

HEALTH ACT 1999

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health Act 1999 which received Royal Assent on 30 June 1999. They have been prepared by the Department of Health, with input from the Scottish Office and Welsh 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. The 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 December 1997 and January 1998, the Government published White Papers on its proposals for the National Health Service in England, Scotland and Wales (Cm 3807 *The new NHS*; Cm 3811 *Designed to Care*; Cm 3841 *Putting Patients First*). Further to the White Paper *The new NHS*, detailed proposals on quality and partnership in England were set out in the consultation document *A First Class Service* (HSC 1998/113), published in July 1998, and the discussion document *Partnership in Action*, published in September 1998. Further to the White Paper *Putting Patients First*, detailed proposals on quality and partnership in Wales were set out in the consultation documents *Quality Care and Clinical Excellence*, published in July 1998 and *Partnership for Improvement*, published in October 1998. Action has already been taken to implement many of the proposals set out in these documents. The Act implements those proposals that require primary legislation.
4. The Act's main purpose is to make changes to the way in which the National Health Service is run in England, Wales and Scotland. The Act abolishes GP fund-holding in all three countries. It amends the National Health Service Act 1977 to make provision for the establishment of new statutory bodies in England and Wales to be known as Primary Care Trusts, and provides for NHS trusts in Scotland to take on additional functions.
5. The Act amends the legislative framework for NHS trusts. It makes changes to the provisions in the National Health Service and Community Care Act 1990 concerning the establishment of NHS trusts, including retrospective changes to the purposes for which NHS trusts are established, and to the current NHS trust financial regime. It extends the Secretary of State's current powers of direction in respect of NHS trusts to cover all their functions, in line with other NHS bodies. It also replaces the provisions about special hospitals to enable NHS trusts in England and Wales, with Secretary of State approval, to provide high security psychiatric services.
6. The Act provides for new arrangements aimed at improving the quality of the care provided to patients receiving NHS services. It places a new statutory duty of quality on Health Authorities, NHS trusts and Primary Care Trusts and establishes a new statutory body for England and Wales, to be known as the Commission for Health Improvement, to monitor and help improve the quality of health care provided by the NHS. It also introduces measures to enable the Secretary of State to require general

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medical practitioners, general dental practitioners, ophthalmic opticians (also known as optometrists) and pharmacists to hold approved indemnity cover.

7. The Act creates a new duty of co-operation within the NHS and extends the duty of co-operation between NHS bodies and local authorities in England and Wales. It provides for local strategies to be developed for improving health and health care, and for new operational flexibilities to allow NHS bodies and local authorities to enter into joint arrangements for the purchase or provision of health and health-related services (e.g. social care). The Act also provides for the allocation of additional funding to Health Authorities on the basis of their past performance.
8. The Act introduces a number of measures designed to tackle fraud against the NHS. It introduces a civil penalty to be imposed where a person fails to pay an NHS charge, or claims a payment to which he is not entitled, towards the cost of an NHS charge or service. It creates a new criminal offence in England and Wales of knowingly making false representations to obtain exemption or remission from NHS charges. It also extends the functions of the NHS Tribunal to enable it to impose sanctions specifically on family health service practitioners who have defrauded the NHS.
9. In addition, the Act provides for the Secretary of State for Health to make regulations and directions securing compliance with aspects of a negotiated pharmaceutical price regulation scheme, to regulate the profits of companies outside the negotiated agreement and to set maximum prices for medicines supplied to the NHS. It amends the powers of the Health Service Commissioner to release information. It also enables Her Majesty to regulate health care professions by Order in Council and to make provision by Order in Council for the exercise of NHS functions across the English/Scottish border.

THE ACT

10. The Act is in three Parts:
 - Part I makes changes to the way the National Health Service is run in England and Wales. Part I also makes provision for the control of prices of medicines supplied to the National Health Service in England, Wales and Scotland, and the control of profits made by suppliers;
 - Part II makes changes to the way the National Health Service is run in Scotland;
 - Part III is concerned with the regulation of health care professions, the English and Scottish border and includes various other miscellaneous and supplementary provisions.
11. **Part I** of the Act is mainly concerned with implementing those proposals set out in the White Papers *The new NHS* and *Putting Patients First* which require primary legislation. This part of the Act therefore makes a number of changes to the structure of the NHS in England and Wales.
12. **Section 1 abolishes GP fund-holding.** Sections 2 to 12 (and Schedule 1) are concerned with the local administration of the NHS. Sections 2 to 7 make provision for the establishment, functions and funding of **Primary Care Trusts** and define the expenditure of Health Authorities and Primary Care Trusts. Section 8 enables the Secretary of State to make **additional payments to Health Authorities** on the basis of their past performance. Section 9 enables the Secretary of State to require general medical practitioners, general dental practitioners, optometrists and pharmacists to hold approved **indemnity cover**. Section 10 makes provision about determinations of remuneration of these practitioners. Section 11 enables local representative committees to represent doctors and dentists who work as assistants and deputies or who provide or perform personal medical and dental services. Section 12 is concerned with **the distribution and exercise of functions**. It provides the mechanism by which Health Authorities and Primary Care Trusts will inherit the majority of their functions and deals

with the powers of the Secretary of State and Health Authorities to direct NHS bodies about the exercise of their functions. Sections 13 to 17 make a number of changes to the **legislative framework for NHS trusts**.

13. **Sections 18 to 25** (and Schedule 2) concern the **quality of services** provided by NHS bodies. They place a duty of quality on Health Authorities, NHS trusts and Primary Care Trusts, establish a new statutory body to be known as the **Commission for Health Improvement** and as a consequence abolish the Clinical Standards Advisory Group.
14. **Sections 26 to 32** implement **measures to strengthen partnership working**, both within the NHS and between the NHS and local authorities. They create a new duty of co-operation within the NHS and extend the duty between NHS bodies and local authorities; provide a new statutory mechanism for strategic planning to improve health and health care services; provide for NHS bodies and local authorities to make payments to one another and make use of new operational flexibilities to improve the way health and health-related functions are exercised; and remove the statutory requirement for Joint Consultative Committees.
15. **Sections 33 to 38** concern the **control of prices of and profits on medicines**. They enable the Secretary of State to make regulations and directions securing compliance with aspects of a negotiated pharmaceutical price regulation scheme, to regulate the profits of companies outside the negotiated agreement and to set maximum prices for medicines supplied to the NHS.
16. **Sections 39 and 40** are designed to tackle **fraud** in the NHS. Section 39 does this in two ways. First, it creates a **civil penalty** to be imposed where a person fails to pay an NHS charge, or claims a payment to which he is not entitled, towards the cost of an NHS charge or service. Secondly it creates a new **criminal offence** of knowingly making false representations to evade or gain a reduction or remission of, or a payment relating to, NHS charges. Section 40 provides for the **disqualification of practitioners** from providing services under Part II of the National Health Service Act 1977 in cases of fraud.
17. **Section 41** enables NHS trusts in England and Wales, with Secretary of State approval, to provide **high security psychiatric services**. Section 42 makes provision for the **Registrar General** to provide the Secretary of State with information about births and deaths for the purpose of the health service. Section 43 amends the powers of the **Health Service Commissioner** to release information. Section 44 enables the Secretary of State to make an order to correct deficiencies which have been identified in the Health Authorities Act 1995 (Transitional Provisions) Order 1996.
18. **Part II** of the Act makes **changes to the National Health Service in Scotland**, implementing those proposals set out in the White Paper *Designed to Care* requiring primary legislation. Section 45 abolishes GP fund-holding. Sections 46 to 49 amend the existing legislative framework for NHS trusts. They make changes to the establishment of NHS trusts, provide a mechanism for NHS trusts to take on the responsibility for making arrangements for the provision of family health services and amend the constitution of NHS trust boards. Section 50 makes provision for the transfer of staff between health service bodies. Section 51 confers a new duty of quality on NHS trusts and sections 52 to 55 make a number of provisions regarding the financing of Health Boards and NHS trusts. Section 56 enables the Secretary of State to require general medical practitioners, general dental practitioners, optometrists and pharmacists to hold approved indemnity cover and section 57 makes provision regarding the determinations of remuneration of these practitioners. Section 58 provides for the disqualification of practitioners from providing Part II services in cases of fraud and section 59 introduces a civil penalty charge to be imposed where a person fails to pay an NHS charge, or claims a payment to which he is not entitled, towards the cost of an NHS charge or service.
19. **Part III** of the Act deals with miscellaneous and supplementary issues. Section 60 (with Schedule 3) makes provision for Her Majesty to make Orders in Council regarding the

regulation of health care professions. Section 61 enables Her Majesty to make an Order in Council regarding the **provision of health services at the border between England and Scotland.** The remainder of this Part of the Act includes a number of supplementary and miscellaneous provisions, relating, in particular, to orders and regulations under the Act, consequential and transitional provisions, amendments and repeals, **devolution**, commencement of the Act's provisions, the extent of the Act and the short title.

OUTLINE OF THE EXISTING LAW

20. The following paragraphs provide a brief description of the current legislative framework for the NHS. 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 enactments, notably by the National Health Service and Community Care Act 1990 ("the 1990 Act"), the Health Authorities Act 1995 ("the 1995 Act") and the National Health Service (Primary Care) Act 1997 ("the Primary Care Act").
21. 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 I 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 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.
22. The other main part of the NHS structure is what might be described as "the NHS in the high street". This is dealt with under Part II 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), general dental practitioners (GDPs), ophthalmic opticians and ophthalmic medical practitioners (also known as optometrists), and pharmacists. They provide what are termed general medical services (GMS), general dental services (GDS), general ophthalmic services (GOS) and pharmaceutical services (PhS) respectively. The remainder of Part II contains other provisions relevant to the provision of these high street services, which are often referred to as family health services.
23. The 1990 Act and the Primary Care Act introduced a number of changes to these systems of health care. Broadly speaking these changes were as follows -
 - the 1990 Act introduced a divide between the planning and purchase of Part I services, on the one hand, and the provision of those services, on the other; and
 - the Primary Care Act in effect enabled what were previously Part II services to be delivered, not under Part II, but under a more flexible system within Part I of the 1977 Act. These changes applied only to doctors and dentists, and not the other family health services practitioners.
24. The two systems, Part I and Part II, 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 II. The changes made by this Act will not alter this divide. What follows is a more detailed description of the two systems.

Part I system: hospital and community health services

25. The system provided for under Part I of the 1977 Act is the system under which all of the NHS, apart from family health services, is provided. The core duty to ensure the

provision of a health service is laid upon the Secretary of State (section 1) in extremely broad terms, and is supplemented by the provisions of the subsequent sections.

26. **Section 2** confers wide-ranging powers for the Secretary of State to provide such services as are appropriate to, and to do any other thing whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of any duty imposed on him by the Act. 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. Section 4 imposes a specific duty on the Secretary of State to provide special hospitals for persons detained under the Mental Health Act 1983 who have dangerous, violent or criminal propensities. The services provided under this section are often referred to as "high security psychiatric services" and are presently managed outside the normal hospital system by Special Health Authorities established under section 11 of the 1977 Act. Further miscellaneous powers and duties are imposed on the Secretary of State by section 5.
27. Part I of the 1977 Act (as amended by the 1995 Act) goes on to provide for the setting up of statutory bodies known as Health Authorities (section 8) and Special Health Authorities (section 11). Health Authorities are established to act for the area set out in their establishment order and together cover all of England and Wales. Special Health Authorities are established for specific functional purposes which the Secretary of State directs them to perform on his behalf (e.g. the National Blood Authority).
28. Although the main functions under Part I of the 1977 Act are conferred on the Secretary of State, the Act provides a mechanism which enables the Secretary of State to devolve to Health Authorities the responsibility for performing these functions, whilst retaining the ability to control how those functions are performed. The Secretary of State may direct a Health Authority or Special Health Authority to exercise his functions on his behalf (section 13). He may also give directions about the exercise of functions by a Health Authority or Special Health Authority (section 17). The Secretary of State has exercised his powers under these sections on many occasions but the principal instrument is the National Health Service (Functions of Health Authorities and Administration Arrangements) Regulations 1996 (S.I. 1996/708). Schedule 1 to those Regulations lists those "specified health service functions" of the Secretary of State that he has delegated to Health Authorities. The Secretary of State has directed Health Authorities to exercise most of his functions under Part I, in particular sections 2, 3, and 5. It is these Regulations by which Health Authorities have their functions in respect of Part I services conferred upon them. There is very little further prescription in primary legislation as to what the Secretary of State must do or how he must do it in relation to the provision of Part I services.
29. Health Authorities and Special 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. 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 dealt with below. 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 towards 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 financial duties imposed upon them by section 97A of the 1977 Act (as substituted by paragraph 48 of Schedule 1 to the 1995 Act and amended by paragraph 23 of Schedule 2 to the Primary Care Act).

Part II system: family health services

30. 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, opticians, and pharmacists. For convenience, therefore, the existing system will be described as it applies to doctors. (There are significant differences in the systems for the other professions, most notably relating to pharmacists and opticians, but those differences are not relevant for the purposes of the Act.)
31. Under section 29 of the 1977 Act, it is the duty of each Health Authority in accordance with Regulations to arrange with 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 this 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 therefore not employees of the HA; 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.
32. It is the duty of each Health Authority, in accordance with Regulations, to administer the arrangements made for the provision of GMS and the other family health services. The Health Authority must also perform such other management and other functions relating to those services as may be prescribed. In contrast to the Part I system, therefore, the duty to make the arrangements for these 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.
33. Remuneration of persons providing Part II services is for the most part 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 expenditure). However, the Secretary of State has the power to designate some categories of Part II remuneration (e.g. reimbursement of certain expenses) as falling within cash-limited "main expenditure". Remuneration for Part II services includes payments to pharmacists and GPs in respect of drugs dispensed to NHS patients, typically in response to prescriptions written by GPs.

The National Health Service and Community Care Act 1990

34. The 1990 Act introduced a number of changes in the systems described above.
35. Section 5 of the 1990 Act, and the immediately following provisions, provided for the setting up of bodies known as NHS trusts. These are semi-autonomous 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 which were not previously so managed or provided. A trust's functions are conferred by its establishment order made under section 5(1) of and by Schedule 2 to the 1990 Act. Some NHS trusts, known as "acute trusts" provide mainly hospital services. Other NHS trusts, known as "community trusts" provide mainly community services. Those which provide both hospital and community services are often known as "integrated trusts".
36. All the NHS hospitals in the country are now run by NHS trusts. NHS trusts have no money paid to them directly by the Secretary of State, but instead obtain orders for their services placed by Health Authorities and GP fund-holders. The nature of the arrangements between Health Authorities and trusts is, however, not that of an ordinary contract enforceable at law. Instead, the 1990 Act provided for a system of NHS

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contracts (section 4), which are explicitly not contracts enforceable at law (section 4(3)), but are subject to arbitration by the Secretary of State.

37. A further change introduced by the 1990 Act was the creation of fund-holding practices of GPs providing services under Part II of the 1977 Act. The fund-holding system did not essentially alter the Part II services they provide. However, the practices in question are given a sum of money known as an allotted sum with which to purchase, on behalf of their patients, from whatever provider they see fit, some of the care under Part I which would otherwise have been purchased by the local Health Authority. Thus there are two types of purchaser or commissioner of services: namely Health Authorities and fund-holding practices.

The National Health Service (Primary Care) Act 1997

38. The Primary Care Act introduced a new option for the 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”. These agreements are made between the Health Authority and one or more of the persons listed in section 2(2) or section 3(2) of the Primary Care Act, which includes NHS trusts, GPs, and NHS employees. Pilot schemes allow PMS and PDS (essentially the same as GMS and GDS) to be provided under the Part I system. The Health Authority funds the services provided under a pilot scheme from its cash-limited allocation under section 97(3).
39. These provisions allow PMS and PDS to be provided otherwise than through the regulatory system of Part II of the 1977 Act. They enable Health Authorities to agree with pilot providers locally the content of the services and the conditions under which those services will be provided. The Primary Care Act also included provision for a permanent regime (under sections 28C and 28D of the 1977 Act, as inserted by section 21 of the Primary Care Act).

Wales

40. Many of the functions of the Secretary of State in relation to the NHS are exercised in Wales (from 1 July 1999) by the National Assembly for Wales (see the National Assembly for Wales (Transfer of Functions) Order 1999 SI 1999/672).

Scotland

41. The legislative framework for the NHS in Scotland is set out in the National Health Service (Scotland) Act 1978 (“the 1978 Act”). It is broadly similar in structure and content to the 1977 Act, being split into Parts I and II in the same way. Instead of Health Authorities, services are commissioned by Health Boards. The 1990 Act and the Primary Care Act described above made similar provisions for Scotland as for England and Wales.

COMMENTARY ON SECTIONS

Part I - the National Health Service

Section 1: Repeal of law about fund-holding practices

42. Sections 14 to 17 of the 1990 Act provide for the establishment of fund-holding practices as part of the NHS internal market. These practices consist of one or more general medical practitioners (GPs) who provide either general medical services (under the 1977 Act) or personal medical services (under the Primary Care Act), but who are also given an additional sum of money (known as an allotted sum) to purchase certain goods or services for their patients.

43. The 1990 Act provided for regulations to be made which set out the procedures for application and recognition as a fund-holding practice, the purposes for which the allotted sum may be used, and renunciation or removal of recognition. The details of the fund-holding scheme can be found in the National Health Service (Fund-holding Practices) Regulations 1996 (SI 1996/706) as amended.
44. The White Papers *The new NHS* and *Putting Patients First* set out the Government's proposals to replace the NHS internal market. As part of these changes fund-holding will be abolished, Primary Care Groups (Local Health Groups in Wales) have been set up and Primary Care Trusts will be established. The NHS (Fund-holding Practices) Amendment Regulations 1999 (SI 1999/261), made on 8 February, provided for the replacement of the existing fund-holding schemes by a single residual scheme from 1 April 1999. Primary Care Groups and Local Health Groups have been established from 1 April 1999 under existing powers as Health Authority committees (c.f. section 16 and paragraph 12 of Schedule 5 to the 1977 Act). Primary Care Groups and Local Health Groups may in time become Primary Care Trusts, which will be established under the powers conferred by the Act (see sections 2 to 7, 12 and Schedule 1).
45. All GPs are covered by a Primary Care Group (Local Health Group in Wales) or will be covered by a Primary Care Trust if one is established in their area. Primary Care Groups and Local Health Groups also involve, as Primary Care Trusts will involve, other health professionals, social services and members of the local community. Primary Care Groups and Local Health Groups are responsible for improving the health of their local community, commissioning services, developing primary and community care and exercising functions delegated to them by Health Authorities. Primary Care Trusts will have similar responsibilities (see the commentary on section 2 below).
46. The repeal of sections 14 to 17 of the 1990 Act by section 1 will abolish the fund-holding system. The transitional arrangements for winding up the fund-holding scheme will be made under the powers conferred by section 63. The transitional provisions will cover arrangements for closing the fund-holding accounts of residual fund-holders; the transfer of those assets, rights and liabilities that need to be transferred to the Health Authority; and any provision for those that are to remain with the former fund-holders.

Section 2 and Schedule 1: Primary Care Trusts

47. **Section 2** provides that the Secretary of State may establish new NHS bodies to be known as Primary Care Trusts. Primary Care Trusts will take on the function of arranging the provision (or "commissioning") of health services, currently exercised by Health Authorities and GP fund-holders. In addition, they may also become providers of services under Part I of the 1977 Act, a function currently performed by NHS trusts. Furthermore, they will be able to exercise some functions in relation to general medical services, for example deploying cash-limited funds to improve general practice infrastructure and support practice staff costs. They will also be able to provide personal medical and dental services under the Primary Care Act 1997. It is envisaged that, at least initially, provider Primary Care Trusts will provide only community health services, or personal medical and dental services. However, section 12 provides the potential to broaden the range of Part I services that they may provide in future.
48. Primary Care Trusts will be established as corporate bodies with their own budget for local health care. The population coverage of a Primary Care Trust is likely to vary from place to place but typically, in England, a Trust is likely to serve a population of at least 100,000 and have a budget of around £60 million or more. They will be accountable to the local Health Authority and subject, like other NHS bodies, to directions given by the Secretary of State (see section 12). Their membership will include local health professionals and managers, with the Chairman and lay members appointed by the Secretary of State.
49. **Section 2(1)** inserts two new sections into the NHS Act 1977: sections 16A and 16B.

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50. The new section 16A gives the Secretary of State the power to establish Primary Care Trusts. Subsection (1) provides that Primary Care Trusts will be established with a view, in particular, to their undertaking the following activities:
- providing or commissioning Part I services (i.e. hospital and community health services)
 - exercising functions in relation to general medical services
 - providing personal medical services or personal dental services under arrangements made under the Primary Care Act (“pilot schemes”) or section 28C of the 1977 Act (“the permanent regime” – see paragraph 39 above).
51. Primary Care Trusts will be established by orders, which will specify the area for which the Trust will be established and certain limitations on the functions it may exercise. The PCT order will also set out the name of the Trust and the date it will become operational (paragraph 1 of the new Schedule 5A to the 1977 Act, as inserted by Schedule 1 to the Act).
52. It is envisaged that proposals to establish a Primary Care Trust will be generated locally. The views of Primary Care Groups, NHS trusts, local health care professionals and local communities will be taken into account in considering such proposals. The Secretary of State will direct Health Authorities under the new sections 16D and 17 of the 1977 Act (see section 12 of the Act) to make preliminary selections on his behalf of those proposals which will go forward to consultation and those which will not. It is the Government’s intention that the directions will provide that Health Authorities must select a proposal if it has been made or endorsed by either a Primary Care Group or an NHS trust providing community services locally, and if it meets certain requirements as to the form and content of the proposals. In addition Health Authorities will also be able to initiate their own proposals.
53. Once a proposal to establish a Primary Care Trust has been selected or initiated by a Health Authority, it will be the subject of a consultation conducted in accordance with the regulations made under subsection (5). These regulations will provide that the consultation must be conducted by the Health Authority and that the result must be reported to the Secretary of State. It is envisaged that they will also make provision for matters such as who must be consulted, the information that must be provided for consultation, the period in which consultation must be conducted and for reporting to the Secretary of State the results of consultation, including the form such a report must take.
54. Regulations will also require consultation to be carried out before the Secretary of State can dissolve a Primary Care Trust, or amend an order to establish a Primary Care Trust, except where the change to the order is a minor change. The requirement to consult will not apply, however, where it appears to the Secretary of State necessary to dissolve the Primary Care Trust as a matter of urgency. A similar power exists in connection with NHS trusts (paragraph 29(3) of Schedule 2 to the 1990 Act). It is designed as a safeguard of last resort if, for example, patient safety is at risk.
55. It is intended that there will be a clear distinction between Primary Care Trusts that are able to commission services, and those which may also provide services directly to patients. Progression from a “commissioning-only” Primary Care Trust to a “commissioning-and-providing” Primary Care Trust will be subject to consultation and the approval of the Secretary of State, in the same way as when a Primary Care Trust is first established. The new section 16A sets the framework for this in two ways. First, subsection (3) allows the Secretary of State to specify in the PCT order whether the Primary Care Trust is prohibited from providing services directly. A Primary Care Trust that is subject to such a prohibition will therefore not be allowed to provide services directly until its order is amended. Second, the Secretary of State will be able to amend a PCT order only after any consultation requirements, set out in regulations made under

subsection (5), have been met. (See commentary on section 12 for further discussion of Primary Care Trust functions.)

56. The provisions for delegation and joint exercise of functions in the new section 16B will be similar to those made for Health Authorities in section 16 of the NHS Act 1977. They will enable Primary Care Trusts to choose how they arrange for the performance of their functions. For example, it will be possible for Primary Care Trusts to pool administrative support services such as IT, estate and payroll management with other NHS bodies. It will also be possible for committees and staff members of a Primary Care Trust to perform functions on behalf of the Trust and for Primary Care Trusts to enter joint commissioning arrangements with Health Authorities and other Primary Care Trusts.
57. Subsection (2) of section 2 gives effect to Schedule 1 to the Act, which inserts a new Schedule 5A in the 1977 Act. The new Schedule makes additional, detailed provisions in respect of Primary Care Trusts. In particular it includes provisions in respect of PCT orders, constitution, membership, staff and property.

New Schedule 5A

58. *Paragraph 1* provides for the matters which must be specified in the PCT order, and should be read with the new section 16A.
59. *Paragraph 2* allows for a preparatory period between the date of establishment of a Primary Care Trust and its operational date. During this period the Primary Care Trust will have limited powers to carry out activities in preparation for becoming fully operational. It is envisaged that the preparatory activities will include:
 - appointing members;
 - advertising for, recruiting and employing staff;
 - entering into contracts and NHS contracts; and
 - planning the internal arrangements for the day to day operation of the Primary Care Trust.

Health Authorities will be able to provide funding for Primary Care Trusts for such purposes, or settle bills incurred by them.

60. *Paragraphs 4 to 7* provide for the membership of a Primary Care Trust. Each Primary Care Trust will have a chairman appointed by the Secretary of State and a number of members. Some of those members will be employees of the Trust, for example the Chief Executive. The members of the Primary Care Trust will be responsible for running the Trust and, in effect, will constitute its governing board. The detailed provisions for the membership and procedure of Primary Care Trusts will be set out in regulations made under the provisions in these paragraphs.
61. *Paragraph 9* confers a power of direction on the Secretary of State which enables him to require Primary Care Trusts to loan their staff to other Primary Care Trusts, or to employ any person who is or was employed by another Primary Care Trust. It mirrors the provision for Health Authority staff under paragraph 10(3) of Schedule 5 to the 1977 Act. The power could be used in the event of a problem in a Primary Care Trust, where there is a short-term need for staff with particular expertise. The exercise of this power is subject to consultation by the Secretary of State with the member of staff involved or his representative body. These provisions will not detract from an employer's duty to consult staff under other mechanisms (e.g. TUPE Regulations or General Whitley Council Regulations).
62. In particular circumstances, such as in cases of temporary emergency or where consultation has previously been fully carried out with the individual concerned, the Secretary of State may require a Primary Care Trust to make the services of its staff

available to another Primary Care Trust without consulting with the member of staff concerned or his representative. Again this mirrors the provisions for Health Authorities in paragraph 11 of Schedule 5 to the 1977 Act. One example where it might be used would be if a Primary Care Trust employed an individual with specialist skills (e.g. public health skills in the case of an epidemic) which were needed in an emergency by a Primary Care Trust elsewhere in the country.

63. *Paragraph 10* brings the staff of Primary Care Trusts within the scope of current powers in paragraph 10(2) of Schedule 5 to the 1977 Act. Under paragraph 10(2) the Secretary of State may make regulations in respect of the transfer of staff from one Health Authority to another and the arrangements under which Health Authority staff are made available to other Health Authorities or local authorities. Paragraph 10 of Schedule 5A therefore enables regulations to be made which provide for permanent staff transfers between Primary Care Trusts, for example where functions transfer from one Primary Care Trust to another. This paragraph also enables the Secretary of State to regulate any temporary arrangements under which Primary Care Trust staff are put at the disposal of other Primary Care Trusts (by direction under paragraph 9 of Schedule 5A) or local authorities. Primary Care Trusts would make their staff available to local authorities under the provisions of section 26(1)(b) and (3)(b) and (c) of the 1977 Act. Paragraph 11 of Schedule 4 to the Act extends these provisions so as to cover Primary Care Trust staff. The intention is to have as much freedom for movement of Primary Care Trust staff as is currently available for Health Authority staff and to facilitate partnership arrangements made under section 31 of the Act between Primary Care Trusts and local authorities. Before making regulations under paragraph 10(2) of Schedule 5 to the 1977, the Secretary of State has a duty to consult any individuals or their representative bodies who are, in his opinion, likely to be affected.
64. *Paragraph 12* confers a general power on Primary Care Trusts to do things ancillary to their main functions. This includes a power to acquire land (which will enable them to obtain their own premises), to enter into contracts, and to accept gifts of money, land and other property. The latter power enables the Primary Care Trust to accept and administer charitable property, e.g. gifts of medical equipment donated by voluntary and charitable organisations, bequests of shares or gifts of vehicles.
65. *Paragraph 13* concerns the enforcement of rights and liabilities. Where a function has been delegated to a Primary Care Trust the rights acquired and the liabilities incurred in the exercise of that function will be enforceable by or against that Primary Care Trust. A Primary Care Trust will therefore take legal proceedings in its own name, and will be sued in its own name, even though it is exercising functions delegated to it by a Health Authority. For example if a Primary Care Trust is providing services in the exercise of a function delegated to it by a Health Authority, a patient who is injured while receiving those services will bring legal proceedings against the Primary Care Trust rather than the Health Authority.
66. *Paragraph 14* enables Primary Care Trusts to carry out and fund research activity, and make their staff and facilities available for that purpose. Funded from the NHS research and development budget (raised by levy on Health Authorities), the Primary Care Trust will be able to host clinical trials of a new drug or the evaluation of different treatments for e.g. chronic back conditions. NHS trusts have similar powers under paragraph 11 of Schedule 2 to the 1990 Act.
67. *Paragraph 15* enables the Primary Care Trust to make staff available to assist the provision of education and training of NHS employees or prospective NHS employees, or persons employed (or to be employed) by local authorities to provide social care (section 63 of the Health Services and Public Health Act 1968 concerns the provision of education and training to such persons). NHS trusts have similar powers under paragraph 12 of Schedule 2 to the 1990 Act.
68. *Paragraphs 16 and 17* confer specific reporting duties on Primary Care Trusts. These paragraphs place duties on a Primary Care Trust to prepare and provide reports and

information on its activities to the Health Authority to whom it is accountable, and to the Secretary of State. This will enable Health Authorities to monitor the performance of Primary Care Trusts in their area.

69. [Paragraph 17](#) provides that regulations must require Primary Care Trusts to publicise their accounts, annual report, any auditor's report pursuant to section 8 of the Audit Commission Act 1998 and any other documents as may be specified in the regulations. The regulations will set out the manner in which and the times at which they must publicise such documents. Under this power the Secretary of State will be able to require any Primary Care Trust to hold a public meeting at which such documents shall be presented. This puts Primary Care Trusts on a similar footing to other NHS bodies.
70. [Paragraph 19](#) provides for the exercise by Primary Care Trusts of powers of compulsory purchase and mirrors the provisions for other NHS bodies (e.g. NHS trusts: paragraph 26 of Schedule 2 to the 1990 Act). The exercise of these powers will be subject to the provisions of the Acquisition of Land Act 1981. The 1981 Act makes provision for the procedures which apply to the compulsory purchase of land by Government departments, local authorities and certain other public bodies, for example, requirements for a compulsory purchase order, the publication of notices and the holding of inquiries.
71. [Paragraph 20](#) provides for the transfer of property, rights and liabilities on the dissolution of a Primary Care Trust. Whenever a Primary Care Trust is dissolved, section 1 of the National Health Service (Residual Liabilities) Act 1996 (as amended by paragraph 87 of Schedule 4 to the Act) will require the Secretary of State to exercise his powers so as to secure that all of the Primary Care Trust's liabilities are dealt with.
72. [Paragraphs 21 and 22](#) make provision for the transfer of property to Primary Care Trusts, similar to that in section 8 of the 1990 Act in respect of NHS trusts. The property which Primary Care Trusts will require in connection with the exercise of their functions will often already be under the ownership or management of the Secretary of State, Health Authorities or NHS trusts. Paragraph 21 gives the Secretary of State the power to make an order to transfer or provide for the transfer of such property, and the attached rights and liabilities, to Primary Care Trusts.
73. [Paragraph 21\(1\)\(b\)](#) is intended to cater, for example, for circumstances where property transfers from an NHS trust to a Primary Care Trust but the NHS trust wishes to continue using the property for the services it retains. In such a case, the Secretary of State might wish to create a right for the NHS trust to continue using the property transferred to the Primary Care Trust.
74. Property, rights and liabilities may need to be apportioned between the different parties, for example where a Primary Care Trust is to provide services previously provided by an NHS trust at premises held by the trust. Any such apportionment will be provided for in the transfer order. The order might provide, for example, that the Primary Care Trust and the NHS trust divide the rights and liabilities under a lease on premises which they both will use.
75. Where the transfer order provides for the transfer of land or assets held on lease from a third person, the transfer will be binding on that person, even though it would otherwise have required his consent. If, for example, the property to be transferred to the Primary Care Trust were a health clinic, leased by the NHS trust from a private company, the lease would automatically transfer to the Primary Care Trust without requiring the consent of the private company concerned. However, under such circumstances the Secretary of State must make appropriate provisions to safeguard the interests of third parties, including, where appropriate, the payment of compensation.
76. [Paragraphs 23 to 26](#) provide for the transfer of staff to a Primary Care Trust. This will frequently occur when a Primary Care Trust is established.

77. **Paragraph 23** confers on the Secretary of State a power to transfer by order staff from a Health Authority, NHS trust or another Primary Care Trust. The exercise of this power is subject to consultation by the Secretary of State with the staff involved.
78. **Paragraph 24** provides for safeguarding the terms and conditions of service of staff transferring by order to a Primary Care Trust. This will ensure that such a member of staff retains his existing terms and conditions of employment, that the contract of employment with the Primary Care Trust is regarded as a continuation of the employee's original contract and that he maintains any rights, powers, duties and liabilities he has under that original contract. Where a member of staff declines to transfer to the Primary Care Trust he will not be treated as having been dismissed. Where there is a change in his terms or conditions of employment that is both significant and to his disadvantage, nothing in these provisions will remove any right he has to terminate his contract.
79. Where staff who are to be transferred are to remain working for part of their time at the original Health Authority, NHS trust or original Primary Care Trust, in addition to working at the Primary Care Trust to which they are to be transferred, paragraph 25 enables an order under paragraph 23 to provide that the person's contract is to be divided into two separate contracts (one with the original employer, the second with the new Primary Care Trust). This will safeguard the employee's terms and conditions of service.
80. **Paragraph 26** gives the Secretary of State the power to transfer staff from a dissolved Primary Care Trust, but only after consulting the staff involved or their representatives. These consultation requirements will be set out in regulations under paragraph 20(2). In these circumstances the terms and conditions of employment will be similarly protected.

Section 3: Primary Care Trusts: finance

81. **Section 3** inserts two new sections into the 1977 Act (sections 97C and 97D) which provide for the funding and financial duties of Primary Care Trusts. The sections are similar to sections 97 and 97A of the 1977 Act which provide for the funding and financial duties of Health Authorities.
82. Health Authorities receive both cash-limited funding (under section 97(3)) and non-cash-limited funding (under section 97(1)) as follows:
- payments under section 97(1) to meet the Health Authority's "general Part II expenditure", i.e. expenditure attributable to the remuneration of persons providing Part II services, subject to certain exceptions (see section 97(1) to (3A) of the 1977 Act, as substituted by section 36 of the Primary Care Act). (It should be noted, however, that section 4 of the Act replaces section 97(2), (3A) and (3B) of the 1977 Act.) This funding is not "cash-limited"; in other words the Secretary of State may not impose a ceiling on general Part II expenditure; and
 - sums paid under section 97(3) towards the Health Authority's "main expenditure", i.e. expenditure attributable to the performance of its functions and certain payments of remuneration to persons providing Part II services which the Secretary of State has designated as falling within "main expenditure" (e.g. certain expenses and the remuneration of persons providing additional pharmaceutical services under section 41A of the 1977 Act). This funding is cash-limited. The Secretary of State has a duty to pay sums to the Health Authority only up to the limit he sets for the Authority for the financial year (the "allotted sum"). The initial limit may subsequently be adjusted during the year.
83. The allotted sum covers the provision of hospital and community health services, the payment of certain expenses incurred by Part II practitioners (in particular the costs of GP practice staff, premises improvements and information technology), and the costs of the drugs and appliances prescribed by GPs (and by some community nurses), although

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section 4 of the Act alters the way in which drug costs are chargeable to a particular Health Authority. In the absence of directions under section 97(6)(a) (see below), the various elements of the allotted sum are not ring-fenced.

84. *New section 97C* provides for the funding of Primary Care Trusts by Health Authorities to mirror as closely as possible the provisions for funding Health Authorities. It provides for the funding of a Primary Care Trust's main (i.e. cash-limited) expenditure and of any non cash-limited general Part II expenditure it incurs. The Health Authority will pay sums to Primary Care Trusts in their area up to a limit set by the Health Authority for the financial year (the "allotted sum"). This limit can however be altered during the year (subsection (3)).
85. The Secretary of State sometimes gives Health Authorities allocations earmarked for particular purposes, under section 97(6)(a) of the 1977 Act. In future these sums will often be passed to Primary Care Trusts. The new section 97C(5) obliges the Health Authority to earmark such sums in the same way, when allocating them to Primary Care Trusts. This will enable the Secretary of State to direct Primary Care Trusts to apply some of their allocation for a particular purpose. The power may be applied to all Health Authorities and Primary Care Trusts or to individual bodies.
86. In the past this power has been used to protect, for example, funding for HIV and AIDS treatment and care. The current power of direction is used only sparingly and exceptionally (for example, to ring-fence the Out of Hours Development Fund for GPs) and when extended to Primary Care Trusts the Government intends to continue to use it in such a way.
87. Subsection (4) of new section 97C regulates the payment of capital charges on Primary Care Trust assets. It is modelled on the existing provision for Health Authorities (section 97(6)(b) of the 1977 Act) and enables Primary Care Trusts to be brought within the capital charging system, placing them in the same position as other NHS bodies. The system ensures that capital costs are included as an overhead when a Primary Care Trust is calculating the cost of any services it provides.
88. *New section 97D* places a financial duty on Primary Care Trusts not to spend more than the sum of the amount allotted to them by their Health Authority (the cash limit) and any other receipts. It also enables the Secretary of State to give directions to Primary Care Trusts to ensure they comply with their financial duty. These provisions mirror those in respect of Health Authorities in section 97A.
89. The rest of the new section 97D is concerned with what is or is not to be covered by the provisions of this section, and with defining expenditure or receipts (mirroring the provisions in section 97A(6) to (9)). In particular subsection (4) ensures that funds held by Primary Care Trusts as charitable trustees or obtained by their fund raising activities are outside the scope of the financial duty. Subsections (7) and (8) enable the Secretary of State to give directions defining the categories of expenditure and receipts which are to be counted when considering whether or not a Primary Care Trust has met its financial duty.

Section 4: Expenditure of Health Authorities and Primary Care Trusts

90. **Section 4** inserts a new Schedule 12A in the 1977 Act, which revises the definitions of Health Authorities' "main expenditure" (which is cash-limited) and "general Part II expenditure" (which is not cash-limited) and introduces comparable definitions for Primary Care Trusts. The main purpose of the changes is to allow the drugs costs of prescriptions written by GPs or nurses to be treated as part of the "main expenditure" of the Health Authority or Primary Care Trust where the prescription is written rather than of the Health Authority where the prescription is dispensed.
91. The situation at present is that responsibility for paying remuneration to chemists and GPs in respect of drugs dispensed to NHS patients belongs to the Health Authority

in whose area the dispensing service is provided. Prior to amendment by the Act, section 97(3A)(b) of the 1977 Act allows the costs of reimbursing the expenses incurred in supplying the dispensed drugs to be designated as part of the cash-limited “main expenditure” of the Health Authority making the payment.

92. The main change arising from the new Schedule 12A (paragraphs 1 to 3) is that Health Authorities will be accountable for the drugs costs which are apportioned to them by the Secretary of State. The costs for which each Health Authority is accountable is will be included in the Authority’s cash-limited “main expenditure”. The power to apportion (paragraph 3) will primarily be exercised so as to provide that Health Authorities will be accountable for the drugs costs arising from the prescriptions written by GPs and nurses in their area, even where those drugs are dispensed in the area of another Authority.
93. Dispensing fees will remain part of “general Part II expenditure”.
94. The power to apportion payments for drugs among Health Authorities, other than on the basis of where the drugs are dispensed, will also enable those elements of the payments that are extraneous to the prescribing decision (e.g. the assumed level of discount obtained by the chemist or GP) to be averaged out amongst Health Authorities (see paragraph 3(4)(b)).
95. Responsibility for making payments to chemists and GPs will remain with the Health Authority in whose area the dispensing service is provided. Where some element of these payments, the other Health Authority will have to be treated as if they had themselves made the payment (paragraph 3(3)). The Health Authority actually making the payments will, however, still need to be reimbursed in some way for the costs involved (paragraph 3(5)). The system that will operate in England is that the Prescription Pricing Authority (for chemists) and Health Authorities (for GPs) will draw down from a central account the funds needed to make all payments for drugs, whichever Health Authority is to be accountable for the payments. The Department of Health will then re-charge these payments to Health Authorities’ cash-limited budgets according to the apportionment made under paragraph 3(1). In Wales, Health Authorities will continue to be directly responsible for paying their chemists and GPs from their cash-limited budgets. These arrangements may be reviewed by the National Assembly for Wales.
96. In the case of drugs ordered by hospital practitioners but dispensed by community pharmacies, NHS Trusts (as now) and Primary Care Trusts may be required to reimburse Health Authorities for the full amount of the remuneration paid to the chemist, i.e. both in relation to the drugs dispensed and the associated professional fees. Paragraph 7(3) enables both these elements of remuneration to be taken into account in re-charging costs to Health Authorities. Section 4(3) amends section 103(3) of the 1977 Act in such a way that the Secretary of State will be able to arrange for a NHS Trust or Primary Care Trust to re-pay such costs to the same Health Authority in each case (rather than necessarily the Health Authority which made the corresponding payment to the chemist). The Health Authority to which these payments are apportioned will be the Health Authority to which the repayment is due.
97. The definitions of Primary Care Trusts’ “general Part II expenditure” and “main expenditure” (paragraphs 4 and 5 of new Schedule 12A) mirror as closely as possible the definitions for Health Authorities.
98. [Paragraph 6](#) allows Health Authorities to apportion the drugs payments for which they are accountable (under paragraph 3) among their Primary Care Trusts, such that these apportioned payments are treated as part of the Primary Care Trust’s “main expenditure”. This will enable Health Authorities to charge to Primary Care Trusts’ cash-limited budgets the costs of prescriptions written by GPs and nurses for which that Primary Care Trust is responsible.

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99. Health Authorities will be accountable for payments on the revised basis from 1999/2000 (section 4(4)).

Section 5: Primary Care Trusts: provision of services etc.

100. This inserts a new section 18A into the 1977 Act, which confers various powers on Primary Care Trusts.
101. Primary Care Trusts will be able to enter pilot scheme arrangements to provide personal medical services and personal dental services under the Primary Care Act (see paragraph 88 of Schedule 4 to the Act). The new section 18A enables a Primary Care Trust also to provide personal medical services and personal dental services under sections 28C and 28D of the 1977 Act (see paragraphs 38 and 39 of the Background section of these notes for a brief explanation of these provisions and the Primary Care Act).
102. **Section 18A** also provides that a Primary Care Trust may arrange to provide any service, which it is able to provide to its own population, to other patients under an NHS contract (under section 4 of the 1990 Act). For example, if it is able to provide health visiting and district nursing to its population, and has the appropriate facilities and staff, it may provide those services to other patients under an NHS contract with a Health Authority or another Primary Care Trust.
103. **Section 18A(3)** provides a power to make premises available for GPs, general dental practitioners, pharmacists and ophthalmists. This power enables Primary Care Trusts to provide for the delivery of all these services from under the same roof.
104. The provisions in subsections (4) to (7) concern powers to recover from private patients the costs of accommodation and services, and to carry out other activities to raise additional income for the health service. The provisions are in line with similar NHS trust powers and are subject to the same restrictions. See the commentary on section 14 below.

Section 6: Delegation of Health Authority functions relating to pilot schemes and section 28C arrangements

105. **Section 6** concerns the delegation to Primary Care Trusts of Health Authority functions relating to Primary Care Act pilot schemes.
106. The Primary Care Act 1997 introduced a new option for the delivery of some family health services and provides for primary care professionals to provide personal medical services (PMS) and personal dental services (PDS) (essentially the same as General Medical Services (GMS) and General Dental Services (GDS)) under agreements with Health Authorities known in the initial stages as pilot schemes with the option in the future for these services to be provided under permanent arrangements (Part II of the Primary Care Act 1997).
107. **Paragraph 88** of Schedule 4 and subsection 18A(1) of the 1977 Act, as inserted by section 5 of the Act, make provision for Primary Care Trusts to take on the role of providing PMS and PDS under both piloted and permanent arrangements.
108. New section 17A of the 1977 Act, as inserted by section 12 of the Act, enables Health Authorities to delegate the power to make agreements as a contract holder with a PMS provider whether under pilot scheme or permanent arrangements. Section 6 inserts new section 8A into the Primary Care Act 1997 in respect of pilot schemes which provides for circumstances when such delegation cannot take place and makes provision for the transfer of rights and liabilities where parties to the contract change.
109. The circumstances when such delegation cannot take place are:-

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- when the Primary Care Trust is the provider of PMS under the same agreement (subsection (b)) – this excludes the possibility of Primary Care Trusts managing a contract for services which they are also involved in providing; and
 - in respect of agreements to provide PDS (subsection (a)) - responsibility for managing PDS is retained by Health Authorities in line with their responsibilities for making arrangements for the provision of dental services through GDS.
110. Sub-sections (c) and (d) also provide further safeguards to avoid potential conflicts of interest by preventing a Health Authority from delegating functions in respect of
- receiving applications from potential pilot scheme providers and turning these into formal proposals to the Secretary of State; and
 - the provision of funds to meet potential pilot scheme providers' preparatory costs.
111. **Section 6** also inserts new section 28EE into the 1977 Act and, taken in conjunction with paragraph 37 of Schedule 4 to the Act, makes similar provisions for PMS provided under permanent arrangements.

Section 7: Primary Care Trusts: trust-funds and trustees

112. **Section 7** enables the Secretary of State to provide for the appointment of trustees for a Primary Care Trust to manage the trust funds held by the trust. Such trustees have a duty to ensure that the trust funds are used effectively and that the wishes of the benefactor are taken into account. The Act provides that Primary Care Trusts will be able to hold and manage charitable property and other property held on trust, and to accept gifts of money and land on trust, for the purpose of the health service (see paragraph 12(2)(c) of the new Schedule 5A to the NHS Act 1977 as inserted by Schedule 1).
113. In addition to this section, paragraphs 27 to 30 and 33(2)(b) of Schedule 4 to the Act extend to Primary Care Trusts the existing provisions of the 1977 Act relating to private trusts for hospitals, the transfer of trust property, and the accounts of trustees.
114. The Act provides that Primary Care Trusts are able to receive and administer the charitable donations. It is expected that this will concern mainly those Primary Care Trusts that provide as well as commission services, as these Trusts may inherit funds from NHS trusts.

Section 8: Payments relating to past performance

115. This section inserts four new subsections into section 97 of the NHS Act 1977, which is concerned with the funding of Health Authorities. The insertions enable the Secretary of State to increase the initial allocation he makes to a Health Authority where certain conditions are satisfied. The White Paper *The new NHS* signalled the intention to reward Health Authorities that perform well with modest extra non-recurrent funding.
116. A key intention of this section is to reward Health Authorities who demonstrate most progress in implementing their plan for improving health and health care, the Health Improvement Programme (see section 28 of the Act). Health Authority performance will be assessed against the achievement of targets and objectives set out in their Health Improvement Programmes. All Health Authorities – including those making good progress from a low baseline – will be eligible.
117. The new subsection (3E) enables the Secretary of State to attach conditions to the use of the additional funding. In the case of Health Improvement Programmes, for example, the intention is that these funds will be used to accelerate Health Improvement Programmes by bringing forward projects contained in the later years of these Programmes and to meet the targets associated with that action. The new subsection (3F) enables the Secretary of State to recover the additional funding, if a Health Authority does not meet the conditions attached to it.

Section 9: Indemnity cover for Part II services

118. **Section 9** gives the Secretary of State new powers to make professional indemnity cover mandatory in the NHS. It enables the Secretary of State by regulation to require professional indemnity cover for all, or any, of the professions providing Part II services under the NHS Act 1977 (GPs, dentists, pharmacists and optometrists).
119. Neither doctors nor dentists are required to maintain professional indemnity cover. The NHS has made arrangements to indemnify those employed by them, but this does not cover practitioners providing Part II services, who are independent contractors.
120. New section 43C enables the Secretary of State by regulation to require all, or any, of the practitioners providing Part II services, to have approved professional indemnity cover provided by an approved body.
121. The regulations may make different provisions for different categories of practitioner or classes of case. For some practitioners, holding approved indemnity cover may be a condition of entry to and continued inclusion on the relevant Part II list. (Part II practitioners must be included on a Health Authority list if they are to provide NHS services in that Health Authority area.) For others it may be a terms of service requirement. This flexibility reflects the widely differing arrangements for the four professions.
122. Once a practitioner who is required to hold professional indemnity cover is included on a Health Authority's list, the Health Authority will need to review the indemnity cover held by that practitioner at regular intervals. Regulations under section 43C of the 1977 Act, as inserted by section 9, may therefore require practitioners to provide the Health Authority with evidence that they hold approved cover when requested. The result of failure to comply would mean removal from the list. Where practitioners are required to provide evidence, the section contemplates that there will be a period of grace to enable the practitioner to comply with the requirements, before the Health Authority removes him from its list.
123. In the case of dental and optical corporate bodies, the clinicians employed by these bodies must also be on the Health Authority list and are responsible for employed assistants within the company. Pharmaceutical companies providing community pharmacy, however, are themselves on the list of each Health Authority in whose area they provide those services. The provisions described above therefore apply equally to corporate bodies.
124. Subsection (3) provides that indemnity cover, which may be through membership of a defence society or a suitable insurance policy, is to be approved indemnity cover with an approved body. This enables the Secretary of State to ensure that the cover is adequate to meet the anticipated level of claims. It is intended that the regulations will ensure through the approval mechanism that cover will still meet claims that arise from events when the clinician was covered but only come to light later, even if this is after the period of cover has ceased.
125. The approved indemnity could also be required to cover other persons, such as employees, assistants or deputies of the practitioner. The intention is that the cover currently held by responsible practitioners should be quite adequate to meet any new requirements, and only those contractors who fall short of reasonable cover will find themselves affected.
126. **Section 9** does not alter the law of tort or contract and accordingly does not confer on any person a right to recover compensation in any case in which he has no such right at present. Its purpose is simply to ensure that where a person does have such a right he will actually be able to recover the compensation.

Section 10: Remuneration for Part II services

127. Determinations of remuneration of family health services practitioners (GPs, dentists, pharmacists and optometrists) are provided for in sections 43A and 43B of the 1977 Act, which were inserted by section 7 of the Health and Social Security Act 1984. They provide for a regulatory structure for the making of determinations of professional remuneration. However, those sections have never been brought into force. Meanwhile, determinations of professional remuneration are validated by section 7(4) of the 1984 Act. The practice prior to 1984 was to make provision about remuneration through published statements (for example, the Statement of Fees and Allowances or “Red Book” for GPs) not contained in regulations. This practice has continued to the present day.
128. The continued reliance on section 7(4) of the 1984 Act as validating determinations is increasingly unsatisfactory. In particular, without sections 43A and 43B in force there is no power to make regulations under those sections and, thus, no explicit method of appointing a determining authority other than the Secretary of State.
129. The Government intends to give Primary Care Trusts the function of determining such GP remuneration as comes from cash-limited funds. It is intended that the Secretary of State will appoint Health Authorities as determining authorities in respect of such remuneration, and direct them to delegate this function to Primary Care Trusts through regulations made under section 17A of the 1977 Act (as inserted by section 12 of the Act).
130. **Section 10** substitutes a new version of sections 43A and 43B in the 1977 Act. The purpose of these revised sections is to make new provision about determinations of remuneration. The new sections rely less on regulations and more on free-standing propositions than the sections they replace and, in particular, provide a new method of appointing Health Authorities as determining authorities which will, indirectly, enable Primary Care Trusts to determine remuneration in respect of certain payments to GPs. The provisions in new sections 43A and 43B derive largely from the existing sections 43A and 43B.
131. *New section 43A* provides for the Secretary of State to determine the remuneration (which includes payments of salary, fees, allowances or the reimbursement of expenses) of family health services practitioners or to appoint Health Authorities or other persons as determining authorities, subject to requirements contained in their instrument of appointment. It provides for regulations to make provision about determining remuneration (including consultation and publication requirements), and subsection (5) provides in particular for regulations to permit determinations to be made by reference to the remuneration of other persons, or scales, indices or other data. Subsection (6) provides that a determination may have retrospective effect provided that taken as a whole it is not detrimental to the persons to whom it relates.
132. *New section 43B* provides in subsection (1) for the Secretary of State to undertake consultation before making a national determination. The Secretary of State will therefore continue to consult the national representative bodies of each group before making changes to payments that potentially affect the whole of that group (these changes would be ones to the GPs’ Statement of Fees and Allowances or equivalent for the other professions). Subsection (3) provides that determinations may be made in several stages, as is currently the case. For GPs, for example, the Secretary of State might make a first stage determination in respect of the profession as a whole and publish it in the Statement of Fees and Allowances, and subsequently Health Authorities might (within parameters set by the Secretary of State) make a second stage determination of claims for allowances or fees from smaller groups or individuals within that profession.
133. As mentioned above, currently determinations of remuneration are validated by section 7(4) of the Health and Social Security Act 1984. The changes to sections 43A

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and 43B are intended to reflect current practice in relation to such determinations. When the new sections are in force it will therefore no longer be necessary to rely on section 7(4) of the 1984 Act.

134. It is intended that when exercising the delegated function of determining cash-limited payments Primary Care Trusts will be subject to any requirements (such as consultation requirements) that apply to the Health Authority.
135. Primary Care Trusts will not be appointed as determining authorities in relation to remuneration for dentists, pharmacists or optometrists. The Act precludes them having any functions in respect of Part II services other than general medical services (see new section 17A(3)(d) of the 1977 Act, as inserted by section 12 of the Act).

Section 11: Local representative committees

136. This section amends sections 44 and 45 of the 1977 Act to enable Local Medical and Local Dental Committees to represent doctors and dentists other than just those on Health Authority lists. Where the Health Authority concerned agrees to recognise such a committee, the Local Medical or Dental Committee will be able to represent such doctors or dentists who work as assistants or deputies to those on the Health Authority list, or in personal medical or personal dental services, as wish to be represented.
137. **Section 11** further amends section 45 of the 1977 Act to allow regulations to require Health Authorities to consult Local Medical and Dental Committees either in the exercise of their functions under Part II of the 1977 Act, or in the exercise of any of their functions relating to personal medical or personal dental services, but makes it clear that this is without prejudice to any other powers to require Health Authorities to consult these committees, such as in directions.
138. The section also amends section 45 of the 1977 Act to allow Local Medical or Dental Committees to apportion the amount of their administrative expenses between those who are on the Health Authority list and those who are not.

Section 12: Directions

139. This section restates the direction-giving powers conferred on the Secretary of State by sections 13 and 17 of the NHS Act 1977, expands section 17 to cover NHS trusts, and provides for a scheme of delegation under which Primary Care Trusts have their functions conferred upon them.
140. The new sections 16D to 17B provide a flexible structure under which the Secretary of State may arrange for the exercise of functions by Health Authorities, Special Health Authorities and Primary Care Trusts and determine the level to which functions are to be devolved while maintaining appropriate control over how those functions are to be exercised.
141. *New section 16D* restates section 13 of the 1977 Act. It enables the Secretary of State to delegate his functions in relation to the health service to Health Authorities and Special Health Authorities. In addition, it enables him to direct a Special Health Authority to exercise specified functions of Health Authorities or Primary Care Trusts. At present the Secretary of State delegates most of his functions to Health Authorities, and he will continue to do so. Schedule 1 to the National Health Service (Functions of Health Authorities and Administration Arrangements) Regulations 1996 (S.I. 1996/708) lists those functions which the Secretary of State has delegated to Health Authorities. For example, the Secretary of State currently delegates to Health Authorities the responsibility for securing the provision of hospital and community health services in their area (see section 3(1) of the 1977 Act).
142. In a similar way, the new section 17A enables Health Authorities to delegate their functions to Primary Care Trusts, subject to certain exceptions in subsection (3). Primarily, the functions exercised by a Primary Care Trust will consist of the

commissioning, and in some cases the provision, of services under Part I of the 1977 Act for their local population. A Health Authority may delegate its Part I functions by directing Primary Care Trusts to exercise those functions. Such directions may encompass both functions delegated by the Secretary of State, and those conferred directly on Health Authorities by statute or by regulations. The Health Authority will be required to issue such directions where directed to do so by the Secretary of State. The Secretary of State will also be able to determine which functions may or may not be delegated to Primary Care Trusts (section 17A(4)), and the extent to which they may be delegated.

143. The practical effect of delegation under these provisions is that the function becomes the function of the Health Authority or Primary Care Trust to which it is delegated. Legal proceedings in relation to the exercise of the function will be brought by, or against, that body, rather than the person or body which made the delegation (see paragraph 13 of Schedule 5A to the 1977 Act as inserted by Schedule 1 of the Act and paragraph 15 of Schedule 5 to the 1977 Act as inserted by paragraph 39(5) of Schedule 4 to the Act).
144. The Act does not specify what services Primary Care Trusts will or will not commission. The intention is that responsibility for commissioning the majority of hospital and community health services will be delegated to Primary Care Trusts (with some exceptions such as some specialised services). With respect to the provision of services, it is envisaged that, initially, Primary Care Trusts will be able to provide and manage only community health services (i.e. those services which the Secretary of State has a duty to provide under sections 3(1)(d) and (e), 5(1) and (1A) and Schedule 1 to the 1977 Act). The Act does not restrict Primary Care Trusts to the provision of community health services, however. Any restrictions will be set out by the Secretary of State in directions or the order establishing a Primary Care Trust. This will provide the flexibility to change the functions of Primary Care Trusts where necessary.
145. Subsection (3) of the new section 17A prohibits the delegation to Primary Care Trusts of functions relating to high security psychiatric services, family health service functions under Part II of the 1977 Act other than general medical services functions, some functions in relation to PMS and PDS (see section 6) and certain other specified functions. A limited range of general medical services functions will be delegated to Primary Care Trusts. The delegation of such functions will be set out in regulations and will not affect GPs' independent status.
146. The Government intends to require Health Authorities to delegate to Primary Care Trusts the function of determining such GP remuneration as is to come from cash-limited funds. It will also consider requiring the delegation of certain other GMS functions: for example, making arrangements for the temporary provision of services where a GP retires or is suspended.
147. *New section 17* extends the current powers of direction under section 17 of the 1977 Act (which currently applies to Health Authorities and Special Health Authorities) to include Primary Care Trusts and NHS trusts. This allows the Secretary of State to give instructions to any of the bodies concerned about how they are to exercise their functions.
148. *New section 17B* provides that Health Authorities will also be able to direct Primary Care Trusts about the exercise of functions they have delegated to them. Any Secretary of State directions under section 17 will take precedence. It is not intended that Health Authorities should use their powers to seek to control the detailed day-to-day operation of Primary Care Trusts.
149. The current direction-giving powers in respect of NHS trusts are conferred by paragraph 6 of Schedule 2 to the 1990 Act and relate to a limited number of very specific matters. The new section 17 replaces these powers of direction with a general power, in line with that relating to Health Authorities and Primary Care Trusts, which enables directions to be given in relation to the full range of NHS trusts' functions.

150. *New sections 18(1) to (1B) specify how directions under sections 16D to 17B of the 1977 Act are to be given. Any directions given by regulations are subject to parliamentary scrutiny. The existing section 18 (and the new section 18(1A)) provides that regulations must be used to give directions delegating the Secretary of State's functions relating to special hospitals (see section 41 for further provisions relating to special hospitals) and any directions about the Secretary of State's functions regarding the establishment of Community Health Councils (section 20(1) and (2) of the 1977 Act). The new section 18(1A) also applies to any directions specifying that Health Authorities may or may not delegate GMS functions to Primary Care Trusts.*

Section 13: Establishment orders

151. NHS trusts are currently established under section 5 of the 1990 Act. This states that the Secretary of State may by order establish NHS trusts,
- to assume responsibility...for the ownership and management of hospitals or other establishments or facilities which were previously managed or provided by Health Authorities (section 5(1)(a)); or
 - to provide and manage hospitals or other establishments or facilities (section 5(1)(b)).
152. **Sections 5(1)(a)** and (b) therefore determine the functions that may be conferred on a trust. All NHS trusts were originally established under section 5(1)(a) of the 1990 Act, in recognition of the fact that they inherited property from Health Authorities or their predecessors on their establishment. Their establishment orders limited them to owning and managing property that had previously been managed by a Health Authority or its predecessors.
153. The section 5(1)(a) function has become increasingly out-dated, both in its reference to property previously managed by Health Authorities, and in its restriction of trusts to owning the property they manage. This is particularly true for trusts entering into Private Finance Initiative (PFI) contracts with private sector partners. These contracts typically involve the trust granting a long-lease on part of its property and receiving a sub-lease from the private sector partner or partners for the duration of the contract. The new public-private partnerships may also involve trusts acquiring brand new hospitals. Section 5(1)(a) does not allow a sufficiently wide power to be conferred to do either of these. It has therefore been necessary to amend individual NHS trusts' establishment orders where required, to give them powers under section 5(1)(b).
154. Subsection (1)(a) of section 13 replaces the current sections 5(1)(a) and (b). It provides for the Secretary of State to establish NHS trusts to provide goods and services for the purposes of the health service. Subsection (1)(b), by replacing the current section 5(6), enables the Secretary of State to confer in a NHS trust's establishment order a duty to provide particular goods or services at or from particular hospitals, establishments or facilities. The function of providing such goods and services includes managing such hospitals, establishments or other facilities. This enables the Secretary of State to specify a particular type of service (such as ambulance services, for example) which the trust must provide and a particular site or associated sites from which those services must be provided.
155. There has been some doubt raised as to whether the functions that may be conferred under the old section 5(1)(a) encompass all property arrangements entered into by NHS trusts to date. There has also been some doubt raised as to whether the functions conferred under section 5(1)(a) allow trusts to acquire new hospitals or facilities not previously managed by a Health Authority. The parties concerned have entered into these arrangements in good faith, so the Government wishes to put their validity beyond doubt. Subsection (3)(b) ensures that existing establishment orders remain valid despite the amendment to section 5(1). Subsection (4) provides that NHS trusts are to be treated as never having been restricted to managing premises previously managed by Health

Authorities or their predecessors. In addition subsection (5) allows for amendments to NHS trusts' establishment orders and elsewhere in legislation to be made with retrospective effect where necessary to give effect to the section in practice.

Section 14: Exercise of powers

156. This section amends section 5(9) of the 1990 Act which places limits on NHS trusts' exercise of their charging and income generation powers conferred by paragraphs 14 and 15 of Schedule 2 to the 1990 Act. Section 5(9) currently provides that NHS trusts may only exercise these powers if this will not to a significant extent interfere with their functions as set out in their establishment order or their obligations under NHS contracts.
157. **Section 14** extends the current provision to ensure that the restriction it imposes on the exercise of income generation powers applies in respect of all NHS trust functions, not just those conferred on an NHS trust in its establishment order. The exercise of an NHS trust's charging and income generation powers should not to a significant extent interfere with, for example, the trust's obligations under the duty of co-operation (section 26). It also allows the Secretary of State to specify in directions circumstances in which NHS trusts will also require his consent to exercise their charging and income generation powers. Directions could, for example, specify an amount of income above which his consent is required.

Sections 15 to 17: Changes to the NHS trust financial regime

158. These sections, together with paragraph 84 of Schedule 4, effect changes to the NHS trust financial regime. The existing financial regime, as set out in the NHS and Community Care Act 1990, was introduced to support the purchaser/provider split. In the White Paper *The new NHS*, the Government signalled its intention to amend the existing regime.
159. The main changes made to the NHS trust financial regime in the Act are:
- NHS trusts' originating capital debt will be comprised wholly of public dividend capital;
 - additional borrowing by NHS trusts other than from the Secretary of State will be at his direction and subject to conditions he may determine, with the consent of the Treasury;
 - investment of temporary surpluses by NHS trusts will be at the direction of Secretary of State.
160. **Sections 15 and 16** change the form in which the originating capital debt of NHS trusts is financed. Assets are transferred to the ownership of a trust by the Secretary of State. These assets are matched in value by a debt, which the trust then owes to the Exchequer (the Consolidated Fund). This is known as the trust's originating capital debt (OCD).
161. The originating capital debt is currently split into two. One part is made up of interest bearing debt (IBD). This type of debt is rather like a bank loan, with defined interest and repayment terms. It is repayable in equal instalments twice yearly in September and March over 25 years. The interest on the debt is based on that charged for an equivalent National Loans Fund loan at the date of establishment. Loan interest is charged on the diminishing balance. The other part of this debt is made up of public dividend capital (PDC). This is similar to share capital or equity, with the Government holding a share in the trust (normally 50%), on which the trust pays dividends to the Government.
162. In practice the total interest and dividend payments are adjusted so that the total return on capital must equal 6% of the trust's average net assets. (The 6% is determined by the Treasury and reflects the long-term cost of Government borrowing.) The Government therefore believes there is now no reason to have separate forms of financing. The Act

therefore replaces the current dual system with a simplified single form of financing for NHS trusts' originating capital debt.

163. The process of phasing out interest bearing debt has already begun for long term loans. Section 16 provides for the replacement of the remaining originating capital debt IBD. It converts the interest bearing debt portion of existing trusts' originating capital debt to public dividend capital. Section 15 provides for the originating capital debt of newly established NHS trusts to be issued wholly as public dividend capital. As a consequence of this it provides that OCD will now be known as originating capital.
164. Unlike interest bearing debt, public dividend capital currently has no repayment terms. To prevent NHS trusts building up cash reserves as a consequence of the removal of IBD, therefore, the Government intends to introduce procedures requiring trusts to make repayments of PDC rather than build up cash surpluses.
165. *Section 17* provides that additional borrowing by NHS trusts (over and above their originating capital) will be subject to Secretary of State direction, and amends the current provisions regarding the interest on loans by the Secretary of State.
166. NHS trusts have a duty to obtain value-for-money when they enter into borrowing arrangements. This will usually result in borrowing from the Secretary of State (in effect the Exchequer) since the interest rates on offer will reflect the Government's own credit rating. NHS trusts can borrow from the private sector, but any borrowing must not be secured borrowing and must offer better value for money than borrowing from the Secretary of State.
167. In future it is intended that, in the main, NHS trust borrowing will be from the Secretary of State. There are certain limited circumstances when a trust needs the ability to borrow from sources other than Government. An example is where an NHS trust wishes to enter "step-in" contracts in Private Finance Initiative schemes. Typically these arrangements involve a contract for a loan between the private sector provider and a bank. The trust's "step-in" term allows it to take on the private sector provider's liabilities under the contract if, for defined reasons, the provider is no longer able to meet them. In such circumstances the trust would in effect be borrowing from the bank. The intention, therefore, is to restrict the ability of NHS trusts to borrow from the private sector rather than rule it out altogether. Section 17 amends paragraph 1(1) of Schedule 3 to the 1990 Act to provide that the ability of NHS trusts to borrow is subject to the Secretary of State's power of direction.
168. Existing legislative provisions (paragraph 1 of Schedule 3 to the 1990 Act) allow the Secretary of State to provide interest bearing loans to trusts, with interest rates determined in accordance with the National Loans Fund. Section 17 revises these provisions to allow the Secretary of State, with the consent of the Treasury, to decide the circumstances and terms and conditions of any loans given to NHS trusts. The Secretary of State, with the consent of Treasury, will be able to decide the interest rate and any charges as appropriate, and will aim to ensure that they are compatible with the funding regime in the NHS and good treasury management.
169. *Paragraphs 84(3) and (4) of Schedule 4* make provision regarding the ability of NHS trusts to invest money. Under paragraph 7 of Schedule 3 to the 1990 Act, NHS trusts are able to invest temporary cash surpluses in Government securities, or other approved public or private sector deposit facilities such as local authorities, nationalised industries, banks and building societies. There is a cost to the Exchequer, however, in allowing NHS trusts to hold large sums of money other than in Paymaster Accounts (where the Government acts as the bank): the sums paid to trusts by Health Authorities would have been borrowed by the Exchequer from the market. It is intended that in future, therefore, any surpluses will be invested in Paymaster Accounts, thereby allowing the Exchequer to take account of these balances in deciding the overall amounts which the Government needs to borrow from the market.

170. For practical reasons, however, NHS trusts will be permitted to hold limited surpluses with other institutions (e.g. their High Street bank), but these will be restricted to an upper limit, to be determined by the Secretary of State and the Treasury. This will enable NHS trusts to continue to use commercial bank accounts for their day to day transactions, if this is value for money, and allow them some flexibility around the levels of cleared balances within which they are required to manage. This is in line with the procedures currently in place for Health Authorities.
171. Paragraph 84(3) of Schedule 4 therefore creates a new paragraph 7 in Schedule 3 to the 1990 Act. It allows NHS trusts to invest money in any investments specified in directions by the Secretary of State. Paragraph 84(4) provides that the maximum amount of these investments may also be set, with the consent of the Treasury. These changes will have the effect of reducing overall Exchequer borrowing costs. Furthermore, they should result in reduced administrative costs for trusts in planning and managing their investments, as where to invest and under what terms will be determined by the Secretary of State.

Section 18: Duty of Quality

172. The White Papers *The new NHS* and *Putting Patients First* announced the intention to place a new duty of quality on NHS trusts. At present there is no statutory duty on NHS trusts in respect of the quality of care they provide to patients (although they owe a duty at common law to exercise reasonable care and skill in providing medical treatment and other services).
173. Under this section Health Authorities, NHS trusts and Primary Care Trusts will be required to put and keep in place arrangements for monitoring and improving the quality of the health care they provide. A fundamental component of those arrangements will be the implementation of clinical governance arrangements. The concept of “clinical governance” was discussed in the consultation documents *A First Class Service* and *Quality Care and Clinical Excellence*, which set out in more detail the Government’s plans to improve the quality of NHS healthcare. The main components of clinical governance as described in the consultation documents are:
- clear lines of responsibility and accountability for the overall quality of clinical care;
 - a comprehensive programme of quality improvement systems (including clinical audit, supporting and applying evidence-based practice, implementing clinical standards and guidelines, workforce planning and development);
 - clear policies aimed at managing risk; and procedures for all professional groups to identify and remedy poor performance.

It is intended that the detail of what is expected of Health Authorities, NHS trusts and Primary Care Trusts in implementing clinical governance will be set out in guidance. The first tranches of clinical governance guidance were published in March 1999 (under HSC 1999/065 in England and WHC (99)54 in Wales).

174. Subsection (3) enables the Secretary of State to extend the duty of quality to Special Health Authorities. The intention is to use this power in respect of the three Special Health Authorities that provide high security psychiatric services (Ashworth, Rampton and Broadmoor).

Section 19 and Schedule 2: The Commission for Health Improvement

175. The White Paper, *The new NHS*, set out the Government’s intention to create a new Commission for Health Improvement. The Commission will be established as a body corporate to provide an independent check that local systems to monitor and improve the quality of health care are working. The Commission’s functions are set out in sections 20 to 22. Proposals for the role and functions of the Commission were set out

in more detail in the consultation documents *A First Class Service* and *Quality Care and Clinical Excellence*, published in July 1998.

176. The Commission will be administered as an executive non-departmental public body. It will be held accountable through Ministers to Parliament for the effective performance of its functions. The Commission will be required to produce an annual report and annual accounts (see paragraphs 11 and 12 of Schedule 2), and will be subject to the jurisdiction of the Parliamentary Commissioner for Administration (see paragraph 17 of Schedule 2). Members of the Commission could be required to appear before the House of Commons Health Select Committee, and the Accounting Officer for the Commission may be required to attend before the House of Commons Public Accounts Committee.
177. Subsection (3) of section 19 introduces Schedule 2 to the Act. This Schedule makes additional, more detailed provisions regarding the Commission for Health Improvement. In particular it includes provisions in respect of the membership and staffing of the Commission and their remuneration, funding arrangements and reporting and accounts procedures.

Schedule 2

178. *Paragraphs 4, 5 and 6* provide for the membership of the Commission. The Commission will consist of a chairman appointed by the Secretary of State, one member concerned with the interests of Wales and appointed by the National Assembly for Wales, and other members appointed by the Secretary of State. It is intended that the membership will include people with a lay background as well as those with relevant professional expertise. Regulations will deal with matters such as how the appointments are made, persons who are to be disqualified, and the procedures of the Commission. The remuneration of members of the Commission will be a matter for the Secretary of State.
179. *Paragraph 7* provides for the staffing arrangements of the Commission. In particular, paragraphs 7(1) to (3) provide for the appointment of the Director of Health Improvement, the chief executive of the Commission. Paragraph 7(4) concerns the appointment of staff. It is expected that the Commission will develop a number of teams to undertake its various functions. Each team would include staff with appropriate expertise who have been employed by the NHS to provide services and also those who make use of NHS services as patients and carers.
180. The Secretary of State will only be able to exercise his powers under paragraphs 4 to 7 of Schedule 2 if he has first consulted the National Assembly for Wales (see section 66(6)).
181. *Paragraph 8* enables the Commission to make arrangements for the performance of its functions by committees or sub-committees, members or employees.
182. *Paragraph 9* enables the Commission to arrange for other individuals and bodies to assist it in its work. Examples of individuals and organisations from which the Commission may seek assistance include experts in particular clinical fields, academic organisations such as universities, professional bodies such as the Royal Colleges, and voluntary organisations.
183. *Paragraph 10* allows both the Secretary of State and the National Assembly for Wales to provide funding to the Commission. The Secretary of State and the Assembly will be able to direct the Commission as to how it applies the funding it receives from them. As the Commission's role develops, it is envisaged that some of the Commission's work may be funded by charges paid by NHS bodies in respect of which it exercises its functions. Such charges may be provided for by regulations made under section 20(2) (e). Paragraph 10 also provides that the Secretary of State and the Assembly may make loans to the Commission.
184. *Paragraph 11* requires the Commission to keep accounts and submit them to the Secretary of State and the Comptroller and Auditor General. The Commission's

accounts will be audited by the National Audit Office, which is headed by the Comptroller and Auditor General.

185. *Paragraph 12(1)* requires the Commission to make an annual report to the Secretary of State, in which it is envisaged that the Commission will set out the progress it has made during the year and the issues emerging from its work. It is intended that each annual report will be published.
186. *Paragraph 15* amends the Public Records Act 1958. The effect of the amendment is that the records of the Commission will be public records for the purposes of that Act. The records will therefore be preserved, stored, and made available for public inspection in accordance with the 1958 Act.
187. *Paragraph 16* amends the Public Bodies (Admissions to Meetings) Act 1960, so that the Commission will be required to conduct its meetings in open session (unless business of a confidential nature is being discussed or for other special reasons) and to make arrangements for the public to attend.
188. *Paragraph 17* amends the Parliamentary Commissioner Act 1967, so that the Commission is subject to the jurisdiction of the Parliamentary Commissioner.
189. *Paragraph 18* amends the House of Commons Disqualification Act 1975, so that members of the Commission are disqualified from membership of the House of Commons. *Paragraph 19* makes an equivalent amendment to the Northern Ireland Assembly Disqualification Act 1975.

Section 20: Functions of the Commission

190. This section, and sections 21 and 22, set out the Commission's functions. It will have four core functions, as set out in subsection (1) of section 20:
 - providing advice and information on arrangements for the monitoring and improvement of health care provided by NHS trusts and Primary Care Trusts (including "clinical governance" arrangements);
 - conducting reviews of the implementation and adequacy of such arrangements;
 - investigating, advising and reporting on specific matters relating to the delivery and management of health care provided by NHS bodies;
 - conducting national reviews on particular types of health care provided by the NHS; and will perform such other functions in relation to health care provided by the NHS as are set out in regulations.
191. The Commission for Health Improvement will cover England and Wales, and will exercise the same functions in each country. The National Assembly for Wales will be able to determine how the Commission exercises its functions in Wales, by exercising the regulation and direction making powers in sections 20(2), 20(3) and 23. These powers are conferred on the Assembly by the National Assembly for Wales (Transfer of Functions) Order 1999 (SI 1999/672) as amended by section 66(5) of the Act. In addition the Secretary of State will only be able to confer new functions on the Commission (under section 20(1)(e)) in relation to Wales if this is first agreed with the Assembly (see section 66(6)).
192. The Secretary of State may draw any advice given by the Commission under subsection (1)(a) to the attention of health service bodies. If necessary, he may also require them to act on that advice, using his powers of direction under new section 17 of the 1977 Act (inserted by section 12 of the Act).
193. Subsection (1)(b) provides for the Commission to conduct reviews of the implementation and adequacy of arrangements to monitor and improve the quality of health care which is the responsibility of NHS trusts and Primary Care Trusts. It

is intended that the Commission should review every NHS trust and Primary Care Trust once every 3 to 4 years. During these reviews, the Commission will be expected to look for evidence that the arrangements are working and that they are consistent with established standards. Regulations under subsection (2) will set out how these reviews are to be conducted. The Commission will also be able to look at the actions of Health Authorities (and their Primary Care Groups or Local Health Groups) in the course of a review if it considers that their actions (for example, as commissioners of the services under review) are related to the issues it is examining. It is intended that the Commission's findings will identify both areas of good practice and areas for improvement. The findings will be reported to the bodies concerned and the Government intends to make appropriate provision as to their publication.

194. Subsection (1)(c) provides for the Commission to investigate, advise and report on specific matters relating to the delivery and management of health care. Regulations will provide that this may be at the invitation of health service bodies such as Health Authorities, NHS Trusts or Primary Care Trusts, or at the direction of the Secretary of State, when concerns have been raised about the quality of the health care they provide. It is anticipated that the Commission's investigation will focus on clinical issues but it may also have regard to management and other issues if it considers that problems in these areas lie behind the matter under investigation. During an investigation the Secretary of State would be able to request that the Commission consider such matters as he thinks appropriate.
195. When the Commission has conducted an investigation, or a local review, follow-up action will be the responsibility of the NHS organisation in question, overseen in England by the NHS Executive Regional Office (for NHS trusts) or the Health Authority (for Primary Care Trusts), and in Wales by the Assembly and Health Authorities respectively. It is intended that the bodies concerned will share their action plans for addressing the Commission's recommendations with the Commission, and the Commission might be involved in follow-up action at local request. The expectation is that the body concerned would act on the Commission's recommendations, but if necessary the Secretary of State will be able to direct the body concerned to do so (using his powers of direction under section 17 of the 1977 Act as inserted by section 12 of the Act).
196. Subsection (1)(d) provides for the Commission to conduct national reviews on topics relating to health care provided by the NHS as requested by the Secretary of State. These topics will include the implementation of National Service Frameworks and of guidance issued by the National Institute for Clinical Excellence (set out in more detail in *A First Class Service*). Similar reviews are currently conducted by the Clinical Standards Advisory Group, which is to be abolished (see section 25).
197. The National Institute for Clinical Excellence (NICE) was established on 26 February 1999 as a Special Health Authority under section 11 of the 1977 Act (see the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 SI 1999/220). NICE will appraise, and disseminate guidance on, the clinical and cost-effectiveness of new and existing health technologies (including drugs) and other interventions in England and Wales. It is intended that the Commission will look at how this guidance is being implemented in the NHS.
198. Subsection (1)(e) provides for the Commission to have such additional functions in relation to the matters set out in the subsection as the Secretary of State may prescribe by regulations. In particular it is envisaged that regulations may provide for the Commission to advise, review and investigate persons and bodies other than those listed in subsections (1)(a) to (c). For example, this will allow the Commission's role to be extended to the Special Health Authorities which manage the special hospitals that provide high security psychiatric services, or to the limited range of health care services provided by Health Authorities.

199. At present, the Secretary of State can institute informal inquiries in the exercise of his powers under section 2(b) of the 1977 Act, and institute formal inquiries under section 84 of the 1977 Act. The Commission will be able to provide advice and assistance to those carrying out such inquiries.
200. Subsection (2) enables the Secretary of State to make regulations which will set out how the Commission performs its functions. For example they may provide for the frequency of the Commission's reviews (subsection (2)(a)), arrangements for working in conjunction with other statutory bodies (subsection (2)(f)), or the publication of reports (subsection (2)(d)).
201. Regulations under subsection (2) will provide that when the Commission has undertaken a local or national review or an investigation, reports will be made to the bodies involved and to the Secretary of State. The regulations will also make provision for their publication. For example, where in a local review visit or investigation, the Commission's findings show clear evidence of very serious and continuing concerns about the performance of a clinical department and/or there has been failure by the NHS organisation to act, it is proposed that regulations will provide that the Commission may issue an immediate report rather than wait until the conclusion of its review or investigation. Regulations will provide that the Commission will bring these findings to the attention of the organisation concerned, the appropriate Health Authority or the Secretary of State. The Commission may also decide to make its findings public if it would be in the public interest to do so.
202. Subsection (2)(e) provides for the Secretary of State to make regulations as to the recovery by the Commission of some of the expenditure it incurs in exercising its functions. It is not intended that the Commission will charge individual health service bodies directly for its work from the outset. However in the longer term, the Government envisages that some of the Commission's work may be funded locally.
203. Subsection (2)(f) provides for regulations to be made regarding joint working between the Commission and other bodies. As well as working closely with health service bodies, the Commission may work in conjunction with organisations such as the Audit Commission, the Social Services Inspectorate, the Health and Safety Executive, the Health Service Commissioner, regulatory bodies and professional bodies such as the Royal Colleges. Particular arrangements for working with the Audit Commission are dealt with in section 21.
204. Subsections (3) and (4) provide that the Secretary of State may issue directions to the Commission as to the exercise of its functions. The Commission will have a work programme agreed with the Secretary of State. The Secretary of State will be able to specify in directions, for example, specific clinical quality issues where it wishes the Commission to have a particular focus.

Section 21: Arrangements with the Audit Commission

205. This section provides for joint working by the Commission for Health Improvement and the Audit Commission. The consultation document *A First Class Service* made clear that the two Commissions would be expected to agree a joint programme of national work and to conduct national and local reviews in a way which made the best use of their particular expertise and their combined resources. Section 21 provides for the two Commissions to undertake joint reviews and to produce a joint report. The joint reviews will look at both health care issues (such as clinical governance, in the local reviews; and the provision and quality of health care, in the national reviews) within the usual remit of the Commission for Health Improvement and issues that are normally within the remit of the Audit Commission, such as economy, efficiency, and effectiveness in the performance of functions ("value for money"), and the management of NHS bodies. In addition, section 21(2) provides for the Commission for Health Improvement to assist the Audit Commission in its wider value for money (VFM) programme of

studies, conducted under section 33 of the Audit Commission Act 1998, where there is a need for informed clinical expertise.

Section 22: Arrangements with Ministers

206. This section enables Ministers of the Crown with responsibility for the provision of publicly funded health services, or Northern Ireland Ministers with responsibility for the health service in Northern Ireland, to enter into arrangements with the Commission for Health Improvement under which the Commission may perform functions in relation to those services. For example, the quality agenda for the NHS in Northern Ireland has yet to be finalised, but the Northern Ireland Assembly may, at some future date, decide that the Commission can assist in monitoring arrangements put in place to improve the quality of NHS services there. Section 22 allows the First Minister or deputy First Minister of Northern Ireland, or the Department of Health and Social Services for Northern Ireland, to enter into arrangements with the Commission for the Commission to exercise functions in relation to the health service in Northern Ireland on behalf of the Minister or the Department. Other examples of arrangements which may be made under this section are arrangements between the Commission and the Secretary of State for Defence in respect of provision of health care to the Armed Forces, and between the Commission and the Home Secretary in respect of healthcare provided to prisoners.

Section 23: Obtaining information etc.

207. This section makes provision for regulations which will set out the Commission's powers to obtain entry to NHS premises and to access information and documents held by the bodies under review or investigation.
208. Subsection (1)(a) provides that regulations may confer a right on persons authorised by the Commission (e.g. its employees or other members of the review or investigation team) to enter and inspect premises for the purposes of carrying out its functions. They may also provide that such persons are able to inspect and take copies of records held on those premises. Persons authorised by the Commission will only be able to enter and inspect premises owned or controlled by Health Authorities, Special Health Authorities, NHS trusts and Primary Care Trusts.
209. Subsections (1)(b) and (c) allow regulations to be made concerning access to information and documents, and the giving of explanations about matters which are the subject of the Commission's functions. Regulations will set out the circumstances in which such information or documents may be obtained or explanations required, and the persons who must provide such information, documents or explanations.
210. Subsection (2) ensures that the Commission will be able to obtain confidential information about individuals, in particular information relating to a person's physical and mental health, only in the limited circumstances set out in paragraphs (a) to (d).
211. Subsection (3) provides that the Commission would not be able to obtain information the disclosure of which is prohibited by another Act, regulations or directions (such as information covered by section 33 of the Human Fertilisation and Embryology Act 1990 (c.37)). If however the prohibition operates because the information would identify an individual, then regulations will provide that the Commission may require that information to be produced in such a way as to prevent the individual being identified.
212. Subsection (4) provides that, where the Commission is exercising its powers conferred by regulations made under this section, it is a criminal offence to obstruct the Commission if it seeks to enter NHS premises. It is also an offence to fail to comply with a request for documents or information or a request to provide an explanation made under the regulations under this section. Proceedings in relation to such an offence would be conducted in the magistrate's court, and the maximum penalty on conviction would be a fine not exceeding level 3 on the standard scale (currently £1000).

Section 24: Restrictions on disclosure of information

213. **Section 24** provides that it is a criminal offence for any person, including a member or employee of the Commission, to knowingly or recklessly disclose confidential information obtained by the Commission which relates to and identifies an individual, except in certain specified circumstances. Subsection (3) provides that such an offence may be tried in either the magistrates' court or the Crown Court. In the magistrates' court the maximum penalty on conviction is a fine not exceeding the statutory maximum (currently £5000) and a prison term of 6 months. In the Crown Court a person convicted is liable to a maximum prison term of 2 years, or a fine, or both.
214. Under subsection (7), the restriction of the disclosure of personal confidential information obtained by the Commission extends to confidential information which does not itself identify the individual, but which does identify the individual when considered in combination with other information obtained by the Commission, or a person authorised by the Commission under section 23(1).
215. Subsections (4) and (6) set out the circumstances in which disclosure of confidential information relating to an individual is permitted. Subsection (4) allows the disclosure of confidential information where it is in a form in which the identity of the individual is protected. The test of whether information is in such a form is contained in subsection (8); the effect is that if the Commission wishes to disclose confidential information about an individual, it must ensure that the individual is not identified from the information itself and cannot be identified from that information in combination with other information which the Commission, or a person authorised by the Commission under section 23(1), has disclosed.
216. Subsection (6) details the other circumstances in which disclosure of this information is permitted. For example, paragraph (a) permits disclosure where the individual to whom the information relates had consented, and paragraphs (d) and (f) permit disclosure, if the disclosure was in accordance with any Act of Parliament or court order, or was for the purposes of criminal proceedings. Paragraph (g) enables the Commission to disclose this information where the information appears to the Commission to reveal that a health professional's performance has fallen substantially below expected standards, or that they have been guilty of serious professional misconduct, or that their fitness to practise may be seriously impaired. In such a case, the Commission would be able to disclose this information only to those who could take appropriate action, normally the employer or appropriate regulatory body.

Section 25: Dissolution of Clinical Standards Advisory Group

217. The Clinical Standards Advisory Group (CSAG) was established under section 62 of the 1990 Act. Its function is to advise as requested on standards of clinical care in the NHS and on access to and availability of services to NHS patients. This function will be taken on by the new Commission for Health Improvement, so section 25 provides for the abolition of CSAG. As CSAG may not have completed its current work programme by the time the Commission is established, the Secretary of State will be able to determine the date on which this section would come into effect.
218. **Section 68(3)** provides that the abolition of CSAG extends to Northern Ireland. In Northern Ireland the application to the integrated health and social services of a quality framework similar to that being established in England and Wales is under consideration.

Sections 26 and 27: Co-operation between NHS bodies and local authorities

219. **Sections 26 and 27** give effect to the intention, set out in *The new NHS* and in *Putting Patients First*, to extend the duty of partnership set out in section 22 of the 1977 Act.

220. *Section 26* introduces for the first time an explicit duty of co-operation between bodies within the NHS, making clear the intention that Health Authorities, NHS trusts and Primary Care Trusts are expected to work together.
221. *Section 27* extends the duty of partnership in section 22 of the 1977 Act between the NHS and local authorities to secure and advance the health and welfare of the people of England and Wales, to cover Primary Care Trusts and NHS trusts as well as Health Authorities and Special Health Authorities. This recognises the need to work in partnership in commissioning and delivering care, as well as at the strategic planning level. Welfare is used in its wide general sense and is designed to cover functions relating to social services, education, housing and the environment.

Section 28: Plans for improving health etc.

222. This section makes provision for the preparation of local plans for improving the health of and the provision of health care to the local population. It gives statutory underpinning to the development of Health Improvement Programmes as set out in *The new NHS and Putting Patients First*.
223. *Subsection (1)* lays a statutory requirement on Health Authorities to prepare plans to improve the health of and provision of health care to their populations, and subsections (3) and (4) lay a duty on Primary Care Trusts, NHS trusts, and local authorities to participate in their preparation. *Subsection (7)* provides that all the parties are required to have regard to their local plan in exercising their functions.
224. The Health Improvement Programme process is intended to engage local communities and voluntary bodies, employers, educational establishments and others. Accordingly, subsection (5)(b) provides for this, while subsection (5)(a) enables the Secretary of State if necessary to direct that particular parties are involved. The Act does not prescribe in detail the processes for developing Health Improvement Programmes, so that local partners can develop their own local arrangements. The Secretary of State's powers of direction under subsections (5)(a) and (6) mean however that it will be possible to prescribe particular aspects of the process if necessary. For example, should there be difficulty in securing proper involvement of voluntary organisations in the Health Improvement Programme process, the power to direct NHS bodies and local authorities offers a safeguard.

Sections 29 and 30 - Payments from NHS bodies to local authorities and from local authorities to NHS bodies

225. Section 28A of the 1977 Act gives Health Authorities powers to transfer money to local authorities for social services functions, and for education, housing and accommodation for disabled people. Directions under section 28A(5) provide that such payments may only be made where better value would be achieved than by equivalent expenditure within the NHS.
226. This power was originally introduced to assist with the provision of replacement services in the community as NHS long-stay hospitals closed. It also encourages alternative and more appropriate models of care for people who might otherwise have to rely on the health service. The emphasis thus far has been on social care and related services.
227. The new provisions are intended to promote partnership between the NHS and local authorities with the aim of improving the health of the community. The measures also aim to ensure that health and local authorities are able to make the most flexible use of the resources they have available to them.
228. *Section 29* amends the current Section 28A provisions by extending the ability of health authorities to make payments to a local authority beyond social services functions (and certain other functions) to allow payments to be made in respect of any local

authority function that is health-related. It also allows Primary Care Trusts to make similar payments to local authorities.

229. *Section 30* introduces a new reciprocal power for local authorities to make payments to Health Authorities or Primary Care Trusts. It gives the Secretary of State powers to set conditions as to local authority payments to these health bodies and to set conditions for repayment of the money. It is intended that the conditions will provide that payments may only be made if doing so will improve the health of the people in the local authority's area. The Secretary of State already has such powers in respect of payments from Health Authorities to local authorities.

Section 31: Arrangements between NHS bodies and local authorities

230. This section allows the NHS and local authorities to work together in new ways by enabling them to pool their resources, delegate functions and resources from one party to another and enable a single provider to provide both health and local authority services.
231. The discussion documents *Partnership in Action* and *Partnership for Improvement* set out the Government's intentions regarding these new operational flexibilities. Broadly, they remove some of the legal barriers to joint working which exist at the moment. The measures set out in this section are intended to allow health and local authorities to agree jointly who is best placed to carry out their functions and how resources might be used more efficiently. These proposals have been developed in greatest depth as regards the interface between health and social care, as the discussion documents made clear. However, the Government believes the potential for cross-boundary working extends beyond this. Accordingly, section 31 creates scope to bring these new flexibilities into play across any point on the interface between NHS functions and local authority functions that are health-related.
232. *Section 31* removes some of these barriers by allowing:
- authorities to pool resources so that the resources lose their health and local authority identity; and allowing staff from either agency to develop packages of care suited to particular individuals irrespective of whether health or local authority money is used;
 - Health Authorities or Primary Care Trust and local authority departments to delegate functions to one another. In the case of health and social care, this will allow, for example, one of the partner bodies to commission all mental health or learning disability services locally. It is expected that this will also reduce the costs associated with having two authorities commissioning services for the same group of people;
 - the provision of health and local authority services (for example, at the health and social services boundary, support involving both domiciliary and community nursing care) from a single managed provider. Currently it is not possible for NHS trusts to offer this except to a limited extent and it is not possible for social services authority in-house providers to do this at all.
233. These flexibilities will not necessarily be appropriate in all areas, or for all client groups. What works for services for people with learning difficulties will not necessarily work for frail elderly people. The powers are therefore not mandatory. If authorities wish to apply for a new flexibility the intention is that need for it should be highlighted in the Health Improvement Programme (see section 28).
234. Subsection (1) provides the powers for the Secretary of State for Health to make regulations setting out the circumstances in which NHS bodies and local authorities can use the flexibilities. The flexibilities may only be used if doing so leads to an improvement in the way the functions are exercised, which includes better outcomes for service users.

235. Subsection (2) sets out examples of the new operational flexibilities.
236. Subsection (2)(a) enables the creation of pooled budgets made up of contributions from the NHS and local authorities. The resources contributed by each authority will lose their identity as health or local authority money. The pool will be able to fund both health and local authority activity as set out in regulations.
237. Subsections (2)(b) and (c) allow both NHS bodies and local authorities to delegate some of their functions to the other partner. These functions will be prescribed in regulations. In the case of the NHS and social care boundary, the effect of these subsections is to
- enable NHS commissioning bodies (Health Authorities and Primary Care Trusts) to delegate their commissioning functions to social services and social services to delegate their commissioning functions to Health Authorities and Primary Care Trusts. This allows the creation of lead commissioner arrangements; and
 - enable NHS trusts (and Primary Care Trusts with a provider role) to delegate their service provider functions to social services and vice versa, thus creating integrated provider arrangements.
238. Subsections (3) and (4) allow the Secretary of State to set out detailed provisions regarding the operational flexibilities in regulations. These provisions may include the circumstances in which the operational flexibilities can be used (for example, which client groups or types of services can be subject to the arrangements) and which health or local authority functions can be subject to the new arrangements. The regulations may also set out how the new arrangements should be managed. This is provided for in more detail in subsection (4).
239. It is intended that use of the new arrangements will be subject, initially, to approval by the Secretary of State. Regulations may set out what criteria must be met in order for the operational flexibilities to be used: for example, who should be consulted on proposals and to what timescale; in what circumstances approval could be refused or withdrawn; and what the arrangements might be for varying the terms of the approval (for example, if local partners wish to extend the range of services to be covered by the arrangement or increase or reduce the size of a pooled budget).
240. Subsection (5) makes clear that, where a NHS body or local authority delegates its functions under the arrangements in this section, that body will remain liable for the exercise of those functions. It also provides that the provisions do not affect local authorities' powers or duties to charge for services.

Section 32: Joint consultative committees

241. Joint Consultative Committees (JCCs) were established by section 22(2) of the NHS Act 1977. Membership of a JCC comprises representatives of the local Health Authority and their associated local authorities. Voluntary sector organisations from the area covered by the JCC are entitled to three seats on the JCC. Such arrangements are no longer necessary in the light of the new provisions for consultation set out in sections 28 to 31. Section 32 therefore removes the statutory requirement for JCCs from section 22 of the 1977 Act. The intention is that this provision will be brought into effect on 31 March 2000.

Sections 33 to 38: Control of prices of medicines and profits

242. Pharmaceutical companies' profits from the sale of branded prescription medicines to the NHS are at present controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The current PPRS is a voluntary, non-statutory agreement between the Government, represented by the Department of Health, and the industry represented by the Association of the British Pharmaceutical Industry (ABPI). It has operated in various forms since 1957. The current agreement commenced on 1st October 1993 and will continue until one side gives six months notice. Not all companies comply fully

with the current scheme. Negotiations are taking place between the Government and ABPI with the objective of agreeing a successor agreement.

243. Section 57 of the 1977 Act enables the Secretary of State by order to control maximum prices for medical supplies. The provision does not provide power to regulate profits. Accordingly it cannot be used to ensure compliance by companies with all elements of the current PPRS or a similar successor scheme. In addition, breach of any Order which sets a maximum price or change thereto is a criminal offence.
244. Branded medicines are specialised products, the development of which incurs considerable research and development costs. The products have limited interchangeability in many circumstances, and new medicines are subject to patent protection. This gives companies a period of market exclusivity. In this context, the Government is taking powers to ensure that prices are fair and reasonable to the NHS and to companies.
245. *Section 33* enables the Secretary of State, after making a scheme with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. This scheme (with additions or modifications agreed in individual cases) would apply only to those companies who consent (subsection (2)). Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the scheme is no longer to apply to him. This can be done where the acts or omissions of the manufacturer or supplier have shown the scheme is ineffective in his case. Subsection (7) read with section 38 gives the Secretary of State power by regulations or direction to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State.
246. *Section 33(8)* read with section 38 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State's approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.
247. In addition to powers to secure compliance with a voluntary scheme, the Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme.
248. *Section 34* read with section 38 provides for the Secretary of State, after consultation with the industry body, by regulations or direction, to limit any price which may be charged by any manufacturer or supplier and for payment of the excess to the Secretary of State within a specified period. This power is only exercisable in relation to companies who are not "scheme members" as defined in section 33(4). This section replaces section 57 of the NHS Act 1977 with respect to controlling the maximum price of health service medicines. Section 38(5) therefore provides that section 57 shall cease to have effect in relation to health service medicines but this does not affect any other powers of the Secretary of State to control profits or prices.
249. *Section 35* read with section 38 enables the Secretary of State, after consultation with the industry body, by regulations or direction to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Section 35(3) provides that such a scheme may in particular require any manufacturer or supplier to whom it applies to record and keep information and provide information to the Secretary of State. Section 35(5) provides for payment to the Secretary of State of profits in excess of the limits determined under the scheme. Section 35(6) enables the Secretary of State to prohibit any manufacturer to whom the scheme applies from increasing prices without his approval and to require a sum representing the amount of that excess to be paid to him. Section 35(7) excludes "scheme members" from any statutory scheme.

250. *Section 36* read with section 38 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.
251. *Section 37* provides for enforcement. Section 37(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of regulations or directions made under sections 33 to 36. Section 37(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 37(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50%. Section 37(4) enables the Secretary of State to provide that the amount payable to him will carry interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.
252. *Section 37(5)* enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 37(7) defines the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.
253. *Section 37(8)* provides that any requirement, prohibition or limit under sections 33 to 35 may only be enforced under this section and not relied on in any other proceedings. Section 37(9) requires the Secretary of State to consult the industry body before making regulations under the section 37. Section 37(10) provides for the maxima set out in section 37(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 62(8).
254. *Section 38* deals with supplementary matters. In particular section 38(1) provides how the powers in sections 33(6) to (8) and 34 to 36 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions, and that regulations may give power to give directions in such particular cases. Section 38 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. The Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of research and development.
255. The provisions in sections 33 to 38 enable the Secretary of State to make regulations in respect of England, Scotland, Wales and Northern Ireland. The operation of a pharmaceutical price regulation scheme in respect of Northern Ireland is a transferred matter under the Northern Ireland Act 1998. In practice, therefore, the Secretary of State will only make regulations which extend to Northern Ireland with the consent of the Northern Ireland Assembly.

Section 39: Evasion of charges etc.

256. The Report of an Efficiency Scrutiny on Prescription Fraud, published in June 1997, recommended specific new penalties for the evasion of prescription charges, upon which the provisions in this section are based. They are consistent with the strategy document *Countering Fraud in the NHS* published in December 1998.
257. *Section 39* inserts new sections 122A, 122B and 122C into the 1977 Act. They contain two provisions, a civil penalty and a new criminal offence, designed to deter the evasion of NHS charges. Both will apply to NHS charges for prescriptions, dental treatment or optical services, including those provided for hospital out-patients, and to payments or benefits such as NHS spectacle vouchers, or free NHS sight tests.

258. It is intended that regulations will be made which will provide for a civil penalty to be imposed where a person fails to pay a NHS charge, or receives a payment to which he is not entitled, towards the cost of a NHS charge or service. Exemptions from charges are granted for a number of reasons such as age, certain medical conditions, receipt of some Social Security benefits, or where the patient is on low income. The regulation making power in the new section 122B will allow regulations to provide for a penalty notice to be issued requiring payment of the original charge or any repayment of an original payment and an additional penalty charge, where it is found that an exemption, reduction or payment has been wrongly obtained.
259. Under the powers in new section 122B, regulations will be made which will set out the information that penalty notices must contain, the amount of the penalty payable, the payment period and the arrangements for payment. The amount of the penalty will be subject to the maximum in subsection (2) which is either £100 or 5 times the unpaid charge, whichever is the less. Subsection (3) provides a power allowing these maxima to be changed by order which, under subsection (8), would be subject to affirmative resolution.
260. Under new section 122B(4) regulations may also provide that where the penalty charge is not paid within the period prescribed, a surcharge would be made of up to 50% of the penalty charge. All sums payable under the penalty provisions will be recoverable as a civil debt.
261. Where more than one person may be liable for payment, for example, where a patient has a representative who signs forms or claims on his behalf, new section 122A(3) provides for them to be liable for payment jointly and severally. In practice, either the patient or the representative could be held liable to pay a penalty according to the circumstances, but the amount in question may only be recovered once. Under new section 122B(7)(b) a person is not to be liable if he shows that he did not act wrongfully, or with any lack of care in respect of the charge or payment in question.
262. [Section 39](#) also creates a new criminal offence where a person secures, for himself or another, the evasion, reduction or remission of a NHS charge, or a payment for which there is no entitlement towards the cost of a NHS charge or service. The acts which will give rise to criminal liability are:
- knowingly making a false statement or representation (or asking or allowing another person to do so); and
 - tendering a document or information which the person doing so knows to be false in a material particular (or asking or allowing another person to do so).
263. New section 122C(7) provides that if a person is convicted of an offence under that section in connection with a charge or payment, then he cannot also be liable to pay a penalty charge in connection with that same charge or payment. The converse is also true, i.e. if a person (having been issued with a penalty notice) pays a penalty charge, then he cannot be convicted of an offence in connection with that particular charge or payment.
264. Such behaviour is already a criminal offence under section 15(1) of the Theft Act 1968, but, to date, no prosecutions relating to the evasion of NHS charges have been brought under that provision. The reason for this appears to be the generally small amounts of money involved compared to the likely cost of such a prosecution. The costs of a prosecution under the Theft Act tend to be high given that offences under that Act can be prosecuted “either way”, meaning that an accused can opt for trial either in the Crown Court (a jury trial) or the Magistrates Court. The former is more costly and is considered to be an option which many defendants would be likely to choose.
265. The new offence will be a summary offence only and will be heard in the Magistrates Court. Where a prosecution is brought by the Secretary of State, new section 122C(4) provides that any person authorised by the Secretary of State may conduct proceedings

without being legally qualified. It is anticipated that the costs of such prosecutions will be much lower than under the existing Theft Act provision, with a consequent increase in the likelihood of prosecution, and thereby in the deterrent effect of the provisions.

Section 40: Disqualification etc. of Part II practitioners

266. This section substitutes new sections 46, 46A, 46B, 46C and 47 in place of sections 46 and 47 of the 1977 Act as amended by the National Health Service (Amendment) Act 1995. It gives new powers to the NHS Tribunal to disqualify practitioners in the family health services who have caused or risked causing detriment to any health scheme by securing financial or other benefits which they knew they were not entitled to. (In addition to the NHS, a “health scheme” can include other publicly funded schemes such as the prison medical service and the defence medical service where these have been prescribed by virtue of the power in new section 46(9).)
267. The NHS Tribunal is an independent statutory body with strictly defined duties and powers. Schedule 9 to the 1977 Act sets out the constitution of the Tribunal. Detailed provisions concerning the procedure for Tribunal inquiries are set out in the National Health Service (Service Committees and Tribunal) Regulations 1992 (S.I. 1992/664) (as amended).
268. The Tribunal’s present purpose (described as “efficiency cases” in the new section 46(11)) is to protect NHS family health services by removing, where necessary, practitioners who prejudice their efficiency. The Tribunal receives representations, usually from Health Authorities, that independent practitioners providing general medical services, general dental services, general ophthalmic services, or pharmaceutical services should be removed from the appropriate Health Authority list. These independent practitioners have to be on a Health Authority list to provide such services in that area.
269. The Report of an Efficiency Scrutiny on Prescription Fraud, published in June 1997, recommended that Health Authorities should have discretion to refuse to enter into arrangements with practitioners found to be guilty of serious financial irregularity. This section enables Health Authorities to make representations about fraudulent practitioners to the NHS Tribunal and extends the Tribunal’s powers to deal with such cases.
270. *New section 46* gives the NHS Tribunal new powers to inquire into cases (described as “fraud cases” in the new section 46(11)) where it is alleged that a practitioner has acted in a way detrimental to any health scheme by securing, or attempting to secure, benefits which he knew he was not entitled to. This includes securing, or attempting to secure, benefits for another who the practitioner knows is not entitled to them. Detriment includes detriment not only to any patient, but also to another person working in that scheme.
271. In fraud cases, representations may be made to the Tribunal in respect of a practitioner who is seeking to be added to a Health Authority’s list, as well as a practitioner already on such a list (new section 46(2)(b)).
272. *New section 46A* allows the Tribunal to disqualify bodies corporate from providing general ophthalmic or pharmaceutical services where any director or, in the case of a pharmacy business, any person controlling the body corporate has acted fraudulently (as defined by new section 46) whether or not he was a director or person controlling the company at the time. It also provides for practitioners to be disqualified where they have failed to take reasonable steps to prevent fraud by an employee or deputy.
273. *New section 46B* sets out for both efficiency and fraud cases the sanctions the Tribunal currently has in efficiency cases:
- to disqualify him/her from the list or lists in respect of which the representations have been made;

*These notes refer to the Health Act 1999 (c.8)
which received Royal Assent on 30 June 1999*

- to disqualify him/her from the corresponding lists of other Health Authorities in England and Wales;
 - to make a declaration that the disqualified practitioner should not be engaged in any capacity connected with the provision of general medical services, general dental services, general ophthalmic services or pharmaceutical services.
274. *New section 46C* contains a new power enabling the Tribunal to make a conditional disqualification in efficiency cases or fraud cases. It can make an order for disqualification which does not come into effect unless the practitioner breaches conditions which are also specified by the Tribunal. Where necessary the Tribunal may vary the terms of service of the practitioner and confer functions on the Health Authority to give effect to the conditions.
275. *New section 47* provides that the Tribunal may review where it considers appropriate any declaration or disqualification, including the conditions attached to a conditional disqualification. It may also review them at the request of the disqualified practitioner or review conditions attached to a conditional disqualification at the request of a Health Authority. It can then remove a disqualification, make it conditional, or in the case of a conditional disqualification, vary the conditions (e.g., where circumstances have changed) or make it unconditional (e.g., where the conditions have been breached). In fraud cases only, the Tribunal may also impose for the first time on review a disqualification from the list of other Health Authorities, or a declaration of unfitness.
276. [Section 40](#) relates to the NHS Tribunal in England and Wales. Determinations by the NHS Tribunal in Scotland or Northern Ireland for national disqualification already apply in England and Wales under section 48 of the 1977 Act. Paragraph 18 of Schedule 4 to the Act provides for a decision for total disqualification (a declaration of unfitness to practice) by the Tribunals for Scotland and Northern Ireland to be recognised similarly. It also provides for the conditions specified in a conditional disqualification made by the Tribunal in Scotland or Northern Ireland to be translated for equivalent effect in England and Wales. Paragraph 19 of Schedule 4 contains provisions for dealing with overlapping cases and paragraph 20 extends the Tribunal's interim suspension powers to fraud cases.

Section 41: High security psychiatric services

277. This section enables hospitals providing high security psychiatric services to be run by NHS trusts. The aim is to address the problems of isolation of the special hospitals by allowing greater integration of secure provision.
278. High security psychiatric services for patients detained under the Mental Health Act 1983 are currently provided by three special hospitals (Ashworth, Broadmoor and Rampton) which are established as Special Health Authorities to perform functions under section 4 of the 1977 Act. Hospitals managed by NHS trusts cannot provide section 4 services because the functions of the managers of the hospital under the Mental Health Act 1983, which in the case of a special hospital means the Secretary of State, cannot be delegated to an NHS trust.
279. Subsection (1) of section 41 replaces the duty of the Secretary of State to provide and maintain special hospitals with a general duty to provide high security psychiatric services for the persons referred to in this subsection. This will enable such services to be provided by other hospitals as well as by the existing special hospitals. High security psychiatric services are to be provided in hospitals, or buildings within a hospital site, which are separate from other hospital facilities and which are not used for the provision of other hospital services.
280. The Secretary of State intends only to commission high security psychiatric services from the existing special hospitals and NHS trusts that are approved by him. Should

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the function of commissioning high security psychiatric services be delegated to Health Authorities in the future, such delegation would be by regulations.

281. Subsection (3) of section 41 provides for the Secretary of State to approve NHS trusts for the purpose of providing high security psychiatric services, and prevents them from entering into contracts for provision of high security psychiatric services unless they have been approved for this purpose.

Section 42: Provision of information by Registrar General

282. The Registrar General has a duty to collect information relating to births and deaths under the Births and Deaths Registration Act 1953. Each week registrars supply the Registrar General with details of all the births and deaths registered during the preceding week. He also receives data about births and deaths outside the UK under various statutory provisions. These are used to update the NHS Central Register.
283. The main function of the NHS Central Register is to support the work of Health Authorities in England and Wales by maintaining a central record of all patients registered for NHS purposes. Primarily it assists in the transfer of patient case notes between GPs, by informing Health Authorities of patients moving out of their area, and supports the maintenance of accurate GP lists by informing Health Authorities of deaths, emigrations and enlistment in the Forces. It holds a basic set of data on registered patients (name, date of birth, sex, NHS number and Health Authority registration).
284. The above arrangements for the weekly transmission of data collected by registrars to the NHS Central Register were introduced at the beginning of the Second World War. The arrangements in respect of certain births and deaths outside the UK were introduced at about the same time. There is no specific power to provide any of this information to the Secretary of State for Health.
285. The purpose of this section is to amend the 1977 Act to bring about the formal, legal, regularisation of the supply of registration data to the Secretary of State for Health for health purposes only.

Section 43: Health Service Commissioners

286. This section amends section 15 of the Health Service Commissioners Act 1993 (as amended by the Health Service Commissioners (Amendment) Act 1996). Section 15 of the 1993 Act sets out the circumstances in which a Health Service Commissioner or any of his officers may disclose information obtained in the course of or for the purposes of an investigation by a Commissioner of a complaint by a patient about services provided under the National Health Service. Section 15 also specifies the type of information which may be disclosed, to whom it may be disclosed and the persons who must be informed of the disclosure.
287. **Section 43** amends section 15 of the 1993 Act in three ways. Firstly it removes some of the restrictions in section 15 as to the circumstances in which a Commissioner has discretion to pass information he obtains as a result of a complaint made to him. In particular it gives him discretion to disclose such information where it is obtained for the purposes of an investigation and is to the effect that a person is likely to constitute a threat to the health or safety of patients.
288. Secondly, section 43 removes the latter half of section 15(1B) of the 1993 Act which deals with persons to whom a Commissioner may disclose information. Although the latter half of that section was worded in terms which implied that it was simply a list of examples of the type of persons to whom information may be disclosed, the provision could be interpreted as defining the class of such persons and thereby restricting a Commissioner's power to disclose information. Section 43 therefore removes the list.

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which received Royal Assent on 30 June 1999*

289. Thirdly, section 43 places a new requirement on a Health Service Commissioner to inform the provider of information that he has disclosed, that he has disclosed such information. This provision is in line with current practice.

Section 44: Power to rectify transitional provisions etc.

290. **Section 44** enables the Secretary of State to make a retrospective Order to correct those deficiencies in the transitional arrangements made for the Health Authorities Act 1995, and in particular deficiencies which have been identified in the Health Authorities Act 1995 (Transitional Provisions) Order 1996, including the omission of Bromley Family Health Services Authority from Part III of Schedule 2 to the Order. The 1996 Order made transitional provision in connection with the abolition of Regional Health Authorities, District Health Authorities and Family Health Service Authorities and the establishment of Health Authorities by the Health Authority Act 1995.
291. This section enables the Secretary of State by order to ensure, amongst other things
- that Part II (family health service) practitioners are treated as having been included on the list of the appropriate authority in cases where they were not solely due to defects in the 1996 Order; and
 - that where appropriate, measures or action taken by the acting authority in relation to such Part II practitioners should be treated as having been carried out by, or on behalf of, the proper authority, or may continue to be treated as done by the acting authority.

Part II - the National Health Service: Scotland

Section 45: Repeal of law about fund-holding practices

292. Sections 87A to 87C of the 1978 Act (inserted by the 1990 Act) provided for the establishment of fund-holding practices in Scotland (see the commentary on section 1 for fuller background on fund-holding). As set out in the White Paper *Designed to Care*, GP fund-holding in Scotland will be abolished and Local Healthcare Co-operatives will be set up. These will be voluntary networks of GPs and other primary care professionals working together to plan and provide primary and community health services and provide support for general practice. Local Health Care Co-operatives will be established from April 1999 as part of the management structure of primary care NHS trusts (see sections 46 to 49) and will draw their powers and functions from these trusts. They do not therefore require separate legislative provision. (For the purposes of these Explanatory Notes only, in order to avoid confusion with the Primary Care Trusts being introduced in England and Wales, these bodies are referred to as “primary care NHS trusts”. In everyday usage they will be called “Primary Care Trusts”, in accordance with the terminology employed in *Designed to Care*.)
293. The repeal of sections 87A to 87C by section 45 will abolish the fund-holding system. The transitional arrangements for winding up the fund-holding scheme will be made under the powers conferred by section 63. The transitional provisions will cover arrangements for closing the fund-holding accounts of residual fund-holders; the transfer of those assets, rights and liabilities that need to be transferred to Health Boards or primary care NHS trusts; and any provision for those that are to remain with the former fund-holders.

Sections 46 to 49: NHS trusts

294. These sections enable the establishment of primary care NHS trusts in Scotland which will bring together community health services, primary care and mental health within a single organisation. They also provide NHS trusts with greater powers in dealing with their estate. This is intended to improve integration and co-ordination of primary and community health services and the provision of organisational support for GPs

and other primary care providers. Through the establishment of Local Health Care Co-operatives (see commentary on section 45) the new organisations will also enable GPs and other primary care staff to become involved in the development and management of services. The new organisations will be governed by the existing legislative provisions relating to NHS trusts (as amended by the Act). In general there will be one primary care NHS trust in each Health Board area.

295. *Section 46* mirrors section 13, achieving the same result for Scotland as section 13 does for England and Wales regarding the establishment of NHS trusts (see the commentary on section 13 for background detail).
296. Subsection (1) provides a new function for NHS trusts. It permits the Secretary of State for Scotland to establish NHS trusts to provide goods and services for the purpose of the health service. In addition, the Secretary of State will be able to confer, in an NHS trust's establishment order, a duty to provide particular goods or services, at or from particular hospitals or facilities. This includes responsibility for services under Part II of the 1978 Act. These Part II services, also known as family health services, are: general medical services; general dental services; general pharmaceutical services; and general ophthalmic services. Primary care NHS trusts will be able to take on the responsibility for a range of functions currently carried out by Health Boards including: making arrangements with suitably qualified Part II practitioners to supply services in their area; ensuring that patients have access to family health services; associated functions relating to the remuneration and discipline of practitioners and the development of primary care services. The intention is that primary care NHS trusts with responsibility for these functions, will be able to develop community and primary care health services in an integrated way.
297. Although it is intended to delegate to primary care NHS trusts the day to day operational functions relating to Part II services, Health Boards will continue to have a responsibility for the overall planning of primary care services. This will be achieved, as now, through Health Boards exercising on behalf of the Secretary of State the duty in section 18 of the 1978 Act to secure the provision of Part II services.
298. *Section 47* inserts a new section 12AA in the 1978 Act which provides for the delegation of Part II services, currently the responsibility of Health Boards, to NHS trusts. For each Board, functions will be delegated to the NHS trust designated by direction of the Secretary of State. This will be the relevant primary care NHS trust established to provide services in the Board's geographic area. In most cases there will be only one primary care NHS trust in each Health Board area, but where there is more than one (as is proposed for Argyll & Clyde and Lothian Health Boards), the Secretary of State will be able to designate which trust will have responsibility for Part II services in which particular area. Where there is no primary care NHS trust (as in Shetland, Orkney and Western Isles Health Boards), Part II services will continue to be the responsibility of the Health Board.
299. *Section 48*: The White Paper *Designed to Care* signalled the intention to modify the existing arrangements for NHS trust boards as part of the new proposals. Provisions for the broad composition of NHS trust boards are set out in section 12A(3) of the 1978 Act. This provides that an NHS trust board is a body corporate with a board of directors consisting of a chairman appointed by the Secretary of State, and executive and non-executive directors. Section 48 amends section 12A(3)(a) of the 1978 Act to provide that in future non-executive directors will be known as "trustees". Regulations made under section 12A(5) allow the Secretary of State to specify the maximum and minimum numbers of members of the trust board. The power is likely to be used to specify that an NHS trust board must have not more than 5 executive directors (who are employees of the trust) and not more than 5 non-executive trustees. In the case of NHS trusts which are teaching hospitals, however, an extra trustee will be appointed to represent the relevant university. The overall intention is to broaden the range of those who can be appointed to act as trustees.

300. *Section 49*: The current direction-giving powers in respect of NHS trusts are conferred by paragraph 6 of Schedule 7A to the 1978 Act and relate to a limited number of very specific matters. Section 49 replaces these powers of direction with a general power, in line with that relating to Health Boards, which enables directions to be given in relation to the full range of NHS trusts' functions. The Government intends to use this power to meet the commitment in the White Paper *Designed to Care* to ensure that the NHS trusts manage their estate in ways which are consistent with local strategic plans.

Section 50: Transfer of staff among health service bodies

301. This section makes provision for the transfer of staff among health service bodies. Section 12B of the 1978 Act ensured that when facilities transferred from Health Board to NHS trusts on the original establishment of NHS trusts, the rights and terms of employment of staff who worked in those facilities transferred with them. Under section 47 of this Act, provision is made for the Secretary of State for Scotland to direct Health Boards to delegate some of their functions to NHS trusts. In most cases no transfer of facilities will be involved. However, there are likely to be other changes in future (for example, some functions in relation to services may move from one NHS trust to another). This section extends to all transfers of functions between health service bodies, the protection for staff that section 12B conferred upon staff transferring from Health Boards to NHS trusts.

Section 51: Quality of Care

302. The White Paper *Designed to Care* announced the intention to amend the statutory duties of NHS trusts to make explicit their responsibility for quality of care. Under the terms of the 1978 Act, NHS Trusts have a duty to meet such financial objectives as are set by the Secretary of State. Section 51 adds a new duty relating to the quality of health care provided to patients.
303. Under section 51, NHS Trusts, the Island Health Boards (which have responsibility for directly managed units), the Common Services Agency and the State Hospital will be required to draw up arrangements which will enable them to monitor and improve the quality of health care for which they have responsibility. A fundamental component of those arrangements will be implementation of the clinical governance arrangements set out in the Scottish Office publication MEL(1998)75, issued in November 1998.

Section 52: Expenditure of Health Boards and other bodies

304. Section 85 of the 1978 Act currently provides for two streams of funding from the Secretary of State to Health Boards to allow them to perform their functions as required by that Act. The section draws a clear distinction between resources for functions covered by Part I of the 1978 Act (hospital and community health services) and functions under Part II of the 1978 Act. Funding for the Part II functions includes provision for the pay and expenses of GPs, dentists, pharmacists and optometrists. In particular, this includes the reimbursement of costs incurred by pharmacists (and other dispensing contractors) in dispensing prescriptions issued by GPs, known as "prescribing costs".
305. The allocations to Health Boards for Part I functions are cash limited whereas the majority of the Part II functions are funded from non-cash limited resources. With the exception of certain general medical services expenditure, it is not possible under the present section 85 of the 1978 Act to include any of the Part II functions in the cash limited stream of funding where so desired. Section 52 inserts a new section 85AA in the 1978 Act to provide for certain Part II expenditure to be funded from within cash limited resources. This underpins the introduction of a single stream of cash limited funding to Health Boards to collectively cover expenditure on hospital and community health services and GPs' prescribing costs. This will give Boards and, in turn, primary care NHS trusts increased financial flexibility in the use of their resources.

306. The new section 85AA retains the Secretary of State's power, currently at section 85(1), to issue cash limited allocations (for "main expenditure") and to provide, as per the current section 85(2)(b), non-cash limited resources (for "general Part II expenditure") to Health Boards. Subsections (4)(a) and (b) provide for certain defined elements of Part II expenditure to be brought within cash limited allocations. Subsection (4)(d) makes the same provision for certain elements of GMS remuneration designated by the Secretary of State.
307. The new section 85AA also retains the Secretary of State's power of direction, currently at section 85(2A), on the application of sums paid to Health Boards for Part I functions, and extends that power to Part II sums.
308. **Section 52** also inserts a new section 85 into the 1978 Act, consequential on the changes described above, which retains the current funding regimes of the other health agencies listed in section 85(1).

Sections 53 to 55: NHS trust financial provisions

309. These sections together with paragraph 63 of Schedule 4 effect changes in the current NHS trust financial regime. The provisions reflect the same changes being made to the equivalent English and Welsh provisions, which are explained fully in the commentary on sections 15 to 17. In summary they provide for the following:
- NHS trusts' originating capital debt will be comprised wholly of public dividend capital – this removes interest bearing debt and the administrative arrangements for its ongoing recovery;
 - additional borrowing by NHS trusts other than from the Secretary of State will be at his direction and subject to conditions he may determine – the aim is to ensure that, in the main, NHS trusts borrow only from the Government, although there will be exceptions to this notably in the area of PFI schemes;
 - investment of temporary surpluses by NHS trusts will be at the direction of the Secretary of State – in practice this will largely be restricted to Paymaster Accounts with the effect of reducing overall Exchequer borrowing.

Section 56: Indemnity cover for Part II services

310. This section (which makes the same provision for Scotland as section 9 does for England and Wales) will allow the Secretary of State to require Part II family health service practitioners (those providing general medical services, general dental services, general ophthalmic services, or pharmaceutical services) to hold indemnity cover.
311. The Secretary of State would be able to enforce the requirement in either (or both) of two ways. Regulations could specify that having approved indemnity cover is a requirement to joining a Health Board's list for a Part II service, and that practitioners on the list must hold approved indemnity in order to remain on the list, in order to practice those services on the NHS. Regulations would also allow the Secretary of State to specify that the holding of approved indemnity cover be set out in terms of service for a Part II service. This would mean that if approved cover was not held, the practitioner in question would be subject to the established Health Board disciplinary committees and, ultimately, to the NHS Tribunal which might strike them from the Health Board list if it was determined that their continued inclusion would be prejudicial to the efficiency of the service.
312. The indemnity could also be required to cover other persons prescribed in relation to the practitioner, i.e. employees, assistants or deputies of the practitioner. The intention is that the cover currently held by responsible practitioners should be quite adequate to meet any new requirements, and only those contractors who fall short of reasonable cover will find themselves affected. Regulations under the amendment would allow the Secretary of State to specify the type of indemnity cover that would be approved.

Section 57: Remuneration for Part II services

313. **Section 57** mirrors section 10, achieving the same result for Scotland as section 10 does for England and Wales regarding the remuneration of Part II practitioners (see the note on section 10 for background detail).
314. This section substitutes new sections 28A and 28B of the National Health Service (Scotland) Act 1978. The intention is to legitimise the current practice in relation to the determination of remuneration for Part II practitioners and in particular to ensure that the existing basis by which Health Boards are appointed as determining bodies is put on a firmer footing. It provides for remuneration for Part II services in Scotland to be determined by determining authorities. The determining authority will be the Secretary of State and any Health Board or other person appointed by him.
315. The new section 28A describes how such remuneration can be paid. Subject to sections 19(3) and 25(3) of the NHS (Scotland) Act 1978, remuneration under section 28B may consist of payments by way of salary, fees, allowances or reimbursement of expenses of FHS practitioners such as doctors, dentists, community pharmacists and optometrists in Scotland. Primary Care NHS Trusts in Scotland will be given the function of determination of such GP remuneration as comes from cash-limited funds.
316. Provision is also made for the Secretary of State to consult national representative bodies of each group before making a national determination that would affect the whole of that group. Determinations may be made in several stages, as is currently the case. The changes in the new sections are intended to reflect and validate current practice.

Section 58: Disqualification of practitioners for fraud etc.

317. **Section 58** substitutes new sections 29, 29A, 29B, 29C and 30 for sections 29 and 30 of the 1978 Act, as amended by the NHS (Amendment) Act 1995, mirroring changes being made to the equivalent English and Welsh provisions. Consequential amendments in Schedule 4 (paragraphs 49 to 53 and 64) amend sections 31, 32, 32A, 32B and 32D and paragraph 8 of Schedule 8 to the 1978 Act. These provisions give new powers to the NHS Tribunal to disqualify practitioners in the family health services who have caused or risked causing detriment to any health scheme by securing financial or other benefits to which they knew they were not entitled. (In addition to the NHS, a “health scheme” can include other publicly funded schemes such as the prison medical service and the defence medical service, where these have been prescribed by virtue of the power in new section 29(9)(b).)
318. The NHS Tribunal is an independent statutory body with strictly defined duties and powers. Its existing role is to decide whether the continued presence of a practitioner on the list of family health service contractors (either nationally or locally) would prejudice FHS efficiency and, where proven, to remove such practitioners from the list and, if it chooses, prevent them from being employed by other FHS practitioners. Such cases are defined as “efficiency cases” in new sections 29(6) and (11). The Tribunal is also able to suspend practitioners pending inquiries in order to protect patients.
319. Practitioners must join family health service lists to offer general medical, dental, ophthalmic or pharmaceutical services and representations to the Tribunal about removal from such lists are usually made by Health Boards. Section 58 gives effect to the recommendation in the Report of an Efficiency Scrutiny on Prescription Fraud, published in June 1997, that Health Authorities (and therefore, in Scotland, Health Boards) should have discretion to refuse to accept onto family health service lists practitioners found guilty of serious financial irregularity. This section enables Health Boards to make representations about such cases (defined as “fraud cases” at new sections 29(7) and (11)) to the NHS Tribunal and extends the Tribunal’s powers to deal with these.

*These notes refer to the Health Act 1999 (c.8)
which received Royal Assent on 30 June 1999*

320. *New section 29* gives the NHS Tribunal new powers to inquire into cases where it is alleged that a practitioner has acted in a way detrimental to any NHS service by securing, or attempting to secure, benefits to which he knew he was not entitled. This includes securing, or attempting to secure, benefits for another who the practitioner knows is not entitled to them. Detriment to a health service is defined in section 29(10) as including detriment not only to any patient, but also to another person working in that scheme.
321. *New section 29A* allows the Tribunal to disqualify pharmaceutical and ophthalmic bodies corporate from FHS lists where any director or, in the case of a pharmacy business, any person controlling the body corporate meets the condition for disqualification, whether or not he was a director or person controlling the company at the time. It also provides for liability for the conduct of employees or deputies in fraud cases where the practitioner failed to take reasonable steps to prevent the acts or omissions concerned.
322. *New section 29B* sets out, for both efficiency and fraud cases, the sanctions the Tribunal already has in efficiency cases:
- to disqualify the practitioner from the list(s) in respect of which representations have been made;
 - to disqualify the practitioner from the corresponding lists of other Health Boards;
 - to make a declaration that the disqualified practitioner should not be engaged in any capacity connected with provision of family health services.
323. In fraud cases representations may also be made to the Tribunal in respect of applicants to family health service lists as well as those already on such lists (new section 29(2)(b)).
324. *New section 29C* contains a new power enabling the Tribunal to make a conditional disqualification in efficiency or fraud cases. It can make an order for disqualification which does not come into effect unless the practitioner breaches conditions which are also specified by the Tribunal. Where necessary, the Tribunal may vary the practitioner's terms of service and confer functions on the Health Board to give effect to the conditions.
325. *New section 30* provides that the Tribunal may review, where it considers appropriate, any declaration or disqualification, including the conditions attached to a conditional disqualification. It may also review them at the request of the disqualified practitioner or review conditions attached to a conditional disqualification at the request of a Health Board. It can then remove a disqualification, make it conditional, or, in the case of a conditional qualification, vary the conditions (e.g. where circumstances have changed) or make it unconditional (e.g. where the conditions have been breached). In fraud cases only, the Tribunal may also impose for the first time on review a disqualification from the lists of the Health Boards, or a declaration of unfitness.
326. The amended section 32A extends the Tribunal's current power of interim suspension to fraud cases. The Tribunal may direct suspension in order to prevent further fraud or prejudice to the investigation of the case or review (new section 32A(2A)(b)).
327. In addition to the NHS Tribunal in Scotland, there are separate NHS Tribunals under corresponding legislation in England and Wales, and in Northern Ireland. Decisions by any of the NHS Tribunals for national disqualification already apply automatically in each country. Section 31(1) now provides for a decision for total disqualification (a declaration of unfitness to practice) by the Tribunals for England and Wales, and for Northern Ireland to be recognised similarly (see paragraph 49 of Schedule 4 to the Act). New section 31(2) provides for the conditions specified in a conditional disqualification made by the Tribunal in England and Wales or in Northern Ireland to be translated for equivalent effect in Scotland. Schedule 4 to the Act also contains provisions for dealing with overlapping cases.

Section 59: Recovery of charges and payments

328. **Section 59** inserts new sections 99ZA and 99ZB into the 1978 Act and amends section 105(3). It contains provisions for a new civil penalty to deter patient evasion of NHS charges. The penalty will apply to NHS charges for prescriptions, dental treatment or optical services, including those provided for hospital outpatients, and to payments or benefits such as NHS optical vouchers or free NHS sight tests.
329. It is intended that regulations will be made to provide for a penalty to be imposed where a person fails to pay an NHS charge, or claims a payment to which he is not entitled, towards the cost of an NHS charge or service. Exemptions from charges are granted on a number of grounds, including age, certain medical conditions, receipt of some Social Security benefits or low income. The regulation making power in the new section 99ZB will allow regulations to provide for a penalty notice to be sent requiring the patient to pay the original charge and an additional penalty, where it is found that an exemption, reduction or payment has been claimed incorrectly.
330. Under the powers in new section 99ZB, regulations will be made which will set out the information that penalty notices must contain, the amount of the penalty payable, the payment period and the arrangements for payment. The amount of the penalty will be subject to the maximum in subsection (2) which is either £100 or 5 times the unpaid charge, whichever is the less. Subsection (3) provides a power allowing these maxima to be changed by Order which, under amended section 105(3), would be subject to affirmative resolution procedure in Parliament.
331. Under new sections 99ZB(4) and (5), regulations may also provide that, where the penalty charge is not paid within the period prescribed, a surcharge may be levied of up to 50% of the penalty charge. All sums payable under the penalty provisions will be recoverable as a civil debt.
332. Where more than one person may be liable for payment, for example, where a patient has a representative who signs forms or claims on his behalf, new section 99ZA(3) provides for them to be liable for payment “jointly and severally”. In practice, either the patient or the representative could be held liable to pay according to the circumstances but the penalty may only be recovered once. Under new section 99ZB(7)(b), a person shall not be liable if he shows that he did not act “wrongfully, or with lack of due care”.

Part III – Miscellaneous and Supplementary

Section 60 and Schedule 3: Regulation of health care and associated professions

333. Parliament has intervened in the regulation of health care professions for nearly 150 years. It has established statutory frameworks for a number of health care professions within which the professions regulate themselves. The purpose of professional regulation is to establish a countrywide, professionally set, independent standard of training, conduct and competence for each profession for the protection of the public and the guidance of employers. This is underpinned by personal accountability of practitioners for maintaining safe and effective practice, wherever they are employed and to include effective measures to deal with individuals whose continuing practice presents an unacceptable risk to the public or otherwise renders them unfit to be a registered member of the profession. For the most part there are separate enactments for each health care profession (doctors; dentists; nurses, midwives and health visitors; opticians; pharmacists; osteopaths; chiropractors; and the nine professions coming within the remit of the Council for Professions Supplementary to Medicine).
334. These enactments make provisions which, with very few exceptions, may only be changed by means of primary legislation, and it has hitherto not proved possible to make amendments as promptly as the professions would like. The Act provides for a procedure that will enable such enactments to be amended and new professions to be regulated, without the need for an Act of Parliament each time.

335. **Section 60** provides for Her Majesty by Order in Council to modify the regulation of pharmacists, doctors, dentists, opticians, osteopaths, chiropractors, nurses, midwives and health visitors and those professions regulated by the Professions Supplementary to Medicine Act 1960; and to regulate any other health care profession. This would cover health care professions not already brought within statutory regulation. An Order may repeal or revoke any enactment, amend it, or replace it (subject to such provisions as paragraphs 7 and 8 of Schedule 3).
336. Subsection (3) makes provision for the repeal of the Professions Supplementary to Medicine Act 1960 and the Nurses, Midwives and Health Visitors Act 1997.
337. The independent review of the Professions Supplementary to Medicine Act, which reported in July 1996, concluded that completely new legislation is needed to streamline existing arrangements. The Government broadly accepted the key recommendations of the review. It is intended that (with the exception of section 10 of the 1960 Act) the repeal will be brought into force when the replacement Order comes into effect. Section 67(3) provides for the repeal of section 10 of the 1960 Act to come into force on 1 July 1999. Section 10 provides for professions to be added to or removed from regulation under the 1960 Act; for the establishment of a single board for amalgamated professions; and for changes to be made to a board's functions. Henceforth, any such changes will be made by Orders under section 60 of this Act.
338. A review of the Nurses, Midwives and Health Visitors Act 1997 was published on 9 February 1999. It recommended new legislation to establish a single UK-wide regulatory body in place of the existing statutory bodies. The Government accepted the key recommendations, except those relating to health visitors who will continue to have separate representation on the new Council. It is intended that the repeal of that Act will be brought into force when the replacement Order comes into effect.
339. The Order-making power covers the professions regulated by the Pharmacy Act 1954, the Professions Supplementary to Medicine Act 1960, the Medical Act 1983, the Dentists Act 1984, the Opticians Act 1989, the Osteopaths Act 1993, the Chiropractors Act 1994 and the Nurses, Midwives and Health Visitors Act 1997. However, the scope of the Order-making power is not limited to those Acts. In particular, it extends to the regulation under the Medicines Act 1968 of persons who are not pharmacists carrying on a retail pharmacy business by the Statutory Committees of the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland.
340. It is intended that Orders will be made to improve the services provided to patients or to improve the regulation of the professions by enabling the legislative framework to be kept up to date and taking account of changing public expectations of the professions and the professions' own views about the development of their regulation. New responsibilities can be given to existing bodies or new professional regulatory bodies established to carry out new or existing regulatory responsibilities (subject to the provisions in paragraphs 7 and 8 of Schedule 3).

Schedule 3

341. **Paragraph 1** of the Schedule gives examples of the matters for which provision may be made by Order. Orders may make changes to any aspect of professional regulation, subject to the limitations in paragraphs 7 and 8.
342. **Paragraph 2(2)** prevents the amendment by Order of the Medicines Act 1968, except in respect of sections 80 to 83 and such other associated amendments to Part IV of the 1968 Act. This makes clear that an Order may amend those limited parts of the Medicines Act which deal with the professional regulation of retail pharmacy businesses.
343. **Paragraph 5** will enable functions to be conferred on Ministers of the Crown, Scottish Ministers or the National Assembly for Wales. An Order could be made, for example, enabling a Minister to pay grants to a body, or setting up bodies for different parts of

the United Kingdom to deal with matters in connection with professional regulation. Any conferment of functions would be subject to paragraph 8.

344. *Paragraph 7(1)* makes it clear that an existing regulatory body, or, where there is more than one, the main one, of the health care professions referred to in subsection (2)(a) of section 60, may not be abolished by an Order. This will also apply to the bodies established to succeed the Council for Professions Supplementary to Medicine and the United Kingdom Central Council for Nursing, Midwifery and Health Visiting, and new regulatory bodies created by Order under section 60(1)(b). Paragraph 7(2) ensures that an Order may not impose a lay majority on the membership of a statutory regulatory body. Paragraph 7(3) provides that functions conferred on the Privy Council in respect of the professions to which section 60(2)(a) applies may not be transferred to another person or body.
345. *Paragraph 8* provides that, where legislation provides for certain specified functions to be exercised by a regulatory body, or any of its committees or officers, an Order may not transfer those functions from that regulatory body. Those functions are: the keeping of the register; the setting of standards of education for entry to the profession; provision of guidance on standards of conduct and performance expected of the profession; and the administration of procedures relating to fitness to practice. Paragraph 8(3) is a transitional measure which ensures that the functions listed in paragraph 8(2) may be transferred from the CPSM and UKCC, when they are abolished by the repeal of the 1960 Act and the 1997 Act, to their successor bodies.
346. It is proposed that the 1960 Act, when repealed, will be replaced by an Order setting up a health professions council with powers to recommend the bringing of further professional groups within the council's remit and provide for such matters as their registration, disciplinary and health procedures, protection of common title and the linkage of remaining on the register with the demonstration of continued competence.
347. Some health care professions not currently regulated by statute may not wish to be regulated by a new health professions council. For example, part of a profession might not provide health care services to patients. In such cases free-standing regulatory schemes can be provided for by Order including the responsibilities referred to in paragraph 1 of the Schedule.
348. *Paragraph 9* provides that before an Order can be made the Secretary of State must consult persons representing the relevant professions, patient interest groups and other persons or bodies that he considers it appropriate to consult. The consultation will be on the basis of the draft. He must publish the proposed Order in draft three months before it is laid before Parliament. Following consultation a draft Order will be laid before Parliament (as originally drafted or with appropriate amendments) and must be accompanied by a report about the consultation. Draft Orders will be subject to parliamentary scrutiny under affirmative procedures (see section 62(9)).
349. Regulation of those health professions currently regulated by Act of Parliament is a matter reserved to the UK Parliament under the Scotland Act 1998 (see Schedule 5 to the Scotland Act at Head G section G2). The regulation of any other health profession, however, is not a reserved matter. An Order could be made under section 30 of the Scotland Act to provide for the reservation of other professions. If such an Order were not made, regulation of those professions would be within the legislative competence of the Scottish Parliament. Paragraph 9(3) sets out the procedures which will apply where a draft Order deals with matters within the legislative competence of the Scottish Parliament. In particular, the draft Order, together with the report on the consultation, must be laid before the Scottish Parliament as well as the UK Parliament. It must be approved by resolution of the Scottish Parliament (under section 62(10)), as well as each House of the UK Parliament, before the Secretary of State can recommend to Her Majesty that the Order be made for the United Kingdom.

350. *Paragraph 11* clarifies whether certain matters are within the scope of an Order under section 60. Paragraph 12(1) recognises that the regulation of the Pharmacy profession in Northern Ireland is already covered by separate legislation for Northern Ireland (Pharmacy (Northern Ireland) Order 1976 (SI 1976/1213 (N.I. 22))). An Order will not be able to change this legislation. Orders may, however, be made on a UK-wide basis to regulate certain aspects of retail pharmacy business relating to misconduct and offences, but paragraph 12(2) ensures that the body responsible for such regulation in Northern Ireland may not be changed by Order.

Section 61: English and Scottish border provisions

351. This section enables Her Majesty to make an Order in Council, approved by both the Scottish and Westminster Parliaments, which would make provision for:
- the Secretary of State in England (or Health Authorities or Primary Care Trusts) to exercise NHS functions in respect of the provision of services for NHS patients who are resident in Scotland, instead of Scottish Ministers or Health Board exercising equivalent functions under the 1978 Act; and
 - similar arrangements under which Scottish Ministers (or Health Boards or Scottish NHS trusts) would exercise NHS functions in relation to NHS patients who are resident in England, instead of the Secretary of State or Health Authorities or Primary Care Trusts exercising equivalent functions under the 1977 Act.
352. The functions which are to be exercisable across the border, and the persons to which these arrangements are to apply will be set out in the Order.
353. *Section 61* only applies to the provision of NHS services to persons living in the area of any Health Authority or Health Board next to the English/Scottish border, i.e. North Cumbria and Northumberland Health Authorities; and Dumfries & Galloway and Borders Health Boards. The intention is to use section 61 to simplify the arrangements for the planning and commissioning of health care services for patients registered with GP practices that have patients on both sides of the English/Scottish border.

Section 63: Supplementary and consequential provision etc.

354. This section enables the Secretary of State to make any transitional, supplementary and consequential provisions necessary to give effect to the Act. For example, it will be used to make amendments consequent upon the introduction of Primary Care Trusts.
355. *Sections 1* and *45* will bring the GP fund-holding system to an end in England and Wales and in Scotland respectively. It is the intention to use the provisions of section 63 to make an order or orders setting out arrangements for the transition from GP fund-holding. The transitional provisions will cover arrangements for closing the fund-holding accounts of residual fund-holders; the transfer of those assets, rights and liabilities that need to be transferred to the Health Authority (in England and Wales) or Health Board (in Scotland); and any provision for those that are to remain with the former fund-holders.

Section 65 and Schedules 4 and 5: Amendments and repeals

356. *Section 65* introduces Schedule 4, which makes amendments to various Acts, and Schedule 5, which sets out the various repeals made by the Act.
357. Many of the amendments in Schedule 4 are consequent upon the provisions of the Act relating to Primary Care Trusts. Some of the other amendments have been referred to above in the context of the sections to which they relate. The following amendments are of particular note.
358. *Paragraph 5* amends section 8 of the 1977 Act, which provides for the establishment of Health Authorities. In particular the amendment provides that Health Authorities are to

“be established for” their area, rather than “act for” their area. This is to make it clearer that Health Authorities may exercise certain functions in respect of patients who are not resident or present in their area. In addition, section 8 is amended so that the Secretary of State is able to change the name of a Health Authority without changing its boundaries.

359. *Paragraphs 6 and 10* have the effect of replacing the existing section 12(1) of the 1977 Act (duty on Health Authorities to make arrangements to secure advice from persons with professional expertise in and experience of health care) with a new provision (section 16C) which places a duty on both Health Authorities and Primary Care Trusts to make arrangements with a view to securing appropriate advice from health care professionals in order to exercise their functions effectively.
360. *Paragraph 84(6)* repeals the provisions in Schedule 2 to the 1990 Act which provide for the re-imbursment of NHS trusts in respect of the provision of goods and services otherwise than under NHS contract. These arrangements became known as extra-contractual referrals (or ECRs). The term extra-contractual referral is also used to describe one-off contracts that arise where an NHS trust provides care for someone which is not covered by an NHS contract with the patient's Health Authority. The system of extra-contractual referrals has been abolished. From April 1999 patients will always be treated under NHS contracts. A new system of comprehensive contract coverage, to be known as Out of Area Treatments, has been established through secondary legislation.

Section 66: Devolution

361. This section sets out how the provisions of the Act are to be treated for devolution purposes.
362. Subsection (1) provides that the provisions in the Act that extend to Scotland (except section 22) are to be taken to be a “pre-commencement enactment”, the meaning of which is set out in section 53 of the Scotland Act 1998. Section 53 (inter alia) provides for the transfer of functions, which are conferred in any Act of Parliament upon the Secretary of State, to the Scottish Ministers in so far as they relate to matters devolved to the Scottish Parliament. By treating the provisions under sections 45 to 59 as a pre-commencement enactment any new Secretary of State function conferred by those sections automatically transfers to the Scottish Ministers by virtue of section 53 of the 1998 Act.
363. *Section 22* of the Act (arrangements with Ministers and the Commission for Health Improvement) is excluded from section 66(1). The effect is that the power to enter into arrangements with the Commission in respect of Scotland will be retained by Ministers of the Crown, and Scottish Ministers will not be able to enter into such arrangements. The Commission will not be exercising functions in relation to the NHS in Scotland; it may however enter into arrangements to exercise functions in relation to the health care provided to prisoners and the Armed Forces in Scotland (such care remains the responsibility of the Home Secretary and the Secretary of State respectively). The provisions of section 22 are explained in more detail in paragraph 206 above.
364. Subsection (2) confers on the National Assembly for Wales the power to commence in relation to Wales certain provisions in the Act which confer new functions on the Secretary of State.
365. Subsection (3) adds the Commission for Health Improvement to the list of bodies whose members or staff can be required to attend the National Assembly for Wales, or its committees, to give evidence or produce documents.
366. Subsections (4) to (5) make textual amendments to Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 1999. In particular, subsection (5) inserts an entry for the "Health Act 1999". The effect of these provisions is that the functions conferred on the Secretary of State by the provisions of the Act listed in subsection (5)

*These notes refer to the Health Act 1999 (c.8)
which received Royal Assent on 30 June 1999*

(c) are, in relation to Wales, exercisable by the Assembly. This does not include functions in respect of the control of prices of medicines and profits or the regulation of health care and associated professions, which will be exercisable by the Secretary of State for Health.

367. The secondary legislation made by the Assembly pursuant to these new functions will generally be subject to the Assembly's own secondary legislation scrutiny procedures, rather than the Westminster procedures set out in section 62 of the Act.
368. Subsection (6) amends Schedule 2 to the National Assembly for Wales (Transfer of Functions) Order 1999 and provides that some functions in relation to the Commission for Health Improvement are to be exercisable only with the agreement of the Assembly or, in some cases, after consultation with the Assembly.

COMMENCEMENT

369. The provisions of the Act will be brought into effect on one or more dates appointed by the Secretary of State by order, with the exception of sections 66 to 69 (provisions concerning devolution, commencement, extent and the short title) and the repeal of section 10 of the Professions Supplementary to Medicine Act 1960 which comes into effect on 1 July 1999. Sections 2 to 7, 12 and Schedule 1 (Primary Care Trusts) in relation to England and sections 33 to 38 (control of prices of medicines and profits) will be brought into effect on appropriate dates at the earliest opportunity after Royal Assent. It is envisaged that the majority of the remaining provisions of the Act will be in force by April 2000. The sections in Part I of the Act may be brought into effect at different times in England and in Wales. In so far as they affect Wales, the majority of the provisions in Part I will be brought into effect by the National Assembly for Wales, rather than the Secretary of State (see section 66(2)). The Scottish Ministers will exercise the order-making power to bring into force the provisions in Part II of the Act.

DETAILS OF THE BILL'S PASSAGE THROUGH PARLIAMENT WERE AS FOLLOWS:

House of Lords	Date	House of Lords Hansard
Introduction	28 Jan	Vol 596 Col 1137
Second Reading	9 February 1999	Vol 597 Cols 106-188
Committee	25 February, 1 March and 4 March 1999	Vol 597 Cols 1243-1360, 1406-1542 and 1801-1856
Report	15 March and 18 March 1999	Vol 598 Cols 474-600 and 830-950
Third Reading	25 March 1999	Vol 598 Cols 1425-1475

House of Commons	Date	House of Commons Hansard
Introduction	29 March 1999	
Second Reading	13 April 1999	Vol 329 Cols 38-128
Committee	20 April to 25 May 1999	Hansard Standing Committee A
Report and Third Reading	14 June and 15 June 1999	Vol 333 Cols 35-110 and 174-266

*These notes refer to the Health Act 1999 (c.8)
which received Royal Assent on 30 June 1999*

Royal Assent - 30 June 1999	House of Lords Hansard Vol 603 Col 271 and
	House of Commons Hansard Vol 334 and Col 361