” means regulations made by the relevant authority and defines “the relevant authority”.

Section 67: Minor and Consequential amendments and repeals

331. *Section 67* gives effect to *Schedule 5* and the repeals specified in *Schedule 6*. *Schedule 5* makes minor and consequential amendments resulting from provisions in the Act. *Schedule 6* repeals provisions of enactments listed in that Schedule.

Section 68: Powers of National Assembly for Wales for Wales under amended Acts

332. *Section 68* provides that in the National Assembly for Wales (Transfer of Functions) Order 1999 any reference to an Act amended by this Act is to be treated as a reference to that Act as amended (except as regards the amendments made by section 27 of this Act).

Section 69: Financial provisions

333. *Section 69* provides for expenditure relating to the Act to be paid out of money provided by Parliament.

Section 70: Short title, commencement and extent

334. *Section 70* gives the short title of the Act and makes provisions for commencement and extent.

COMMENCEMENT AND EXTENT

335. Section 70 provides that this Act extends only to England and Wales, except sections 50 to 52 and 59 (preserved rights), section 63 (prescribing rights) and 64 to 66 and 65 (supplementary provisions) which also extend to Scotland and sections 63 to 65 which also extend to Northern Ireland.

336. Some technical provisions of the Act will come into force on Royal Assent together with those conferring powers to make orders or regulations. The other provisions of the Act will come into force on such a day, or days, as the relevant authority (or in certain cases, the Secretary of State or Scottish Ministers) may appoint by order.

Timetable

Stage	***Date***	***Hansard reference***
House of Commons		
Introduction	20 December 2000	Vol 360, col 377
Second reading	10 January 2001	Vol 360, cols 1080-1196
Committee	18, 23, 25 and 30 January 2001	Standing Committee E
	1,6 and 8 February 2001	
Report and third reading	14 February 2001	Vol 363, cols 324 – 428
House of Lords		
Introduction	15 February 2001	Vol 622, col 398
Second reading	26 February 2001	Vol 622, cols 987 –1064
Committee	15 March 2001	Vol 623, cols 1024 –1100
	19 March 2001	Vol 623, cols 1160-1278
	20 March 2001	Vol 623, cols 1380-1415
	22 March 2001	Vol 623, cols 1624-1708
Report	24 April 2001	Vol 624, cols 1226 –1305
	26 April 2001	Vol 624, cols 1475- 1554
Third reading	3 May 2001	Vol 624, cols 1971- 2010
House of Commons		
Commons consideration of Lords amendments	10 May 2001	Vol 368, cols 269 –286
House of Lords		
Lords consideration of Commons amendments	10 May 2001	Vol 624, cols 2268 – 2280
Royal Assent	11 May 2001	Vol 368, col 406 (HoC)
		Vol 624, col 2282 (HoL)

ANNEX A: OUTLINE OF THE EXISTING LAW

337. The following paragraphs provide a brief description of the current legislative framework for the NHS and social services. The legislative framework for the NHS in England and Wales is mostly set out in the National Health Service Act 1977 ("the 1977 Act"). This has been amended quite substantially by various enactment's, notably by the National Health Service and Community Care Act 1990 ("the 1990 Act"), the Health Authorities Act 1995 ("the 1995 Act"), the National Health Service (Primary Care) Act 1997 ("the Primary Care Act") and the Health Act 1999 ("the Health Act") .

338. The legislative framework for social services in England and Wales is set out in the National Assistance Act 1948, the National Health Service Act 1977 ("the 1977 Act"), the National Health Service and Community Care Act 1990 ("the 1990 Act") and the Community Care (Direct Payments) Act 1996 (the "Direct Payments Act") .

339. This Annex describes the existing legislation about the NHS. Annex B describes the existing legislation about social care; and Annex C describes other relevant legislation.

EXISTING LEGISLATION ABOUT THE NHS

National Health Service Act 1977

340. Under the 1977 Act, the NHS is essentially split into two different systems. The first is the system which consists primarily in the provision of health care in hospitals. It also covers those services described as "community health services", for example the services provided by district nurses, midwives or health visitors in clinics or individuals' homes, and the provision of medical services to pupils in state schools. This system is the subject of Part 1 of the 1977 Act. The responsibility for securing the provision of these services to patients rests with the Secretary of State, although under his powers in section 16C (formerly section 13) of the 1977 Act he has delegated most of his functions to Health Authorities. Health Authorities enter into arrangements with bodies known as NHS trusts for the provision by the Trusts of hospital and community health services.

341. The other main part of the NHS structure is what might be described as "the NHS on the high street". This is dealt with under Part 2 of the 1977 Act which governs the arrangements made by Health Authorities for the provision of services by the following professionals:general medical practitioners (GPs) (i.e. family doctors), general dental practitioners (GDPs), ophthalmic opticians and ophthalmic medical practitioners (also known as optometrists), and pharmacists . They respectively provide what are termed general medical services (GMS)(section 29ff), general dental services (GDS) (section 35ff), general ophthalmic services (GOS)(sections 38-40) and pharmaceutical services (PhS)(sections 41-43) respectively. The remainder of Part 2 contains other provisions relevant to the provision of these "high street" services, which are often referred to as family health services.

342. The 1990 Act, the Primary Care Act and the Health Act introduced a number of changes to these systems of health care. Broadly speaking, these changes were as follows:

(a) the 1990 Act introduced what is known as the internal market; by creating a divide between the planning and purchase of Part 1 services, on the one hand, and the provision of those services, on the other:

(b) the Primary Care Act in effect enabled what were previously Part 2 services to be delivered, not under Part 2, but under a more flexible system within Part 1 of the Act – these changes applied only to doctors and dentists, and not the other family health services practitioners; and

(c) the Health Act made a number of changes, but in particular provided for the abolition of GP fund-holding (introduced by the 1990 Act), the establishment of Primary Care Trusts (a new type of NHS body to both commission and provide

NHS care) and new arrangements to improve the quality of NHS services and co-operation between NHS bodies and local authorities.

343. The two systems, Part 1 and Part 2, are very different. It should be noted that despite the changes introduced by the Primary Care Act the provision of Part I services is distinct from the provision of services under Part 2. The changes proposed in this Act will not alter this divide. The following is a more detailed description of the two systems.

Part I system – hospital and community health services

344. The system provided for under Part 1 of the 1977 Act (and Part 1 of the 1990 Act – discussed below) is the system under which all of the NHS, apart from family health services, is provided, including its hospitals. The core duty to ensure the provision of a health service is laid upon the Secretary of State (1977 Act, section 1) in extremely broad terms, and is supplemented by the provisions of the sections 2 to 5.

345. Section 3 sets out those general services which it is the Secretary of State's duty to provide to such extent as he considers necessary to meet all reasonable requirements. Most of the services that may be described as hospital and community health services are included under this section.

346. Section 5(1) and (1A) impose duties on the Secretary of State to provide medical and dental services to state school pupils. This is the basis for what is described as the school nursing service.

347. Section 2 confers wide ranging powers for the Secretary of State to provide such services as are appropriate to discharge any duty imposed on him by the Act (including his general duty under section 1), and to do any other thing whatsoever which is calculated to facilitate, or is conducive to or incidental to, the discharge of any duty imposed on him by the Act . Further miscellaneous powers relating to specific matters are conferred by section 5(2) (for example, the conduct and assistance of research and development (section 5(2)(d)).

348. Sections 8 to 18 of the 1977 Act go on to provide for the administration of the NHS. These sections have been substantially amended since 1977, most recently by the Health Act. As amended, they provide for the setting up of Health Authorities (section 8), Special Health Authorities (section 11) and Primary Care Trusts (section 16A, as inserted by section 2 of the Health Act). Health Authorities, Special Health Authorities and Primary Care Trusts are independent statutory bodies, although their membership is determined in accordance with regulations (and in the case of Special Health Authorities, the establishment order) and some of the appointments to their membership are made by the Secretary of State. Health Authorities and Primary Care Trusts are established for territorial purposes. Each Health Authority is established for such area of England and Wales as set out in the establishment order made under section 8. The entire area of England and Wales is covered by Health Authorities . Each Primary Care Trust is established for the area specified in its establishment order under section 16A(3). Each Primary Care Trust area is wholly contained within the area of a Health Authority, but there is no requirement for total coverage. Some areas of England are covered by Primary Care Trusts , others are not. There are no Primary Care Trusts in Wales, as the relevant provisions of the Health Act have yet to be brought into force in Wales. Special Health Authorities are established for specific functional purposes – they are established for the purpose of performing any functions of the Secretary of State which he may then direct them to perform under section 16C.

349. The Secretary of State may direct a Health Authority or Special Health Authority to exercise his functions (section 16C, formerly 13, of the 1977 Act). A Health Authority may direct a Primary Care Trust established in their area to exercise those of its functions which it is permitted to delegate (section 17A, inserted by section 12 to the Health Act). The Secretary of State may direct Health Authorities that delegable Health Authority functions are or are not to be exercisable by Primary Care Trusts, or are

to be exercisable by Primary Care Trusts to any specified extent (section 17A(4)). The Secretary of State may also give directions to a Health Authority, Special Health Authority or Primary Care Trust about the exercise of any of their functions (section 17). A Health Authority may also give directions to a Primary Care Trust about the exercise of any functions which the Health Authority has directed the Primary Care Trust to exercise (section 17B). These Direc -tions may be given by regula -tions or by instru - ment in writing (section 18). There is very little further prescrip -tion in pri -mary legislation as to what the Secretary of State must do or how he must do it in rela -tion to the provision of that part of the NHS which is not concerned with family health services. It will be seen that this way of providing services is a great deal more flexible than the regula -tory system envisaged under Part II. There are probably historical reasons for this, but those reasons are no longer relevant.

350. Health Authorities - may, in accordance with regulations and any relevant directions, delegate their functions (whether Part I or Part II) to each other, or to committees or others (section 16 of the 1977 Act (as substituted by paragraph 9 of Schedule 5 to the Health Act)). Similar provision is made for Primary Care Trusts (section 16B of the 1977 Act (as inserted by section 2(1) of the Health Act)). Regulations have been made under both provisions.

351. Health Authorities and Special Health Authorities are funded under the provisions of section 97, as substituted by paragraph 47 of Schedule 1 to the 1995 Act and amended by section 36 of the Primary Care Act and by sections 4 and 8 of the Health Act. Health Authorities are paid money in each year under section 97(1) and section 97(3). Section 97(1) concerns the remuneration of persons providing Part II services and is not cash-limited (in other words the Secretary of State must pay whatever it has cost the Health Authority, and he cannot impose a ceiling on the expendi -ture). Under section 97(3) a Health Authority is paid money not exceeding the amount allotted to them by the Secretary of State. This amount is allotted towards meeting their "main expendi -ture" which includes all expenditure attributable to the performance of their Part I functions, and all their administrative costs. The money paid in respect of Part I services is therefore ultimately cash-limited. To enforce the cash-limits set by the Secretary of State, Health Authorities have various financial duties imposed upon them by section 97A of the 1977 Act (as substituted by paragraph 48 of the 1995 Act and amended by paragraph 23 of Schedule 2 to the Primary Care Act).

352. Primary Care Trusts are funded by Health Authorities under section 97C of the 1977 Act, as inserted by section 3 of the Health Act. There is a similar distinction between cash-limited and non-cash-limited funding. PCTs are also subject to a set of financial duties similar to those for HAs.

NHS TRUST Part II system – family health services

353. The system provided for under Part II of the Act is quite different. The broad structure of the Part II system is similar for doctors, dentists, persons providing ophthalmic services and persons providing pharmaceutical services. The existing system will first be described as it refers to doctors. The different arrangements as they apply to the other professional groups will be set out later.

General Medical Services

354. Under section 29 of the 1977 Act, it is the duty of each Health Authority in accordance with regulations to arrange for medical practitioners to provide personal medical services for all persons in the area who wish to take advantage of the arrangements. These services are described as general medical services (GMS). A principal feature of the system as it operates in practice is that (apart from certain exceptional cases) it is not the Health Authority itself which provides the GMS; instead, it enters into separate statutory arrangements with independent practitioners for the provision of those services. GPs are not employees of the Health Authority; they

are independent professionals who undertake to provide GMS in accordance with the body of regulations governing that activity. Those Regulations are currently the National Health Service (General Medical Services) Regulations 1992 (S.I. 1992/635) as amended.

355. The remainder of 1977 section 29 sets out certain things which must or may appear in the Regulations. Section 30 deals with the matter of applications by medical practitioners to be included in what is known as the "medical list": that is the list kept by each Health Authority of GPs who provide GMS in its area. Sections 31 and 32 provide for each GP on a medical list to have undergone vocational training. Section 33 provides for the system for admitting GPs to medical lists. Section 34 provides for regulations to be made relating to the Medical Practices Committee ("MPC"), which has a role in admitting GPs to the medical list. The MPC is set up under section 7 of the 1977 Act. Sections 29A and 29B (as inserted by section 32 of the Primary Care Act) make further provision relating to medical lists and vacancies.

356. It is the duty of each Health Authority, in accordance with the Regulations, to administer the arrangements made for the provision of GMS and other family health services (section 15 of the 1977 Act). The Health Authority must also perform such management and other functions relating to those services as may be prescribed.

357. In contrast to the Part I system, therefore, the duty to make arrangements for those services is conferred directly upon Health Authorities, rather than upon the Secretary of State. Nonetheless, in exercising functions under Part II, Health Authorities may be the subject of Secretary of State directions issued under section 17 of the 1977 Act. Health Authorities are able to delegate their Part II functions in accordance with regulations made under section 16 of the Act.

358. Subject to any Secretary of State directions under section 17A(4) of the 1977 Act, Health Authorities may direct Primary Care Trusts to exercise their functions in relation to GMS, but not in relation to other Part II services (see section 17A(3) of the Act). The Secretary of State has directed Health Authorities that they may delegate only a limited range of GMS functions to Primary Care Trusts.

359. This broad structure of the Part II system is similar for dentists, persons providing ophthalmic services and persons providing pharmaceutical services, but there are significant differences, most notably relating to persons providing ophthalmic and pharmaceutical services.

360. The provision for dentists (section 35 of the 1977 Act) is in very similar terms to that for doctors in section 29, although it will be noted that the duty upon the Health Authority is subtly different. In the case of doctors, the Health Authority - must arrange for suffi - cient PMS to be provided for everybody in the area who wishes to take advantage of the arrange -ments. In the case of dentists this duty is not quite the same: the duty is not to arrange the provision of GDS for every -body in the area who wishes to have GDS, but rather to arrange with dentists in the area that any person for whom those dentists have under -taken to pro -vide GDS receive the promised GDS . There is also no equi -valent of the MPC to control the entry of GDPs to dental lists; and there is no equivalent of section 29(2)(c) of the 1977 Act (which provides for the assign -ment of patients to doctors). How -ever, subject to that, the systems are by no means dissimi - lar: there exists a dental list of GDPs who under -take to provide GDS. There is a system of dental vocational train -ing (although it has been introduced by regula -tions and not by primary legislation). The relation -ship between the Health Authority and the GDP is (usually) again a statutory one between a Health Authority and an indepen -dent pro - fessional. Unlike the case of GPs, how -ever, there is in regulations provision in the case of dentists for the employ -ment of salaried dentists at health centres. These dentists are employed by the Health Authority, and repre -sent one of the rare occa -sions when it is the Health Authority itself which provides the services in ques -tion via its employees.

361. So far as chemists and opticians are concerned, opticians are provided for in section 38 of the 1977 Act, again according to the same scheme where -by the Health Authority - makes statutory arrangements with independent practi -tioners (who, in this case, might be individuals or bodies such as companies). However, the range of services to be provided by opticians is very much smaller. The only content now surviving of general ophthal -mic services ("GOS") is sight testing for children, for persons whose resources are less than their requirements, and for other prescribed persons.

362. For pharmaceutical services ("PhS"), pro -vided for under section 41 of the 1977 Act the arrangements are again made by Health Authorities with independent persons or bodies. The system is gov -erned by regula -tions; but the duty this time is to arrange for the provi -sion, to persons who are present in the Health Authority's area, of drugs, medicines and listed appli -ances which are pre -scribed for them by health service doctors, dentists, or nurses, and of such other services as may be prescribed . So far as PhS are con -cerned, there are detailed regula -tions (made under sections 42 and 43) relating to entry on to a phar -maceuti -cal list.

363. Sections 43A and 43B of the 1977 Act, as substituted by section 10 of the Health Act, provide a structure for the remuneration of persons providing Part II services. Section 10 of the Health Act has, however, yet to be brought into force. Neither have the original sections 43A and 43B inserted by the Health and Social Security Act 1984 (c.48) been commenced. In effect the original sections inserted by the 1984 Act must be complied with because of section 7 of the Act, which provides that a determina -tion of remuneration made before the coming into force of those provisions is deemed to be validly made if regulations authorising it could have been made had that provision been in force at that time . It is therefore not open to the Secretary of State or anyone else to make a determination which is inconsist -ent with the provisions of sections 43A and 43B as inserted by the 1984 Act. What in fact happens is that the Secretary of State makes and publishes a determi -na -tion for each of the professions, which takes the form of the separate document referred to in each of the sets of Regula - tions governing the four professions. These determina -tions therefore have the force of law, although they are not subject to any further degree of formality or Parliamentary procedure. The revised version of sections 43A and 43B, substituted by section 10 of the Health Act, were intended to provide a new framework to govern the remuneration of Part II practitioners, but have yet to be brought into force.

364. Each profession has in each Health Authority area a local representative committee (called the Local Medical Committee, the Local Dental Committee, and so on). These represent local practitioners and are provided for under sections 44 and 45 of the 1977 Act.

365. Practitioners may be removed or suspended from the list in which their names are included by the NHS Tribunal, which is pro -vided for under sections 46-49 of the 1977 Act. The NHS Tribunal is an independent body which hears representations by Health Authorities and others against family health service practitioners, that is people with whom Health Authorities have made arrangements for the provision of general medical, general dental, general ophthalmic or pharmaceutical services under Part II of the NHS Act 1977 . Health Authorities (and others) may make representations that to allow a person to continue to be family health service practitioner would be prejudicial to efficiency of the service in question. The Tribunal may direct that a practitioner's name is to be removed from one or more lists of people with whom Health Authorities have made arrangements for the provision of family health services. A person who has been removed from a list is no longer entitled to provide the service in question. The NHS Tribunal may also disqualify a person from involvement in any capacity in the provision of family health services.

366. The powers of the NHS Tribunal were extended by the National Health Service (Amendment) Act 1995, amongst other things to give it powers of interim suspension from lists. The powers of the NHS Tribunal were further extended by section 40 of

the Health Act 1999, in particular to extend its jurisdiction to people who have acted fraudulently towards or in connection with the NHS (although this section has yet to be brought into force).

367. The remainder of Part II contains a number of miscellaneous provisions.

Funding the NHS

368. Health Authorities are funded under the provisions of section 97 of the 1977 Act, as substituted by paragraph 47 of Schedule 1 to the 1995 Act and amended by section 36 of the Primary Care Act and sections 4 and 8 of, and paragraph 31 of Schedule 5 to, the Health Act . Health Authorities are paid money in each year under section 97(1) and section 97(3). Section 97(1) concerns the remuneration of persons providing Part II services and is covered in the next section. Section 97(3) concerns Part I expenditure and administrative costs. Under section 97(3) a Health Authority is paid money not exceeding the amount allotted to it by the Secretary of State. This amount is allotted toward meeting its "main expenditure", which includes all expenditure attributable to the performance of its Part I functions, all its administrative costs, and certain other expenditure. The money paid in respect of Part I services is therefore cash limited. To enforce the cash-limits set by the Secretary of State, Health Authorities have various duties imposed upon them by section 97A of the 1977 Act (as substituted by paragraph 48 of the 1995 Act and amended by paragraph 23 of the Schedule 2 to the Primary Care Act and paragraph 32 of Schedule 5 to the Health Act) . It is possible for the Secretary of State to make one off direct payments to NHS trusts by way of public dividend capital, loans or payments under NHS contracts. Direct payments to Primary Care Trusts can only be made by NHS contracts.

Intervention Powers

369. Section 84 of the 1977 Act enables the Secretary of State to appoint an inquiry in connection with matters arising under the 1977 Act, Part I of the 1990 Act or Part I of the Health Act. In addition to these formal inquiries, the Secretary of State conducts or appoints a variety of 'informal' inquiries, investigations and reviews in the exercise of his powers under section 2(b) of the 1977 Act. Finally, the Commission for Health Improvement may investigate matters relating to the management, provision and quality of health care for which NHS bodies are responsible (see section 20(1)(c) of the Health Act).

370. The Secretary of State has powers to intervene if NHS bodies fail to perform their functions or fail to comply with regulations or directions (section 85) and if, by reason of an emergency, a service under the 1977 Act may cease to be provided (section 86).

Community Health Councils

371. Community Health Councils ("CHCs") were established in 1974 and are now provided for in section 20 of, and Schedule 7 to, the 1977 Act. The Secretary of State has a duty to establish CHCs for Health Authority areas or parts of Health Authority areas. The members of each CHC include local authority and voluntary organisation representatives and persons appointed by the Secretary of State. Each CHC has a duty to represent the interests in the health service of the public in its district. Further provision for CHCs is made under the regulations under paragraph 2 of Schedule 7 - see the Community Health Councils Regulations 1996 (S.I. 1996/640, as amended by S.I. 1999/646, 1999/2906 and 2000/657). In particular-

- CHCs review the operation of the health service in its district and make recommendations and provide advice to their local Health Authority
- Health Authorities must consult CHCs on proposals for substantial developments of the health service in the CHCs' districts and on proposals for substantial variations in the provision of such service

- Health Authorities must provide information to CHCs about the planning and operation of health services in their area and meet CHCs at least once a year
- CHCs may inspect premises controlled by NHS bodies

372. In addition to their general duty, CHCs have various specific functions relating to reviewing the operation of the health service in their districts, which are conferred by regulations. They also provide advice and information to the public on local health services and assist patients making complaints about the services provided by NHS bodies and practitioners, although these additional functions are not specified in regulations.

373. CHCs are advised and assisted by the Association of Community Health Councils in England and Wales ("ACHCEW"), which was established by the Secretary of State under paragraph 5 of Schedule 7 to the 1977 Act. The National Health Service (Association of Community Health Councils) Regulations 1977 (SI 1977/874) provides for the establishment and operation of ACHCEW.

Health and Medicines Act 1988

374. Section 7 of the Health and Medicines Act 1988 extended the Secretary of State's powers for financing the NHS, by providing that he had powers to undertake a range of activities (for example, supplying goods or services, or exploiting intellectual property) in order to make more income available for improving the health service . The exercise of these powers is however limited by the provisos in subsection (8); in particular that anything he proposes to do will not to a significant extent interfere with the performance by him of any duty imposed on him by the 1977 Act.

375. The Secretary of State has directed Health Authorities that they may exercise these powers. NHS trusts and PCTs exercise similar powers by virtue of paragraph 15 of Schedule 2 to the 1990 Act and section 18A (5) of the 1977 Act (inserted by section 5 of the Health Act), respectively. Authorities and trusts are however subject to any directions the Secretary of State may make under section 17 of the 1977 Act about the exercise of such powers.

The National Health Service and Community Care Act 1990

NHS trusts

376. Section 5 of the 1990 Act, and the immediately following provisions, provide for the setting up of bodies known as NHS trusts. These are not Health Authorities but are separate, independent bodies set up to assume responsibility for the ownership and management of hospitals or other establishments or facilities previously managed or provided by a Health Authority; or to provide and manage hospitals or other establishments or facilities that were not previously so managed or provided . Section 5(1), as amended by section 13 of the Health Act, now provides that trusts are established to provide goods and services for the purposes of the health service. A trust's functions are conferred by its establishment order made under section 5(1) and by Schedule 2 to the 1990 Act.

377. Nearly all the hospitals in the country are now run by NHS trusts, although increasingly, smaller "community" hospitals are being run by Primary Care Trusts. The essential difference between NHS trusts and the hospitals run directly by Health Authorities is that the latter were funded by money paid to Health Authorities for the purpose by the Secretary of State under (what is now) section 97(3) of the 1977 Act; whereas (subject to certain exceptions) NHS trusts have no money paid to them directly by the Secretary of State, but instead must compete with each other for orders for their services placed by Health Authorities . Health Authorities are thus now seen as "purchasers" or "commissioners" of health care on behalf of the local population; while trusts are

included among the "providers" of this health care. Health Authorities may also choose to purchase health care from private sector institutions.

378. This system created the "internal market", whereby the whole of the operation (including trusts) is still the NHS, but for internal purposes the purchasers or commissioners were split from the providers.

379. The 1990 Act conferred on NHS trusts a substantial degree of autonomy. As well as not being funded centrally, the Secretary of State was able to give directions to NHS trusts only in relation to a limited range of subjects (paragraph 6 of the Schedule). The Health Act restricted this freedom by extending to NHS trusts the Secretary of State's power of direction under section 17 of the 1977 Act (section 12 of the Health Act).

NHS Contracts

380. The nature of the arrangements between Health Authorities and trusts is not that of an ordinary contract enforceable at law. Instead the 1990 Act provided for a system of NHS contracts (section 4), which are explicitly not contracts enforceable at law (section 4(3)), but which had attached to them a special form of internal arbitration by the Secretary of State. The list of bodies between whom certain agreements take the form of NHS contracts rather than ordinary contracts is contained in section 4(2).

The National Health Service (Primary Care) Act 1997

Personal Medical Services and Personal Dental Services

381. The Primary Care Act introduced a new method of delivery of family health services. Personal medical services (PMS) and personal dental services (PDS) may be provided under agreements known (in the initial stage at least) as "pilot schemes" (sections 1-3 of the Primary Care Act). These agreements are made between the Health Authority and one or more of the persons listed in section 3(2), which includes NHS trusts, GPs and NHS employees. Before a pilot scheme may be made, the proposals for the scheme must be submitted to, and approved by, the Secretary of State (section 4 and 5). The system of pilot schemes is intended ultimately to be replaced by a permanent regime.

382. Pilot schemes allow PMS and PDS (essentially the same as GMS and GDS) to be provided under the Part I system. The provisions of the 1977 Act apply in relation to functions of the Secretary of State in relation to pilot schemes as if the functions were functions under Part I of the Act. NHS trust may enter into a pilot scheme as a provider of PMS or PDS. The 1977 Act (and in particular section 17) has effect in relation to services under pilot schemes as if the services were provided as a result of delegation by the Secretary of State (by directions given under section 13 of that Act) of functions of his under Part I (section 9 of the Primary Care Act) .

383. These provisions allow PMS and PDS to be provided otherwise than through the rigid regulatory system of Part II of the 1977 Act. They allow Health Authorities the power to determine locally the content of the service in their area or the practitioners with whom they choose to make the arrangements.

The Health Act 1999

384. Part I of the Health Act made further changes to both the Part I system and the Part II system.

Primary Care Trusts

385. Primary Care Trusts are a new tier of administrative body below Health Authorities, and are primarily concerned with the Part I system, although they may exercise certain Health Authority functions relating to GMS. Primary Care Trusts are established by the Secretary of State by orders under section 16A of the 1977 Act (as inserted by

section 2(1) of the Health Act), with a view to their carrying out the activities listed in paragraphs (a) to (c) of that section. Their functions are conferred, in the main, by directions given by Health Authorities under section 17A of the 1977 Act, as inserted by section 12 of the Health Act.

386. In the exercise of the functions under Part I of the 1977 Act delegated to them by their Health Authorities, Primary Care Trusts have taken on the "commissioning" activities of Health Authorities. Unlike Health Authorities, however, they also provide certain services (usually community health services rather than hospital services) in the exercise of those functions. A Primary Care Trust is something of a "hybrid" between a Health Authority and an NHS trust. The other significant feature of Primary Care Trusts is that the regulations for the membership of Primary Care Trusts made under paragraph 5 of Schedule 5A to the 1977 Act, as inserted by Schedule 1 to the Health Act, provide that a substantial number of Primary Care Trust members and Primary Care Trust committee members must be GPs, local nurses and other health care professionals providing or assisting the provision of services under the 1977 Act .

Part II services

387. The Health Act provides new powers for the Secretary of State to require persons providing Part II services to have indemnity cover (section 9), a new structure for the remuneration of Part II practitioners (section 10, which has not yet been brought into force) and makes further provision for the disqualification of such practitioners by the NHS tribunal on the grounds of fraud (section 40, which again has not yet been brought into force) .

Quality

388. Section 18 of the Health Act imposes a "duty of quality" on Health Authorities, Primary Care Trusts and NHS trusts. Sections 19 to 24 provide for the establishment and operation of a new independent statutory body known as the Commission for Health Improvement, which is responsible for monitoring the quality of care for which NHS bodies have responsibility. The Commission is able to conduct a variety of reviews and investigations (section 20(1)).

The NHS and Local Authorities

389. Local Authorities are responsible for the provision of what may be described as "social care", e.g. residential accommodation for the disabled or elderly. The enactment's under which functions in this respect are conferred on Local Authorities are set out in Schedule 1 to the Local Social Services Act 1970 (c.42) and other legislation. Section 21 and Schedule 8 of the 1977 Act make provision for the exercise of certain specified functions. Local Authorities also exercise functions in respect of housing (eg. the Housing Act 1985 (c.68)) and education (the Education Act 1996 (c.56)).

390. Sections 22 and sections 26 to 28BB of the 1977 Act, as amended by sections 27, 29 and 30 of the Health Act, make provision for co-operation between the NHS and Local Authorities. Section 22(1) of the 1977 Act, as substituted by section 27(2) of the Health Act, places a general duty on NHS bodies (on the one hand) and Local Authorities (on the other) to co-operate in the exercise of their functions in order to secure and advance the health and welfare of the people of England and Wales . Sections 26 to 28 make provision for the supply of goods and services by the Secretary of State to Local Authorities and vice-versa. Section 28A of the 1977 Act, as amended by section 29 of the Health Act, makes provision for Health Authorities in England to make payments towards expendi -ture by various Local authority bodies on community services, such as social services, housing and education for the disabled. Section 28B makes similar provision for Wales.

391. The Health Act makes further provision for co-operation between the NHS and local authorities. Most importantly, section 31 makes provision for NHS bodies and Local

Authorities to enter arrangements under which an NHS body exercises Local authority functions or vice-versa. Provision is also made for arrangements to operate a "pooled fund" from which payments may be made towards expenditure on either NHS or Local authority functions. In addition to section 31, section 28 provides for Health Authorities, with the assistance of Primary Care Trusts, NHS trusts and Local Authorities, to prepare plans setting out a strategy for improving both the health of the local population and the provision of health care to that population. Section 30 of the Health Act inserts a new section 28BB into the 1977 Act, which makes provision for Local Authorities to make payments towards expenditure incurred by NHS bodies: this provision mirrors section 28A of the 1977 Act.

Health Authority funding and performance

392. The Act made it possible for the Secretary of State to increase a Health Authority's allocation where certain conditions around performance are satisfied. The intention was to reward Health Authorities that demonstrated the most progress in implementing their plan for improving health and health care. All Health Authorities including those making good progress from a low baseline are eligible. The Secretary of State is allowed to attach conditions to how the money should be spent and if it is not spent in accordance with the conditions he can claw it back.

ANNEX B: EXISTING LEGISLATION ABOUT SOCIAL CARE

393. A key concept in the legislation relating to social care is that of "community care services". This term is defined in section 46 of the National Health and Community Care Act 1990. Community care services are services which a local authority may provide or arrange under:

Part 3 of the National Assistance Act 1948,

Section 45 of the Health Services and Public Health Act (promotion by local authorities of the welfare of old people),

Section 21 of and Schedule 8 to the National Health Service Act 1977; and

Section 117 of the Mental Health Act 1983 (after-care).

394. Local Authorities are under given by section 47 of the 1990 Act a duty to assess a person's needs for community care services.

NATIONAL ASSISTANCE ACT 1948

395. Part 3 of this Act deals with local authorities' responsibilities with regard to arranging and charging for residential and nursing care placements.

396. In particular the Act gives powers to and imposes duties on local authorities in respect of accommodation. Section 21 of the 1948 Act enables local authorities (with the approval of the Secretary of State) to provide residential care for people over the age of 18 where they need residential care and care and attention is not otherwise available. Where the Secretary of State directs a local authority to provide such care, a local authority has a duty to provide it. The Secretary of State's approvals and directions are set out in Department of Health Circular LAC (93) 10. Section 26 of the 1948 Act enables local authorities to discharge their responsibility under section 21 by entering into arrangements with certain private and voluntary sector care homes.

397. A local authority may be required under section 21 of the 1948 Act to provide nursing care incidental or ancillary to the provision of accommodation. The Court of Appeal so decided in the case of *R v North Devon Health Authority ex parte Coughlan* [2000] 3 All E R 850, [2000] 2 WLR 622.

398. Sections 22 and 26 of the 1948 Act set out the system whereby a charge may be made for the provision of accommodation under sections 21 and 26. The charge is determined in accordance with a means test. This means testing system is set out in regulations, namely the National Assistance (Assessment of Resources) Regulations (S.I. 1992/2977). It follows that where a local authority provides nursing care incidental or ancillary to the Part 3 accommodation such services fall within the means testing system

399. Where a person is required to make a contribution towards his care under the means testing regime, but falls behind with the payments, the local authority may take a charge over any interest in land that the person has in the circumstances set out in section 22 of the Health and Social Services and Social Security Adjudication's Act 1983 .

THE 1977 ACT

400. The 1977 Act places a duty on the Secretary of State to continue to promote a comprehensive health service in England and Wales. It provides that NHS services are in general to be free. The Secretary of State is required by section 3 of the 1977 Act to provide such health services as he considers necessary to meet all reasonable requirements in England and Wales. Section 3(d) specifically mentions nursing services. As mentioned above, however, the NHS is not currently solely responsible for providing nursing care. Nursing services which are incidental and/

or ancillary to the provision of accommodation provided by local authorities can be provided by those local authorities.

THE NHS AND COMMUNITY CARE ACT 1990

401. This Act introduced community care. It requires a local authority to assess a person's need for community care services (see sections 46 and 47 of the 1990 Act). Where a local authority considers that a person needs NHS or housing authority services, it is required to involve those authorities in the assessment.

402. When the community care provisions were brought into effect (on 1 April 1993) those already in residential accommodation on 31 March 1993 were excluded from the obligation on local authorities to provide residential accommodation under section 21 of the 1948 Act (except in circumstances set out in regulations) (see section 26A of the 1990 Act) . Instead , those people already in residential accommodation on 1 April 1993, retained the right to higher rate benefits (the relevant benefits are now income support and jobseeker's allowance). These higher rate benefits were intended to enable people to continue to make their own arrangements for residential accommodation.

THE COMMUNITY CARE (DIRECT PAYMENTS) ACT 1996

403. This Act enables (but does not require) local authorities to make cash payments to adults specified in regulations as an alternative directly to providing or arranging community care services. The Act provides that where an authority makes a direct payment the authority ceases to be under a duty with respect to the provision of the service to which the direct payment relates, provided that they are satisfied that the person's need will be met by the person's own arrangements. The Act also enables regulations to set out a category of person from whom services may not be secured by means of a direct payment and also the maximum period of residential accommodation which may be secured by means of a direct payment (see the Community Care (Direct Payments) Regulations 1997 . The Carers and Disabled Children Act 2000 makes amendments to the 1996 Act to enable local authorities to make direct payment to carers in lieu of services under section 2(1) of the 2000 Act. Under the provisions persons who are to be provided with carers services are eligible for direct payments in respect of those services *unless* they are of a description specified in regulations. The 2000 Act also inserts section 17A into the Children Act 1989 to enable local authorities to make direct payments to persons having parental responsibility for a disabled child and also to make direct payments to disabled children aged 16 or 17. Regulations under section 17A may prescribe categories of person from whom a person may not secure services with a direct payment.

ANNEX C: MISCELLANEOUS

OTHER RELEVANT LEGISLATION

The Medicines Act 1968

404. The Medicines Act 1968 regulates the licensing, sale, supply and administration of medicinal products, and applies to both the private sale, supply and administration of medicinal products and to the supply and administration of such products in the NHS.

405. Section 58 of the Medicines Act 1968 provides for the designation of descriptions or classes of health professional, falling within the classes listed in section 58(1), for the purpose of prescribing or administering prescription only medicines. It is unlawful for such medicines to be sold or supplied – whether privately or on the NHS – except under the prescription of a designated health professional, or administered except by or under the directions of such a professional.

Wales

406. Many of the functions of the Secretary of State in relation to the NHS are exercised in Wales by the National Assembly for Wales . This Act has been drafted in consultation with the National Assembly for Wales and they agree with the provisions contained in it.

Scotland

407. The legislative framework for the NHS in Scotland is devolved. However this Act will amend the Social Work (Scotland) Act 1968 and some amendments relating to the dispensing and prescribing of medicines will also extend to Scotland.