These notes refer to the Health Act 2006 (c.28) which received Royal Assent on 19 July 2006

HEALTH ACT 2006

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1 - Smoking

Chapter 1 - Smoke-Free Premises, Places and Vehicles

29. Chapter 1 of Part 1 of the Act contains provisions that will make virtually all enclosed and substantially enclosed public places and shared workplaces smoke-free. The White Paper *Choosing Health: Making healthy choices easier,* published in November 2004, set out proposals to shift the balance significantly in favour of smoke-free environments, and in June 2005 the Department of Health published a consultation document with proposals for smoke-free legislation.

30. The Act requires that enclosed public places and shared workplaces be smoke-free, unless exempted by regulations to made under section 3 of the Act. Regulations can also provide for vehicles to be smoke-free in certain circumstances and for additional places not covered by section 2 of the Act to be smoke-free.

31. Health Ministers intend that the smoke-free provisions within the Act will come into force in England in Summer 2007.

32. Chapter 2 of Part 1 of the Act provides the Secretary of State with power to amend the minimum age of sale of tobacco products through secondary legislation. The Act specifies that when amending the age of sale through such secondary legislation the age specified may not be lower than 16 years or higher than 18 years. The Department of Health published a 12-week public consultation on amending the age of sale of tobacco products in July 2006.

33. The provisions in Part 1 of the Act extend to England and Wales. The Act also amends the Merchant Shipping Act 1995 to include provisions for smoke-free ships. The Merchant Shipping Act extends throughout the United Kingdom, and the amendments to that Act also do so.

Section 1: Introduction

34. Section 1 introduces the smoke-free premises, places and vehicles provisions within the Act. *Subsection (1)* explains that Chapter 1 of Part 1 makes provision prohibiting smoking in certain premises, places and vehicles. *Subsection (2)* defines "smoking" for the purposes of Chapter 1 of Part 1 and provides that "smoking" refers to smoking tobacco, or anything which contains tobacco, or smoking any other substance, and includes being in possession of lit tobacco, or anything lit which contains tobacco, or being in possession of any other lit substance in a form which could be smoked. "Smoking" therefore includes the smoking of cigarettes, pipes, cigars, herbal cigarettes and waterpipes (often known as hookah or shisha pipes) etc.

Section 2: Smoke-free premises

35. Section 2 makes provision for enclosed or substantially enclosed premises which are open to the public, and shared workplaces, to be smoke-free.

36. *Subsection (1)* provides that premises that are open to the public are to be smoke-free when they are open to the public. However, unless such premises also fall within the provisions of *subsection (2)*, they are smoke-free only when open to the public.

37. *Subsection (2)* provides that if premises are used as a place of work by more than one person, irrespective of whether such people work there at the same time, or if they are used a place of work where the public might attend to seek or receive goods or services, then they are to be smoke-free all the time. *Subsection (3)* provides that if only part of any premises are open to the public or used as a place of work, then the premises are only smoke-free to that extent.

38. *Subsection (4)* provides that only enclosed or substantially enclosed premises are smoke-free under section 2. The appropriate national authority (the Secretary of State in the case of England and the National Assembly in the case of Wales) may define in regulations under *subsection (5)* the meaning of "enclosed" or "substantially enclosed".

39. *Subsection (6)* is a signpost to section 3, which provides that premises that would otherwise be smoke-free under section 2 may be exempted from that requirement by regulations made under section 3.

40. *Subsections (7) and (8)* make provision as to what is covered by the terms "open to the public" and "work".

Section 3: Smoke-free premises: exemptions

41. Section 3 enables regulations to be made by the appropriate national authority to specify descriptions of premises, or specified areas within such premises, which are not to be smoke-free where they would otherwise be covered by the provisions of Section 2.

42. *Subsection (2)* gives examples of the types of premises that might specified under such regulations. These might include, in particular, premises where someone has their home or where they are living, whether permanently or temporarily. Such premises might include places such as rooms in a hotel, bed and breakfast accommodation, a hostel or a care home. They could also include a place where a person is detained, such as a prison. .

43. *Subsection (3)* provides that such regulations may not exempt from the smoke-free requirement premises where the sale of alcohol is permitted under a premises licence under the Licensing Act 2003 (which could include places such as pubs, bars, discos and nightclubs) or premises which operate under a club premises certificate under the Licensing Act. However, by virtue of *subsection (4)*, if someone has their home, or is living either temporarily or permanently, in some area within such premises, the regulations may specify that particular living area as being exempt from the smoke-free requirement. This could permit, for example, a publican's living accommodation above a pub to be exempt from the smoke-free requirement that applies to the pub itself.

44. *Subsection (5)* provides that such regulations may make provision for those taking part in performances, so as to permit smoking by such performers if artistic integrity so requires. Performances may, by virtue of *subsection (8)*, include the performance of a play or a performance in connection with a film or television production (including rehearsals in each case but only if the regulations so provide). This would, for example, enable provision to be made enabling those participating in an artistic performance to smoke (where the artistic integrity of the performance made it appropriate) where that performance takes place on licensed premises.

45. *Subsection (6)* makes provision in respect of the matters such regulations may deal with, including the circumstances and conditions under which, and the times at which,

premises may be exempt from the smoke-free requirement. *Subsection (7)* provides that regulations may also make provision for the designation of rooms in which smoking may be permitted. This would enable provision to be made for designated smoking rooms, for example, in premises such as hotels, prisons or long term adult care homes or in other premises where it may be impossible for smoking to take place outside for safety, health or practical reasons, such as oil rigs.

Section 4: Additional smoke-free places

46. Section 4 enables regulations to be made that designate additional smoke-free places. These will be places that are not already covered by section 2 of the Act. Such places will not need to be enclosed or substantially enclosed. The appropriate national authority may designate a place under this section only if, in the authority's opinion, there is significant risk that, without designation, persons present in the place would be exposed to significant quantities of smoke. Examples of such places that might possibly be covered by regulations made under this section are sports stadia, bus shelters or entrances to buildings that are not covered within section 2 of the Act. Regulations made under this section may provide for additional places to be smoke-free only in certain circumstances, at certain times, if certain conditions are satisfied or in certain areas (or any combination of those).

Section 5: Vehicles

47. Section 5 provides powers for the appropriate national authority to make regulations providing for vehicles to be smoke-free. These regulations may make provision for the types of vehicles that are to be smoke-free, the circumstances in which the vehicles are to be smoke-free, any limitations to specified areas of the vehicle which is to be smoke-free and any exemptions. *Subsection (5)* defines vehicle as meaning every type of vehicle, including train, vessel, aircraft and hovercraft.

48. By s*ubsection (3)*, the power to make regulations to provide for smoke-free vehicles is not exercisable in relation to ships or hovercraft (or any persons on any such ship or hovercraft) for which regulations could be made under section 85 of the Merchant Shipping Act 1995. *Subsection (4)* amends section 85 of the Merchant Shipping Act to enable safety regulations made under that Act to provide for smoke-free provision for ships and hovercraft which corresponds with provisions in the Health Act.

Section 6: No-smoking signs

49. Section 6(1) imposes a duty on any person who occupies or is concerned with the management of smoke-free premises to display no-smoking signs which comply with the requirements of regulations to be made by the appropriate national authority under this section. *Subsection (2)* provides that regulations may also provide for a similar duty, imposed on such people as may be specified in the regulations, to display signs in relation to any premises designated smoke-free under regulations made under section 4 or in relation to any vehicle designated smoke-free under regulations made under section 5.

50. *Subsection* (5) provides that anyone who fails to comply with such a duty commits an offence. *Subsection (6)* sets out the defences that may be relied upon by a person charged with such an offence. *Subsection (7)* provides that if a person charged with an offence relies on a defence in *subsection (6)*, and presents evidence that is sufficient to raise an issue in respect of such a defence, then the court must assume that the defence is satisfied unless the prosecution can show beyond a reasonable doubt that it is not so satisfied.

51. *Subsection (8)* provides that a person who is found guilty of an offence under section 6 will be liable to a fine up to a level on the standard scale specified in regulations. It is intended that the regulations will prescribe a fine on summary conviction not exceeding level 3 on the standard scale, which is currently up to £1,000.

Section 7: Offence of smoking in smoke-free place

52. Section 7 sets out the offence of smoking in a smoke-free place. Smoke-free places comprise enclosed or substantially enclosed premises as defined in section 2, additional smoke-free places as set out in section 4, and vehicles required to be smoke-free as set out in section 5 of the Act. By *subsection (2)*, a person who smokes in any of these places commits an offence. However, by *subsection (3)*, a performer who smokes during a performance, where the premises have been exempted from the smoke-free requirement in relation to such performance by virtue of regulations under section 3(1) and (5) of the Act does not commit an offence.

53. *Subsection (4)* provides that it is a defence for a person charged with smoking in a smoke-free place to show that he/she did not know, and could not reasonably have been expected to know, that the premises, place or vehicle was smoke-free.

54. By *subsection (5)*, where a defendant wishes to rely on this defence, he/she must provide evidence that supports the defence. Where a defendant does provide evidence, the defence must be taken to be satisfied unless the prosecution proves beyond reasonable doubt that the evidence provided does not satisfy the defence.

55. *Subsection (6)* provides that a person who is found guilty of an offence under this section will be liable to a fine up to a level on the standard scale specified in regulations. It is intended that the regulations will prescribe a fine on summary conviction not exceeding level 1 on the standard scale, which is currently up to £100.

Section 8: Offence of failing to prevent smoking in smoke-free place

56. Section 8 imposes a duty on any person who controls or is concerned in the management of smoke-free premises to prevent smoking from taking place within the smoke-free premises. *Subsection (3)* provides that regulations may also provide for a similar duty, imposed on such people as may be specified in the regulations, to prevent smoking in relation to premises designated smoke-free under regulations made under section 4 or in relation to vehicles designated smoke-free under regulations made under section 5. However, *subsection (2)* provides that the duty to stop people smoking does not extend to stopping a person smoking where that person is a performer who smokes during a performance and the premises have been exempted from the smoke-free requirement, in relation to such performance, by virtue of regulations under section 3(1) and (5) of the Act.

57. By *subsection (4)*, anyone who fails to comply with such a duty commits an offence. *Subsection (5)* sets out the defences for a person charged with an offence under subsection (4), namely that:

    a. He/she took reasonable steps to stop the person smoking, such as requesting a person to stop smoking or taking steps to have the smoker evicted.

    b. He/she did not know, and could not reasonably be expected to know that the person was smoking, for example if the manager was not present at the time the smoking occurred.

    c. He/she has other grounds that show it was reasonable for him/her not to comply with the duty, for example during a period when priority had to be given to another duty, such as preventing other illegal activity or dealing with disorderly conduct.

58. *Subsection (6)* provides that if a person charged with an offence under this section relies on a defence in subsection (5), and presents evidence that is sufficient to raise an issue in respect of such a defence, then the court must assume that the defence is satisfied unless the prosecution can show beyond a reasonable doubt that it is not so satisfied.

59. *Subsection (7)* provides that a person who is found guilty of an offence under this Section will be liable to a fine up to a level on the standard scale specified in regulations.

It is intended that the regulations will prescribe a fine on summary conviction not exceeding level 4 on the standard scale, which is currently up to £2,500.

Section 9: Fixed penalties

60. An authorised officer (as defined in section 10(5)) who has reason to believe a person has committed an offence under section 6(5) (not displaying no-smoking signage that complies with regulations in smoke-free premises, places or vehicles) or 7(2) (smoking in smoke-free premises, or in a smoke-free place or vehicle) may issue a penalty notice in respect of the offence. If the person pays the penalty in accordance with the Act, he/she will be discharged of all liability for the offence and will not be able to be prosecuted for the offence for which the penalty notice was issued.

61. Schedule 1 contains provisions on fixed penalties.

Schedule 1

This Schedule contains provisions relating to fixed penalties. Provision is made for the contents of the penalty notice, the amount of the penalty, the discounted amount and the period for payment, as well as the time given to make payment. Paragraphs 14 and 15 of the Schedule enable a person to request to be tried for the offence in court instead of paying a fixed penalty. Paragraph 16 of the Schedule makes provision in relation to withdrawal of notices.

For the offence of smoking in a smoke-free place it is intended that regulations will prescribe a fixed penalty of £50. If the person pays the penalty, he will be discharged of any liability to conviction for the offence. A discounted amount can be paid if the fixed penalty notice (FPN) is settled within 15 days. The discounted amount will be set out in regulations, but is expected to be £30.

For the offence of failing to comply with signage requirements, it is intended that regulations will prescribe a fixed penalty of £200. If the person pays the penalty, he will be discharged of any liability to conviction for the offence, and will not be taken to court. A discounted amount can be paid if the FPN is settled within 15 days. The discounted amount will be set out in regulations, but is expected to be £150.

Section 10: Enforcement

62. The appropriate national authority may make regulations to designate the bodies which are to be enforcement authorities for the purposes of smoke-free legislation. *Subsection (3)* places a duty on bodies specified as enforcement authorities to enforce the smoke-free requirements of the Act in those premises, places or vehicles where the enforcement authority has functions (which will also be specified in regulations).

63. Provision may also be made for the transfer of enforcement cases between designated enforcement authorities. *Subsection (4)* provides that the appropriate national authority may exercise enforcement functions itself in particular cases or types of case.

64. *Subsection (5)* provides that within Chapter 1 of Part 1 of the Act, "authorised officer" in relation to an enforcement authority means any person whom the enforcement authority authorises in writing to enforce smoke-free legislation. Such written authorisation can be either general or specific. Regulations may be made under s*ubsection (6)* to specify any qualifications required to be held by an authorised officer of an enforcement authority.

65. Schedule 2 makes provision about powers of entry, etc.

Schedule 2

This Schedule contains provisions relating to powers of entry for enforcement. The Schedule sets out the powers of an officer who is an authorised officer of an enforcement

authority for the purposes of Chapter 1 of Part 1 of the Act. He/she may enter premises (other than premises used only as a private dwelling which is not open to the public), require and take possession of samples and substances, and request information. Provision is also made for a justice of the peace to issue warrants where admission is likely to be refused and in certain other cases. In enforcement cases where the appropriate national authority acts as the enforcement authority, the same provisions apply to persons discharging enforcement authority functions on behalf of the appropriate national authority.

Section 11: Obstruction etc. of officers

66. Section 11 provides that any person who intentionally obstructs an authorised officer of an enforcement authority, enforcing smoke-free provisions of this Act, commits an offence. By *subsection (2)*, a person who fails to give to an authorised officer any facilities, assistance or information which the authorised officer reasonably requires for the purposes of enforcement commits an offence. By *subsection (3)*, a person commits an offence if he/she makes a statement which is false or misleading, and he/she either knows that is false or misleading or is reckless as to whether it is false or misleading. For the purposes of this section, "false or misleading" means false or misleading in a material particular. In enforcement cases where the appropriate national authority acts as the enforcement authority, the same provisions apply to persons discharging enforcement authority on behalf of the appropriate national authority.

67. *Subsection (4)* provides that a person who obstructs an authorised officer as specified in section 11 is liable on summary conviction to a fine not exceeding level 3 on the standard scale, which is currently up to £1,000.

Section 12: Interpretation and territorial sea

68. *Subsection (1)* contains definitions that apply to Chapter 1 of Part 1 of the Act, apart from the definition of "smoking" which is in section 1. *Subsection (2*) enables the definition of premises in subsection (1), which currently includes a reference to regulation 3 of the Offshore Installations and Pipeline Works (Management and Administration) Regulations 1995, to be amended by order so as to substitute reference to another enactment for the current reference to the 1995 Regulations, should those Regulations, for example, be amended or revoked. *Subsections (3) and (4)* provide that Part 1 has effect in relation to the territorial sea which is adjacent to England and Wales as it has effect in relation to England and Wales.

Part 1 Chapter 2

Age for Sale of Tobacco Etc.

Section 13: Power to amend age for sale of tobacco etc

69. Chapter 2 of Part 1 of the Act enables an order to be made by the Secretary of State to change the minimum age for sale of tobacco products. Section 13 provides that the Secretary of State may change the minimum age of sale of tobacco products by amending by order any age specified in section 7 of the Children and Young Persons Act 1933 (sale of tobacco etc. to persons under 16) and any age specified in section 4 of the Children and Young Persons (Protection from Tobacco) Act 1991 (display of warning statement in retail premises and on vending machines). However, by virtue of *subsection (2)*, any new age specified in such an order may not be lower than 16 years or higher than 18 years. The age specified in the provisions mentioned is currently 16.

Part 2

Prevention and Control of Health Care Associated Infections

Section 14: Code of practice relating to health care associated infections

70. This section inserts three new sections into Part 2 of the Health and Social Care (Community Health and Standards) Act 2003 (the "2003 Act").

71. The first is new *section* 47A (code of practice relating to health care associated infections). This gives the Secretary of State the power to issue a code of practice ("the code") on the prevention and control of health care associated infections. The code will set out the measures which he considers are an important part of best practice in reducing those infections which are related to health care that is provided by, or commissioned for, the NHS bodies to which the code applies.

72. Health care associated infections are defined in *subsection (8)*. A health care associated infection is any infection to which an individual may be exposed or made susceptible or more susceptible where the risk of exposure or susceptibility is directly or indirectly attributable to the provision of the health care. The individual who may be at risk does not have to be the individual receiving the health care.

73. "Health care" has the same meaning as in section 45(2) of the 2003 Act. It means services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness and the promotion and protection of public health.

74. The code may be applied to all English NHS bodies (other than Strategic Health Authorities) and to cross-border SHAs (*subsection (2)*). These bodies are defined in section 148 of the 2003 Act. English NHS bodies include an NHS trust all or most of whose hospitals, establishments and facilities are situated in England, an NHS foundation trust and a Primary Care Trust ("PCT"). The code may specify which of its provisions apply to which bodies, and it may do so by description or by naming them (*subsection (3)*).

75. *Subsection (4)(a)* makes it clear that the code may include measures designed to protect people who are not themselves receiving health care, but who may nonetheless be at risk from health care associated infections, such as staff and visitors. *Subsection (4)(b)* makes it clear that the code may place obligations on those NHS bodies to which the code applies in connection with the health care that they commission.

76. It is envisaged that the provisions of the code will need to operate by reference to the content of other documents, whether published by the Secretary of State or other relevant sources. *Subsection (5)* allows the code to incorporate other documents (in whole or part), and to take effect by reference to a document as revised from time to time. Where the code refers to a document in this way, the code will be automatically changed each time the document that it refers to is revised.

77. The code may make different provision for different cases or circumstances (*subsection (5)(c)*). This allows the code to reflect the fact that NHS bodies have different functions.

78. The Secretary of State must keep the code under review, and may revise all or any part of it (*subsection* (7)).

79. Section 14 also inserts new section 47B (consultation etc.) into the 2003 Act.

80. *Subsections (1) and (2)* of the new section 47B provide that where the Secretary of State proposes to issue a code or to issue a revised code which he thinks would result in a substantial change in the code, he must prepare a draft of it and consult such persons as he thinks appropriate about the draft.

81. *Subsections (4) and (5)* are concerned with a situation where any provision of the code operates by reference to another document as revised from time to time. Before the Secretary of State revises any document published by him in relation to his health functions, he must consult appropriate persons about any change which would, in his view, lead to a substantial change in the code *(subsection (4)*). In the case of revisions to other such documents, where the Secretary of State thinks that the code has been substantially altered as a consequence, *subsection (5)* places a duty on him to consult appropriate persons about whether the code should be revised.

82. *Subsection (6)* allows consultation for the purposes of this section to have taken place before the commencement of the section.

83. Lastly, section 14 also inserts new section 47C (effect of code under section 47A) into the 2003 Act. It places a duty on those NHS bodies to which provisions of the code apply to observe them in discharging their duty of quality under section 45 of the 2003 Act (*subsection (1)).* Section 45 places a duty on each NHS body to ensure that appropriate arrangements are in place with a view to monitoring and improving the quality of health care that they provide or commission.

84. A failure to observe any provision of the code does not, of itself, make a person liable to criminal or civil proceedings, but the code is admissible in evidence in such proceedings, for example in a negligence action (*subsections (2) and (3)).*

Section 15: Code of practice: effects on existing functions of Commission for Healthcare Audit and Inspection

85. This section amends the 2003 Act to provide for new functions of the Healthcare Commission in relation to the code.

86. *Subsection (2)* amends section 50 of the 2003 Act (annual reviews) so that the Healthcare Commission must take the code into account when it conducts an annual review of health care under this section. It places a duty on the Healthcare Commission to consider the extent (if any) to which a body is observing any provisions of the code that apply to it.

87. The Healthcare Commission also has the function of conducting reviews of NHS health care across England and Wales under section 51 of the 2003 Act (reviews: England and Wales). *Subsection (3)* amends section 51(4)(a) so that the Healthcare Commission must also take account of the code when reviewing health care provided by or for an English NHS body or cross-border SHA in the context of a review under this section.

88. This section also amends section 52 of the 2003 Act (reviews and investigations: England) so that the Healthcare Commission must take the code into account when conducting a review or investigation under section 52 (*subsection (5)*). *Subsection (5A)* provides that when the Healthcare Commission undertakes a review of the arrangements made by a particular English NHS body or cross-border SHA for the purpose of discharging their duty of quality in health care, the Healthcare Commission must consider the extent (if any) to which the body in question is observing any applicable provisions of the code (see section 52(3) of the 2003 Act (as amended by *subsection (4)).*

89. *Subsection (6)* amends section 54(2) of the 2003 Act so that it refers to the code and allows the Healthcare Commission to give advice to the Secretary of State on changes that it thinks should be made to the code in order to secure improvements in the quality of NHS health care.

Section 16: Code of practice: improvement notices

90. This section inserts two further new sections, sections 53A (failings in connection with code under section 47A: improvement notices) and 53B (code of practice: action by

the Healthcare Commission following service of an improvement notice), into the 2003 Act.

91. New section 53A(1) gives the Healthcare Commission the power to serve an improvement notice in relation to the code. The power applies where, following a review or investigation (as the case may be) under sections 50, 51 or 52 of the 2003 Act, the Healthcare Commission is of the view that any provisions of the code applying to an English NHS body or a cross-border SHA are not being observed in any material respect in relation to the provision of health care by or for that body.

92. The Healthcare Commission may issue an improvement notice where it considers that this is the most appropriate course for it to take with a view to securing that the failure in question is remedied (*subsection (2)).*

93. It is considered that a failure to observe the code in any material respect would include any failure to observe the code that, in the Healthcare Commission's view, could compromise the body's ability to ensure health care associated infections are appropriately tackled.

94. However, the Healthcare Commission may only issue a notice if, having regard to all the circumstances, it is not required to make a report to the Secretary of State under section 53(2) of the 2003 Act and to the regulator under section 53(6), where the body in question is an NHS foundation trust (*subsection (1)(b)).*

95. Section 53 of the 2003 Act (failings) requires the Healthcare Commission to make such a report where it is of the view that there are significant failings in relation to the provision of health care by or for an English NHS body or cross-border SHA, in the running of such a body, or in the running of any body or the practice of any individual providing health care for an English NHS body or cross-border SHA. Such a report may include a recommendation that the recipient take special measures with a view to remedying the failing in question (*see* below). It is considered that significant failings related to the code could be the subject of reporting under this section.

96. A significant failing is not defined in the 2003 Act. It is considered that a significant failing is one that, in the view of the Healthcare Commission, is serious enough to be drawn to the immediate attention of the Secretary of State or the regulator with a view to a decision being taken about whether special measures are required. Whether the failing is significant is a mixed question of fact and law. It is considered that the Healthcare Commission's decision would be informed by its overall conclusions following the review or investigation. This could include an assessment of (amongst other things) any action that the NHS body is taking to resolve the issue, the nature of, and reason for the failure, and any impact on the health care provided by or for the body. It is considered that significant failings could, therefore, include (but are not limited to) a failure related to the provision of health care or the running of the body that endangers the lives of patients or the viability of the body.

97. Special measures are not defined in the 2003 Act, but they may include practical assistance or organisational support. For example, the Secretary of State could invite a Director of Infection Prevention and Control from another NHS Trust to act as an advisor to an NHS Trust who require advice on how to implement the code.

98. A report under section 53 may lead to intervention in relation to the NHS body by the Secretary of State using his direction-making or intervention powers under the NHS Act 1977 or by the regulator under section 23 of the 2003 Act (significant failings) in the case of an NHS foundation trust. For example, if an NHS foundation trust or an NHS trust proved unable to provide adequate training on infection control for its staff, it could be required to take particular measures to put adequate training in place.

99. *Subsection (3)* sets out what the Healthcare Commission must include in an improvement notice. In particular, the notice must specify the period by which the body in question must remedy the failure. The notice may also (but need not) include

a recommendation by the Healthcare Commission about how the failure should be remedied (*subsection (4)*). This would be advisory only, but the body would be expected to take the Healthcare Commission's views into account. More than one failure to observe the code may be included in a single notice, in which case the Healthcare Commission may specify different periods for compliance for different failures (*subsection (5)*), and may make several recommendations in a single notice.

100. Where the Healthcare Commission serves an improvement notice, it must notify the Secretary of State, the regulator, in the case of a NHS foundation trust, and any relevant Strategic Health Authority, in the case of a NHS trust or PCT (*subsection (6)*). The "relevant Strategic Health Authority" is defined in *subsection (7)*.

101. *Subsections (8) and (9)* prohibit the Healthcare Commission from responding to any failure by the body to comply with an improvement notice served on it by serving another improvement notice concerning the same failure, but allow the Healthcare Commission to serve another notice where, on reviewing compliance with the notice, it identifies a different failure to observe the code.

102. New section 53B is concerned with action by the Healthcare Commission after it has served an improvement notice on an NHS body.

103. *Subsection (2)* provides that the Healthcare Commission may, at the request of the body in question and by notice, extend the length of time that the body has been given to rectify the non-observance of the code specified in the improvement notice. Time can only be extended where the Healthcare Commission believes that this is justified by exceptional circumstances. The length of time may be extended more than once as long as the conditions in subsection (2) are met on each occasion.

104. *Subsection (4)* places a duty on the Healthcare Commission to undertake a review into whether the body has complied with the improvement notice. That review will be carried out under section 52(3)(b) of the 2003 Act. The review will take place at the end of the period specified in the improvement notice unless the body informs the Healthcare Commission that it has complied with the improvement notice before this time, in which case it can take place sooner.

105. Having conducted the review, the Healthcare Commission must then report to the Secretary of State, and to the regulator if the body is a NHS foundation trust, in accordance with *subsection (5) or (6)*.

106. If the Healthcare Commission remains of the view that the body is not observing the code in material respects and, having regard to all the circumstances, considers that it must report to the Secretary of State or the regulator under section 53 of the 2003 Act at this stage, then *subsection (5)* makes it clear that the Commission must make such a report. In deciding whether to make such a report, the Healthcare Commission must take the overall situation into account. This would include the fact of, and the reasons for, the body's failure to comply with the improvement notice, and any effect on the quality and effectiveness of the health care.

107. Where the Healthcare Commission does not report significant failings as described above, then it must report to the Secretary of State and to the regulator (as the case may be) setting out particular matters. Those matters are specified in *subsections (7) and (8)*.

108. If the Healthcare Commission considers that the body has complied with the improvement notice and is observing the provisions of the code which resulted in the notice being served, then the Healthcare Commission must state this fact and give its reasons for this view (*subsection (7)*). If, however, the Healthcare Commission continues to believe that the body is not observing those provisions, *subsection (8)* provides that the Healthcare Commission's report must set out:-

- that it is of that view and the reasons for that view;

- its reasons for not reporting significant failings to the Secretary of State or the regulator under section 53 where the body is failing to observe the code in any material respect; and
- in any case, details of any action that the Healthcare Commission intend to take in relation to the body concerned in relation to the body's failure to observe those provisions. For example, the Healthcare Commission could request that the body supply regular information that would allow the Healthcare Commission to see whether the body was continuing to make progress towards full observance of the relevant provisions of the code.

109. *Subsection (9)* provides that the Healthcare Commission must send a copy of any report to the relevant Strategic Health Authority, as defined in new section 53A(7) where the body in question is a PCT or a NHS Trust.

Part 3 Drugs, Medicines and Pharmacies

Part 3Chapter 1

Supervision of Management and Use of Controlled Drugs

110. Part 3 of the Act contains provisions intended to strengthen the arrangements for the safe management of controlled drugs in health and social care settings. It provides the legislative underpinning to the programme of action set out in *Safer management of controlled drugs*, the government's response to the Fourth Report of the Shipman Inquiry. The key elements are:

- all NHS healthcare organisations, and larger private healthcare organisations such as independent hospitals, will be required to nominate an officer of sufficient seniority – an "accountable officer" – to ensure that the organisation has robust arrangements for the safe and effective handling of controlled drugs. In NHS primary care, primary care organisations will exercise this responsibility on behalf of all the contractors with which they have contracted to provide services;
- a duty of collaboration will be placed on healthcare organisations, and on other local and national agencies such as professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care Inspection, requiring them to share intelligence on controlled drugs issues and to coordinate the action they take to protect patients and the public
- police officers, accountable officers and their staff and other authorised persons will have a right of entry and inspection into the premises of relevant healthcare providers to enable them to discharge these responsibilities. The power of entry will not necessarily be exercisable by all accountable officers.

111. The relevant authority regarding the regulation making powers within this Chapter are the Secretary of State in respect of England and Scotland, the National Assembly for Wales in respect of Wales and the Department of Health, Social Services and Public Safety in respect of Northern Ireland.

Section 17: Accountable officers and their responsibilities as to controlled drugs

112. Section 17 allows the relevant authority by regulations to determine the organisations which are to be required to appoint an accountable officer, the functions of the accountable officer, and the criteria to be satisfied in making appointments. The intention is that all NHS hospital trusts and primary care trusts, and the larger private sector healthcare organisations such as independent hospitals, should appoint accountable officers.

113. *Subsection (1)* sets out the general power to make regulations under which certain organisations ("designated bodies") are required to appoint accountable officers with specified responsibilities. The responsibilities are to relate to the management and use of controlled drugs in connection with activities carried on by or on behalf of the organisation (eg a hospital trust) or by third parties under arrangements with the organisation (eg a primary care trust). *Subsection (2)* introduces the term "accountable officer". *Subsections (3) and (4)* define more closely the types of organisations which may be required to appoint an accountable officer, ie those which are directly or indirectly involved in providing healthcare or other activities which may involve the supply or administration of a controlled drug. *Subsections (5) and (6)* give examples of the detailed requirements which may be laid down in regulations, including criteria for appointment, funding, the requirement to follow best practice guidance, and responsibilities of the accountable officer. The regulations may also create offences or other procedures for enforcing any provisions of the regulations. *Subsections (7) and (8)* ensure that requirements set out in regulations can have application to a wide variety of settings in which controlled drugs may be supplied or administered, including care provided by third parties under contract to a designated body (eg a primary care trust). *Subsection (10)* allows regulations to cover issues not listed in (5) or (6).

Section 18: Co-operation between health bodies and other organisations

114. Section 18 allows the relevant authority to make regulations to require organisations ("responsible bodies") described in the regulations to co-operate, by sharing intelligence and coordinating action, in order to ensure the safe management of controlled drugs and to safeguard patients from harm. The intention is that the duty to co-operate would be applied to all bodies required to appoint an accountable officer under section 17, to police forces, to local authorities, and to regulatory bodies with inspection rights such as the Royal Pharmaceutical Society of Great Britain, the Healthcare Commission and the Commission for Social Care Inspection.

115. *Subsection (1)* sets out the power to make regulations for requiring organisations described in the regulations to co-operate and describes in broad terms the areas to be covered by the duty of co-operation. *Subsections (2) to (4)* specify the types of body to which the duty would apply ie. bodies that are concerned with the provision of healthcare, or carry on activities that involve the supply or administration of controlled drugs. *Subsections (5) to (7)* give examples of the requirements as to co-operation that may be included in the regulations, including the circumstances in which the duty to disclose information to other organisations could be triggered (subsection (5)(a)) and the duties which may be imposed on the accountable officer of the bodies concerned to make recommendations for action (subsection (6)) including recommendations relating to disciplinary action (subsection (7)).

Section 19: Meaning of "relevant person in section 18

116. Section 19 defines the term "relevant person" referred to in subsection (1) of section 18. This would allow any information that comes to the attention of responsible bodies, in relation to the use or management of controlled drugs by people who have no connection or contract with a designated or responsible body, to be shared by them under section 18. Examples of such people might be private doctors, individuals working for independent care homes which are not providing services to a Primary Care Trust or local authority and private dentists (and their staff).

Section 20: Controlled drugs: power to enter and inspect

117. Section 20 creates a power for police constables or other authorised persons to enter the premises of healthcare providers and to inspect the arrangements for the safe management of controlled drugs. This power would go beyond the existing provision in section 23 of the Misuse of Drugs Act 1971 (the "1971 Act"), which is limited to entering the premises of a person carrying on business as a producer or supplier of any

controlled drugs. The intention is that the inspections would generally be carried out by police constables or by accountable officers appointed under section 17 and their staff, or by the regulatory bodies with inspection rights such as the Royal Pharmaceutical Society of Great Britain, the Healthcare Commission and the Commission for Social Care Inspection although the section allows for other persons to be authorised by the relevant authority.

118. *Subsection (1)* sets out the general power. *Subsection (3)* prevents an authorised person from entering relevant premises which are or form part of a private dwelling unless they are accompanied by a police constable. However, it also creates regulation making powers which can prescribe circumstances in which this regulation does not apply, for example, in the regular inspection of care homes which are legally defined as private dwellings.

119. *Subsection (4)* allows the authorised person to take copies of relevant records and retain them. *Subsection (5)* defines the persons who would be authorised to carry out inspections, including accountable officers and staff of designated bodies and allows the relevant authority to authorise other persons in addition to accountable officers and their staff, while *subsection (6)* enables the relevant authority to exclude particular categories of designated bodies from the general authorisations under subsection (5). *Subsection (7)* allows the relevant authority to define more closely the categories of premises which are subject to inspection, subject to the general constraints of *subsection (8).*

Section 21: Offences in connection with power to enter and inspect

120. Section 21 creates an offence of obstructing a person making an inspection or deliberately concealing material or information relevant to the inspection. The offence is similar to that in section 23 of the 1971 Act. *Subsection (1)* defines the circumstances in which an offence is committed and *subsections (2) and (3)* the maximum penalties on conviction.

Section 22 Guidance

121. Section 22 allows the relevant authority to give guidance to designated bodies and responsible bodies about the appointment of the accountable officer, the accountable officer's functions and the duty to co-operate. Designated bodies and responsible bodies must have regard to guidance in exercising their functions *(subsection (4))*. The intention is that regulations will set out the essential requirements relating to accountable officers.

Section 23: Crown application

122. Section 23 extends the provision in this Chapter to the Crown and to people in the public service of the Crown. *Subsection (2)* provides that the Crown will not be criminally liable for contravention of any provision in this Chapter but any such contravention maybe declared unlawful by the relevant court.

Section 24 Relevant authorities

123. Section 24 sets out which authorities (the relevant authorities) have responsibility for the powers set out in this Chapter. The Secretary of State will exercise the functions to cover England and (after consulting the Scottish Ministers) Scotland. The National Assembly for Wales will exercise the functions for Wales and the Department of Health, Social Services and Public Safety will exercise the functions for Northern Ireland. Under *subsection (4)* any of the powers of a relevant authority to make regulations under this Chapter are exercisable, in relation to cross-border bodies (as defined under *subsection (5)*), by the Secretary of State (after consultation with the Assembly).

Section 25 Interpretation

124. Section 25 defines the terms used in this Chapter.

Part 3Chapter 2

Medicines and Pharmacies

125. Chapter 2 of Part 3 of the Act provides for the amendment of provisions of the Medicines Act 1968 (the "Medicines Act"), and also a provision of the Health Act 1999, relating to pharmacies, pharmacists and the sale and supply of medicines.

126. Part 4 of the Medicines Act (sections 69 to 84) contains provisions relating to the registration of retail pharmacies, the lawful conduct of retail pharmacy businesses and prohibitions on the use of certain titles, emblems etc. relating to pharmacy. Under the existing provisions, a person, whether a corporate body or an individual, is only lawfully conducting a retail pharmacy business if at each pharmacy premises from which they conduct their business, the retail supply of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the dispensing of medicines in accordance with NHS prescriptions) is under the "personal control" of a pharmacist. The provisions of this Chapter of the Act change these arrangements, by removing the requirement for personal control and substituting new requirements under which there must be a "responsible pharmacist", responsible for the safe and effective running of the pharmacy business.

127. Other provisions of the Medicines Act require that certain activities relating to medicines may be conducted only by or under the supervision of a pharmacist. The provisions of the Act amend the Medicines Act in order to enable Ministers to prescribe conditions which must be complied with if that activity is to be considered as done under the supervision of a pharmacist. The intention is to clarify the pharmacist's obligations to supervise.

128. In addition to the provisions of the Act, the Government propose to make orders under the existing powers of the Medicines Act, so as to enable registered and suitably trained staff working in a pharmacy to supervise the preparation, dispensing, sale and supply of medicines, without direct supervision by a pharmacist. The intention is that the pharmacist can use his clinical skills and training to offer a wider range of services, including away from the pharmacy (for example, in health centres and clinics).

129. These provisions extend to the entire United Kingdom.

Section 26: Requirements about supervision

130. Section 26 relates to the requirements in the Medicines Act relating to the supervision of certain activities by pharmacists.

131. Section 26(1) amends section 10 of the Medicines Act. Under the Medicines Act a licence is required to manufacture or supply medicinal products; section 10 of the Medicines Act provides for various exemptions from the licensing requirements of the Medicines Act where, in certain circumstances, a pharmacist, or a person acting under the supervision of a pharmacist, prepares, assembles, dispenses or supplies a medicine. Section 26(1) inserts new subsections in section 10. These confer on the "Health Ministers" (i.e. the Secretary of State for Health and the Northern Ireland Department for Health, Social Services and Public Safety) a power to make regulations prescribing conditions which must be complied with if that activity is to be considered as done under the supervision of a pharmacist. If any of the prescribed conditions apply to that activity and are met, that will be sufficient for the activity in question to be considered as done under supervision. In addition, the new powers will extend to prescribing conditions in relation to "remote supervision" – i.e. where the pharmacist supervises an activity without being present at the pharmacy (e.g. by using a video link).

If no such conditions are prescribed, the pharmacist cannot supervise remotely. The intention is that the regulations will clarify the pharmacist's obligations to supervise.

132. Section 26(2) amends section 52 of the Medicines Act. Section 52 of the Medicines Act imposes conditions on the sale or supply of any medicine which is not a "general sale list" medicine; in particular that any transaction for the sale or supply of a medicine to a customer must be carried out by, or under the supervision of, a pharmacist. A general sale list medicine is one which may be sold in retail premises which can be secured so as to exclude the public, but which are not a pharmacy (e.g. a supermarket or newsagent shop). Section 26(2) makes amendments to section 52 of the Medicines Act, identical to those for section 10; i.e. enabling the Health Ministers to make regulations relating to the requirements for supervision by a pharmacist.

Sections 27 to 30: Pharmacy premises

133. Under section 75 of the Medicines Act, a retail pharmacy must be registered. The register is administered by a registrar appointed by the Royal Pharmaceutical Society of Great Britain (or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland). The applicant for registration must be a person "lawfully conducting a retail pharmacy business". In addition, section 52 of the Medicines Act requires that a medicine, other than a general sale list medicine, must be sold or supplied by such a person. Sections 69 to 72 of the Medicines Act specify the conditions which must be complied with if a person is to considered to be lawfully conducting the business. Section 70 specifies conditions for individual pharmacists or partners. Section 71 specifies those for corporate bodies. Section 72 specifies conditions that apply where a pharmacist carrying on a retail pharmacy business dies or is otherwise prevented from carrying on his business (e.g. if he is adjudged bankrupt) and a representative carries on his business.

134. Under the existing provisions, at each pharmacy premises the business of retail sale of medicines (whether general sale list medicines or not) or the supply of such medicines in circumstances corresponding to retail sale (e.g. the supply of medicines in response to NHS prescriptions) must at all times be under the personal control of a pharmacist.

135. Sections 27 to 30 amend these provisions; in particular, to remove the requirement for personal control and replace this with a requirement that for each pharmacy premises, there must be a "responsible pharmacist" in charge of the business of retail sale or supply of medicines.

Section 27: Control of pharmacy premises: individuals and partnerships

136. Section 27(1) substitutes a new section 70 of the Medicines Act, which relates to the requirements for retail pharmacy businesses carried on by individuals or partnerships. The effect of the substitution is to replace the requirement for each pharmacy to be under the personal control of a pharmacist with a requirement that for each pharmacy premises, there should be a responsible pharmacist. The responsible pharmacist must be in charge of the pharmacy business, in so far as it relates to the retail sale of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the supply of the medicines in accordance with NHS prescriptions).

137. The new section 70(3) replaces the existing requirement in section 70 for the pharmacist in personal control of the pharmacy to exhibit conspicuously in the pharmacy his registration certificate. In practice, where there is more than one pharmacist working in a pharmacy, each will display his or her registration certificate. To avoid doubt as to the responsible pharmacist in charge of the pharmacy, section 70(3) requires the responsible pharmacist to display conspicuously in the pharmacy a notice stating that he is the pharmacist in charge at that time, and which includes details of his registration number.

138. New section 70(4) provides that where the pharmacy business is carried on by an individual, the responsible pharmacist must be that person or another pharmacist.

Where a pharmacy business is carried on by a partnership, the responsible pharmacist must be one of the partners (in Scotland, one of the partners who is a pharmacist) or another pharmacist.

139. New section 70(5) sets out a requirement that where pharmacy premises in Great Britain have been registered for less than three years, the responsible pharmacist may not be a pharmacist who is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (i.e. a pharmacist who is qualified in another EU state whose qualification is recognised in the UK). Article 2(1) of Directive 85/433/EEC provides for Member States to recognise specified diplomas etc awarded by other Member States. Article 2(2) of the Directive, however provides for a derogation under which member States need not give effect to the diplomas with respect to pharmacies open to the public, which have been in operation for less than 3 years. Section 70(5) exercises that derogation in relation to Great Britain.

140. Section 27(2) makes a consequential amendment to section 78 of the Medicines Act (which relates to the prohibition on the use of certain titles, emblems etc relating to pharmacy), replacing references to "personal control" with references to the pharmacist in charge of the pharmacy business at the premises.

Section 28: Control of pharmacy premises: bodies corporate

141. Section 28 substitutes section 71 of the Medicines Act, which relates to the requirements for a retail pharmacy business carried on by a body corporate. The requirement in section 71 for a body corporate conducting a pharmacy business to have a superintendent pharmacist remains. Section 71 is however altered so as to remove the existing requirement that at pharmacy premises where the business is carried on, the retail sale or supply of medicines must be under the personal control of a pharmacist. This requirement is replaced by a requirement to have a responsible pharmacist, subject to the same conditions as apply under the new section 70 of the Medicines Act substituted by section 27. Section 28(2) makes a consequential amendment to section 124(2)(b) of the Medicines Act, which concerns offences by bodies corporate.

Section 29: Control of pharmacy premises: representative of pharmacist in case of death or disability

142. Section 29 amends section 72 of the Medicines Act, which specifies the conditions that apply where a pharmacist carrying on a retail pharmacy business dies or is otherwise prevented from carrying on his business (e.g. if he is adjudged bankrupt) and a representative carries on his business. Section 29 amends the provisions so as to remove the requirement that at each premises the retail pharmacy business is under the personal control of a pharmacist, replacing it with a requirement for there to be a responsible pharmacist, as in the amended sections 70 and 71.

Section 30: The responsible pharmacist

143. Section 30 inserts two new sections 72A and 72B of the Medicines Act, to make provision in relation to the "responsible pharmacist" mentioned in sections 70, 71 and 72 of the Medicines Act (as amended by this Act).

144. Section 72A(1) places a duty on the responsible pharmacist to secure the safe and effective running of the pharmacy business in question, insofar as this concerns the retail sale of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the supply of medicines in accordance with NHS prescriptions). Section 72A(2) states that a pharmacist may not be in charge of more than one set of pharmacy premises except in circumstances specified in regulations made by the Health Ministers (i.e. the Secretary of State for Health and the Northern Ireland Department for Health, Social Services and Public Safety), and then only if such conditions as may be specified are complied with. Section 72A(3) to (5) impose requirements relating to the procedures

which must be established and maintained by the responsible pharmacist and as to record keeping.

145. Section 72A(6) provides for the Health Ministers to make further provision in regulations in relation to the responsible pharmacist. Section 72A(7) provides that those regulations may in particular make provision about the matters referred to in section 72A(1) to (4); i.e. the duties of the responsible pharmacist, the circumstances in which a person may be a responsible pharmacist in respect of more than one set of premises at a time, the duty to establish and maintain procedures and the duty to keep records. Furthermore, section 72A(7) provides that the regulations may make provision for a variety of related matters including: the qualifications and experience that a pharmacist must have to be a responsible pharmacist; the responsible pharmacist's absence from the pharmacy (for example, to impose conditions as to how long a responsible pharmacist may be absent); his supervision of the preparation, assembly, dispensing and supply of medicines at the pharmacy when he is not present; the circumstances in which he may supervise such activities at a pharmacy when he is not the responsible pharmacist for that pharmacy; the format and content of procedures to secure the safe and effective running of the business; and the form and content of the records which must be made by the responsible pharmacist.

146. New section 72B(1) provides that where a person fails to comply with any requirements of new section 72A of the Medicines Act, or of regulations made under that section, this may constitute misconduct for the purposes of section 80 of the Medicines Act, section 8 of the Pharmacy Act 1954 and Article 20 of the Pharmacy (Northern Ireland) Order 1976; and the Statutory Committee of the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland may deal with such a failure accordingly. Section 72B(2) provides that if a pharmacist does not have the qualifications and experience specified in the regulations, he cannot act as a responsible pharmacist. If such a person is in charge of the retail sale/supply of medicines at a pharmacy, the person carrying on the retail pharmacy business in question will not be lawfully conducting that business.

147. Under section 72B(3) and (4), if a pharmacist is absent from the pharmacy for a period longer than that permitted in the regulations, or is named as responsible pharmacist for more than one pharmacy without satisfying the requirements in the regulations which govern such matters, they cannot be considered for the purposes of these provisions as being in charge of the business at the pharmacy. Unless another responsible pharmacist is appointed for the pharmacy, the person carrying on the retail pharmacy business in question will not be lawfully conducting that business.

148. Section 30(2) makes a consequential amendment to section 77 of the Medicines Act, which deals with the annual return, which every person carrying on a retail pharmacy business must make to the registrar responsible for keeping the register of retail pharmacies under the Medicines Act. The amendment removes the requirement to send to the registrar the name of the pharmacist in personal control of the retail pharmacy business.

149. Section 30(3) amends section 84 of the Medicines Act, which relates to criminal offences under Part 4 of the Medicines Act. The new provision makes it a criminal offence for a person to fail to comply with the record keeping requirements imposed under the new section 72A. Any person guilty of the offence would be liable on conviction in the magistrates' court to a fine not exceeding level 3 on the standard scale, currently up to £1,000.

Section 31: Enforcement

150. Section 31 makes consequential amendments to sections 108, 109 and 110 of the Medicines Act, which relate to enforcement. New sections 108(6A) and 110(3A) ensure that, as with the enforcement of other provisions of the Medicines Act relating to the retail sale and supply of medicines, arrangements may be made for the enforcement of

the provisions of section 72A relating to record keeping by the Pharmaceutical Societies of Great Britain and Northern Ireland. Also, new sections 108(6B) and 110(3B) place a specific duty on both the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland to enforce those elements of section 72A which are not subject to an offence, as a matter of professional misconduct, for example, the content of the standard operating procedures that must be maintained in each pharmacy. This duty applies wherever the registered pharmacy is located, in a hospital or in the community.

151. New sections 108(6C) and 110(3C) clarify that the appropriate Minister does not have a duty to enforce those provisions which are not subject to offences, as the appropriate Minister has no means under the Medicines Act to do so. However, sections 108(6D) and 110(3D) do give the appropriate Minister a right of entry to inspect and investigate in relation to the other provisions in section 72A which are not subject to an offence, reflecting the arrangements in Northern Ireland where the Health Department Inspectorate inspect and investigate matters in pharmacies, rather than the Pharmaceutical Society of Northern Ireland. Similar provisions have been made for England, Scotland and Wales to maintain consistency in the legislation.

152. However, the provision in section 108(10) which provides that the Secretary of State may prosecute in respect of the offences in section 72A if satisfied that the Royal Pharmaceutical Society has failed to do so is not replicated for Northern Ireland. This is to reflect the fact that in Northern Ireland it is the policy intention that the Health Department Inspectorate (not the Pharmaceutical Society) will have primary responsibility for prosecuting in respect of those criminal offences, and would therefore not be appropriate to include this qualification for Northern Ireland.

Section 32: Order-making powers

153. Section 32 amends section 129(5) of the Medicines Act, which provides that regulations under the Medicines Act may make different provision for different areas or in relation to different cases or different circumstances. The amendment extends this power to orders made under the Medicines Act. This means that if, as is proposed, the Health Ministers make further orders under the Medicines Act to enable acts to be carried out by registered and suitably trained pharmacy staff, rather than by or under the supervision of a pharmacist, those orders may make different provision for different parts of the United Kingdom.

Section 33: Orders under section 60 of the Health Act 1999

154. Section 33 amends Schedule 3 to the Health Act 1999, which makes provision about Orders in Council under section 60 of the Act. Orders under that section may make provision in relation to the regulation of health care professions. Section 33 omits paragraph 2(2) of Schedule 3, so as to remove the limitation that orders under section 60 may not make amendments to the Medicines Act except in relation to a profession regulated by the Pharmacy Act 1954.

Part 4 The National Health Service

PART 4CHAPTER 1

Pharmaceutical Services

155. Chapter 1 concerns pharmaceutical services provided under section 41 of the National Health Service Act 1977 (“the 1977 Act”) and in the case of one section only, corresponding services in Scotland.

156. Pharmaceutical services are provided by pharmacy contractors (who may supply and sell medicines, drugs and appliances) and by appliance contractors (who may only

supply or sell appliances such as trusses, wigs and stomacare aids). Collectively, pharmacy contractors and appliance contractors are known as "chemists".

157. In order to provide pharmaceutical services, it is necessary for a chemist to make an application to a Primary Care Trust (PCT) in England to be included in its pharmaceutical list (see section 42(2)(a) of the 1977 Act).

158. In Wales, following the abolition of Health Authorities in April 2003, the applications envisaged by section 42(2)(a) would, by operation of section 27 of the Government of Wales Act 1998, be made to the National Assembly for Wales (the Assembly). However, the Assembly has delegated the functions in respect of pharmaceutical services that were formerly undertaken by Health Authorities, to Local Health Boards (LHBs).

159. An application may only be granted where the PCT or the LHB is satisfied that it is necessary or desirable to grant the application in order to secure in the neighbourhood in which the premises are located the adequate provision of pharmaceutical services. This is known as the "necessary or desirable test" or "control of entry test".

160. This is provided for in section 42(2)(c) of the 1977 Act. For England, the relevant regulation is regulation 12 of the National Health Service (Pharmaceutical Services) Regulations 2005 S.I. 2005/641 ("the Regulations") (as amended). Certain exemptions to that test are set out in regulation 13 of the Regulations.

161. In Wales, the necessary or desirable (or control of entry) test is contained within regulation 4 of the National Health Service (Pharmaceutical Services) Regulations 1992 S.I.1992/662 ("the 1992 Regulations"). There are currently no exemptions to the test contained within the 1992 Regulations.

162. Chapter 1 provides for two changes. First, section 34 provides for charges to be levied in respect of a chemist's application to a pharmaceutical list. Secondly, section 35 provides for regulations to be made authorising a PCT or LHB to take account of any proposals contained in applications relating to the sale or supply of over the counter medicines and other healthcare products and advice in relation thereto.

Section 34: Power to charge

163. Section 34(1) inserts new sections 42A and 42B into the 1977 Act. These sections give the Secretary of State for Health (section 42A in relation to England) and the Assembly (section 42B in relation to Wales) powers to enable charges to be levied in respect of an application to be included in a pharmaceutical list. The fee may be determined either by the Secretary of State (or the Assembly) or by PCTs (or LHBs) where the Secretary of State (or Assembly) so directs.

164. New section 42A(1) enables the Secretary of State to give directions to PCTs requiring them to charge a fee for two types of applications to the pharmaceutical list. First, an application from a person who is not already included in a pharmaceutical list (section 42(2)(c)(i) of the 1977 Act). Secondly, an application from a person who is already included in a pharmaceutical list, but who wants to provide different services or to provide services from different premises (section 42(2)(c)(ii)).

165. New section 42A(4) requires the Secretary of State to publish any directions he gives under this section. Publication may be by electronic means.

166. Section 42A(5) requires a Primary Care Trust, where it determines the fee, to publish the fee. This would most likely be achieved by publishing the amounts of fees on the PCT website or, where the PCT does not have one, on the website of its Strategic Health Authority.

167. Section 42B makes equivalent provision in relation to Wales, save that section 42B(2) additionally enables the Assembly to specify the level of the fee or fees and, as the

powers within section 126(4) of the 1977 Act would not be available if the Assembly were to specify the level of the fee or fees payable, it also contains power to enable the Assembly to vary the level of any fee or fees charged and to make different provision for different cases or descriptions of cases.

168. Additionally, section 42B(3) makes provision for the operation of sections 42B(4) and (5) in circumstances where the Assembly delegates its functions of receiving or determining the applications referred to in section 42(2)(c)(i) or (ii) of the 1977 Act. Sections 42B(4) and 42B(5) are in analogous terms to sections 42A(1) and 42B(2).

169. Section 34(2) makes a minor amendment to section 126(4) of the 1977 Act which will in particular allow directions under section 42A or 42B to make different provision for different cases or classes of cases.

Section 35: Applications for provision of pharmaceutical services

170. Section 35 amends the 1977 Act by inserting new subsections (2B) and (2C) into section 42. Subsection (2B) provides for regulations to be made authorising a PCT or, in Wales, the National Assembly for Wales to take account of any proposals contained in the application relating to the sale or supply of over the counter medicines and other healthcare products and advice related to the supply of such products. In practice, in Wales, this function will be delegated to Local Health Boards.

171. *Subsection (2B)* sets out the circumstances in which the sale or supply of over the counter medicines and other health care products and advice related thereto can be taken into account.

172. First, subsection (2B)(a) requires that there must be two or more applications for inclusion in a PCT's (or LHB's) pharmaceutical list. The applications may be from:

- a person not already included in the PCT's (or LHB's) pharmaceutical list;
- or a person already included in the PCT's (or LHB's) pharmaceutical list in respect of pharmaceutical services or premises other than those listed in relation to him.

173. The applications must relate to the same neighbourhood as each other. Accordingly, the provision does not apply where a PCT (or LHB) receives and determines a single application alone, or two or more applications each relating to different neighbourhoods.

174. Secondly, those applications must be considered together by the PCT (or LHB) (subsection (2B) (b).

175. Thirdly, the PCT (or LHB) must be satisfied that, if each application was considered separately, each would meet the "necessary or desirable test" (as described above). However, the PCT (or LHB) must also be satisfied that if all the applications were taken together, the necessary or desirable test would not be met (subsection (2B)(c)).

176. Where the conditions of subsection (2B) are met (and assuming the Secretary of State or the Assembly makes Regulations), *subsection (2C)* enables the PCT (or LHB) to take into account, in their assessment of which application or applications to grant, the proposals in such applications relating to the sale or supply of over-the-counter medicines or other healthcare products or advice related thereto (other than by way of NHS services or in accordance with a private prescription). Sale or supply of over-the-counter medicines are not usually pharmaceutical services since such products are not supplied as part of NHS pharmaceutical services (unless ordered as part of a NHS service – for example by means of a NHS prescription). Over-the-counter medicines do not include the supply of medicines against a private prescription. Healthcare products are products and services for the diagnosis, prevention, monitoring or treatment of illness or handicap or for the promotion or protection of health.

Section 36: Arrangements for dispensing of medicines

177. Section 36 of the Act amends section 43 of the National Health Service Act 1977, which concerns the persons who may be authorised to provide NHS pharmaceutical services in England and Wales. Section 36 makes provision in relation to the supervision of transactions by pharmacists, in addition to those in section 26 of the Act (requirements about supervision in the Medicines Act).

178. The existing section 43(2) of the 1977 Act provides that, except as may be provided for by or under regulations, arrangements for the dispensing of medicines shall be made only with persons who are registered pharmacists, or are persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act, and who undertake that all medicines supplied by them under arrangements for the provision of pharmaceutical services shall be dispensed by or under the direct supervision of a registered pharmacist. Section 36(1) substitutes a new subsection (2), to clarify that regulations made by the Secretary of State under section 43(2) may provide for exemptions from the second requirement; i.e. that the registered pharmacist, or the person lawfully conducting a retail pharmacy business, undertakes that medicines will be dispensed by or under the supervision of a pharmacist. The policy intention is that the regulations would allow arrangements under which medicines are to be dispensed by registered and suitably trained pharmacy staff, without the supervision of a pharmacist.

179. Section 36(2) relates to NHS legislation in Scotland concerning the eligibility to be a contractor under a pharmaceutical care services contract. Amendment of section 17S of the NHS (Scotland) Act 1978 will allow regulations to be made in Scotland which will bring NHS legislation in Scotland into line with the proposed changes to the Medicines Act 1968 implemented by Part 2 of the Health Act. This will allow arrangements under which medicines are to be dispensed by registered and suitably trained pharmacy staff, without the supervision of a pharmacist.

PART 4CHAPTER 2

Ophthalmic Services

180. General ophthalmic services (GOS) are at present provided by optometrists (previously known as ophthalmic opticians) and ophthalmic medical practitioners (OMPs) under Part 2 of the National Health Service Act 1977 (“the 1977 Act”). These services are purely sight testing services.

181. Part 2 of that Act previously governed the services not only of optometrists and OMPs but also of general medical practitioners, dentists and chemists (the NHS “in the high street”).

182. The Health and Social Care (Community Health and Standards) Act 2003 repealed the provisions in Part 2 of the 1977 Act regarding the provision of services by general medical practitioners and dentists and provided in their place for primary medical services and primary dental services respectively under Part 1 of the 1977 Act. The general effect of these new provisions was to replace the previous arrangements for such services with new general medical services (GMS) or general dental services (GDS) contracts with providers (i.e. those bodies that provided the services contracted for), whilst having a new list system for performers (i.e. the health service professionals who actually perform the services).

183. The provisions in this Act will introduce a new “contract system” for the provision of ophthalmic services in place of the present system, very much on the model of what has already been done for primary medical services and primary dental services.

184. Part 2 of the 1977 Act will remain in force for the delivery of pharmaceutical services.

Section 37: Provision of primary ophthalmic services

185. Section 37 makes provision for primary ophthalmic services by inserting into the National Health Service Act 1977 new sections 16CD and 16CE.

186. As regards section 16CD, *subsection (1)(a)* sets out the duty of a Primary Care Trust to provide or secure the provision of a sight testing service. The testing of sight will be, as at present, carried out in accordance with section 26 of the Opticians Act and the Sight Testing (Examination and Prescription) (No. 2) Regulations 1989. The Primary Care Trust must also, by *subsection (1)(b)*, provide or secure the provision of other primary ophthalmic services prescribed in Regulations. Finally, by *subsection (1)(c)*, a PCT must provide or secure the provision of such further primary ophthalmic services to the extent it considers necessary to meet reasonable requirements.

187. *Subsection (2)* sets out the groups for which a Primary Care Trust must provide or secure a sight test pursuant to subsection (1)(a) (except any such testing which takes place in circumstances specified in regulations). Regulations may be made for other groups to become eligible for sight tests. Regulations will be made to cover all groups currently eligible for NHS funded sight tests where they are not expressly mentioned. *Subsections (3) to (10)* and section 16CE make further provision for regulations as to sight-testing and other arrangements for the provision of primary ophthalmic services.

Section 38: General ophthalmic services contracts

188. Section 38 makes provision for general ophthalmic services contracts. It inserts new sections 28WA, 28WB, 28WC, 28WD, 28WE and 28WF into the 1977 Act.

General ophthalmic services contracts: introductory

189. Provision for general ophthalmic services contracts is set out in section 28WA.

190. *Subsections (1), (2) and (3)* allow Primary Care Trusts to enter into contracts under which primary ophthalmic services are provided, specify that these contracts are to be called "general ophthalmic services contracts" and allow general ophthalmic services contracts to make provision in relation to services to be provided, remuneration and any other matters.

191. *Subsection (4)* specifies that services provided under a general ophthalmic services contract may include services which are not primary ophthalmic services and services provided outside of a Primary Care Trust's own area. This provision allows for Primary Care Trusts working in partnership with other Primary Care Trusts to provide a service.

192. *Subsection (5)* defines "contractor" in relation to a general ophthalmic services contract as any person who enters into a general ophthalmic services contract with the Primary Care Trust. A "contractor" can be either an individual or a corporate body.

Persons eligible to enter into GOS contracts

193. Provisions around persons eligible to enter into GOS contracts are set out in section 28WB.

194. *Subsections (1) and (2)* allow a Primary Care Trust, subject to such conditions and exceptions as may be prescribed, to enter into a general ophthalmic services contract with any person, apart from someone who has been disqualified from doing so by virtue of regulations made under the 1977 Act. This is wider than the present position which is restricted to registered professionals. Regulations will be made to cover disqualifications.

Exclusion of contractors

195. Provisions around exclusion of contractors are set out in section 28WC.

196. *Subsection (1)* allows the Secretary of State to make regulations providing for a Primary Care Trust, or other prescribed person, to apply to the Family Health Service Appeal Authority (FHSAA) for a person to be disqualified from entering into a general ophthalmic services contract anywhere in England.

197. *Subsection (2)* specifies that regulations may in particular provide for review by the FHSAA of a disqualification and what is to happen to the general ophthalmic services contracts to which the disqualified person is a party when they are disqualified.

General Ophthalmic Services contracts: payments

198. Provisions around General Ophthalmic Services contracts and payments are set out in section 28WD.

199. *Subsections (1) and (2)* allow the Secretary of State for Health to give directions as to the payments to be made under these contracts and to specify that general ophthalmic services contracts must require payments to be made in accordance with any such directions that are in force.

200. *Subsection (3)* provides that directions may provide for payments to be made by reference to standards, the achievement of levels of performance or to a specified scheme or scale. They provide for conditions to be imposed in respect of a payment or part of a payment; and allow provisions to be made which have effect before the date of the direction itself.

201. *Subsection (4)* requires the Secretary of State to consult representatives of those providing services or any other appropriate bodies before making a direction on payments under *subsection(1)*.

202. *Subsection (6)* defines payments in this section as including fees, allowances, reimbursements, loans and repayments.

General Ophthalmic Services contracts: other required terms

203. Provisions around General Ophthalmic Services contracts and other required terms are provided in section 28WE.

204. *Subsection (1)* allows general ophthalmic services contracts to contain such provision as may be prescribed in addition to those already specified in this Part.

205. *Subsection (2)* specifies that regulations may make provision as to standards of provision of service, who may perform the service and who the service may be provided to, variation and termination of contracts, rights of entry and inspection and adjudication of disputes. These powers allow for regulations to be made to ensure that primary ophthalmic services are properly regulated, as at present: by, for example (as now) allowing for PCTs to have the right to inspect premises of contractors and for ending contracts if a contractor is found to be unsuitable for any reason.

206. *Subsections (3) and (4)* allow for regulations which make provision for Primary Care Trusts to impose a variation of terms in a contract. The regulations may also suspend or terminate a duty under the contract to provide services of a prescribed description; in such a case the regulations may prescribe services by reference to the manner or circumstances in which they are provided. This allows a PCT to act in cases of sub-standard performance not meriting termination of the contract.

207. *Subsection (5)* requires that regulations must make provision as to patients choosing the person from whom they are to receive services which ensures that eligible patients have an appropriate choice.

General Ophthalmic services contracts: disputes and enforcement

208. Provisions around disputes and enforcement are provided for in section 28WF.

209. *Subsections (1) and (2)* allow regulations to be made for the resolution of disputes as to the terms of a proposed general ophthalmic services contract and for referral to the Secretary of State, or a person appointed by her, to determine the terms on which the contract may be entered into.

210. *Subsection (3)* allows for regulations which may make provision for persons entering into a general ophthalmic services contract to be regarded as a health service body for the purposes of section 4 of the National Health Service and Community Care Act 1990, but only so far as concerns the general ophthalmic services contract. This allows the PCT and the person providing primary ophthalmic services to enter into an NHS contract, which is not a contract in law, but an agreement subject to determination by the Secretary of State in the event of dispute between the parties, if one of them so requests.

211. *Subsection (4)* allows for regulations made under *subsection (3)* to include provision for the case where there is a change in membership of a partnership which has elected to become a health service body.

212. *Subsection (5)* allows for directions on payments made in relation to persons who have elected to become a health service body under *subsection 3* to be enforceable in a county court as though it were a judgment of the court.

Section 39 Persons performing primary ophthalmic services

213. Section 39 amends section 28X of the 1977 Act, so that, in common with primary medical services and primary dental services, only a person on the performers list of a Primary Care Trust may perform primary ophthalmic services. It also allows the Secretary of State to prescribe the qualifications and experience which a medical practitioner who applies for inclusion in a primary ophthalmic services list must have. The testing of sight (which is the only primary ophthalmic service required by these provisions) is reserved to registered optometrists and medical practitioners so only such registered practitioners may be on a performers list.

Section 40 Assistance and support

214. Section 40 amends section 28Y of the 1977 Act so PCTs may provide assistance or support to those providing or purposing to provide primary ophthalmic services. This would allow PCTs to help providers or intending providers to set up or expand primary ophthalmic services in its area

Section 41 Local Optical Committees

215. Section 41 inserts new section 45C in the 1977 Act. The new section relates to Local Optical Committees and largely mirrors the existing provision.

216. *Subsections (1), (2) and (3)* allow a Primary Care Trust to recognise a committee formed for its area that is representative of those who have entered into a general ophthalmic services contract and those who are performing primary ophthalmic services in that area and who have notified the committee that they wish to be represented. At present Local Optical Committees are representative of those on the ophthalmic list, and this will make the Committee more representative of professionals performing primary ophthalmic services in an area.

217. *Subsections (4 to 11)* specify that the committee shall be the Local Optical Committee and allow for regulations to be made in respect of consultation of that committee by the Primary Care Trust in respect of primary ophthalmic services, allows for co-option of persons to membership of the Committee, for other functions to be prescribed, for determination of committee expenses and for a levy on fees paid to contractors to meet those expenses. Subsection (10) permits the administrative expenses of the committee to be defrayed by a levy on the fees paid to those providing the services. This follows the present arrangements for funding the Committees.

Section 42 Payments in respect of optical appliances

218. Section 42 amends Schedule 12 to the 1977 Act by inserting a new paragraph 2B. Paragraph 2B allows for regulations to be made providing for the Secretary of State to give a notice to a provider of optical appliances to the effect that no further payments will be made to that person in respect of optical appliances supplied in a specified area (or for their replacement or repair) ("a local disqualification"). Regulations may also make provision for appeal rights for the person to whom the notice was given. Further, the Secretary of State may, following a local disqualification, apply to the FHSAA for a notice to be given in respect of the whole of England. This provides machinery for preventing any suppliers abusing the system from continuing to receive monies in respect of it.

Section 43 General ophthalmic services: transitional

219. Section 43 makes transitional provision.

220. *Subsections (1), (2) and (3)* require the Secretary of State to make transitional provisions in respect of persons who, immediately before coming into force of the new provisions about general ophthalmic services, were providing general ophthalmic services in England under section 38 of the 1977 Act, provide that regulations made under this section may provide that a Primary Care Trust must, under specified circumstances, and if the person wishes, enter into a general ophthalmic services contact with that person and allow the regulations to make provision as to the terms of the contract.

221. *Subsection (*4) allows regulations made under this section to make provision for the resolution of disputes in relation to a contract, entered into or proposed, and for the determination of disputes by the Secretary of State or someone appointed by the Secretary of State.

222. *Subsection (5)* allows regulations made under this section to make provision in respect of a period beginning before the coming into force of that provision or of section 38 of the Act. It is intended to exercise this power so that payments can be made on the coming into force of sections 38 or 43 to maintain the provision of ophthalmic services.

Part 4Chapter 3

Protection of Nhs from Fraud and Other Unlawful Activities

Section 44: Compulsory disclosure of documents for purposes of counter fraud or security management functions

223. *Subsection (1)* sets out the general purpose of Chapter 3, which is to confer power to require the production of documents in connection with the appropriate national authority's counter fraud functions and the Secretary of State's security management functions. The appropriate national authority is defined in section 82 as the Secretary of State in relation to England and the National Assembly for Wales in relation to Wales.

224. *Subsection (2)* explains that the appropriate national authority's "counter fraud functions", which are derived from section 2(b) of the NHS Act 1977 ("the 1977 Act"), include the power to take action to prevent, detect or investigate fraud and corruption affecting the NHS in England or Wales.

225. *Subsection (3)* explains that the Secretary of State's "security management functions", which are also derived from section 2(b) of the 1977 Act, mean his powers to take action to protect and improve the security of the persons, property and information listed in paragraphs (a) to (f).

Section 45: Meaning of "NHS body" etc.

226. Section 45 provides definitions of those who are subject to the powers in this Chapter.

227. *Subsection (7)* provides that the appropriate national authority may make changes to *subsections (2) to (6)* of this section, and if they do this they may also make any consequential amendments to this Chapter. Any such order is subject to the affirmative parliamentary procedure under section 79(4)(d).

Section 46: Notice requiring production of documents

228. Section 46 sets out when the appropriate national authority may serve a notice requesting production of documents relevant to the exercise of their counter fraud functions (defined in section 44) and where the Secretary of State may serve a notice requesting production of documents relevant to the exercise of his security management functions (also defined in section 44). They may do so where they have reasonable grounds to suspect that such documents are in the possession or under the control of an NHS body, statutory health body, health service provider, or NHS contractor and that a member, officer, director or manager of the body or provider or an employee of that organisation (or where a health service provider is an individual, that person) is accountable for the documents.

229. *Subsection (4)* requires the notice to identify either specifically or by a general description, the documents which are required.

230. *Subsection* (*5)* sets out that the notice may require when, where and how the documents will need to be produced.

231. *Subsections (8)* and (*9)* state that the deadline for producing the documents requested may be altered by an authorised officer by agreement with the person on whom the notice was served. If the notice is varied that variation must be put in writing.

232. *Subsection (10*) provides for a person to be regarded as accountable for the documents if he has either day-to–day, or overall, responsibility for managing the documents required.

Section 47: Production of documents

233. Section 47 applies once a notice has been given under section 46 by the appropriate national authority.

234. *Subsection (2)* makes it clear that an authorised officer may: take away any documents produced under the notice; take copies of the whole or specific parts of those documents; and ask the person producing those documents to explain them. An authorised officer is defined in section 55 as an officer authorised by the appropriate national authority or where these functions are to be exercised by a Special Health Authority, an appropriately authorised officer of that body.

235. *Subsection (3)* makes it clear that, if a person produces a document for the authorised officer to take away and he makes a request to the officer for a copy of that document, and the officer considers that request reasonable, the officer must as soon as is reasonably practicable give him a copy of the document.

236. *Subsection (4)* states that documents may be kept by the appropriate national authority for as long as it considers it necessary to retain them (rather than copies of them) in connection with the exercise of functions of the authority to which this Chapter applies.

237. *Subsection (5)* allows any of the produced documents that are relevant to any legal proceedings to be kept until the completion of any legal proceedings if the appropriate national authority believes that they might otherwise not be available for those proceedings.

238. *Subsection (6)* provides that if a person fails to produce the requested documents, as stated in the notice, he may be required by the authorised officer to state where those documents are.

239. *Subsection (7)* states that a person is only required to produce documents, or state to the best of his knowledge and belief where he believes the documents to be, to those who show appropriate evidence of authority.

240. *Subsection (8)* states that a person may not be required to produce documents or disclose any information which is subject to legal professional privilege.

Section 48: Delegation of functions

241. Section 48 sets out that the appropriate national authority may direct a Special Health Authority to carry out its functions of serving and executing notices for the production of documents.

242. *Subsection (3)* provides that any such directions must be given in regulations.

243. *Subsection (4)* makes it clear that regulations may make further provision in connection with the Special Health Authority's exercise of functions which have been delegated to it under *subsection (1)*.

244. *Subsection (5)* explains that the regulations may, as well as making general provision about how the Special Health Authority is to exercise delegated functions, require authorised officers investigating fraud and security incidents or breaches to be appropriately trained. The regulations may also make provision for authorised officers investigating fraud and security breaches or incidents to seek specific authorisation before personal information is required.

245. *Subsection (6)* sets out that any direction under subsection (1) is to be treated as if it had been made under section 16D of the1977 Act.

Section 49: Code of practice relating to delegated functions

246. *Subsections (1) and (2)* state that the appropriate national authority may publish a code of practice relating to the exercise of delegated functions by a Special Health Authority and to the procedures to be followed for the disclosure of information obtained through the use of these powers. The appropriate national authority must keep the code under review and may amend it as and when appropriate.

247. *Subsections (3) and (4)* provide that where the appropriate national authority decides to issue a code of practice, it must prepare a draft of that code and must consult persons or bodies which it considers appropriate before publishing the code. Similar provisions as to the publication of and consultation on a draft apply where any revisions are proposed and the changes would be substantial. *Subsection (8)* allows consultation for these purposes to have taken place before the commencement of this section.

248. *Subsection (6)* makes clear that no criminal or civil liability attaches to a failure to follow the code.

249. *Subsection (7)* provides that the code may be used in criminal or civil proceedings.

Section 50: Disclosure of information

250. Section 50 relates to the disclosure of information. It relates to information held by, or on behalf of, the appropriate national authority which has been acquired under this Chapter. The information can only be disclosed in the circumstances set out in *subsection (3)* unless the person to whom the information relates has given his consent (see *subsection (7)).*

251. *Subsection (5)* states that where information is disclosed in accordance with subsection (3) the information cannot be used or disclosed to another person unless this is for purposes connected with the functions, investigation or proceedings for the purpose of which it was initially disclosed, or in accordance with legislation or an order of a court or a tribunal.

252. *Subsection (6)* makes clear that information may be disclosed under subsection (3) despite any obligation of confidence that would otherwise apply.

Section 51: Protection of personal information disclosed for purposes of proceedings

253. Section 51 provides special protection in relation to proceedings for information obtained from personal records (as defined in the Police and Criminal Evidence Act 1984) in compliance with a notice served under section 46 where either

- the identity of an individual can be ascertained from that information alone; or
- the discloser has reasonable cause to believe that any person who may receive the information, either directly or indirectly, will be able to identify an individual by using that information and other information obtained by the appropriate national authority through the use of powers under this Chapter and disclosed by or on behalf of that national authority.

This information is referred to as 'protected information'

254. If a person discloses protected information for the purposes of any civil, criminal or relevant disciplinary proceedings they must take all reasonable steps to ensure that information is not further disclosed to any person who does not need to have that information for the purposes of the proceedings.

255. *Subsection (4)* requires the appropriate national authority to make provision through the code of practice under section 49 or otherwise to require the disclosing officer to ensure that the information is clearly identified as protected information, either by using a distinguishing mark or in some other way.

256. *Subsection (5)* provides that protected information must not be disclosed during proceedings unless the proceedings are held in private or the court or tribunal, having considered an application under *subsection (6)*, grant permission.

257. *Subsections (6) to (9)* set out the procedure to be followed by a court or tribunal on an application by a party for protected information to be disclosed. If the court or tribunal considers it necessary in the interests of justice, then it can give permission for the information to be adduced as evidence with any conditions it thinks necessary, and it must consider whether the whole or part of the proceedings should be held in private.

Section 52 Offences in connection with production of documents

258. Section 52 creates offences of failing to comply with section 46 or 47.

259. *Subsections (1) to (3)* provide that a person commits an offence if they fail to comply with section 46 or 47 by failing to produce documents that are requested or failing to provide explanations of those documents or to state where they believe they may be found. If found guilty a person could be sentenced to a maximum of 51 weeks imprisonment (3 months until the relevant provisions of the Criminal Justice Act 2003 are commenced – see section 78) or fined, or both. Further offences are committed if a person fails to produce documents after conviction and a continuing fine applies.

260. *Subsections (4)* and (*5)* state that it is an offence if a person makes a false or misleading statement in answer to questions put to them under section 46. If found guilty after a trial or indictment, a person could be sentenced to a maximum of 2 years' imprisonment or fined, or both. (see section 78 for the transitional modification of the summary penalty).

Section 53: Offences relating to disclosure or use of information

261. Section 53 relates to the offences in connection with disclosure of information obtained under this Chapter.

262. *Subsection (1)* states that a person commits an offence if he fails to comply with the provisions of section 50(2) or (5) relating to the disclosure of information or section 51(2), which relates to safeguards protecting personal information.

263. *Subsection (3)* states that if a person is charged with an offence in respect of the disclosure of information, it is a defence if he can prove (on the balance of probabilities) that he reasonably believed:

- that sharing the information was lawful; or
- that the information had already been lawfully made available to the public, or
- that the disclosure was necessary or expedient for the purpose of protecting the welfare of any individual; or
- that the disclosure was made in a way that ensured personal anonymity.

264. *Subsection (2)* provides that on conviction on indictment the penalty is a maximum of 2 years' imprisonment, a fine or both (see section 78 for the transitional modification of the summary penalty).

Section 54: Manner in which disclosure notice may be served

265. Section 54 explains the procedures associated with serving a notice requiring the production of documents.

266. *Subsection (2)* states that a notice may be delivered to a person, left at his proper address or sent to him by post.

Section 55: Interpretation

267. Section 55 defines the terms used in this Chapter.

PART 4CHAPTER 4

Audit

Section 56: Accounts and audit

268. Section 56 amends section 98 of the National Health Service Act 1977 to add a new Schedule 12B to the 1977 Act. New Schedule 12B in effect re-enacts section 98 with amendments. The provisions of the new Schedule 12B are set out in Schedule 3 to the Act.

269. Paragraph 7 of the Schedule makes new provisions to make the Comptroller and Auditor General the auditor of the annual accounts (other than those relating to charitable funds) of English and cross-border Special Health Authorities (SpHAs). This is a new provision in primary legislation, although the same substantive effect is currently in place for all existing SpHAs through orders made under section 25 of the Government Resources and Accounts Act 2000. The effect of paragraph 8 is to remove the legislative requirement for the Secretary of State to prepare summarised accounts for English and cross border SpHAs.

270. A new provision in paragraph 10 removes the requirement for English and cross border SpHAs to submit accounts to the Secretary of State in relation to funds held on charitable trust - this makes the position consistent with that for other NHS bodies.

271. Paragraph 11 provides for the accounts of any non-charitable trust fund managed by an NHS body to be excluded from summarised accounts prepared under paragraphs 8 and 9. There is no equivalent exclusion from the requirement in paragraph 4 to prepare annual accounts. Such accounts prepared by English NHS bodies which are not Special

Health Authorities are to be audited under paragraph 5 by auditors appointed by the Audit Commission.

Part 5

Appointments Commission

Section 57: The Appointments Commission

272. Section 57 provides for the Appointments Commission to be established as a body corporate in accordance with the further provisions in Schedule 4, and provides for the NHS Appointments Commission ("the NHSAC"), which is a Special Health Authority, to be abolished on such day as the Secretary of State may by order appoint under section 83.

Section 58: Commission to exercise Secretary of State's appointment functions

273. Section 58 enables the Secretary of State to direct the Appointments Commission to exercise all or part of his power to appoint the following:

- Chairmen and non-executive members of Strategic Health Authorities, Primary Care Trusts, NHS trusts and Special Health Authorities;
- Trustees for NHS trusts or Primary Care Trusts;
- Special trustees to which section 95 of the NHS Act 1977 applies;
- Chairmen and non-executive members of the statutory bodies listed in Schedule 5 to the Act; and
- Chairmen and non-executive members of any other body specified in subsection (4) ie. a body which has functions in relation to health, social care or the regulation of professionals working within the health or social care field.

274. *Subsection (5)(a)* makes it clear that the functions of the bodies to which *subsection (4)* refers may include functions which relate to matters other than health, social care or the regulation of professions associated with health and social care and may be exercisable more widely than just in England.

275. This section reproduces with amendments most of section 187 of the Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act").

Section 59: Cases where appointment functions exercisable jointly etc

276. Section 59 contains provisions which relate to the appointment functions of the Secretary of State referred to in section 58 which are exercisable by the Secretary of State jointly or concurrently with a devolved authority or any other person who is not a Minister of the Crown. The Secretary of State may direct the Appointments Commission to exercise his functions in accordance with section 58, but is required to first consult with the body or person with whom he exercises his functions jointly or concurrently. Section 59 expressly excludes powers of appointment which are exercised jointly or concurrently with Scottish Ministers. This does not, however, prevent the Secretary of State from giving a direction to the Appointments Commission in relation to functions he has in relation to that body, but he cannot give directions in relation to the powers of the Scottish Ministers.

277. *Subsection (3)* provides that when the Secretary of State delegates to the Appointments Commission appointment functions that are exercisable by him jointly or concurrently with a devolved authority or any other person who is not a Minister of the Crown, those functions are exercisable by the Appointments Commission acting alone.

278. This section replaces the provisions of section 188 of the 2003 Act.

Section 60: Commission to exercise Privy Council's appointment functions

279. *Subsection (1)* provides for the Appointments Commission to exercise the functions of the Privy Council to appoint members to the health regulatory bodies listed in Schedule 6 to the Act to the extent directed by the Privy Council.

280. *Subsection (2*) provides for the Appointments Commission to exercise any function of the Privy Council relating to the appointment of members of the Council of the Royal Pharmaceutical Society of Great Britain, to the extent directed by the Privy Council.

281. There are various minor consequential amendments to the legislation relating to these regulatory bodies in Schedules 8 and 9 to the Act.

Section 61: Commission to exercise Assembly's appointment functions

282. Section 61 enables the National Assembly for Wales to direct the Appointments Commission to exercise its appointment functions relating to the appointment of members to the Healthcare Commission and the Health Protection Agency. There are consequential amendments to Schedule 6 to the 2003 Act and Schedule 1 to the Health Protection Agency Act 2004 in Schedule 8, and repeals in Schedule 9, to the Act.

Section 62: Exercise of appointments functions

283. Section 62 provides that where directions are issued to the Appointments Commission by the Secretary of State, the Privy Council or the National Assembly for Wales in relation to their appointment functions referred to in sections 58, 60 and 61, the Appointments Commission may exercise the functions it is directed to perform in such manner as it thinks fit subject to the provisions in any enactments which relate to the making of the appointments and anything contained in the directions relating to the manner in which the function is to be exercised. This includes those matters specified in *subsection (5)*, and there is also a requirement to have regard to any guidance published by the Commissioner for Public Appointments or any government department, which is intended to ensure the Appointments Commission complies with best practice in relation to public appointments.

Section 63: Commission to assist other bodies with appointments

284. *Subsections (1) and (2)* enable the Appointments Commission to enter into an arrangement with the board of governors of an NHS foundation trust to assist it with its functions relating to the appointment of chairmen and non-executive members of the board under paragraphs 17 and 19 of Schedule 1 to the 2003 Act to such extent as may be agreed. This provision does not enable arrangements to be made so that the Appointments Commission actually makes the appointment itself. That function is exercised by the board of the foundation trust.

285. *Subsections (3) and (4)* enable the Appointments Commission to enter into arrangements to assist any Minister exercising functions in relation to England or any official acting on behalf of such a Minister, in connection with the exercise of powers relating to the appointment of the chairmen and non-executive members of any body specified in the arrangements The Minister or official would retain the power to make the appointments.

286. *Subsection (5)* provides that any body to which the powers in subsections (3) and (4) relate may be a body with functions that are exercisable more widely than only in England.

287. *Subsection (6*) limits the arrangements that a Minister may make with the Appointments Commission to assist with his appointment powers under subsection (4) to those powers that he may exercise alone and excludes any such powers that he may exercise jointly, concurrently or after consultation with a devolved administration or any other person who is not a Minister.

288. *Subsection (7)* provides that the arrangements may be contractual or otherwise but cannot include arrangements to make appointments.

Section 64: Functions connected with appointments to bodies to which section 58 or 60 applies

289. Section 64 allows the Appointments Commission to provide a range of additional services connected with appointments when it is directed to exercise appointment functions under section 58 or 60 or when it makes arrangements under section 63. These services include the giving of general advice, mentoring and other assistance and the provision of training to specified people.

Section 65: Prescribed functions

290. Section 65 provides that the Secretary of State may make regulations to confer additional functions on the Appointments Commission relating to appointments to bodies to which appointments may be made under section 58, 60 or 61 or to those to which assistance may be given as provided in section 63.

291. *Subsection (2)* includes some of the functions envisaged such as administering schemes in relation to the payment of remuneration and allowances to chairmen and non-executive members of certain bodies.

Section 66: Exercise of functions

292. This section outlines the standards the Appointments Commission must maintain in the exercise of its functions and contains provisions about other things the Appointments Commission may do in connection with the exercise of its functions.

293. *Subsection (2)* permits the Appointments Commission to engage in research, obtain and analyse data, make available materials and facilities and provide information, advice and guidance, both generally and more specifically as provided in *subsection (3)* in relation to bodies to which appointments may be made under sections 58, 60 or 61 or to those in relation to which assistance may be given as provided in section 63.

294. *Subsection (5)(d)* enables the Appointments Commission to make material available for sale (otherwise than for profit) for use in connection with appointments to those bodies it may be directed to make appointments to or provide assistance to in connection with appointments. The Appointments Commission will be covered by the Data Protection Act 1998, and all powers exercisable under this section must be exercised subject to the restrictions of that Act.

Section 67: Annual reports

295. Section 67 requires the Appointments Commission to prepare an Annual Report at the end of each financial year and sets out specific requirements which must be met.

Section 68: Other reports and information

296. Section 68 requires the Appointments Commission to provide the Secretary of State, the Privy Council, the Commissioner for Public Appointments or any government department with such information or reports in connection with its functions as they may request.

297. *Subsection (2)* requires the Appointments Commission to provide information to the National Assembly for Wales in connection with appointments to the bodies specified in section 61 as it may request.

298. *Subsections (3) and (4)* require the Appointments Commission to provide information to any of the bodies for which it has been directed to exercise appointments functions

under sections 58, 60 or 61, or to whom it is providing assistance with appointments functions under section 63.

Section 69: Transfer of staff and property etc

299. Section 69 refers to Schedule 7 to the Act, in which provision is made for the transfer of the staff, property, rights, and liabilities of the NHSAC to the Appointments Commission on the date to be appointed by the Secretary of State for the abolition of the NHSAC.

Section 70: Directions

300. *Subsection (1)* provides that any direction given by the Secretary of State, the Privy Council or the National Assembly for Wales is to be given in writing and may be varied or revoked by another direction.

301. *Subsection (2)* provides that where the Secretary of State, the Privy Council or the National Assembly for Wales has directed the Appointments Commission to exercise their appointments functions this does not preclude them from exercising those powers themselves.

Section 71: Interpretation

302. This section defines the terms used within Part 5.

303. The definition of "appointment" includes removal or suspension from office and includes any process involving an appointment and nominations for posts; and a "devolved authority" means the Scottish Ministers, the National Assembly for Wales and any Northern Ireland department.

Part 6 Miscellaneous

Social Care Bursary

Section 72: Exercise by Special Health Authority of social care training functions

304. The purpose of Section 72 is to extend the powers of the Secretary of State to enable him to direct a Special Health Authority to carry out a function that relates to the training of social care workers.

305. Section 72 inserts a new section, 67A, after section 67 of the Care Standards Act 2000 to enable the Secretary of State to direct a Special Health Authority to administer such of his functions under section 67(4)(a) of the Care Standards Act 2000 in relation to the social care bursary scheme as he may specify. These functions relate to the payment of grants, and travelling and other allowances to persons training in the work of social care workers.

306. Subsection (2) in effect extends the Secretary of State's direction making power, under section 16D of the NHS Act 1977, to enable him to direct a Special Health Authority for this purpose. It provides that a direction under new section 67A has effect as if it had been made under section 16D.

307. Subsection (3) sets out that any directions made by the Secretary of State under section 67A are to be in writing and may be varied or revoked by further directions.