Health Bill : explanatory notes.

These notes refer to the Health Bill
as introduced in the House of Commons on 27 October 2005 [Bill 69]

HEALTH BILL

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health Bill as introduced in the House of Commons on 27 October 2005. They have been prepared by the Department of Health in order to assist the reader of the Bill and help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.

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

3. Different parts of the Bill apply to different territorial areas. The application of each is set out in the paragraphs below.

SUMMARY AND BACKGROUND

4. The Bill would make a number of changes intended to protect the health of the public as well as improve the running of the NHS. The Bill covers smoke-free public places and workplaces; prevention and control of health care associated infections; management of controlled drugs in the NHS; improved provision of pharmacy and ophthalmic services; countering NHS fraud; and replacing the NHS Appointments Commission with a new body with a wider role. In addition the Bill contains changes relating to administration of the Social Care Bursary scheme; the audit of special health authorities; injury cost recovery in the NHS; and transfer of criminal liability in the NHS.

OVERVIEW OF THE STRUCTURE OF THE BILL

5. The Bill is in 7 parts:

[Bill 69–EN] 54/1

Part 1

6. Part 1 of the Bill includes provisions to make enclosed public places and workplaces smoke-free. This follows the publication of the White Paper, *Choosing Health: Making healthy choices easier*[1] in November 2004 which set out proposals to shift the balance significantly in favour of smoke-free environments. The Bill will also give the Secretary of State for Health the power to make regulations specifying places or specified areas within them that do not have to be smoke-free. These will include licensed premises as well as premises where a person has his home or is living either permanently or temporarily, for example: hotels, care homes and prisons, membership clubs and all licensed premises that do not prepare and serve food.

7. This part of the Bill extends to England and Wales.

Part 2

8. Part 2 of the Bill introduces new provisions which are concerned with the prevention and control of health care associated infections. The Bill gives the Secretary of State the power to issue a code of practice containing a range of actions to reduce the levels of health care associated infections in connection with health care that is provided or commissioned by the NHS. The NHS bodies to which the code applies, which may include any English NHS body (except Strategic Health Authorities) and any cross-border Special Health Authority ("cross-border SHA"), must observe it in discharging their duty of quality in health care under the Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act").

9. The Bill also places duties on the Commission for Healthcare Audit and Inspection ("the CHAI"), which is referred to in these notes as "the Healthcare Commission", to consider observance of the code when it carries out reviews and investigations of health care under Chapter 3 Part 2 of the 2003 Act. Where the code is not being observed, the provisions in the Bill gives the Healthcare Commission the power to serve an improvement notice, and places a duty on the Commission to report significant failings to the Secretary of State or the regulator of NHS foundation trusts ("the regulator") with a view to remedying the situation.

10. This Part of the Bill extends to England and Wales.

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1 http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4094550&chk=aN5Cor

Part 3

11. Part 3 of the Bill has two chapters:

12. Chapter 1 responds to recommendations in the Fourth Report of the Shipman Inquiry[2]. It would enable a duty to be imposed on specified organisations in the health sector to appoint an Accountable Officer to ensure the safe use of controlled drugs within the organisation's sphere of responsibility. It also enables a duty to be imposed on specified organisations concerned with controlled drugs issues in the health sector to share information about controlled drug use by health and social care professionals and to agree joint action as needed. The provisions also create a right of entry and inspection into NHS hospitals, GP practices, community pharmacies and other organisations contracted to provide services to the NHS.

13. This part of the Bill extends to the whole of the United Kingdom.

14. Chapter 2 provides for the amendment of provisions of the Medicines Act 1968, and the Health Act 1999, relating to pharmacies, pharmacists and the sale and supply of medicines. In particular, it includes changes to the requirement in the Medicines Act 1968 for a pharmacist to be in personal control of the retail sale and supply of medicines at each retail pharmacy, and changes to the provisions of the Act relating to supervision by pharmacists of the preparation, dispensing, sale and supply of medicines. This part of the Bill extends to the entire UK.

Part 4

15. Part 4 of the Bill has four chapters:

16. Chapter 1 makes changes to the National Health Service Act 1977 ("the 1977 Act") to enable charges to be levied on applications to provide NHS pharmaceutical services. The changes are in response to recommendations made in a report from The Office of Fair Trading (OFT) report: *The control of entry regulations and retail pharmacy services in the UK* published on 17 January 2003[3]. These charges may either be determined by the Secretary of State or by Primary Care Trusts (PCTs) under directions from the Secretary of State. The Chapter also makes changes to enable PCTs to consider in their assessment of applications from pharmacists to provide NHS services, what improvements they would bring to local provision of, or access to, over-the counter medicines and

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[2] See http://www.the-shipman-inquiry.org.uk/. Government's response to the fourth report at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4097904&chk=isA3Eo

[3] http://www.oft.gov.uk/business/market+studies/pharmacies.htm

other healthcare products. The Chapter also makes changes in relation to the requirement that a person who enters arrangements to provide pharmaceutical services must undertake that medicines are dispensed by, or under the supervision of a pharmacist. This part of the Bill extends to England and Wales.

17. Chapter 2 proposes changes to the 1977 Act which will remove current restrictions on who PCTs may contract with to provide general ophthalmic services. The changes will create a legal framework which is closer to that of other parts of primary care. The Bill is intended to strengthen the protection of public funds through improved controls over who may redeem optical vouchers. The provisions extend to England and Wales. They apply in England only.

18. Chapter 3 provides for a power to require the production of documents, records and data in connection with the appropriate national authority's NHS counter fraud or security management functions. This will give NHS counter fraud organisations the same powers as other regulators and auditing organisations. This measure is in response to the Department of Health consultation document entitled, *Access to Relevant Documents, Records and Data to Counter NHS Fraud: A Paper for Consultation,* launched in October 2004[4]. The response to the consultation was published on 27 May 2005. The provisions extend to England and Wales.

19. Chapter 4 makes provision for the auditing of the accounts of certain NHS bodies in England and Wales.

Part 5

20. Part 5 of the Bill covers provisions to replace the NHS Appointments Commission with a new organisation called the Appointments Commission. This is in line with the Government's response to the Public Administration Select Committee (June 2003)[5], which indicated that some Departments could benefit from using the services of the NHS Appointments Commission to support their sponsor teams in making appointments but that statutory authority would be needed to achieve this. The Bill will establish the Appointments Commission as a Non-Departmental Public Body and give it powers to exercise, if directed to do so, the appointment functions of the Secretary of State for Health and the Privy Council in relation to the appointment of chairmen and non executive members to NHS and other health and social care bodies and health professional regulatory bodies and certain appointment powers of the National Assembly for Wales. The Appointments Commission may also assist, if requested to do so, the Boards of

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[4] see consultation document and summary of responses at:
http://www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4112148&chk=T68WA5

[5] http://www.publications.parliament.uk/pa/cm200203/cmselect/cmpubadm/165/16502.htm

NHS Foundation Trusts with their similar powers of appointment and also assist, if requested to do so English ministers with their similar powers of appointment to other public bodies

Part 6

21. Part 6 of the Bill makes changes in three areas:

- Amends the Care Standards Act 2000 to enable the Secretary of State for Health to direct a special health authority to administer the Social Care Student Bursary Scheme.

- Amends the 2003 Act to allow for contributory negligence to be taken into account in a wider range of cases when the NHS recovers hospital treatment and/or ambulance costs where people receive compensation for injuries. This is an expansion of the current scheme for road traffic accident cases as set out in the Road Traffic (NHS Charges) Act 1999. This section extends to England and Wales.

- Amends the 1977 Act, the National Health Service and Community Care Act 1990 ("the 1990 Act") and the 2003 Act to give the Secretary of State for Health, or in the case of Wales, the National Assembly for Wales, the power to transfer criminal liabilities of NHS bodies on their dissolution or abolition to other specified NHS bodies.

Part 7

22. Part 7 of the Bill deals with various matters of general application, including provisions relating to orders and regulations, interpretation, commencement and extent.

TERRITORIAL EXTENT

23. The territorial extent of the Bill is set out in the summaries of each provision. The table below summarises this information.

Element	Extent
Smoke-free Workplaces	England and Wales
Prevention and Control of Health Care Associated Infections	England and Wales
Supervision of Management and use of Controlled Drugs	UK
Medicines and Pharmacies	UK
Pharmaceutical Services	England and Wales
Ophthalmic Services	England and Wales
Protection of NHS from Fraud and other Unlawful Activities	England and Wales
Audit of Special Health Authorities	England and Wales
Appointments Commission	UK
Social Care Bursary Scheme	England
NHS Injury Cost Recovery	England and Wales
Transfer of Criminal Liability	England and Wales

TERRITORIAL APPLICATION: WALES

24. There are two provisions that affect Wales differently.

25. The Protection of NHS from Fraud and other Unlawful Activities clauses in Part 4 Chapter 3 provide for powers to require the production of documents for counter fraud and security management purposes. The powers provided for counter fraud purposes are given to the Secretary of State and the National Assembly for Wales. The powers for security management purposes are limited to the Secretary of State and are not provided for the National Assembly for Wales.

26. The Appointments Commission clauses in Part 5 of the Bill provide for the Secretary of State to direct the Appointments Commission to exercise his appointments functions that are exercisable jointly or concurrently with the National Assembly for Wales after consultation with the Assembly. Other provisions enable the National Assembly for Wales to direct the Appointments Commission to exercise its appointments functions relating to the appointment of members to the Healthcare Commission and the Health Protection Agency and provides for the Assembly to make payments to the Commission in respect of the appointments functions it is directed to undertake.

COMMENTARY ON CLAUSES

PART 1

SMOKE-FREE WORKPLACES

27. Part 1 of the Bill contains provisions that will make the vast majority of enclosed places to which the public have access and enclosed workplaces smoke-free. The White Paper, *Choosing Health: Making healthy choices easier* published in November 2004 sets out proposals that will shift the balance significantly in favour of smoke-free environments, and in June 2005, a consultation document put forward further details on the policy outlined in the White Paper. The proposals would make over 99% of enclosed public places and workplaces smoke-free.

28. The Bill will ensure that all enclosed public places and workplaces (other than for example membership clubs, all licensed premises that do not prepare and serve food and a limited number of other exempt premises - predominantly places occupied as residential premises or as living accommodation) will be smoke-free.

29. It is proposed to implement these provisions so as to ban smoking in all enclosed public places and workplaces, (apart from the above exemptions), from Summer 2007.

30. The provisions extend to England and Wales.

Clause 1: Introduction

31. Clause 1, subsection (1), explains that Part 1 contains prohibitions on smoking in certain premises, places and vehicles. Subsection (2) defines "smoking" for Part 1. The definition covers being in possession of tobacco, substances that include tobacco or other substances which are alight.

Clause 2: Smoke-free premises

32. Clause 2 makes provision for enclosed or substantially enclosed premises to be smoke-free. By subsection (1) all premises to which the public have access will be smoke-free unless specifically exempted by regulations under Clause 3. However, private premises, for example, stately homes which are open to the public for one day a year and are not a person's workplace, will only need to be smoke-free for the period when the public may be present. This only applies where they are not a workplace.

33. Subsection (2) sets out that premises used as a place of work by more than one person, irrespective of whether they work there at the same time, and premises

where members of the public go to give or receive goods or a service, including for example a solicitor's office or a dressmaker's shop, will be smoke-free at all times.

34. Subsection (3) covers cases of premises which are, for example, someone's home as well as their workplace. When members of the public come to them to give or receive goods or a service, only the parts of the premises, which are used for work purposes, will be smoke-free. Those parts might include the waiting room and the area in which they receive the service.

35. Clause 2 applies only to premises, which are enclosed or substantially enclosed (subsection (4)) and the appropriate national authority will be able to specify in regulations what enclosed and substantially enclosed means (subsection (5)). By clause 75(1) the appropriate national authority in relation to England is the Secretary of State and in relation to Wales is the National Assembly for Wales. Subsection (6) is a reference to exemptions that may be made by regulations under clause 3. For example, an exemption may apply to premises where designated smoking rooms will be allowed, such as in residential care homes and psychiatric hospitals and units.

36. Subsection (7) provides that premises are open to the public if a section of the public has access to them. It includes premises to which a section of the public has free access and premises to which a section of the public has access on the payment of a fee. The word "work" also constitutes voluntary work (subsection (8)), so even if a village hall was being used to hold an event, which required volunteers, such as a scout meeting, it would still have to be smoke-free. The hall would be both a workplace and a public place.

Clause 3: Exemptions

37. Clause 3 enables regulations to be made which specify the premises in which smoking will be permitted.

38. Subsection (2) gives examples of the type of exempted premises currently envisaged. These include premises which act as an individual's dwelling or are clearly private space, whether this is on a permanent or temporary basis. This would include bedrooms in a hotel, bed and breakfast or hostel, which are designated for the use of a particular person or groups of persons by the proprietor. In premises such as prisons and care homes, which are a person's full time place of residence for an extended period, designated smoking rooms/areas may be allowed as it may be impossible for smoking to take place outside for either safety or health reasons.

39. Also included in exemptions in the examples are membership clubs and licensed premises.

40. The power in subsection (3) enables regulations to provide that premises may in certain circumstances or at specified times be smoke-free and that in other circumstances or at other times smoking may be permitted. Subsection (4) makes provision for the regulations to contain conditions. Paragraph (a) applies to the conditions that may be made for licensed premises, such as public houses. In such premises the conditions may include restrictions on what may be sold, offered for consumption or consumed there. These restrictions are intended, for example, to restrict the food that may be prepared and served. Paragraph (b) applies to all premises. It enables the regulations to provide for the designation of smoking areas by proprietors.

Clause 4: Additional smoke-free places

41. Clause 4 enables regulations to be made that designate additional smoke-free places. These will be places which are not covered by Clause 2. However, they will be places/areas where the appropriate national authority consider that there is risk of harm from second-hand smoke due to, for example, the inevitable close grouping of people (subsection (3)). Examples might be sports stadia and other outdoor areas such as entrances or exits to public buildings or workplaces, as well as bus shelters. The regulations will provide details of the circumstances in which such places will be smoke-free.

Clause 5: Vehicles

42. Clause 5 covers vehicles, vessels, aircraft, and other means of transport. It enables regulations to be made to provide smoke-free business and public transport. The regulations will set out all the descriptions of the vehicles that are to be smoke-free and the circumstances and specified areas in which they are to be smoke-free. The regulations may also exempt classes of vehicles, such as private vehicles.

Clause 6: No-smoking signs

43. Clause 6 creates a duty to display no-smoking signs and sets out whose duty it is, as well as the signage requirements, the offence provision and the defences, which may apply.

44. No-smoking signs will designate smoke-free areas and vehicles etc. Subsection (1) states that it is the duty of the person who occupies or is concerned in the management of smoke-free premises to make sure that the no-smoking signs are displayed that conform to the requirements as set out in regulations. There is also power to make requirements for the signs that must be displayed in the additional smoke-free premises mentioned in Clause 4, and smoke-free vehicles mentioned in Clause 5 (subsection (2)). The regulations will set out how and where the signs are to

be displayed. For example, they may allow special provision to be made in relation to the display of signage in listed buildings (subsection (3)). Subsection (4) states that regulations will specify the content, size, design, colour or wording of the signs. For example, it may be appropriate to have smaller signs in motor cars than in buildings or different language requirements in England and Wales.

45. By subsection (5) anyone who occupies or who is concerned in the management of smoke-free premises who does not comply with the requirements for no-smoking signs, as set out in regulations, will be guilty of an offence. Subsection (6) goes on to explain that there is however a defence which may arise where a defendant produces evidence to show that he or she was not aware, and could not reasonably be expected to have been aware, that the premises were smoke-free. This defence would be relevant where there is a dispute about the extent to which premises are enclosed. There is also a defence where the defendant produces evidence to show that he or she was not aware, and could not reasonably be expected to have been aware, that signs complying with requirements had not been displayed. For example, this defence may be relevant where vandals have removed signs. Finally, there is a defence where on other grounds it was reasonable for a defendant not to comply with the duty in subsection (1). For example, this defence might apply to a period which begins when a defendant becomes aware that a required sign has been removed by vandals and ends when he has had a reasonable period in which to display a replacement sign.

46. By subsection (7), where a defendant wishes to rely on any of these defences, he or she must provide evidence that supports the defence on which they wish to rely. Where a defendant does that, the defence should be taken to be proved unless the prosecution establishes beyond reasonable doubt that the defence does not apply. For example, a defendant might call evidence to show that a sign had been defaced as a basis for relying on the defence in subsection (6)(b) but the prosecution may establish that even before the sign was defaced it did not comply with the requirements as set out in regulations.

Clause 7: Offence of smoking in smoke-free place

47. Clause 7 sets out the offence of smoking in a smoke-free place. Smoke-free places comprise enclosed or substantially enclosed premises covered in Clause 2, additional smoke-free places covered in Clause 4, and vehicles etc covered in Clause 5.

48. By subsection (2), a person who smokes in any of these places may be guilty of an offence.

49. Subsection (3) sets out that it is a defence for a person charged with smoking in a no-smoking area to show that he or she was not aware, and could not have reasonably been expected to have been aware, that the place was smoke-free. For example, this defence may arise where no-smoking signs have been removed or are obscured.

50. Where a defendant who is charged with smoking in smoke-free premises wishes to rely on that defence, he or she must provide evidence that supports it. (subsection (4)). A person who is found guilty under this Clause will be liable to a fine as specified in regulations (subsection (5)).

Clause 8: Fixed penalties for offence of smoking in smoke-free place

51. A person who smokes in smoke-free premises, an additional smoke-free place or a vehicle may be given a penalty notice by an authorised officer of an enforcement authority who believes that the smoker has contravened clause 7 in his area. If the person pays the penalty, he will not be prosecuted for an offence. Schedule 1 contains the fixed penalty provisions.

Schedule 1

Covers the fixed penalties provisions. 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 effect of the time given to make the payment. Paragraphs 14 and 15 enables a person to request to be tried for the offence instead of paying a fixed penalty. Paragraph 16 makes provision in relation to withdrawal of notices.

Clause 9: Offence of failing to prevent smoking in smoke-free place

52. Any person who controls or is concerned in the management of smoke-free premises (and designated persons in relation to additional smoke-free places, vehicles etc) has a duty to prevent smoking in the premises. They may be guilty of an offence if they fail to comply with that duty.

53. Subsection (4) sets out that it is a defence to the offence for a defendant to show that he or she

a. took reasonable steps to stop a person smoking in a smoke-free area, such as requesting a person to stop smoking and taking steps to have the smoker evicted;

b. did not know, and could not reasonably be expected to know, that the contravention was occurring, such as where a person is given false

information by his employees; or

c. has other grounds that show that it was reasonable for him or her not to comply with the duty, for example during a period when priority had to be given priority to some other legal duty, such as preventing disorderly conduct.

54. Subsection (5), provides that where a defendant wishes to rely on that, defence, he or she must provide evidence that supports it. A person who is found guilty under this Clause will be liable to a fine as specified in regulations (subsection (6)).

Clause 10: Enforcement

55. The enforcement authorities will be designated by the Secretary of State for England and by the National Assembly for Wales for Wales (subsection (1)). Regulations will set out descriptions of places where an enforcement authority has enforcement functions and provision will be made for the transfer of investigations and prosecutions between designated enforcement bodies (subsection (2)). The enforcement authority has a duty to enforce all of the smoke-free provisions in the areas in which they have enforcement functions as set out in regulations (subsection (3)). The Secretary of State in relation to England and the National Assembly for Wales in relation to Wales may exercise enforcement functions themselves (subsection 4). Provision is made for the authorisation of officers by enforcement authorities (subsection (5)) and for regulations to provide for the qualifications which authorised officers must possess (subsection (6)). Subsection (7) introduces Schedule 2 which makes provision in relation to powers of entry, etc

Schedule 2

Covers powers of entry for enforcement. The Schedule sets out the powers of an officer who has been authorised by an enforcement authority. He/she may enter premises (other than premises used as a private dwelling), require and take possession of substances, and request information. The provision is also made for a justice of the peace to issue warrants where admission is likely to be refused etc.

56. It is intended that regulations made under subsection (1) will provide that local authorities will be enforcement authorities. It is thought that the enforcement officers of those authorities are likely to be environmental health officers. In addition the power in subsection (1) may be exercised so that health and safety officials can act as enforcement officers in specified situations. It may be that the areas of two enforcement bodies overlap (e.g. Local Authority and Health and Safety Executive).

Clause 11: Obstruction etc of officers

57. Clause 11 sets out the offence which may be committed where an authorised officer of an enforcement authority is obstructed and related provisions. The offence may be committed, for example, where a person fails to give assistance or information to the authorised officer in order for him or her to carry out the functions of his job, or where a person knowingly or recklessly gives false or misleading information. A person who obstructs an authorised officer may be liable on summary conviction to a fine not exceeding level 3 on the standard scale, as set out in regulations. The same provisions would apply to the obstruction of an enforcement officer who is acting on behalf of the Secretary of State or the National Assembly for Wales, if they take over enforcement functions.

Clause 12: Interpretation and territorial sea

58. Subsection (1) contains definitions that apply to Part 1, other than the definition of "smoking" which is in Clause 1. Subsection (2) enables the definition of premises in subsection (1) to be amended as regards offshore installations. This is needed because the reference to offshore installations in the definition of premises is to a set of regulations that might 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.

PART 2

PREVENTION AND CONTROL OF HEALTH CARE ASSOCIATED INFECTIONS

Clause 13: Code of practice relating to health care associated infections

59. This clause inserts three new sections into Part 2 of the 2003 Act.

60. 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.

61. Health care associated infections are defined in *subsection* (8). A health care associated infection is any infection to which an individual may be exposed where the risk of exposure 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.

62. "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.

63. 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)).

64. *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.

65. 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.

66. 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.

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

68. Clause 13 also inserts new *section* 47B (consultation etc.) into the 2003 Act.

69. *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.

70. *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.

71. *Subsection* (6) allows for the consultation for the purposes of this section to take place before the Act is passed.

72. Lastly, clause 13 also inserts new *section* 47C (effect of code under section 47A). 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.

73. 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)).

Clause 14: Code of practice: effects on existing functions of Commission for Healthcare Audit and Inspection

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

75. *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.

76. 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.

77. This clause 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 this section (*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)).

78. *Subsection* (6) amends section 54(2) of the 2003 Act so that it refers to the code and allows for 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.

Clause 15: Code of practice: improvement notices

79. This clause 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.

80. 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 section 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.

81. 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)).

82. 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.

83. 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)).

84. 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.

85. 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.

86. 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.

87. 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 1977 Act (c. 49) 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 existing staff, it could be required to take particular measures to put adequate training in place.

88. *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.

89. 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).

90. *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 allows the Healthcare Commission to serve another notice where, on reviewing compliance with the notice, it identifies a different failure to observe the code.

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

92. *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 believe 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.

93. *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) 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.

94. 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).

95. 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 Healthcare 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.

96. 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).

97. 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 is continuing to make progress towards full observance of the relevant provisions of the code.

98. *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* 53(A)(7) where the body in question is a PCT or a NHS Trust.

PART 3

PART 3 CHAPTER 1

SUPERVISION OF MANAGEMENT AND USE OF CONTROLLED DRUGS

99. Part 3 of the Bill contains provisions intended to strengthen the arrangements for the safe management of controlled drugs in healthcare 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 Trusts will exercise this responsibility on behalf of all the contractors with which it has 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 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.

100. 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.

Clause 16: Accountable officers and their responsibilities as to controlled drugs

101. Clause 16 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.

102. 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).

Clause 17: Co-operation between health bodies and other organisations

103. Clause 17 allows the relevant authority to make regulations to require organisations 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 cooperate would be applied to all bodies required to appoint an accountable officer under clause 16, to police forces, to social care 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.

104. 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 eg. 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 imposing duties on the accountable officer of the bodies concerned to make recommendations for action (subsection (6)) including recommendations relating to disciplinary action (subsection (7)).

Clause 18: Controlled drugs: power to enter and inspect

105. Clause 18 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, 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 clause 16 and their staff, although the clause allows for other persons to be authorised by the relevant authority.

106. Subsection (1) sets out the general power. Subsection (3) allows the authorised person to take copies of relevant records and retain them. Subsection (4) 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 (5) enables the relevant authority to exclude particular categories of designated bodies from the general authorisations under subsection (4). 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 (6).

Clause 19: Offences in connection with power to enter and inspect

107. Clause 19 creates an offence for 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 Misuse of Drugs Act. Subsection (1) defines the circumstances in which an offence is committed and subsections (2) and (3) the maximum penalties on conviction.

Clause 20 Guidance

108. Clause 20 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.

Clause 21: Crown application

109. Clause 21 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.

Clause 22 Relevant authorities

110. Clause 22 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.

Clause 23 Interpretation

111. Clause 23 defines the terms used in this chapter and details of the relevant legislation.

PART 3 CHAPTER 2

MEDICINES AND PHARMACIES

112. Chapter 2 of Part 3 of the Bill provides for the amendment of provisions of the Medicines Act 1968, and certain other enactments, relating to pharmacies, pharmacists and the sale and supply of medicines.

113. Part 4 of the Medicines Act 1968 (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 the Bill 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.

114. 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 Bill amend the 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 policy intention is to clarify the pharmacist's obligations to supervise.

115. In addition to the provisions of the Bill, 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 policy 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).

116. This part extends to the entire United Kingdom.

Clause 24: Requirements about supervision

117. Clause 24 relates to the requirements in the Medicines Act 1968 relating to the supervision of certain activities by pharmacists.

118. Clause 24(1) amends section 10 of the Medicines Act. Under the Act a licence is required to manufacture or supply medicinal products; section 10 of the Act

provides for various exemptions from the licensing requirements of the Act where, in certain circumstances, a pharmacist, or a person acting under the supervision of a pharmacist, prepares, assembles, dispenses or supplies a medicine. Clause 24(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). The policy intention is that the regulations will clarify the pharmacist's obligations to supervise.

119. Clause 24(2) amends section 52 of the Medicines Act. Section 52 of the 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). Clause 24(2) makes amendments to section 52, identical to those for section 10; i.e. enabling the Health Ministers to make regulations relating to the requirements for supervision by a pharmacist.

Clauses 25 to 28: pharmacy premises

120. 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 requires that a medicine, other than a general sale list medicine, must be sold or supplied by such a person. Sections 69 to 72 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 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.

121. 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.

122. Clauses 25 to 28 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.

Clause 25: Control of pharmacy premises: individuals and partnerships

123. Clause 25(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).

124. 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.

125. 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.

126. 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) 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.

127. Clause 25(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.

Clause 26: Control of pharmacy premises: bodies corporate

128. Clause 26 alters section 71 of the 1968 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 substituted by clause 25. Clause 26(2) makes a consequential amendment to section 124(2)(b) of the Act, which concerns offences by bodies corporate.

Clause 27: Control of pharmacy premises: representative of a pharmacist in case of death or disability

129. Clause 27 amends section 72 of the Medicines Act 1968, which specifies the conditions 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. Clause 27 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.

Clause 28: The responsible pharmacist

130. Clause 28 inserts a new section 72A of the Medicines Act, to make provision in relation to the "responsible pharmacist" mentioned in sections 70, 71 and 72 of the 1968 Act (as amended by the Bill).

131. 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). 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.

132. Section 72A(6) provides for the Health Ministers to make further provisions in regulations in relation to the responsible pharmacist. Section 72A(7) then 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.

133. Section 72A(8) 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.

134. Under section 72A(9) and (10), 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.

135. Clause 28(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 Act. The clause removes the requirement to send to the registrar the name of the pharmacist in personal control of the retail pharmacy business.

136. Clause 28(3) amends section 84 of the Medicines Act 1968, which relates to criminal offences under Part 4 of the 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 £1,000).

137. In relation to other obligations under section 72A, e.g. those requiring the responsible pharmacist to ensure safe and effective running of the pharmacy business and to maintain procedures to secure such running, it is proposed that enforcement will be dealt with under the legislation governing the provision of pharmaceutical services under the NHS and/or the regulation of the pharmacy profession.

138. Clause 28(4) and (5) makes consequential amendments to sections 108 and 110 of the Medicines Act, which relate to enforcement. The amendments ensure that, as with the enforcement of other provisions of the Act relating to the retail sale 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.

Clause 29: Order-making powers

139. Clause 29 amends section 129(5) of the Medicines Act, which provides that regulations under the 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 Act. This means that if, as is proposed, the Health Ministers make further orders under the 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.

Clause 30: Orders under section 60 of the Health Act 1999

140. Clause 28 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. Clause 28 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 1968 except in relation to a profession regulated by the Pharmacy Act 1954.

PART 4

PART 4 CHAPTER 1

PHARMACEUTICAL SERVICES

141. Chapter 1 concerns pharmaceutical services provided under section 41 of the National Health Service Act 1977 ("the 1977 Act").

142. 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, stomacare aids). Collectively, pharmacy contractors and appliance contractors are known as "chemists".

143. 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).

144. 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).

145. 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".

146. This is provided for in section 42(2)(c) of the 1977 Act and, for England, in 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.

147. 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.

148. Chapter 1 provides for two changes. First, clause 31 provides for charges to be levied in respect of a chemists' application to a pharmaceutical list. Secondly, clause 32 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.

Clause 31: power to charge

149. Clause 31(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.

150. 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)).

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

152. 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.

153. 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.

154. 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).

155. Clause 31(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.

Clause 32: Applications for provision of pharmaceutical services

156. Clause 32 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 LHB 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.

157. 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.

158. 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.

159. 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.

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

161. 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)).

162. 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. Sale or supply of over-the-counter medicines are not 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.

Clause 33: Arrangements for dispensing of medicines

163. Clause 33 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. The clause makes provision in relation to the supervision of transactions by pharmacists, in addition to those in clause 24 (requirements about supervision in the Medicines Act).

164. 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. Clause 33 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.

PART 4 CHAPTER 2

OPHTHALMIC SERVICES

165. 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).

166. 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").

167. 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).

168. The provisions in this Bill 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.

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

Clause 34: Provision of primary ophthalmic services

170. *Clause 34* makes provision for primary ophthalmic services by inserting into the National Health Service Act 1977 new sections 16CD and 16CE.

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

172. *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.

Clause 35 General ophthalmic services contracts

173. *Clause 35* makes provision for a general ophthalmic services contract. It inserts new sections 28WA, 28WB, 28WC, 28WD, 28WE and 28WF into the 1977 Act:

- *Section 28WA: General ophthalmic services contracts (GOS): introductory*

- *Section 28WB: Persons eligible to enter into GOS contracts*
- *Section 28WC: Exclusion of contractors*
- *Section 28WD: General Ophthalmic Services contracts: payments*
- *Section 28WE: General Ophthalmic Services contracts: other required terms*
- *Section 28WF: General Ophthalmic services contracts: disputes and enforcement*

Clause 36: Persons performing primary ophthalmic services

174. Clause 36 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.

Clause 37: Assistance and support

175. Clause 37 amends section 28Y of the 1977 Act to include providers of primary ophthalmic services alongside providers of primary medical and dental services as being eligible for assistance and support under that Act.

Clause 38: Local Optical Committees

176. Clause 38 inserts new section 45C in the 1977 Act. The new section relates to Local Optical Committees.

Clause 39: Payments in respect of optical appliances

177. Clause 39 amends Schedule 12 to the 1977 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 may be made to that person in respect of optical appliances supplied at a particular location or in a particular area (or replaced or repaired) ("a local disqualification" or "stop notice"). 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 Family Health Services Appeals Authority (FHSAA) for an order to be given to that person in respect of the supply of optical appliances

(or their replacement or repair) wherever it occurred ("a national disqualification" or "stop order").

Clause 40: General ophthalmic services: transitional

178. Clause 40 makes transitional provision.

179. *Schedule 8*

180. Schedule 8 makes amendments consequential to the provisions relating to primary ophthalmic services.

PART 4 CHAPTER 3

PROTECTION OF NHS FROM FRAUD AND OTHER UNLAWFUL ACTIVITIES

Clause 41: Compulsory disclosure of documents for purposes of counter fraud or security management functions

181. 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 clause 78 as the Secretary of State in relation to England and the National Assembly for Wales in relation to Wales.

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

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

Clause 42: Meaning of "NHS body" etc.

184. Clause 42 provides definitions of those who are subject to the powers in this Chapter.

185. *Subsection (7)* explains that the appropriate national authority may make changes to subsections (2) to (6) of this clause, 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 clause 75(4)(c).

Clause 43: Notice requiring production of documents

186. Clause 43 sets out when the appropriate national body investigating fraud and security incidents and breaches may serve a notice requesting production of documents relevant to the exercise of their functions defined in clause 41. 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 or 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.

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

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

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

190. *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.

Clause 44: Production of documents

191. Clause 44 applies once a notice has been given under clause 43 by the appropriate national authority.

192. *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 clause 52 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.

193. *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.

194. *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).

195. *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.

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

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

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

Clause 45: Delegation of functions

199. Clause 45 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.

200. *Subsection (3)* provides that any such directions should be given in regulations.

201. *Subsection (4)* makes it clear that regulations may make further provision in connection with the Special Health Authority's exercise of this function.

202. *Subsection (5)* explains that the regulations may, as well as making general provision about how the Special Health Authority is to exercise the delegated function, 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.

203. *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.

Clause 46: Code of practice relating to delegated functions

204. *Subsection (1)* states that the appropriate national authority may publish a code of practice relating to the exercise of these functions by a Special Health Authority. The appropriate national authority must keep the code under review and may amend it as and when appropriate.

205. *Subsections (3) and (4)* require the appropriate national authority to consult persons or bodies which the authority considers appropriate before publishing the code of practice or any amended versions where the changes are substantial. Subsection (8) provides that consultation for these purposes will include any consultation undertaken before this section is commenced.

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

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

Clause 47: Disclosure of information

208. Clause 47 relates to the disclosure of information. It relates to information held by, or on behalf of, the appropriate national authority and which has been acquired under these provisions. 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)).

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

210. *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 done for purposes connected with the function, proceedings, enactment or order in relation to which it was disclosed.

Clause 48: Special protection for personal records

211. Clause 48 provides special protection for information obtained from personal records (as defined in the Police and Criminal Evidence Act 1984) and from which the identity of an individual can be ascertained either from that information alone or that information and other information held by the appropriate national authority and disclosed by or on behalf of the appropriate national authority.

212. If a person discloses such personal records for the purposes of any court proceedings they must take such measures as are necessary to ensure that information contained in the records is not disclosed to a member of the public without an order from a court (*subsection (3).* However a party to those proceedings may apply for permission to use the records as evidence (subsection (4)).

213. *Subsection (5)* makes it clear that if the party applies for such permission from the court, and the court 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.

214. *Subsection (6)* explains that the conditions could require some of the proceedings being held in a closed court.

Clause 49 Offences in connection with production of documents

215. Clause 49 creates offences of failing to comply with clause 43 or 44.

216. *Subsections (1) to (3)* provide that a person commits an offence if they fail to comply with clause 43 or 44 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 clause 74) or fined, or both. Further offences are committed if a person fails to produce after conviction and a continuing fine applies.

217. *Subsection (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 clause 44. If found guilty, a person could be sentenced to a maximum of 2 years' imprisonment or fined, or both. (see section 74 for the transitional modification of the summary penalty).

Clause 50: Offences relating to disclosure or use of information

218. Clause 50 relates to the offences in connection with disclosure of information obtained under these clauses.

219. *Subsection (1)* states that a person commits an offence if he fails to comply with the provisions of clause 47(2) or (5) relating to the disclosure of information or clause 48(3) which relates to safeguards protecting personal information.

220. *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 for the purpose of protecting the welfare of any individual; or
- that the disclosure was made in a way that ensured personal anonymity.

221. *Subsection(2)* provides that on conviction on indictment the penalty is a maximum of 2 years' imprisonment, a fine or both (see clause 74 for the transitional modification of the summary penalty).

Clause 51: Manner in which disclosure notice may be served

222. Clause 51 explains the procedures associated with serving the notice for the production of documents.

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

PART 4 CHAPTER 4

AUDIT OF SPECIAL HEALTH AUTHORITIES

Clause 53: Accounts and audit

224. Clause 53 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.

225. 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 .

226. 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.

227. The effect of paragraph 11 is that the accounts of any non-charitable trust funds which an NHS body manages are only to be excluded from summarised accounts. There is therefore a new requirement for all NHS bodies to submit accounts of any non-charitable trust funds which they manage to the Secretary of State, and for these to be audited by auditors appointed by the Audit Commission.

PART 5

APPOINTMENTS COMMISSION

Clause 54: The Appointments Commission

228. Clause 54 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 clause 79.

Clause 55: Commission to exercise Secretary of State's appointments functions

229. Clause 55 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 1977 Act applies;
- Chairmen and non-executive members of the statutory bodies listed in Schedule 5; and
- Chairmen and non-executive members of any other body exercising functions in relation to health, social care or the regulation of professionals working within the health or social care field.

230. *Subsection (5)(a)* makes it clear that the functions of the bodies to which subsection (4) refers may 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.

231. This clause reproduces with amendments most of section 187 of the 2003 Act.

Clause 56: Cases where appointments functions exercisable jointly etc

232. Clause 56 contains provisions which relate to the appointment functions of the Secretary of State referred to in clause 55 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 clause 55, but is required to first consult with the body or person with whom he exercises his functions jointly or concurrently. Clause 56 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 alone has in relation to that body, but he cannot give directions in relation to the powers of the Scottish Ministers.

233. *Subsection (3)* provides that when the Secretary of State delegates those of his 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 to the Appointments Commission, those functions are exercisable by the Appointments Commission acting alone.

234. This clause replaces the provisions of section 188 of the 2003 Act

Clause 57: Commission to exercise Privy Council's appointments functions

235. *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 when and to the extent directed by the Privy Council.

236. *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.

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

Clause 58: Commission to exercise Assembly's appointment functions

238. Clause 58 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 Bill.

Clause 59: Exercise of appointments functions

239. Clause 59 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 clauses 55, 57 and 58, 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.

Clause 60: Commission to assist other bodies with appointments

240. *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.

241. *Subsections (3) and (4)* enable the Appointments Commission to enter into arrangements to assist any Minister or any official acting on behalf of the Minister with his appointment powers relating to the appointment of the chairmen and non-executive members of any body to which the powers relate. This provision is limited to the Minister's powers in connection with his appointment functions for England. The Minister retains the power to make the appointments.

242. *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.

243. *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.

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

Clause 61: Functions connected with appointments to bodies to which sections 55 or 57 applies

245. Clause 61 allows the Appointments Commission to provide a range of additional services connected with appointments when it is directed to exercise appointment functions under clause 55 or 57 or when it makes arrangements under clause 60. These services include the giving of general advice, mentoring and other assistance and the provision of training to specified people.

Clause 62: Prescribed functions

246. Clause 62 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 clauses 55, 57 or 58 or to those to which assistance may be given as provided in clause 60.

247. *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 specified boards.

Clause 63: Exercise of functions

248. This clause 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.

249. *Subsection (2)* permits the Appointments Commission to engage in research, to obtain and analyse data, make available materials and facilities and provide information, advice and guidance generally and more specifically as provided in subsection (3) in relation to bodies to which appointments may be made under clauses 55, 57 or 58 or to those in relation to which assistance may be given as provided in clause 60.

250. *Subsection (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.

Clause 64: Annual reports

251. Clause 64 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.

Clause 65: Other reports and information

252. Clause 65 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 their functions as they may request.

253. *Subsection (2)* requires the Appointments Commission to provide information to the National Assembly for Wales in connection with appointments to the bodies specified in clause 58 as it may request.

254. *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 clauses 55, 57 or 58, or to whom it is providing assistance with appointments functions under clause 60.

Clause 66: Transfer of staff and property etc

255. Clause 66 refers to Schedule 7, 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.

Clause 67: Directions

256. *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.

257. *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.

Clause 68: Interpretation

258. This clause defines the terms used within Part 5.

259. 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

SOCIAL CARE BURSARY

Clause 69: Exercise by the Special Health Authority of social care training functions

260. The purpose of Clause 69 is to extend the powers of the Secretary of State to direct a Special Health Authority to enable it to carry out a function that relates to the training of social care workers.

261. Clause 69 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 2000 Act 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.

262. Subsection (2) in effect extends the Secretary of State's direction making power, under section 16D of the 1977 NHS Act, 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.

263. 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.

NHS COSTS RECOVERY

Clause 70: NHS Costs Recovery

264. Clause 70 amends section 153 of the Health and Social Care (Community Health and Standards) Act 2003 by substituting new wording for subsection (9) of that section. The substitution changes the meaning of "qualifying claim" for the purposes of subsection 153(10) of the 2003 Act so that it no longer refers solely to claims settled by mediation, but to any claim other than those identified in subsection (3) of section 153 or described in regulations. This will allow contributory negligence to be taken into account in cases where the primary claim is settled by a wide range of alternative dispute resolution mechanisms, rather than only where it has been settled by mediation.

TRANSFER OF CRIMINAL LIABILITY

Clause 71: Transfer of criminal liabilities of certain NHS bodies

265. The purpose of clause 71 is to address a lacuna which arose from the case of R v The Pennine Acute Hospitals NHS Trust formerly Rochdale Health Care NHS Trust 2003. In that case, the Court of Appeal held that the general power in paragraph 30 of Schedule 2 to the NHS and Community Care Act 1990 to transfer property, rights and liabilities on the dissolution of an NHS trust did not include the power to transfer criminal liabilities. The policy of the Department is that there should be a power to transfer the criminal liabilities of NHS bodies on their dissolution or abolition to other NHS bodies so that accountability for criminal offences committed by any such bodies can be retained within the NHS and will not wither away. Clause 71, therefore, gives the Secretary of State for Health the power to transfer the criminal liabilities of any English NHS body on its abolition or dissolution to another specified English NHS body and the National Assembly for Wales the power to transfer the criminal liabilities of a Welsh Special Health Authority, a Local Health Board and a Welsh NHS Trust on its abolition or dissolution to another specified Welsh NHS body.

266. Subsection (1) amends the NHS Act 1977 to provide the power to transfer the criminal liabilities of a Strategic Health Authority on its abolition to another Strategic Health Authority, a Special Health Authority, a Primary Care Trust, an NHS trust and an NHS foundation trust.

267. Subsection (2) amends the NHS Act 1977 to provide the power to transfer the criminal liabilities of a Special Health Authority on its abolition to another Special Health Authority, a Strategic Health Authority, a Primary Care Trust, a Local Health Board, an NHS trust and a NHS foundation trust.

268. Subsection (3) amends the NHS Act 1977 to provide the power to transfer the criminal liabilities of a Primary Care Trust on its dissolution to another Primary Care Trust, a Strategic Health Authority, a Special Health Authority, an NHS trust and an NHS foundation trust. Subsection (4) amends the NHS Act 1977 to provide the power to transfer the criminal liabilities of a Local Health Board on its dissolution to another Local Health Board.

269. Subsection (5) amends the National Health Service and Community Care Act 1990 to provide the power to transfer the criminal liabilities of an NHS Trust on its dissolution to another NHS trust, a Strategic Health Authority, a Special Health Authority, a Primary Care Trust, a Local Health Board and an NHS foundation trust.

270. Subsection (6) amends the 2003 Act to provide the power to transfer the criminal liabilities of an NHS Foundation Trust on its dissolution to another NHS foundation trust, a Primary Care Trust and an NHS trust.

271. Subsection (7) amends section 28 of the 2003 Act. Section 28 of the 2003 Act is a supplementary section to section 27 of the same Act regarding the merger of one NHS Foundation Trust with another NHS Foundation Trust or NHS Trust. The effect of the amendment is threefold. Firstly, it places a requirement on the applicant to set out in the application to the independent regulator of foundation trusts for authorisation to merge which criminal liabilities it proposes should transfer to the new NHS foundation trust. Secondly, where an authorisation for a merger is given, it places a requirement on the independent regulator of foundation trusts to specify the criminal liabilities to be transferred to the new NHS foundation trust and on the Secretary of State to make an order transferring those specified criminal liabilities to the new NHS foundation trust. Thirdly, it gives the Secretary of State the power to transfer any remaining criminal liabilities by order to another NHS foundation trust, a Primary Care Trust or an NHS trust.

PART 7

FINAL PROVISIONS

Clause 72: Offences by bodies corporate etc.

272. Clause 72 clause provides that if an offence under any provision of the Bill is committed by a body corporate (e.g. a company), a partnership or some other unincorporated body, and it is proved that the offence was committed with the consent or connivance of an officer of the company, or of a partner in the case of the partnership, or of an officer or member of the unincorporated association, then that individual is guilty of the offence too. Proceedings can therefore be brought against that individual as well as against the company etc.

273. Such an individual is similarly liable if the offence is proved to be attributable to any neglect on their part.

Clause 73: Offences committed by partnerships and other unincorporated associations

274. Clause 73 contains provisions regarding certain procedural matters where criminal proceedings are brought against partnerships or other unincorporated associations. First, subsections (1) and (2) provide that proceedings are to be brought against the partnership (and not individual partners) or, in the case of an unincorporated association, against the association (and not any of the individual members). However, subsection (7) makes it clear that these provisions do not prejudice the liability of such individuals under clause 72. Secondly, subsections (3) and (4) provide that the rules of court applicable to a body corporate shall apply to a

partnership or an unincorporated association. Thirdly, subsections (5) and (6) provide for fines to be paid out of partnership assets or the funds of the association.

Clause 74: Penalties for offences: transitional modification for England and Wales

275. Certain offences under this Bill may be punished, on summary conviction, by terms of imprisonment, up to given maximum periods, These are the maximum periods permitted under the provisions of the Criminal Justice Act 2003. Clause 74 provides that where the offence concerned was committed prior to the commencement of those provisions in the Criminal Justice Act 2003, the maximum possible period of imprisonment on summary conviction shall be the (shorter) maximum period that was previously possible.

Clause 75: Orders and regulations

276. Clause 75 provides that all regulation and order making powers will be subject to the negative resolution procedure, unless subsection (4) applies or the order is a commencement order under clause 79.

277. Subsection (3) lists those orders and regulations which will be subject to greater Parliamentary scrutiny than the negative resolution procedure provides for. The orders and regulations, which will be subject to the affirmative resolution procedure, are as follows:

- regulations to specify the exemptions (cluse 3), designate additional smoke-free places (clause 4), standard scale of fine for the offences of failing to display no smoking signs (clause 6(8)), of smoking in a smoke-free place (clause 7(5)) and of failing, if controlling or concerned with the management of a smoke-fee place, to stop a person from smoking there (clause 9(6));

- regulations to make provision for or in connection with accountable officers (controlled drugs) where such provision would have the effect of amending or repealing any provision of an Act or of an Act of the Scottish Parliament (clause 16);

- an order amending the provisions of clause 42(2) to (6), which define the meanings of "NHS Body", "health service provider", "NHS contractor" and "statutory health body" for the purposes of the provisions relating to the protection of the NHS from fraud etc, and making such consequential amendments to these "counter fraud" provisions as are considered appropriate (clause 42(7));

- an order making supplemental or other provision for the purposes of or in consequence of the Act, or to give full effect to it, where such provision would amend or repeal any provision of an Act or of an Act of the Scottish Parliament (clause 76(3));

- regulations specifying the level of financial penalty (and discount for early payment) payable under a fixed penalty notice issued for a smoking related offence (paragraphs 5 or 8 of Schedule 1).

Clause 76: Amendments, repeals and revocations

278. Clause 76 makes provision in respect of amendments, repeals and revocations.

Clause 77: Expenses

279. Clause 77 makes provision for expenditure incurred under or attributable to the provisions of the Bill to be paid out of money provided by Parliament.

Clause 78: Interpretation

280. Clause 78 makes provision regarding the interpretation of certain terms.

Clause 79: Commencement

281. Clause 79 makes provision for the coming into force of the provisions of the Bill.

Clause 80: Short title and extent

282. Clause 80 makes provision as to the short title and as to the extent of the provisions of the Bill. Clause 80(5) concerns the provisions of Chapter 2 of Part 3 of the Act, which amend provisions of the Medicines Act 1968 relating to pharmacies, pharmacists and retail supply of medicines. Section 109 of the Medicines Act provides that enforcement of the provisions of the Act in Scotland is the responsibility of the Secretary of State. Those enforcement functions have been transferred to the Scottish Ministers by the Scotland Act 1988 (Transfer of Functions to the Scottish Ministers etc) Order 1999. Clause 80(5) modifies the effect of the Order, so that the function of enforcing the new provisions of the Medicines Act relating to pharmacies does not transfer to the Scottish Ministers. Responsibility for enforcing the new provisions would therefore remain with the Secretary of State.

FINANCIAL EFFECTS

283. There are financial implications for three of the provisions contained in the Bill. Details of these as well as information on the Appointments Commission are given below.

Smoke-free Provisions

284. The estimated costs to the public sector of the smoke-free provisions in the Bill can be broken down as follows:

- Enforcement – costs to local authorities of between £7 and £20 million per annum. These costs will be met from existing Department of Health budgets.

- Falling cigarette sales - revenue losses to the Exchequer of between £859 and £972 million per annum.

- Education/communication - £1 million per annum, to be met from existing budgets.

285. It is also estimated that between £40 and 100 million per annum of NHS expenditure will be saved through reduced smoking prevalence. There will also be considerable benefits for public health, estimated to be worth between £2,321 and £2,601 million per annum in averted deaths.

Health Care Associated Infections

286. The estimated costs to the NHS of the provisions in the Bill to tackle health care associated infection can be broken down as follows:

- Additional investment in infection control – £50 million per annum.

- Additional spending on Trust cleanliness – £4 million per annum.

- Regulatory burden on the NHS – £34 million per annum.

287. There will also be estimated additional costs to the Healthcare Commission of £3.3 million per annum. All these costs will be met from existing budgets.

Controlled Drugs

288. It is estimated that the proposed new arrangements for monitoring and inspecting the use of controlled drugs as detailed in the Bill will have set-up costs to the NHS of £1 million, and running costs of £4 million per annum. These costs will be met from existing budgets.

Appointments Commission

289. These provisions set up the Appointments Commission as a new non-departmental public body. This will be funded from existing budgets currently used to fund the NHS Appointment Commission, which will be abolished by these provisions.

PUBLIC SERVICE MANPOWER

290. It is proposed that local enforcement officers dealing with smoke-free enclosed public places and workplaces. Based on consultation response we estimate this might be between 220 and 318 enforcement staff initially, tailing off as legislation becomes embedded.

291. These provisions set up the Appointments Commission as a new non-departmental public body. This will be staffed by staff currently employed by the NHS Appointment Commission, which will be abolished by these provisions.

SUMMARY OF THE REGULATORY IMPACT ASSESSMENT

292. The Partial Regulatory Impact Assessment can be found at www.dh.gov.uk/actsandbills. Two elements of the Bill are considered to have the greatest potential impact on charities, business, the voluntary sector or the public sector. These are the proposals on smoke-free public places and workplaces and on the prevention and control of healthcare associated infections. Other elements will have less significant impacts.

COMMENCEMENT DATE

293. The commencement clause (clause 79) provides that the Bill, with certain exceptions, will come into force on a day appointed by order by the Secretary of State. The exceptions to that provision are as follows.

294. The following provisions will come into force on the day on which the Bill is passed:

- clause 71,
- clauses 75, 76(3) and (4), 77, 78, 79 and 80, and
- Paragraphs 36, 51 and 52 of Schedule 8 and clause 76(1) so far as relating to those paragraphs.

295. Part 5 comes into force on such day as the Secretary of State, after consultation with the National Assembly for Wales, may by order appoint.

296. Part 1 comes into force on such day as the appropriate national authority may by order appoint.

297. The following provisions come into force on such day as the Scottish Ministers may by order appoint:

- clause 33(2);
- so far as extending to Scotland, clause 70 and paragraph 53 of Schedule 8, and
- clause 76(1) so far as it relates to paragraph 53 of Schedule 8 (so far as it so extends).

298. The following provisions come into force in relation to Wales on such day as the National Assembly for Wales may by order appoint:

- Part 1 and clauses 72 and 73, so far as relating to offences under that Part, and
- Paragraphs 24(a) and 43 of Schedule 8 and clause 76(1), so far as relating to those paragraphs.

299. The following provisions come into force on such day as the National Assembly for Wales may by order appoint:

- Chapter 1 of Part 3 and clauses 72 to 74 so far as relating to the Assembly's functions under that Chapter or to offences committed in relation to those functions;
- Chapter 1 of Part 4 so far as relating to the Assembly's functions under clauses 42 and 42B of the National Health Act 1977;
- Chapter 3 of Part 4 and clauses 72 to 74 so far as relating to the Assembly's counter fraud functions in relation to the health service in Wales or to offences committed in relation to those functions;
- clause 53 and Schedule 3 so far as relating to Welsh NHS bodies;
- paragraphs 42 and 60 of Schedule 8;
- Schedule 9 so far as it repeals provisions of the Public Audit (Wales) Act 2004, and
- clause 76(1) and (2) so far as relating to these provisions in Schedule 8 and 9.

300. The following provisions come into force on such day as the Department of Health, Social Services and Public Safety may by order appoint:

- Chapter1 of Part 3 so far as relating to the functions of the Department of Health, Social Services and Public Safety under that Chapter, and
- Clauses 72 and 73 so far as relating to offences committed in relation to those functions.

EUROPEAN CONVENTION ON HUMAN RIGHTS

301. The Secretary of State has made a statement under section 19 of the Human Rights Act 1998 that the Bill is, in her view, compatible with the European Convention on Human Rights.

302. The following issues are considered to be particularly engaged in relation to the Bill, although careful consideration has been given to all aspects of human rights in relation to these proposals.

Part 1: Smoking

303. The question of whether taking measures of the kind provided for in this Bill to control the use of products which are lawfully on sale to persons over 16 would breach the rights in Article 8 (right to respect for private and family life) was considered. However, it was not felt that, even if such rights were engaged, there would be any breach of such rights. Any interference with such rights is justified on the grounds of protection of health.

Part 2: Prevention and control of health care associated infections

304. The powers to enter and inspect premises, to obtain and disclose information and to require explanation may potentially infringe an individual's rights under Article 8 of the Convention. However the Department is of the opinion that the provisions pursue a number of legitimate aims, including public safety, the protection of health and the protection of the rights and freedoms of others and it is considered that the provisions are proportionate.

305. It is possible that the rights in Article 1 of the First Protocol (the right to the peaceful enjoyment of possessions and protection of property) are also engaged but again the provisions are felt to be proportionate to the legitimate aim of protecting public safety and public funds and to strike a fair balance between the protection of an individual's right to property and the benefit to the public as a whole.

Part 3: Controlled drugs

306. The duty to disclose information and the entry and inspection powers may engage the rights in Article 8. However, in both cases it is considered that any such interference with Article 8 rights would be justified as being for a legitimate aim (the protection of the health of patients or the general public) and proportionate to the pursuit of such aim.

307. The power of entry and inspection may also engage the rights under Article 1 of the First Protocol. However, it is again considered that the use of such powers, being for the purpose of securing the safe, appropriate and effective management and use of controlled drugs, would be proportionate to the pursuit of the legitimate aim of protecting patients and the public.

308. It is considered that Article 6 (the right to a fair trial), in particular the right against self incrimination inherent in that Article, may potentially be engaged where a police officer or authorised person inspects stocks of controlled drugs or precautions taken for the safe custody of such drugs as the person in charge of the drugs may have committed an offence under the Misuse of Drugs Act 1971. However it is considered that the limitation on the purpose for which such powers of entry and inspection may

be used (for securing the safe, appropriate and effective management and use of controlled drugs) strikes a fair balance between and individual's privilege against self incrimination and the wider benefit to the public as a whole in the proper control of the management and use of controlled drugs.

Part 4: Drugs, Medicines and Pharmacies

Ophthalmic services

309. The power of entry and inspection, which are necessary to monitor compliance with quality standards and to make providers and suppliers accountable for the funding distributed to them, could amount to an interference with the rights in Article 8 and in Article 1 of the First Protocol. However, it is considered that any such interference would be justified, being for a legitimate aim and proportionate.

Protection of NHS from fraud and other unlawful activities

310. The powers to require the production of documents in Chapter 3 could be considered to be an interference with the rights in Article 8. Any such interference is considered justifiable. The exercise of such powers will be subject to regulations and to a code of practice. The provisions pursue a legitimate aim, the prevention of crime, the protection of health and the protection of rights and freedoms of others. The powers are considered to be proportionate to that aim and to strike the right balance between the protection of an individual's right to respect for his private and family life and the benefit to the wider public.

311. Article 6 of the Convention may be engaged where a disclosure is sought from a person in the course of an investigation and in relation to the defences to the criminal charges . However, it is considered that the powers are proportionate and will be exercised in accordance with regulations and a code of practice and that a fair balance is struck between the rights of the individual not to incriminate himself and the benefit to the wider public such as reduction of wastage of resources which may otherwise be spent on healthcare.

Part 6: Transfer of criminal liabilities

312. It is not considered that these provisions would breach Article 7 (the right not to be held guilty of a criminal offence on account of an act or omission that was not a criminal offence at the time) as the act for which any body to which the liability transferred may be prosecuted would have been an offence at the relevant time.

313. It is not considered that Article 6 would be contravened as, even if there was difficulty in any particular case in gathering evidence in defence of any charge, such matters could be dealt with by the trial judge in that particular case.

HEALTH BILL

EXPLANATORY NOTES

These notes refer to the Health Bill
as introduced in the House of Commons on 27th October, 2005 [Bill 69]

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