These notes refer to the Health Bill [HL]
as introduced in the House of Lords on 15th January 2009 [HL Bill 18]

HEALTH BILL [HL]

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health Bill [HL] introduced in the House of Lords on 15th January 2009. They have been prepared by the Department of Health in order to assist the reader of the Bill and to 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. A glossary of terms and abbreviations used in these explanatory notes is provided at the end of these notes.

OVERVIEW OF THE STRUCTURE

4. The Bill contains provisions on a range of policies. Part 1 contains provisions arising directly from the NHS Next Stage Review regarding quality and delivery of NHS services.

5. Part 1 establishes a framework for the NHS Constitution, requires NHS providers to publish Quality Accounts, enables direct payments for health care to be made to patients (initially as part of a pilot scheme) and enables payments as prizes to be made to promote innovation in the provision of health services in England.

6. Part 2 contains powers in relation to health bodies that arise out of a Government review of the NHS performance regime. The provisions enable the appointment of trust special administrators and relate to suspension of Ministerial appointees to NHS and other health bodies.

7. Part 3 contains miscellaneous provisions relating to advertising and display of tobacco products and the sale of such products from vending machines, pharmaceutical services, a complaints procedure for privately arranged or funded adult social care and the disclosure of

information relating to general medical practitioners (GPs) or dental practitioners by Her Majesty's Revenue and Customs (HMRC).

BACKGROUND AND SUMMARY

Part 1

General Background: NHS Next Stage Review

8. In a statement to the House of Commons on 4th July 2007[1], the Secretary of State for Health, Rt Hon. Alan Johnson, announced a review of the National Health Service (NHS). The NHS Next Stage Review, which was led by Lord Darzi of Denham, sought to develop a plan for the NHS over the next decade by engaging with patients, staff and the public.

9. On 4th October 2007 the Interim Report, *Our NHS, Our Future*,[2] was published. The Interim Report set out a 10 year plan for the NHS and considered how the NHS could become fairer and more personalised, effective and safe. It set out immediate and longer term priorities in these areas.

10. The NHS Next Stage Review Final Report, *High Quality Care for All*,[3] was published on 30th June 2008. The Final Report responds to the 10 Strategic Health Authority strategic plans and sets out a strategy for an NHS with a focus on quality.

11. This Bill implements those parts of the NHS Next Stage Review that require primary legislation. These include provisions concerning the NHS Constitution, Quality Accounts and direct payments for NHS healthcare services.

Chapter 1 - NHS Constitution

12. The Interim Report published in October 2007 set out the case for an NHS Constitution. This was said to be—

> "to enshrine the values of the NHS and increase local accountability to patients and public."

13. In June 2008, the Department of Health published *A Consultation on the NHS Constitution*[4].

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1 Available at: http://www.publications.parliament.uk/pa/cm200607/cmhansrd/cm070704/debtext/70704-0004.htm#07070441000007

2 Department of Health (2007). – *Our NHS, Our Future - NHS Next Stage Review Interim Report.* Department of Health, London.
Available at: http://www.ournhs.nhs.uk/fromtypepad/283411_OurNHS_v3acc.pdf

3 Department of Health (2008). *High Quality Care for All - NHS Next Stage Review Final Report,.* CM 7432. Department of Health, London.
Available at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825

14. The clauses on the NHS Constitution set out the proposed duties on specified bodies involved in the provision, commissioning or regulation of NHS care and on other persons providing NHS services under contracts or arrangements. The clauses provide that those bodies are to have regard to the NHS Constitution, and for the Secretary of State to review the NHS Constitution at least every ten years, after consultation with patients, the public, staff and providers. They also provide that the Secretary of State must revise the accompanying Handbook to the NHS Constitution at least every three years. The Secretary of State must also report on the effect of the NHS Constitution on patients, public and staff every three years.

Chapter 2 - Quality Accounts

15. *High Quality Care for All* said that from April 2010 all healthcare providers working for or on behalf of the NHS would be placed under a legal requirement to publish an annual Quality Account. Clauses 6 and 7 of the Bill therefore propose placing a duty on those providers although clause 6 also gives the Secretary of State a regulation-making power enabling him to exempt prescribed persons, or the providers of prescribed services, from this requirement.

16. The duty is to publish prescribed information about quality of services for the period 1st April to 31st March each year. Clause 6 gives the Secretary of State a further regulation-making power, including the power to determine the form, content and timetable for publication of a Quality Account.

Chapter 3 - Direct payments

17. The Government made a commitment in *High Quality Care for All* to pilot personal health budgets, including pilots of direct payments for health care where this makes most sense for particular patients in certain circumstances. Direct payments are monetary payments to patients with which they can procure health care services.

18. Direct payments have been used in lieu of social care services for some time. These are payments for individuals to purchase services from various providers directly, to meet their social care needs. This Bill allows for a similar model of direct payments to be used for health care.

19. Clause 9 in Chapter 3 of Part 1 of the Bill allows the Secretary of State to make monetary payments to patients in lieu of providing them with health care services. In practice, this power will be delegated to local NHS organisations, generally Primary Care

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[4] Department of Health (2008). *The National Health Service Constitution – A Draft for Consultation, July 2008. Department of Health, London.*
Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085814

Trusts (PCTs), though some Strategic and Special Health Authorities may also wish to use direct payments. Initially, this power will be available in pilot schemes only.

20. Direct payments for health care will allow patients to purchase health care services directly from a variety of providers, including private organisations and the voluntary sector.

21. The Bill provides powers to allow the Secretary of State to make regulations to govern the operation of direct payments and direct payment pilot schemes. The regulations will set out the persons who might receive direct payments, potentially appropriate health conditions and the services in respect of which payments could be made. The regulations might also set out specific categories of patients who would not be able to access direct payments for health care, or services that could not be purchased. The regulations will also make provision for the necessary monitoring in order to ensure accountability and that direct payments are effective in meeting the health outcomes agreed between the patient and the NHS. Provision could also be made for money to be recouped in the event of a large surplus or misuse of direct payments.

22. Each pilot scheme will be reviewed. Following a review there is a power, subject to approval by each House of Parliament under the affirmative resolution procedure, to remove the requirement that payments be made through a pilot scheme so that direct payments could become more generally available while still following rules in the framework established by regulations.

Chapter 4 - Innovation prizes

23. *High Quality Care for All* stated the Government's intention to create prizes for innovations that directly benefit patients and the public. Clause 12 will enable the Secretary of State to make payments to promote greater innovation in the provision of health services.

Part 2

Chapter 1 – Trust special administrators

24. A consultation, entitled *Developing an NHS Performance Regime*[5], published in June 2008, announced the Government's intention to—

> "establish a failure regime for state-owned providers that reflects the Government's obligations to ensure service continuity and protect public assets."

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[5] Department of Health (2008). Developing an NHS performance Regime , Department of Health, London. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085215

25. It detailed the steps that would be taken if an NHS organisation failed, either for clinical or organisational reasons.

26. Following the responses to *Developing an NHS Performance Regime*, the Government published a further consultation entitled *Consultation on a regime for unsustainable NHS providers*[6], in September 2008, which set out Government proposals and sought views on such a regime.

27. Chapter 1 of Part 2 of the Bill amends the National Health Service Act 2006 (NHS Act) to make provision for the appointment of trust special administrators (TSAs) for NHS trusts, NHS foundation trusts and PCTs in England. These NHS bodies are all established under the provisions of the NHS Act. The provisions of the Bill are intended to form part of a wider process for dealing with the poor performance and failure of such NHS bodies. The appointment of a TSA will be the final stage in this process, where earlier attempts to improve performance using existing powers have failed and the continuation of the body in its present situation is not considered to be in the interests of the health service.

28. Under the existing provisions of the NHS Act, there are various means to address poor performance of NHS trusts and PCTs. Strategic Health Authorities are responsible for the performance management of PCTs and NHS trusts; and the arrangements between NHS trusts and PCTs may include provisions relating to performance. The Secretary of State has power to give directions to NHS trusts and PCTs about their exercise of functions (section 7 of the NHS Act) and has powers to remove the chairs and non-executive directors (regulations made under Schedules 3 and 4 to the NHS Act). If the Secretary of State considers that a trust is not performing its functions adequately or at all, or that there are significant failings in the way the body is being run, and he considers it appropriate to intervene he may make an intervention order under sections 66 and 67. Finally, the Secretary of State may dissolve a PCT or an NHS trust (section 18(2) of, and paragraph 28 of Schedule 4 to, the NHS Act).

29. NHS foundation trusts are regulated by the Independent Regulator of NHS foundation trusts (Monitor). NHS foundation trusts must comply with the terms of the authorisation given by Monitor under the NHS Act. Under the NHS Act, Monitor has powers to require a failing trust to do specified things or to remove its directors (section 52), and to require it to enter a voluntary arrangements with creditors (section 53). If a trust fails to comply and Monitor considers that the further exercise of its powers would not be likely to secure the provision of the goods or services which the authorisation required the trust to provide, the Secretary of State may make an order to dissolve the trust, transfer property or liabilities to other NHS bodies and apply the provisions of insolvency legislation relating to the winding up of companies to the trust, in order to deal with outstanding liabilities, etc (and see below) (section 54).

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[6] Department of Health (2008). *Consultation on a regime for unsustainable NHS providers.* Department of Health, London Available at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_087835

30. Historically, failing NHS trusts have been dealt with in a relatively *ad hoc* way. The policy intention is to provide for a regime in legislation which will ensure clarity and transparency and ensure that key processes of the regime are applied systematically. For NHS foundation trusts, the provisions of the Health and Social Care (Community Health and Standards) Act 2003, now consolidated in the NHS Act, provide for a regime in which a dissolving trust could be subject to insolvency procedures similar to the statutory provisions for the winding up of companies (Part 4 of the Insolvency Act 1986), but there has been continuing discussion about how such procedures would be modified and applied. The Department has now concluded that it is not appropriate to apply insolvency procedures to NHS foundation trusts. *Consultation on a regime for unsustainable providers*[7], September 2008 and *The Regime for Unsustainable NHS Providers: response to consultation*, January 2009 provide further background and set out more detail on the policy.

31. The clauses in Chapter 1 of Part 2 of the Bill enable the Secretary of State to appoint, or in the case of a PCT, require a body to appoint, a TSA to take control of the body for a temporary period, during which the TSA would be responsible for ensuring that the body continued to exercise its functions (for example, in the case of an NHS trust, that it continued to provide services in accordance with its NHS contracts). During the period of appointment, the TSA must produce a report stating the action which the TSA recommends the Secretary of State should take in relation to the trust. The TSA will be obliged to consult various persons before finalising the report. The Secretary of State will be obliged to make a decision as to what action to take in the light of the final report, within 20 working days of receiving the report. In the case of NHS foundation trusts, it will be for Monitor to initiate the regime, by giving a notice to the Secretary of State in accordance with the draft provisions. On receiving such a notice, the Secretary of State will be obliged to make an order providing that the trust shall cease to be a foundation trust and instead become an NHS trust, and appointing a TSA (described as "de-authorisation"). A de-authorised NHS foundation trust will become an NHS trust and be subject to the other provisions of the Chapter relating to such trusts.

Chapter 2 – NHS and other health appointments: suspension

32. The Healthcare Commission report in October 2007 on outbreaks of *Clostridium difficile* at Maidstone and Tunbridge Wells NHS Trust[8] highlighted the need for swift action, in extreme cases, to suspend chairs and members of NHS boards. A Review of NHS public appointments processes carried out with the NHS and published in January 2008, recommended that the Secretary of State should have powers to suspend those he appoints and that powers to suspend should, as with powers to appoint, be delegated to the Appointments Commission.

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[7] Department of Health (2008). *Consultation on a regime for unsustainable NHS providers.* Department of Health, London Available at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_087835

[8] Healthcare Commission (2007) Investigation into outbreaks of Clostridium difficile at Maidstone and Tunbridge Wells NHS Trusts, Commission for Healthcare Audit and Inspection

33. The Government consulted on proposals to introduce new powers of suspension for chairs and other non-executives of PCTs and NHS trusts between January and March 2008[9]. The Government stated during the consultation that the Government's intention was to introduce the same powers for chairs and non-executives of Strategic Health Authorities and national bodies established by the Department of Health in a second phase of legislation to follow later in 2008/09. The proposals for local trusts and PCTs received full support from the NHS and, following amendments to regulations[10], the Appointments Commission was provided with the new powers on 16th June 2008.

34. A Government consultation document,[11] published in July 2008, considered proposals to introduce powers of suspension and a single approach to the removal of chairs and non-executives of this second group of bodies - Strategic Health Authorities, national health sector bodies and arms length bodies. The consultation concluded on 9 October and, as with the previous local consultation, it was supportive of introducing the new suspension proposals.

35. Chapter 2 of Part 2 of the Bill introduces a Schedule providing for new powers of suspension of chairs and other members of NHS and other health bodies. The provisions in the Schedule amend the relevant legislation dealing with appointments to Strategic Health Authorities, Special Health Authorities, Monitor, standing advisory committees (which advise the Secretary of State pursuant to section 250 of the NHS Act such as the Joint Committee on Vaccination and Immunisation), community health councils in Wales, the Human Tissue Authority, the Health Protection Agency, the Human Fertilisation and Embryology Authority, bodies established under the Medicines Act 1968, the Alcohol Education and Research Council and the Appointments Commission itself. The provisions will also ensure that appropriate procedures are or could be put in place for notification of suspension, review on request after a given period of time and provision for temporary replacement of a suspended chair.

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9 Department of Health (2008). *Removing or suspending chairs & non-executives from PCTs and NHS Trusts: Consultation on introducing powers of suspension.* Department of Health, London.

10 [10] The Primary Care Trusts and National Health Service Trusts (Membership and Procedure) Amendment Regulations 2008 (SI 2008/1269)

11 Department of Health (2008). *Removing or suspending chairs & non-executives of Health Bodies – Consultation on introducing new powers of suspension.* Department of Health, London.
Available at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_086308

Part 3

Miscellaneous

Tobacco

36. The Department of Health's *Consultation on the Future of Tobacco Control,* [12] published on 31st May 2008, sought views from stakeholders and the public on further action to combat smoking and the negative effects it has on public health. The consultation was expressed as the first step in developing a new national tobacco control strategy and focused on four main areas: reducing smoking rates and health inequalities caused by smoking; protecting children and young people from smoking; supporting smokers to quit; and, helping those who cannot quit.

37. The consultation ran for three months and sought views on possible measures to reduce young people's access to tobacco and on reducing exposure to tobacco promotion. The consultation received over 96,000 responses, details of which can be found in the consultation report published on 8th December 2008[13].

38. The Bill includes a series of amendments to the Tobacco Advertising and Promotion Act 2002 (the 2002 Act), the Children and Young Persons (Protection from Tobacco) Act 1991 (the 1991 Act) and the Children and Young Persons (Protection from Tobacco) (Northern Ireland) Order 1991 (the 1991 (NI) Order) to adopt some of these measures for protecting public health. The amendments make further provision in relation to the display of tobacco products and the sale of such products from vending machines.

39. The new provisions to be inserted into the 2002 Act subject to exclusions, prohibit the display of tobacco products in the course of a business. Powers are also given to the Secretary of State, the Welsh Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland (DHSSPSNI) to regulate (but not prohibit) the display of prices of tobacco products and (Secretary of State only) the display of tobacco products and their prices in the course of a business on a website where such products are offered for sale. The 1991 Act and the 1991 (NI) Order are also amended to give power to the Secretary of State, the Welsh Ministers, and DHSSPSNI to prohibit, or otherwise impose requirements in relation to, the sale of tobacco from vending machines.

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[12] Department of Health (2008). *Consultation on the Future of Tobacco Control.* Department of Health, London. Available at: http://www.dh.gov.uk/en/consultations/liveconsultations/dh_085120

[13] Department of Health (2008). *Consultation on the Future of Tobacco Control – Consultation Report:December 2008.* Department of Health, London. Available at: http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_091382

Pharmacy

40. The Department of Health published a pharmacy White Paper, *Pharmacy in England: Building on strengths - delivering the future*[14] on 3rd April 2008. The White Paper set out the Government's programme for a reformed pharmaceutical service. A series of consultation events were held in May to consider the proposals in more detail[15]. The White Paper also provided the Government's response to the *Review of NHS pharmaceutical contractual arrangements*[16] commissioned in 2007 and conducted by Anne Galbraith. In addition, the White Paper took account of recommendations of the All Party Pharmacy Group's report, *The Future of Pharmacy*[17] published in June 2007.

41. The White Paper was developed to align closely with the NHS Next Stage Review and the development of a new primary and community care strategy, *Our Vision for primary and community care,*[18] which was published on 3rd July 2008.

42. The White Paper promised consultation on a number of proposals for structural change, including any necessary revisions to primary legislation. That consultation, *Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change,*[19] began on 27th August 2008 and ended on 20th November 2008. A series of national listening events were held in October 2008 in support and a report of these events, together with the Department's report of the consultation concerning the primary legislation proposals contained within this Bill, is expected to be published on 16th January 2009.

43. The purpose of the pharmacy provisions contained in the Bill is threefold. First, the provisions concerning market entry replace the current "control of entry" test which is applicable to all pharmaceutical contractors seeking to enter onto a pharmaceutical list. The new test requires PCTs first to develop and to publish statements of pharmaceutical needs and then to use these to determine applications. This would replace the current test which refers to the adequacy of the pharmaceutical services in the neighbourhood in which the premises are to be located.

44. Second, the market exit provisions enable PCTs to be given new powers to take action where there are concerns about the quality or performance of services provided by pharmacy contractors.

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[14] Department of Health (2008). *Pharmacy in England: Building on strengths - delivering the future,* Cm 734. Department of Health, London.
Available at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_083815
[15] A summary report of those is now available at http://www.dh.gov.uk/en/Publicationsandstatistics/index.htm
[16] Anne Galbraith (2007). *Review of NHS pharmaceutical contractual arrangements – Report by Anne Galbraith*
[17] All-Party Pharmacy Group (2007). *The Future of Pharmacy- Report of the APPG Inquiry.*
Available at: http://www.appg.org.uk/home.htm
[18] Department of Health (2008). *Our Vision for primary and community care,* Department of Health, London.
Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085937
[19] Department of Health (2008). *Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change.* Department of Health, London.
Available at: http://www.dh.gov.uk/en/consultations/Liveconsultations/DH_087324

45. Third, the pharmacy provisions enable PCTs themselves to provide local pharmaceutical services (LPS) in certain circumstances.

Adult social care

46. An issue raised in the House of Lords during the debate on the Health and Social Care Act 2008 was that users of adult social care that has been arranged or funded privately do not have recourse to an independent complaints procedure. A government commitment was made in Parliament[20] to address this matter at the next legislative opportunity.

47. The objective of the policy is to enable the Local Commission for Administration (the LGO) to investigate complaints made by people whose adult social care is not arranged or provided by a local authority. This group comprises people who arrange or pay for their own care, estimated to be about 35 per cent of adult social care service users, and also those who are given direct payments by local authorities to purchase their own adult social care services.

48. People whose care is funded and arranged by a local authority have access to the existing statutory local authority social services complaints procedure, under the Health and Social Care Act 2003, and have the right to refer their complaints to the LGO if they are dissatisfied with the local authority's response. During 2007, Department of Health Ministers became concerned, as a result of representations made by stakeholders, that the current arrangements for people arranging and paying for their own care were unsatisfactory and that such people should also have access to independent investigation of their complaints. The Government made a commitment in Parliament to address this issue.

49. The LGO is responsible for investigating complaints of injustice arising from maladministration by local authorities and certain other bodies. The LGO comprises three Local Commissioners, and they each deal with complaints from different parts of the country. They investigate complaints about most council matters including housing, planning, education, social services, consumer protection, drainage and council tax.

50. The Bill inserts a new Part 3A into the Local Government Act 1974 (the 1974 Act), the legislation that established the LGO. Part 3A creates a new scheme, which extends the remit of the LGO to include the investigation of complaints about adult social care not arranged or funded by a local authority. The new scheme is largely modelled on the existing legislation for investigation of complaints concerning local authorities in Part 3 of the 1974 Act.

[20] Available at: http://www.publications.parliament.uk/pa/ld200708/ldhansrd/text/80616-0015.htm

Disclosure of Information

51. HMRC holds information relating to the tax affairs of individuals – including those of GPs and dentists who provide medical and dental care on behalf of the NHS. It has been the practice of HMRC, over a number of years, to assist in statistical enquiries carried out by or on behalf of the Department of Health relating to the earnings and expenses of GPs and dentists by providing summarised data in aggregate anonymised form.

52. This annual exercise is currently conducted on behalf of the Secretary of State and the devolved administrations by the NHS Information Centre for Health and Social Care. The dental exercise does not currently include Scotland or Northern Ireland but there are proposals to extend the scope to include them in future.

53. The Commissioners for Revenue and Customs Act 2005 prohibits officials of HMRC from disclosing information of any kind held by HMRC in connection with a function of the HMRC – subject to certain exceptions.

54. The Bill provides a further exception to the current restrictions on the disclosure of information by HMRC to enable them to continue to participate in these annual earnings and expenses exercises.

55. The Bill will allow HMRC to disclose certain information relating to the income and expenses of GPs and dental practitioners to the Secretary of State and to the devolved administrations or to persons providing services to, or exercising functions on behalf of, the Secretary of State or the devolved administrations. The information disclosed will be an anonymised summary of the earnings and expenses of GPs and dental practitioners and will not extend to other details disclosed to HMRC as part of the tax assessment process, such as matters unconnected with their professional activities.

TERRITORIAL EXTENT: FURTHER INFORMATION

56. Most of the provisions contained in the Bill extend to England and Wales only, with a small number of provisions extending more widely. The Bill contains provisions that apply to England only, to Northern Ireland only, to England and Wales, to England Wales and Northern Ireland, and to the United Kingdom.

Part 1: NHS Constitution, Quality Accounts, Direct payments and Innovation prizes

57. Part 1 of the Bill extends to England and Wales, but applies only to England.

Trust special administrators

58. Chapter 1, Part 2 of the Bill extends to England and Wales but the provisions apply only in relation to NHS bodies in England.

NHS and other health appointments: suspension

59. The amendments made by clause 17 in Chapter 2, Part 2 of, and Schedule 3 to, the Bill have the same extent as the Acts which are being amended. Some of the new powers of suspension relate to bodies operating in more than one part of the UK.

Tobacco

60. The clauses relating to tobacco in Part 3 of the Bill have the same extent as the enactments which the provisions amend. The 2002 Act extends to the whole of the UK, the 1991 Act extends to England and Wales and Scotland, and the 1991 (NI) Order extends to Northern Ireland only. However, the amendments made to the 2002 Act by clauses 18 and 19, and those to the 1991 Act made by clause 20, do not apply in relation to Scotland.

Pharmaceutical services

61. The changes regarding pharmaceutical services in clauses 23, 24, 25, 26 and 27 extend to England and Wales but apply only in England. The amendments made by clauses 28, 29 and 30 extend to England and Wales but apply only in relation to Wales.

Adult social care

62. The changes to the powers of the LGO in England in clause 31 and schedule 5 extend to England and Wales, but apply only in relation to England.

Disclosure of information

63. The provisions in clause 32 for disclosure of information held by HMRC extend to the whole of the UK.

Territorial application: Wales

64. The Bill confers a number of new or expanded powers on the Welsh Ministers. The following table lists the clauses within the Bill which affect the existing powers of, or confer new powers or duties on, the Welsh Ministers.

Clause	Subject of clause	Effect on the powers of the Welsh Ministers
Part 2, clause 17 and Schedule 3	Powers to suspend chairs and non-executive directors	Schedule 3 gives the Welsh Ministers new or expanded powers in relation to the suspension of members of Special Health Authorities, community health councils and standing advisory committees. In relation to Special Health Authorities and standing advisory committees which are cross-border bodies, functions exercisable by the Welsh Ministers under the National Health Service (Wales) Act 2006 (the NHS (Wales) Act) are exercisable concurrently with the Secretary of State and functions exercisable by the Secretary of State under the NHS Act are exercisable concurrently with Welsh Ministers.
Part 3, clause 18	New section 6(A1) of the 2002 Act (prohibition of advertising: exclusion for specialist tobacconists)	Enables the Welsh Ministers to provide in regulations that specialist tobacconists do not commit an offence under section 2 of the 2002 Act (prohibition of tobacco advertising) if a tobacco advertisement on their premises meets certain requirements. This power replaces an automatic exclusion for specialist tobacconists currently provided by section 6(1) of the 2002 Act.
Part 3, clause 19	New section 7A(2) and (3) of the 2002 Act (prohibition of tobacco displays)	Enables the Welsh Ministers to make regulations to provide for the meaning of "place" and to distinguish between displays and advertisements for the purposes of the prohibition on displaying tobacco products (under the new section 7A(1) of the 2002 Act).
Part 3, clause 19	New section 7B(3) of the 2002 Act (tobacco displays: exclusions	Enables the Welsh Ministers to make regulations providing for exclusions from the prohibition on displaying tobacco products

	and defence)	(under the new section 7A(1) of the 2002 Act).
Part 3, clause 19	New section 7C(1) of the 2002 Act (displays: prices of tobacco products)	Enables the Welsh Ministers to make regulations imposing requirements in relation to the display in a place in Wales of the prices of tobacco products.
Part 3, clause 20	New section 3A of the 1991 Act (sales from vending machines in England and Wales)	Enables the Welsh Ministers to make regulations prohibiting or imposing requirements in relation to the sale of tobacco from vending machines in Wales.
Schedule 4, paragraph 7(6)	New section 13(5A) of the 2002 Act (enforcement)	Creates a power for the Welsh Ministers to take over the conduct of any proceedings, in respect of an offence under the 2002 Act committed in Wales, instituted in England and Wales by another person.
Schedule 4, paragraph 12	Substitutes a new definition of "appropriate Minister" in section 21(1) of the 2002 Act (interpretation)	By amending the definition of "appropriate Minister" for the purposes of the 2002 Act, powers under section 4(3) (power to grant exclusions from the section 2 prohibition of tobacco advertising) and section 13(3) (power to direct that any duty imposed on an enforcement authority shall be discharged by the appropriate Minister) of the 2002 Act are transferred to the Welsh Ministers.
Part 3, clause 30	Powers of Local Health Boards in Wales	Enables Welsh Ministers to make regulations which will permit Local Health Boards to provide local pharmaceutical services (LPS) in certain circumstances, which will be set out in regulations made by the Welsh Ministers.
Part 3, clause 29	Pharmaceutical and ophthalmic services	Enables Welsh Ministers to make regulations setting out requirements as to the quality of services provided by pharmaceutical and ophthalmic practitioners.
Part 3, clause	Legal gateway for data on GP and	Enables the disclosure of summarised anonymised statistical information relating to

32	dentists' pay	GPs and dental practitioners to Welsh Ministers and persons providing services to them or exercising functions on their behalf.

Territorial application: Scotland

65. This Bill does not contain any provisions falling within the terms of the Sewel Convention. Because the Sewel Convention provides that Westminster will not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish Parliament, if there are amendments relating to such matters which trigger the Convention, the consent of the Scottish Parliament will be sought for them.

Northern Ireland

66. The Bill makes provision for DHSSPSNI in relation to one matter that invokes a legislative consent motion, namely the provisions on suspension of members of the Human Tissue Authority and bodies established under the Medicines Act 1968 contained in clause 17 and Schedule 3.

COMMENTARY ON CLAUSES

PART 1 – QUALITY AND DELIVERY OF NHS SERVICES

Chapter 1 - NHS Constitution

Clause 1: NHS Constitution

67. Clause 1 identifies the NHS Constitution and the Handbook as the documents published before the day on which Bill receives Royal Assent entitled *The NHS Constitution* and *The Handbook to the NHS Constitution*, or as any revised versions of those documents published in accordance with the provisions of Chapter 1.

Clause 2: Duty to have regard to NHS Constitution

68. Clause 2 requires specified bodies to have regard to the NHS Constitution when performing their NHS functions. Those functions include the commissioning or provision of NHS services or, in the case of Monitor and the Care Quality Commission, the regulation of those services. The bodies to which the new duty applies are: Strategic Health Authorities, PCTs, NHS trusts, Special Health Authorities, NHS foundation trusts, Monitor and the Care Quality Commission.

69. In addition, those bodies that provide or assist in providing NHS services under arrangements under section 12(1) of the NHS Act or who are providing NHS services under contracts or other arrangements made pursuant to the provisions of the NHS Act listed in *subsection (6)*, must (in doing so) also have regard to the NHS Constitution. This includes bodies providing primary care services, such as pharmaceutical services, dental services and general medical services.

70. *Subsection (7)* defines 'NHS services' as being health services provided in England for the purposes of the NHS in England. *Subsection (8)* provides that references to the provision of services include the provision of services carried out jointly with another person.

71. The Constitution is for the NHS in England only. However, on 3rd July 2008, England, Scotland, Northern Ireland and Wales committed to a high-level statement declaring the principles of the NHS across the UK. This was to reaffirm that the underlying principles of the NHS across the UK remain the same, even as the way the NHS provides care may vary between the four countries, reflecting their different needs and circumstances.

Clause 3: Availability, review and revision of NHS Constitution

72. Clause 3 provides that the Secretary of State must ensure that the NHS Constitution continues to be available to patients, staff and members of the public. The NHS Constitution and the Handbook will be published under the general powers of the Secretary of State in relation to the NHS. The effect of *subsection (1)* (and clause 4(1)) is to prevent the Secretary of State from using those general powers to withdraw either document. The Secretary of State is able to revise the NHS Constitution from time to time but will be obliged to undertake appropriate consultation before any revision.

73. The Secretary of State is obliged to review the whole NHS Constitution at least once every ten years, with the first review to be completed by 5th July 2018, ensuring that patients, staff, members of the public, the providers of NHS services and the independent regulators are consulted. After any change is made to the NHS Constitution, the Secretary of State is obliged to republish it.

74. This clause defines "patients" as those to whom NHS services are being provided. It defines "staff" as those persons who are employed by, or working in some other capacity for, the bodies and other persons who, in providing NHS services, are obliged to have regard to the NHS Constitution where those persons are employed or work in (or in connection with) the provision, commissioning or regulation of NHS services.

Clause 4: Availability, review and revision of Handbook

75. Clause 4 provides that the Secretary of State must ensure that the Handbook continues to be available to patients, staff and members of the public (see discussion in paragraph 72 above).

76. The Secretary of State is able to revise the Handbook at any time, but is obliged to review it at least once every three years, with the first review completed by 5th July 2012. After any change to the Handbook, the Secretary of State is obliged to republish it. The intention is for this document to be updated periodically, as Department policy evolves.

Clause 5: Report on effect of NHS Constitution

77. This clause provides that the Secretary of State must publish a report on the effect that the NHS Constitution has had on patients, the public and staff. Each report is required to be laid before Parliament. The first report must be published no later than 5th July 2012 and subsequent reports will be required to be published every 3 years thereafter.

78. The Department intends to use the reports on the effect of the NHS Constitution to assess what further measures are required in order for the NHS Constitution to be effective. The aim of the report is to ensure that all bodies who are required to do so are having regard to the NHS Constitution – and so to the principles, values, as well as the legally-binding rights and the pledges, that the NHS is committed to achieve.

Chapter 2 – Quality Accounts

79. *Subsection (1)* provides that NHS providers in public ownership (as defined in *subsection (2)*)must publish prescribed information, which will be known as a Quality Account, in respect of each reporting period, covering the NHS services they provide or make arrangements for the provision of. The intention is to ensure that providers of NHS services produce regular reports on the quality of the services they provide, and that these reports are publicly available. The definition of "reporting period" in clause 7(2) means that NHS providers will have to publish an annual Quality Account covering the period 1 April to 31 March each year. Regulations will set out the content of a Quality Account.

80. *Subsection (2)* defines those NHS providers in public ownership.

81. *Subsection (3*) provides that bodies or other persons not in NHS ownership who provide, or make arrangements for the provision of, NHS services must publish Quality Accounts. It defines these persons by referring back to clause 2(4) and (5). These subsections set out different types of private sector provider of NHS services, including providers of primary medical and other primary healthcare services, by reference to the type of service they provide, and the legislation under which these services are provided.

82. *Subsection (4)* ensures that any reference to NHS services includes services which are provided jointly with another provider. The intention is to ensure that each provider should publish their own Quality Account for the services for which they are responsible under any joint arrangement.

83. *Subsection (5)* gives the Secretary of State power to make regulations to exempt NHS providers from the requirement to publish a Quality Account. The intention is to ensure that certain NHS providers, or types of NHS provider, can be exempted if necessary from the requirement to publish a Quality Account, either on a temporary basis to allow certain types of provider, particularly those who are smaller or who are new to providing services for the NHS, to gear themselves up for publication, or on a more permanent basis, in cases where the provider carries out too few NHS services to make it reasonable to require that provider to publish an Account. This subsection also gives the Secretary of State power to make regulations to exempt certain services from appearing in a Quality Account. The intention of this subsection is to exempt certain services if it would not be practicable to include them, for example if the volumes of a particular service are too small to allow users of the Account to draw conclusions about the quality of services offered.

84. *Subsection (6)* defines NHS services by reference back to clause 2(7), which defines these services as being those which are provided in England for the purposes of the health service continued by section 1(1) of the NHS Act.

Clause 7: Supplementary provision about the duty

85. *Subsection (2)* defines the reporting period for the purposes of section 6. The first reporting period for Quality Accounts will be 1st April 2009 – 31st March 2010, and subsequent reporting periods will run from 1st April – 31st March each year.

86. *Subsection (3)* provides that a provider must republish their Quality Account if they are notified of an error or omission by either the Care Quality Commission or a Strategic Health Authority. Providers must republish the revised Account within 21 days.

87. *Subsection (4)* requires a provider to send a copy of their Quality Account to the Department of Health. The Department of Health intends to publish provider Quality Accounts on the NHS Choices website, which is owned by the Department.

88. *Subsection (5)* sets out some of the matters which may be addressed in regulations made under section 6(1) or (3). These regulations may address the form and content of a Quality Account and the date on which it must be published, may place duties on the provider for ensuring the accuracy of the information contained in the Quality Account, and may require the provider to have regard to any guidance issued by the Secretary of State. The intention is to ensure that the content and timetable for publication can be changed easily and speedily in the future to reflect changing national and local healthcare quality priorities, as well as to ensure that providers take responsibility for the reliability of the content of their Quality Account.

89. *Subsection (6)* provides that any person can ask the provider to supply a copy of their Quality Account for the current and the preceding two years. All provider Quality Accounts will be available on the NHS Choices website, but the purpose of this subsection is to ensure

that providers are required to supply a hard copy of their Quality Account(s) to anyone who requests one.

90. *Subsection (7)* requires providers to display a notice in their premises informing patients that the latest copy of their Quality Account is available and how a copy can be obtained.

91. *Subsection (8)* defines "premises" for the purposes of *subsection (7).*

Clause 8: Regulations

92. Clause 8 addresses the procedure for making regulations under section 6. The first set of regulations made under section 6(5) are to be subject to approval by each House of Parliament under the affirmative resolution procedure since the intention is to use that power on that occasion to limit the ambit of the duty. Any other regulations will be subject to the negative procedure.

Chapter 3 – Direct Payments

Overview of provisions

Direct Payments for health care

93. Clause 9 inserts new sections 12A to 12D into the NHS Act. New section 12A(1) allows the Secretary of State to make monetary payments directly to a patient, or another person nominated by the patient, to allow them to procure goods and services in connection with their health care. Such a payment is referred to as a "direct payment" (see new section 12A(5)).

94. Before a direct payment could be made, the patient would have to give their consent, either to receiving a direct payment themselves, or to a direct payment being made to a person nominated by them. For patients who lack capacity to consent, regulations under new section 12B(2)(c) allow for provision for a direct payment to be made to a person on the patient's behalf.

95. The Secretary of State could provide in regulations for PCTs to be able to make direct payments for mental health after-care services that PCTs must provide to patients under section 117 of the Mental Health Act 1983 (the Mental Health Act) (see new section 12A(4)). The patient would be required by the regulations to give consent before a direct payment could be made, as in the case of a payment under section 12A(1).

96. A health care direct payment would be analogous to a direct payment for social care. The health care that could be procured using this money is health care for which the Secretary

of State is responsible under sections 2(1) or 3(1) of the NHS Act, anything for which the Secretary of State must arrange under paragraph 8 of Schedule 1, or vehicles that Secretary of State may provide under paragraph 9 of Schedule 1 (see new section 12A(2)). Under section 3(1) of the NHS Act the Secretary of State must provide specified services or facilities to such extent as he considers necessary to meet all reasonable requirements. This includes hospital and other accommodation for the purpose of the services provided under the Act, medical, nursing and services or facilities for the care of pregnant women and children and for the prevention of illness, care of persons suffering from illness and the after-care of persons who have suffered from illness and for the diagnosis and treatment of illness.

97. Initially, the Secretary of State would have powers to make direct payments for health care only in pilot schemes, as required by subsection 12A(6), although direct payments for health care could in the future be made more widely available following review and an order made by the Secretary of State under section 12C(6)(a). The order would be subject to approval by each House of Parliament under the affirmative resolution procedure.

Regulations about direct payments

98. New section 12B(1) will give the Secretary of State the power to make regulations covering how direct payments would operate. The factors that regulations could provide for are identified in new section 12B(2) to 12B(4) and are similar to those already available for social care direct payments.

99. The regulations could identify the groups of patients who might benefit, such as mental health patients, the health conditions for which direct payments could be made, such as those which are long term, stable and predictable, and the services that could be provided such as nursing care (see new section 12B(2)(a)).

Direct payments pilot schemes

100. New section 12C(1)(a) provides the power to enable the Secretary of State to be able to make pilot schemes under regulations under new section 12B through which the Secretary of State could make direct payments. By directions in writing under sections 7 and 273(4)(c) of the NHS Act, the Secretary of State could delegate the operation of a pilot scheme to a PCT (or a Strategic or Special Health Authority). In accordance with regulations under section 75 of the NHS Act a PCT might enter into a pooled fund arrangement with a local authority to deliver health services using a direct payment. The Government intends to set up a programme of pilot schemes led by different PCTs to assess the effectiveness of direct payments.

101. A pilot scheme must have a specified period and be subject to review (new section 12C(3) and (4)). The geographical scope may be specified (new section 12C(2)(a)), and a pilot scheme could also be distinguished by characteristics set out in regulations under new section 12B(2) (see subsection 12C(1)(b)). The Secretary of State will also be able to make

provision in regulations for changing, or discontinuing a pilot scheme or schemes under new section 12C(2)(b).

102. New section 12C(5) to (8) provide for the Secretary of State to be able by order either to repeal the requirement for direct payments to be made only in accordance with a pilot scheme (see new section 12C(6)(a)), or to repeal new sections 12A, 12B, 12C and 12D (see new section 12C(8)). However new section 12C(5) requires that the Secretary of State have carried out a review of one or more pilot schemes before making any such order. Any such order would be subject to approval by each House of Parliament under the affirmative resolution procedure. If the Secretary of State chose to make an order under section 12C(6)(a), direct payments for health care would no longer need to be made as part of a pilot scheme, and the power to make pilot schemes provided by sections 12C(1) to (4), would be repealed. However, similar time limited schemes could be set up under regulations under section 12B, to continue to test possible extensions or adaptations of a direct payments model.

103. After reviewing a scheme or schemes, an order under new section 12C(6)(b) would enable the Secretary of State to amend, repeal or otherwise modify any other provision of the NHS Act to facilitate the making of direct payments, so long as the changes were necessary or expedient (see section 12C(7)). The power would enable lessons learnt about the legislation from piloting in schemes to be addressed. The order would be subject to approval by each House of Parliament under the affirmative resolution procedure. New section 12C(7) would not allow provision by order to alter unrelated aspects of the NHS Act.

104. New section 12C(8) allows the Secretary of State to repeal sections 12A, 12B, 12C and 12D, if, following a review, he does not believe that direct payments are a viable way of delivering services.

Arrangements with other bodies relating to direct payments

105. New section 12D(1) to (3) provides authority for the Secretary of State to arrange with bodies in addition to local authorities such as a mental health charity or private sector body involved in the provision of health care or social care services to assist in making direct payments. In particular, subsection (2) enables such arrangements to be made with voluntary organisations. In practice, a PCT or other NHS body might be making the arrangements on behalf of the Secretary of State. These organisations could help with any aspect of making direct payments, such as assessing patients, setting budgets or reviewing care plans.

Jurisdiction of Health Service Commissioner

106. Clause 10 amends the Health Service Commissioners Act 1993 (the 1993 Act) to enable the Commissioner to hear complaints about services for which direct payments were made, including those provided by independent organisations. This gives patients receiving direct payments for health care similar rights to those enjoyed by patients accessing services from NHS organisations or from private sector organisations commissioned by PCTs.

Detailed explanation of provisions

Clause 9: Direct Payments for health care

107. Clause 9 inserts new sections 12A to 12D into the NHS Act.

108. New section 12A(1) allows the Secretary of State to make a direct payment to a patient or their representative, in order to purchase goods or services that might otherwise be provided by the NHS. The goods or services are those identified in new section 12A(2). Section 12A(1) also requires that direct payments be made only with the consent of the patient. However, where a patient lacks capacity, provision could be made in regulations for consent to be given by a representative of the patient under section 12B(2)(c).

109. New section 12A(2) specifies that direct payments may be made in respect of services the Secretary of State may or must provide under sections 3(1) or 2(1) of the NHS Act, must arrange under paragraph 8 of Schedule 1 to the NHS Act or vehicles that that Secretary of State may provide under paragraph 9 of Schedule 1 to the NHS Act.

110. New section 12A(3) causes the Secretary of State's ability to make direct payments to be subject to regulations made under new section 12B.

111. New section 12A(4) provides for regulations to enable a PCT to make a direct payment for after-care services it is obliged to provide by section 117 of the Mental Health Act 1983.

112. New section 12A(5) defines a payment of the kind described in new section 12A(1) or 12A(4) as a direct payment.

113. New section 12A(6) provides that direct payments may only be made as part of a pilot scheme established under regulations under new section 12C and 12B. However, this section may be repealed by order, as laid out in new section 12C(6)(a).

114. New section 12B(1) enables the Secretary of State to make regulations about direct payments. These regulations enable provision to describe in more detail when and how direct payments can be made.

115. New section 12B(2) enables regulations to define the scope of direct payments, which, under new section 12C(1), includes the way pilot schemes will operate. Under new section 12B(2)(a), it will be possible to set out in regulations which services may or may not be suitable, in what circumstances, and which patients may or may not be allowed to receive direct payments in order to purchase services. The regulation- making power is subject to the negative resolution procedure.

116. Direct payments will often be made directly to the patient themselves, but a patient may prefer to nominate someone else to receive and manage direct payments on their behalf. New section 12B(2)(b) allows for circumstances to be prescribed in which direct payments may or must be made to a person nominated by the patient.

117. Where a patient lacks capacity, new section 12B(2)(c) allows for circumstances to be prescribed in which direct payments may or must be paid to someone other than the patient. This will make it possible, where the individual lacks capacity to make the necessary decisions about consenting to and managing a direct payment, to make direct payments to a suitable surrogate on the individual's behalf. The reference to a person who lacks capacity has the same meaning as in the Mental Capacity Act 2005 (see new section 12B(6)(b)). Regulations could also provide for direct payments to be made to a parent or other person in respect of a child where a child is unable to consent to the making of payments.

118. New section 12B(2)(d) allows regulations to set out conditions that must be complied with by the Secretary of State (in effect, by the NHS organisation granting the direct payment on behalf of the Secretary of State) or the PCT (in relation to after-care under section 117 of the Mental Health Act) when making a direct payment. This might include ensuring that there is an agreed care plan, that there are proper arrangements in place for paying the money into a secure bank account or for carrying out regular reviews of the payments and of the patient's care.

119. New section 12B(2)(e) enables regulations to set out conditions the patient or payee should comply with when a direct payment is granted. These might include: maintaining a separate bank account; agreeing to a care plan that specifies the agreed health outcomes and the types of services to be purchased to help meet those outcomes; or providing records of their spending to demonstrate that it is in line with the care plan.

120. New section 12B(2)(f) enables regulations to make provision about the amount of a direct payment or how it is to be calculated. For example, the regulations are likely to require that the amount be sufficient to cover the whole of the services set out in a care plan for which they are to provide. As methodologies for estimating the required budget emerge these may also be specified in regulations.

121. New section 12B(2)(g) allows regulations to set out when the Secretary of State, or the PCT when making direct payments for after-care under section 117 of the Mental Health Act, may or must stop making direct payments. Relevant circumstances might include when a patient's health is deteriorating such that it cannot be managed within the budget or where there is evidence that the direct payments have been abused.

122. New section 12B(2)(h) allows regulations to describe circumstances in which the Secretary of State, or the PCT when making direct payments for after-care under section 117 of the Mental Health Act may or must require all or part of direct payments to be repaid, for example, when a significant surplus has accumulated.

123. New section 12B(2)(i) allows regulations to include appropriate monitoring arrangements as regards the making of direct payments, their use by the payee, or the services which they are used to secure. For example the PCT, acting on behalf of the Secretary of State, might require the payee or providers contracted using a direct payment on the payee's behalf, to periodically submit copies of receipts. Similar provision could be made in respect of the making of direct payments for after-care under section 117 of the Mental Health Act.

124. New section 12B(3) allows regulations to make provision to govern situations where a patient has fluctuating capacity, for example where, at the time of initially being granted a direct payment, they do not have the ability to consent, but later regain capacity. Regulations might specify circumstances where direct payments should continue to be paid to a surrogate in the period immediately following the regaining of capacity, subject to the consent of the patient.

125. In the event that repayment to the Secretary of State or the PCT is needed and the seeking of repayment under regulations made under new section 12B(2)(h) has been unsuccessful, regulations under new section 12B(4) would allow the sum owed to be recoverable as a civil debt due to the Secretary of State or the PCT. In addition, for serious abuse of the system, criminal sanctions will be available through the Fraud Act 2006 or the Theft Act 1968.

126. New section 12B(5)(a) and (b) allow regulations to define the extent to which, while patients or another person on the patient's behalf may have procured the goods or services directly, those services should be regarded as goods or services provided by the Secretary of State or a PCT. This means that in prescribed circumstances, but only in prescribed circumstances, the Secretary of State could be considered to have fulfilled his duty to provide a service described at new section 12A(2) by making a direct payment. Similarly, a PCT could be considered, in prescribed circumstances, to have fulfilled its obligations under section 117 of the Mental Health Act by making a direct payment.

127. New section 12B(6) contains definitions. New section 12B(6)(a) specifies that a "service" includes anything for which a direct payment may be made, as set out in new section 12A(2) or section 117 of the Mental Health Act. New section 12B(6)(b) defines references to capacity as being consistent with the meaning in the Mental Capacity Act 2005.

128. New section 12C(1)(a) enables the regulations that may be made under section 12B to provide for the Secretary of State to be able to make pilot schemes in accordance with which direct payments may be made.

129. New section 12C(1)(b) allows the pilot schemes provided for by regulations to include provision for any of the matters covered by new section 12B(2) as long as the pilot schemes comply with the regulations under new section 12B. For example, a pilot scheme might apply to patients with a particular health condition in particular circumstances for which bespoke monitoring arrangements are appropriate.

130. New section 12C(2)(a) allows provision in regulations to provide for or require specification of the geographical area of a pilot scheme. New section 12C(2)(b) allows the regulations to make provision for or require the pilot scheme to provide for the scheme's revocation or amendment.

131. New section 12C(3) requires that regulations must provide that when a pilot scheme is created, its duration is specified, although they may provide for the initial period to be subject to extension by the Secretary of State. This may occur if, for example, the pilot scheme took longer than anticipated to become established and needs to be extended to allow enough patients to use it for robust review.

132. New section 12C(4) requires that regulations must provide for the review of a pilot scheme or require the pilot scheme to include provision for review.

133. New section 12C(5) allows the Secretary of State, having carried out a review of one or more pilot schemes, to either repeal section 12A(6) and section 12C (1) to (4), using an order described at section 12C(6)(a), or repeal sections 12A to D using an order described at section 12C(8). Repeal pursuant to section 12C(6)(a) would make direct payments generally available subject to any regulations under section 12B. Repeal pursuant to section 12C(8) would prevent the making of direct payments in future.

134. New section 12C(6)(b) provides for other provisions of the NHS Act to be amended, modified or repealed, for example where it has become apparent that this is necessary for a general roll out of direct payments. Any orders made under section 12(5) are subject to Parliamentary approval by each House of Parliament under the affirmative resolution procedure (see the amendment made by paragraph 10 of Schedule 1 to the Bill to section 272(6) of the NHS Act) .

135. New section 12C(7) specifies that any amendments, repeals or modifications to the NHS act carried out by an order described at section 12C(6)(b) must be necessary or expedient for the delivery of direct payments. This means that changes could be made to the NHS act to reflect the lessons learnt from the pilot schemes, but the subsection prevents the power at section 12C(5) being used to make other changes to the Act.

136. New section 12C(8) provides for the Secretary of State to be able to repeal sections 12A, 12B, 12C and 12D. In the event that the pilot schemes show that direct payments are not a viable way to deliver services, these provisions allow him to remove the powers from the NHS Act through an order subject to approval by each House of Parliament under the affirmative resolution procedure.

137. New section 12D(1) authorises the Secretary of State to make arrangements with other bodies for their assistance in providing or operating or otherwise in connection with direct payments.

138. New section 12D(2) confirms that the bodies with whom such arrangements may be made include voluntary organisations.

139. New section 12D(3) confirms that the Secretary of State is free to agree terms with such bodies. The Secretary of State may pay a body for its part in the arrangements concerning direct payments.

Clause 10: Jurisdiction of Health Service Commissioner

140. Clause 10 amends the jurisdiction of the Health Services Commissioner set out in the 1993 Act.

141. *Subsection (2)* expands the scope of persons subject to investigation to include persons delivering direct payment services who are not health service bodies.

142. *Subsection (3)* expands the definition of independent providers in the 1993 Act to include persons providing direct payment services who are not health service bodies.

143. *Subsection (4)* expands the general remit of the Health Services Commissioner to allow the Commissioner to investigate a complaint made about a service or other action provided by a person providing direct payment services.

144. *Subsection (5)* allows the Commissioner to investigate matters arising from commercial and contractual arrangements for the provision of direct payment services.

145. *Subsection (6)* makes a consequential amendment in respect of independent providers who are not persons providing direct payment services.

146. *Subsection (7)* defines direct payment services by reference to section 12A of the NHS Act.

Clause 11: Direct payments: minor and consequential amendments

147. Clause 11 introduces Schedule 1, which contains minor and consequential amendments relating to direct payments.

Schedule 1: Direct Payments: Minor and consequential amendments

148. *Paragraph 1* amends the National Assistance Act 1948 to include accommodation in respect of which a direct payment is made within the definition at section 24(6A) of the 1948 Act of NHS accommodation referred to at section 24(6).

149. *Paragraph 2* amends the Health Services and Public Health Act 1968 to clarify that pilots in section 63(2)(bb) are pilots set up under section 134(1) of the NHS Act or section 92(1) of the NHS (Wales) Act.

150. *Paragraph 3* has the effect that references to after-care services in the Mental Health Act 1983 include services provided in respect of which a direct payment for social care or a direct payment for health care is made.

151. *Paragraph 4* amends section 2(5) of the Disabled Persons (Services, Consultation and Representation) Act 1986 with the effect that the authorised representative of a disabled person may at any reasonable time visit him and interview him in private in hospital accommodation that has been procured using a direct payment made under new section 12A(1).

152. *Paragraphs 5(1) and (2)* amend section 45 of the Health and Social Care (Community Health and Standards) Act 2003. The amendments have the effect that the obligations of a Welsh NHS body pursuant to Chapter 2 of the 2003 Act apply where the Welsh body provides health care in respect of which an English NHS body has made direct payments, until sections 45 and 46 of the 2003 Act are repealed on the coming into force of paragraphs 37 and 38 of the 2008 Act.

153. *Paragraphs 6 to 11* provide for amendments to the NHS Act. *Paragraphs 7 and 11* have the effect that references to pilot schemes in the NHS Act do not refer to pilot schemes for direct payments for health care. They define the pilot schemes referred to in the provisions identified as a "pilot scheme" established under section 134(1) of the NHS Act, which relates to pharmaceutical services, so as to distinguish them from direct payment pilot schemes set up under new section 12C(1)(a) of the Act.

154. *The provisions of paragraph 7* have the effect that references to various pilot schemes elsewhere in the NHS Act are defined as pilot schemes established under section 134(2) of the NHS Act.

155. *Paragraph 8* confines the definition of a "pilot scheme" set out at section 134(2) so that it applies only to that Part 7 of the NHS Act, rather than the whole Act.

156. *The provisions of paragraph 9* amend the order making power of the Secretary of State at section 246(3) with the effect that an order may vary the descriptions at Schedule 17 to the NHS Act to include descriptions of services in respect of which direct payments are made by a body in respect of which an overview and scrutiny committee exercises functions. Schedule 17 describes information that is exempt for the purposes of excluding the public from meetings so as to prevent disclosure of the information in relation to an item of business at a meeting of an overview and scrutiny committee.

157. *Paragraph 10* amends provision for the procedure that applies to a statutory instrument under the NHS Act in section 272(6) so that an order mentioned in new section 12C(5) under new section 12C(6) or 12C(8) is subject to approval by each House of Parliament under the affirmative resolution procedure.

158. *Paragraph 11* removes the entry for "pilot scheme" from the index of defined expressions at section 276 of the NHS Act.

159. *Paragraphs 12 to 15* provide for amendments to the Safeguarding Vulnerable Groups Act 2006.

160. The amendments made by *paragraph 13* provide that the Secretary of State (or an NHS body to whom he has delegated a function of making direct payments) or a Primary Care Trust acting under regulations (in the case of section 117 after-care) is not a regulated activity provider by virtue of anything he or it does in connection with the making of direct payments under new sections 12A to 12D.

161. The amendment made by *paragraph 14(2)* has the effect that making a direct payment is controlled activity to the extent that it is not a regulated activity relating to children, and that by sub-paragraph *(3)* that health care, treatment or therapy which is provided to a child out of direct payments is controlled activity.

162. The amendments made by *paragraph (15)* have the effect that a person who has attained the age of 18 and to whom, or on whose behalf, direct payments are made is a vulnerable adult for the purposes of the Safeguarding Vulnerable Groups Act 2006.

Chapter 4: Innovation

Clause 12: Innovation prizes

163. *High Quality Care for All* stated the Department of Health's intention to create prizes for innovations in areas such as the prevention and treatment of lifestyle diseases.

164. Under the NHS Act, the Secretary of State can currently award grants for research. However, the power is limited to research and does not extend to awarding money retrospectively for work that has already been completed.

165. Clause 12 enables the Secretary of State to make payments as prizes to promote and reward innovation in the provision of health services in England. Prizes may be awarded for work that has already been completed or for the completion of future challenges.

166. To assist in this matter, Secretary of State may establish a committee to advise on the form and allocation of any such prizes. *Subsection (3)* enables Secretary of State to pay remuneration, allowances or expenses to a member of the committee.

PART 2 – POWERS IN RELATION TO HEALTH BODIES

Chapter 1 –Trust special administrators for NHS bodies in England

Clauses 13 and 14 and Schedule 2: Trust special administrators: NHS trusts and NHS foundation trusts

167. Clause 13 inserts a new Chapter 5A of the NHS Act (sections 65A to 65O). The new sections provide for the Secretary of State to appoint Trust Special Administrators (TSAs) to NHS trusts and NHS foundation trusts; for the de-authorisation of NHS foundation trusts, and for the functions of the TSA during the period of appointment. In particular, provision is made for consultation by the TSA, the preparation of a draft report making recommendations to the Secretary of State and a final decision by the Secretary of State in relation to the trust. Clause 14 and Schedule 2 make further provision for de-authorised NHS foundation trusts.

Application

168. New section 65A applies the new provisions to English NHS trusts only (those trusts all or most of whose hospitals, establishments or facilities are situated in England), and to NHS foundation trusts which were authorised after an application by an NHS trust under section 33 of the Act (a "section 33 foundation trust"). The provisions also apply to NHS foundation trusts which have been established under section 56 of the Act (mergers between NHS foundation trusts, or between NHS trusts and foundation trusts), but only where at least one of the trusts which formed part of the merged trust was an NHS trust or a section 33 foundation trust or, where there has been a succession of mergers under section 56, only if any of those mergers involved an NHS trust or a section 33 foundation trust.

Appointment

169. New section 65B gives the Secretary of State the power to make an order authorising the appointment of a TSA to run an NHS trust, after consulting the trust, any Strategic Health Authority in whose area the trust has hospitals, establishments or facilities, and any other person who commissions services from the trust, for example a Strategic Health Authority or a PCT, where the Secretary of State considers it appropriate. The Secretary of State must be satisfied that the appointment of the TSA to the trust is in the interests of the health service (*subsection (2)*). An example where this might occur is if a key service provided by a small trust has to stop because of new clinical guidance about 24 hour cover and relatively small patient numbers mean that the trust can only provide such cover at a financial loss. Stopping this service may result in the organisation becoming unsustainable. A TSA is only likely to be

appointed after previous performance interventions have been unsuccessful. The TSA would be appointed by the Secretary of State (*subsection (6)*) and would hold and vacate office in accordance with the terms of his appointment (*subsection (7)*). Under new section 65C, when the TSA's appointment takes effect the members of the trust's board of directors, including the chair, executive directors (for example, the Chief Executive) and non-executive directors, would be suspended from performing their duties as members of the board. Although suspended from the board, the executive directors would remain employed in their post with the trust (for example, as Chief Executive, Medical Director or Director of Finance).

De-authorisation of NHS foundation trusts

170. New sections 65D and 65E make specific provision for NHS foundation trusts. New section 65D enables Monitor to give a notice to the Secretary of State which has the effect that the Secretary of State must make an order under new section 65E providing that the trust shall cease to be a foundation trust and instead become an NHS trust (described as "de-authorisation") and an order under new section 65B appointing a TSA for the trust. Monitor would be able to give such a notice only where it was satisfied that the trust had failed to comply with a notice under section 52 and that a further notice would be unlikely to secure the provision of services which the trust is required by its authorisation to provide (new section 65D(1)). This is similar to the existing statutory test for the dissolution of an NHS foundation trust under section 54 of the NHS Act. A notice under section 52 of the NHS Act requires a specified trust, the directors or board governors of the trust to do, or not to do, specified things within a specified period.

171. New Schedule 10A to the NHS Act, to be inserted by clause 14 of, and Schedule 2 to, the Bill makes further provision for de-authorised NHS foundation trusts. In particular the trust's constitution is to cease to have effect on de-authorisation (*paragraph 2*) and, subject to modifications in provisions of the Schedule, the trust is to be subject to the provisions for the constitution of NHS trusts in Schedule 4 to the NHS Act. The modifications include:

- the number of directors is to be that of the former NHS foundation trust (*paragraph 4);*
- the trust retains its name except for the removal of the words "foundation trust" and its functions are the provision of goods or services for the purposes of the NHS (*paragraph 5*); and
- the public dividend capital (PDC) of the trust continues as public dividend capital of the NHS trust (*paragraph 7*).

172. In addition, the Schedule provides that the de-authorisation of the NHS foundation trust does not prevent the trust from continuing as a party to contracts entered into as an NHS foundation trust, continuing to hold property held as an NHS foundation trust or continuing as a member of another corporate body, even if being a party to those contracts, holding that property or retaining that membership would not have been lawful if the trust had not been an

NHS foundation trust (*paragraphs 9 to 11*). These provisions ensure continuity and that the rights of third parties are not affected by de-authorisation. Paragraph 12 of the new Schedule 10A clarifies that the provisions for continuity do not affect the power of the Secretary of State to direct the new NHS trust; for example, to direct them to dispose of certain property.

Consultation and report

173. New section 65F requires that, within 45 working days of appointment, the TSA must produce for the Secretary of State and publish a draft report, outlining the action which he recommends that the Secretary of State should take in relation to the trust. The Secretary of State must lay this report in Parliament. The TSA must set out, in a published statement, how he plans to consult on his draft report (new section 65G(1)). The consultation period will last for 30 working days (new section 65G(2)).

174. New section 65H specifies the duties which apply during the consultation period. In particular, it specifies that the TSA must publish a notice stating that the TSA is seeking responses to the draft report and describing how people can give their responses (*subsection (2)*). *Subsections (4) and (5)* provide that the TSA must hold meetings with the public and the staff of the trust and staff representatives. Staff for these purposes includes staff employed by contractors and volunteers working for the trust (*subsection (11)*). Section 65H also requires the TSA to seek written responses from and meet with any Strategic Health Authority in whose area the trust has hospitals, establishments or facilities, and any person who commissions services from the trust which the Secretary of State directs the TSA to consult, (*subsections (7)(a) and (b) and (9)*). The TSA is also required to request a written response from such of the persons named in *subsection (8)* as may be prescribed in regulations. In addition, the Secretary of State is given power to make regulations to impose additional requirements to hold meetings or seek written responses; this may include, for example the local university medical school, if the organisation has a training role (*subsection (10)).*

175. New section 65I provides that within 15 working days of the consultation closing, the TSA must provide the Secretary of State with a report containing his final recommendations for the trust. The TSA must attach to the report a summary of all oral and written responses to the consultation received during the consultation process. The Secretary of State must publish this report and lay it before Parliament *(subsection (3)).*

176. New section 65J enables the Secretary of State to make an order extending any of the time periods for preparing the draft report, conducting the consultation or providing the final report. The power will be exercisable only where it would not be reasonable to expect the administrator to complete the relevant activity in the specified period and it is envisaged that the power will only be used in exceptional circumstances; for example, where the TSA was seriously ill or if the organisation had to deal with a significant unplanned event, for example a SARS (severe acute respiratory syndrome) outbreak. Where the time is extended, the TSA must publish a notice stating the date when the revised period expires (*subsections (3) and (4)*).

Action by the Secretary of State

177. New section 65K requires the Secretary of State to decide what action to take in relation to the trust within 20 working days of receiving the final report. The decision must be laid before Parliament as well as published.

178. If the Secretary of State decides to take any action in relation to the trust (for example, to dissolve the trust and merge it with another trust, or to direct it to close or transfer particular establishments or services), he will exercise existing powers under the NHS Act. If the Secretary of State decides not to dissolve the trust, however, new section 65L provides for the Secretary of State to make an order specifying when the appointment of the TSA and the suspension of the chairman and directors of the trust will come to an end (*subsection (2)*). If the trust is a de-authorised NHS foundation trust, an order must be made specifying the name of the NHS trust, the functions of the NHS trust and the number of non-executive and executive directors. If the trust has significant teaching commitments then one of the non-executive directors should be a person from a university with a medical or dental school (*subsection (4)*). In the case of a de-authorised NHS foundation trust, the number of suspended directors may exceed the number permitted under the regulations governing NHS trust membership, or there may be an insufficient number. New *subsection (5)* therefore enables the Secretary of State to remove directors or appoint new directors to meet requirements for NHS trusts.

Supplementary

179. New section 65M provides that if the TSA ceases to hold office either before the Secretary of State has dissolved the trust or before he has reinstated the chairman and directors to the trust, the Secretary of State must appoint another TSA and publish his name. At this point the new TSA takes over from the same stage in the process, unless the Secretary of State directs that the new TSA should start from a different point (for example to start at the beginning of the process) (*subsection (2)*).

180. New section 65N requires the Secretary of State to publish guidance for TSAs, which must include guidance in relation to the publication of notices relating to consultation and extensions of time and also the preparation of the draft report.

Clause 15: Trust Special Administrators: Primary Care Trusts

181. Clause 15 inserts a new Chapter 5B of the NHS Act (new sections 65P to 65Z3). The new sections provide the Secretary of State with powers to direct a PCT to appoint a TSA to exercise specified "provider" functions of the PCT. The new sections also set out the functions of the TSA during the period of appointment which will apply if the directions making power is exercised. In particular, provision is made for consultation by the TSA, the preparation of a draft report making recommendations to the Secretary of State and a final decision by the Secretary of State.

Appointment

182. New section 65P gives the Secretary of State the power to give directions requiring a PCT to appoint a TSA to exercise certain "provider" functions of the PCT on its behalf (*subsection (1)*). A "provider" function is any function which (i) involves the provision of goods and services, but only where that function is exercised by the PCT by means of direct provision (for example not by the making of commissioning arrangements with other persons) and (ii) is not a function of providing goods and services but which may be exercised for that purpose (e.g. employing staff) (*subsection (10)*). Precisely which functions are to be exercised by the TSA will be specified in the directions; that may differ in each case. The Secretary of State may only exercise the direction making power if he considers it appropriate in the interests of the health service to do so (*subsection (2)*) and only after consulting the PCT, any Strategic Health Authority whose area includes any part of the PCT's area, and any other person which commissions services from the PCT, where the Secretary of State considers it appropriate (*subsection (4)*). The TSA holds and vacates office in accordance with the terms of his appointment (*subsection (7)*) and the Secretary of State can require in the directions that the terms of appointment contain specified terms for example provision could be included to ensure that the Board of the PCT cannot interfere in the exercise of the TSA's functions (*subsection (8)*). New section 65Q provides that when the TSA's appointment takes effect, the relevant functions (meaning those exercisable by the TSA) will no longer be exercisable by any committee, subcommittee or officer of the PCT, but that provision will not affect the employment of any PCT employee (*subsection (2)*).

Consultation and report

183. New section 65R requires that, within 45 working days of appointment, the TSA must produce and publish a draft report, recommending the action that the Secretary of State should take in relation to the performance of the relevant functions. The Secretary of State must lay this report before Parliament (*subsection (3)*). The TSA must set out, in a published statement, how he plans to consult on the draft report (new section 65S(1)). The consultation period will last for 30 working days (new section 65S(2)).

184. New section 65T specifies the duties which apply during the consultation period. In particular, it specifies that the TSA must publish a notice stating that the TSA is seeking responses to the draft report and describing how people can give their response (*subsection (2)*). It provides that the TSA must hold meetings with the public and staff of the PCT and staff representatives (*subsection (4) and (5)*). Staff for these purposes only includes staff who are employed in connection with the relevant functions (i.e. the provider functions which are being exercised by the TSA) and it includes staff employed by contractors and volunteers working for the PCT (*subsection (10)).* The TSA is required to seek written responses from and meet any Strategic Health Authority in whose area any part of the PCT's area falls, and any person who commissions services from the PCT which the Secretary of State directs the TSA to consult (*subsections (7)(a) and (b) and (8*). The TSA is also required to request a written response from such persons within section 65H(8) as the Secretary of State may direct

(*subsection 7(c)*). The Secretary of State may also direct the TSA to seek written responses from or hold meetings with additional persons specified in the directions (*subsection (9)*).

185. New section 65U provides that within 15 working days of the end of the consultation period, the TSA must give the Secretary of State a report containing his recommendations. The TSA must attach to the report a summary of all oral and written responses to the consultation received during the consultation process. The Secretary of State must publish the TSA's report and lay it before Parliament (*subsection (3)*).

186. New section 65V enables the Secretary of State to make an order extending any of the time periods for preparing the draft report, conducting the consultation or providing the final report. The power will be exercisable only where it would not be reasonable to expect the administrator to complete the relevant activity in the specified period and it is envisaged that the power will only be used in exceptional circumstances; for example, where the TSA was seriously ill or if the organisation had to deal with a significant unplanned event, for example a SARS (severe acute respiratory syndrome) outbreak. Where the time is extended, the TSA must publish a notice stating the date when the revised period expires (*subsection (2) and (3)*).

Action by the Secretary of State

187. New section 65W requires the Secretary of State to decide what action to take in relation to the performance of the relevant provider functions within 20 working days of receiving the final report. The decision must be laid before Parliament as well as published.

188. If the Secretary of State decides to take any action in relation to the relevant provider function (for example, he may decide that the PCT should stop providing services itself and commission them from elsewhere) he will exercise existing powers under the NHS Act.

189. New section 65X allows the Secretary of State to give directions to the PCT and the TSA, requiring that the TSA is removed with effect from a specified day.

Supplementary

190. New section 65Y provides that if the TSA ceases to hold office before the Secretary of State has published his decision, the Secretary of State must appoint a new TSA and publish his name. The new TSA takes over from the same stage in the process, unless the Secretary of State directs that the new TSA should start from a different point (for example to start at the beginning of the process) (*subsection (3)*).

191. New section 65Z allows the Secretary of State to give further directions to the TSA about the exercise of the TSA's functions.

192. New section 65Z1 requires the Secretary of State to publish guidance for TSAs, which must include guidance in relation to the publication of notices relating to consultation and extensions of time and also the preparation of the draft report.

193. New section 65Z2 requires the following directions to be laid before Parliament: the initial directions requiring the appointment of a TSA and specifying which functions are to be exercised by the TSA on the PCT's behalf; additional directions about the TSA's exercise of functions; directions bringing the appointment of the TSA to an end.

Clause 16: Consequential amendments

194. Clause 16 makes consequential amendments to the NHS Act. In particular, subsections (2) to (6) amend sections 53 and 54 so that the existing provisions for voluntary arrangements and the dissolution of NHS foundation trusts apply only to NHS foundation trusts to which the new regime does not apply (meaning those authorised on an application by a body other than an NHS trust under section 34 of the Act, or those established under section 56 which are not within section 65A(2)).

195. *Subsection (7)* amends section 242 of the Act (public involvement and consultation), so that PCTs, NHS trusts and NHS foundation trusts will not be obliged to consult, or make other arrangements for involvement, in relation to matters to which the draft report or final report relates as relevant consultation will be undertaken by the TSA under the new sections.

Chapter 2 – NHS and other health appointments: suspension

Clause 17: NHS and other health appointments: suspension

196. Clause 17 gives effect to Schedule 3.

Schedule 3: NHS and other health appointments: suspension

197. Part 1 of Schedule 3 amends enactments to allow for suspension from office of chairs and members of NHS and other health bodies and to make provision required in consequence of the new powers of suspension. The powers to suspend will allow a flexible approach to enable investigation of allegations or circumstances while considering decisions about whether to remove chairs or members from office. The amendments provide (or enable provision to be made in regulations) for an initial period of suspension, procedures for reviewing, revoking or extending suspension, a right for the person suspended to have the suspension reviewed, the appointment of an interim chair or, in a case where there is a vice or deputy chair appointed by the body in question for the appointment by the Secretary of State of a new vice or deputy chair. The amendments also provide for the membership of a suspended person not to count where legislation provides for a maximum number of members. What is required by way of amendments to primary legislation to achieve the policy varies from case to case.

198. Part 2 of Schedule 3 makes supplementary provision.

199. **Paragraph 1 of Schedule 3** amends Schedule 1A to the Medicines Act 1968 (provisions relating to Commission on Human Medicine and Committees) as follows—

200. New paragraph 6(2) of Schedule 1A enables the Secretary of State to make certain ancillary provisions in regulations as seem fitting relating to the terms on which members of the Commission on Human Medicine, committees established under section 4 of the 1968 Act or Expert Advisory Groups hold and vacate office. Such provision may be required to give full effect to the suspension regime.

201. **Paragraph 2** amends Schedule 1 to the Licensing (Alcohol Education and Research) Act 1981 (the Alcohol Education and Research Council) as follows—

202. New paragraph 3A of Schedule 1 enables the Secretary of State to suspend a member of the Council from office if it appears to him that one of the grounds for termination of the member's appointment may apply.

203. New paragraph 3B of Schedule 1 sets out details as to how the suspension process will operate including details about notification of suspension, the initial period of suspension, procedures for reviewing, revoking or extending a suspension and providing that a suspended member is not to be counted for the purposes of determining whether the membership of the Council exceeds 15 (the maximum permitted by the 1981 Act).

204. New sub-paragraph (4) of paragraph 4 of Schedule 1 will have the effect that when the chairman is suspended from office as a member of the Council, he will also be suspended from office as chairman of the Council.

205. New paragraph 4A of Schedule 1 will enable the Secretary of State to appoint an interim chairman where the chairman has been suspended, and sets out procedural details including for holding and vacating office, the term of office, resignation or termination of the appointment.

206. **Paragraph 3** amends Schedule 1 to the Human Fertilisation and Embryology Act 1990 (the Human Fertilisation and Embryology Authority: supplementary provisions) as follows—

207. New paragraph 5A of Schedule 1 enables the Secretary of State to suspend a member from office as the chairman, deputy chairman or other member of the Human Fertilisation and Embryology Authority if it appears there may be grounds for the Secretary of State to declare the office vacant.

208. New paragraph 5B of Schedule 1 sets out details as to how the suspension process will operate, including details about notification of suspension, the initial period of suspension and reviewing, revoking or extending a suspension.

209. **Paragraphs 4, 5 & 6** amend Schedule 1 to the Health Protection Agency Act 2004 (the Health Protection Agency) as follows—

210. New sub-paragraph (3A) of paragraph 1 of Schedule 1 will have the effect that where a member of the Agency appointed by the Scottish Ministers, DHSSPSNI or the Welsh Ministers is suspended by that authority pursuant to regulations under the Schedule, another member could be appointed by the authority pursuant to paragraph 1(3). The suspended member would also not be counted toward the total number of members of the Agency prescribed in regulations.

211. New sub-paragraph (5A) of paragraph 1 of Schedule 1 will enable regulations made by the Secretary of State to address what would happen in relation to the deputy chair (who is appointed by the other members of the Agency, not the Secretary of State) if the chairman of the Agency were suspended. Regulations could enable the Secretary of State to direct that the appointment of the deputy chairman would end and provide for the Secretary of State to appoint another non-executive member to be deputy chairman.

212. New sub-paragraph (3) of paragraph 29 of Schedule 1 will enable the Secretary of State to include in regulations under the Schedule certain ancillary provisions that appear to him to be suitable. Such provisions may be required to give full effect to the proposed suspension regime.

213. **Paragraph 7** amends Schedule 2 to the Human Tissue Act 2004 (the Human Tissue Authority) as follows—

214. New paragraph 9A of Schedule 2 will enable the authority who appointed the chairman or a member (the Secretary of State in the case of the chairman or such other number of members as he thinks fit, the Welsh Ministers in the case of one member and DHSSPSNI in respect of one member) to suspend the chairman or member they have appointed as members of the Human Tissue Authority.

215. New paragraph 9B of Schedule 2 sets out procedural details about how the suspension process will operate, including details about notification of suspension, the initial period of suspension and reviewing, revoking or extending a suspension. Sub-paragraph (9) of new paragraph 9B will ensure that where a member appointed by the Welsh Ministers or DHSSPSNI was suspended by that authority another member could be appointed by the authority pursuant to paragraph 1(1)(c) or (d) of Schedule 2.

216. New paragraph 9C of Schedule 2 will enable the Secretary of State to appoint an interim chairman where the chairman has been suspended, and sets out procedural details including for holding and vacating office, the term of office, or resignation or removal from office.

217. **Paragraph 8** amends Schedule 4 to the Health Act 2006 (the Appointments Commission: supplementary) as follows—

218. New paragraph 6(2) of Schedule 4 will enable regulations by the Secretary of State to address what would happen in relation to the vice-chairman (who is appointed by the members of the Commission, not the Secretary of State) if the chairman of the Appointments Commission is suspended from office. Regulations could enable the Secretary of State to direct that the appointment of the vice-chairman would end and provide for the Secretary of State to appoint another non-executive member to be vice-chairman.

219. **Paragraphs 9, 10, 11, 12 and 13** amend Schedules 2 (Strategic Health Authorities), 6 (Special Health Authorities), 8 (Independent Regulator of NHS foundation trusts), and 19 (further provision about standing advisory committees) of the NHS Act as follows—

220. Substituted sub-paragraph (d) of paragraph 9 of Schedule 2 amends the Secretary of State's regulation-making power at paragraph 9 of the Schedule to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Strategic Health Authority.

221. Substituted sub-paragraph (d) of paragraph 5 of Schedule 6 amends the Secretary of State's regulation-making power at paragraph 5 of Schedule 6 to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Special Health Authority.

222. New sub-paragraph (c) of paragraph 2(2) of Schedule 8 will enable the Secretary of State to suspend the chairman or another member of Monitor on suspicion of there being grounds that would enable him to remove the member from office.

223. New paragraph 2A of Schedule 8 sets out procedural details about how the suspension process would operate, including details about notification of suspension, the initial period of suspension, reviewing, revoking or extending the suspension and that the suspended member would not be counted towards the maximum number of members of Monitor during the suspension.

224. New Paragraph 5A of Schedule 19 expands the regulation-making power at paragraph 1 of that Schedule to enable regulations to provide for the Secretary of State to appoint an interim chairman following removal or suspension from office of the chairman of a standing advisory committee. The amendment to paragraph 1(b) of Schedule 19 enables regulations

under paragraph 1 could make provision with respect to removal or suspension from office of members of any standing advisory committee.

225. **Paragraphs 14, 15, 16 and 17** amend Schedules 5 (Special Health Authorities established under section 22), 10 (further provision about community health councils), and 13 (further provision about standing advisory committees) of the NHS (Wales) Act as follows—

226. Substituted sub-paragraph (d) of paragraph 5 of Schedule 5 amends the Welsh Ministers' regulation-making power at paragraph 5 to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Special Health Authority.

227. New paragraph 2A of Schedule 10 will enable regulations about the membership of community health councils to include provision, in cases where the chair elected by the members is removed or suspended from office, for the appointment by Welsh Ministers of a member as interim chair. The omission in paragraph 2(a) of Schedule 10 is consequential on this amendment.

228. New paragraph 5A of Schedule 13 will enable regulations under paragraph 1(b) of that Schedule to provide for the appointment by Welsh Ministers of an interim chairman following removal or suspension of the elected chairman of a standing advisory committee. The amendment to paragraph 1(b) enables regulations under paragraph 1 to address removal or suspension from office of members of a standing advisory committee.

229. **Paragraph 18 of Part 2 of Schedule 3** (supplementary) provides that in the case of a cross-border body, regulation-making powers in relation to such a body conferred on the Secretary of State and the Welsh Ministers by the amendments made in Part 1 of the Schedule are exercisable concurrently. This replicates the existing position in respect of regulation-making powers in relation to such bodies. A cross-border body is a body exercising functions, or carrying out activities in or with respect to Wales (or any part of Wales) and England (see section 158(1) of the Government of Wales Act 2006).

230. **Paragraph 19** has the effect that the changes relating to suspension will apply to existing appointees to the bodies mentioned in Part 1 of the Schedule as well as to future appointees.

PART 3 – MISCELLANEOUS

Tobacco

Clause 18: Prohibition of advertising: exclusion for specialist tobacconists

231. Clause 18 amends section 6 of the 2002 Act (specialist tobacconists) by inserting a new subsection (A1) at the beginning of that section. This new subsection gives the Secretary

of State (in relation to England), the Welsh Ministers (in relation to Wales), and DHSSPSNI (in relation to Northern Ireland) power to provide that specialist tobacconists do not commit an offence under section 2 of the 2002 Act (prohibition of tobacco advertising) if a tobacco advertisement on their premises meets certain requirements (including those to be set out in regulations). This power replaces (except in relation to Scotland) an automatic exclusion for specialist tobacconists currently provided by section 6(1) of the 2002 Act. Accordingly, **paragraph 3** of Schedule 4 amends section 6(1) of the 2002 Act to limit its application to Scotland.

Clause 19: Prohibition of tobacco displays etc.

232. Section 8 of the 2002 Act (displays) currently gives the Secretary of State power to impose requirements on the display in England, Wales and Northern Ireland of tobacco products or their prices in a place or on a website where such products are offered for sale. Clause 19 inserts new sections 7A to 7D into the 2002 Act, which replace section 8 in so far as it relates to England, Wales and Northern Ireland (it will continue to have effect in its existing form for Scotland).

233. The new section 7A (prohibition of tobacco displays) makes it an offence for a person, in the course of a business, to display tobacco products, or cause tobacco products to be displayed, in a place in England, Wales, or Northern Ireland. It also provides powers for the appropriate Minister to provide by regulations for the meaning of "place" and whether a display, which also amounts to an advertisement, is to be treated as a display, or whether it is to be treated as an advertisement, for the purposes of offences under the 2002 Act. For the purposes of the new sections 7A to 7D, the "appropriate Minister" means the Secretary of State in relation to England, the Welsh Ministers in relation to Wales, and DHSSPSNI in relation to Northern Ireland.

234. The new section 7B (tobacco displays: exclusions and defence) provides for a number of exclusions from the new section 7A prohibition on tobacco displays. The exclusions cover: displays in the course of a business which is part of the tobacco trade which are for the purposes of that trade and are accessible only to persons engaged in, or employed in, the tobacco trade; and, displays made following a particular request by an individual of at least 18 years of age to purchase, or for information about, a tobacco product (a requested display). The appropriate Minister is also given a general power to provide in regulations that no offence is committed under the new section 7A if the display complies with any requirements which are specified in the regulations. New section 7B(5) provides that for the purposes of the offence of making a display to an individual aged under 18 following a request by that individual, it is a defence that the person making the display believed the individual was 18 or over, and had reasonable grounds for that belief. Section 7B(6) provides that a person has reasonable grounds for so believing only if the individual was asked for evidence of their age and the evidence produced would have convinced a reasonable person; or no person could reasonably have suspected that the person was less than 18 years of age. It is a defence for a

person charged with causing a requested display to an individual aged under 18 that they exercised all due diligence to avoid committing the offence (new section 7B(7)).

235. The new section 7C (displays: prices of tobacco products) gives the appropriate Minister power by regulations to impose requirements in relation to the display, in England, Wales, or Northern Ireland (as the case may be) in the course of a business, of prices of tobacco products (subsection (1)). A person who displays or causes to be displayed, prices of tobacco products in breach of any such requirements is guilty of an offence (subsection (2)).

236. The new section 7D (displays on a website) replaces section 8(1) of the 2002 Act in relation to England and Wales and Northern Ireland, in so far as it applies to websites. It provides power for the Secretary of State by regulations to impose requirements in relation to the display in England and Wales, or Northern Ireland, in the course of a business of tobacco products or their prices on a website where tobacco products are offered for sale.

237. New section 7D makes it an offence to display, or cause to be displayed, tobacco products or their prices in breach of any requirements imposed by regulations (subsection (2)), except where this is in the course of providing information society services by a person established outside the United Kingdom (subsection (4)). A person established in England, Wales, or Northern Ireland who, in the course of providing information society services, does anything in another EEA state which would constitute an offence under new section 7D(2) is also guilty of an offence (new section 7D(3)). For these purposes "EEA state" includes member states of the European Union, as well as Norway, Iceland and Liechtenstein.

Clause 20: Power to prohibit or restrict sales from vending machines

238. Subsection (1) of clause 20 inserts a new section 3A (sales from vending machines in England and Wales) into the 1991 Act. New section 3A provides power for the appropriate national authority (defined as the Secretary of State in relation to England, and the Welsh Ministers in relation to Wales) by regulations to prohibit, or impose requirements on the sale of tobacco from vending machines. Such requirements may, in particular, relate to the location of the vending machine, or the design, construction or operation of the machine. These could include, for example, a requirement that the vending machine is located in sight of the individual managing or running premises where it is used, or that it have age-restricting operational requirements (preventing those who are under 18 years of age from being able to purchase cigarettes from the machine).

239. The regulations must include provision as to the persons who are liable for a breach of a prohibition or requirement. For example, where the requirement relates to the operation of a vending machine (such as bar staff supplying a special token), the owner or occupier of the premises may be the appropriate persons liable for a breach of the requirement. Alternatively, where the requirement relates to the location of the machine, it may also be appropriate to make the supplier of the machine (who in practice often has a say in where their machine is located) liable for a breach of the requirement. It is an offence for a person liable to breach

any prohibition or requirements imposed by the regulations, punishable with a fine not exceeding level 4 on the standard scale (currently £2,500). Subsection (6) of the new section 3A applies sections 13 (enforcement), 14 (powers of entry, etc) and 15 (offences of obstruction, etc of officers) of the 2002 Act for the purposes of the new section. Section 13 of the 2002 Act sets out the authorities who will be responsible for enforcing any prohibition or requirements imposed; section 14 sets out the powers of entry which enforcement officers may exercise; and, section 15 makes obstructing an officer of an enforcement body, or making false statements to an officer, an offence.

240. Subsection (2) of clause 20 inserts a new paragraph (c) into section 12D(1) of the Children and Young Persons Act 1933 (restricted premises orders and restricted sales orders: interpretation). This extends the definition of "tobacco offence" for the purposes of sections 12A and 12B of that Act to include an offence committed under the new section 3A of the 1991 Act. The effect of this is to enable a magistrates' court to impose a restricted premises order or a restricted sales order in response to breaches of the new section 3A, where the conditions for imposing such orders are met. Under sections 12A and 12B if three "tobacco offences" are committed (the last of which must have led to a conviction) within a period of two years, then the offender or the relevant premises may be banned from selling tobacco products for up to one year.

Clause 21: Power to prohibit or restrict sales from vending machines: Northern Ireland

241. Clause 21 inserts a new Article 4A into the 1991 (NI) Order. New Article 4A makes equivalent provision for Northern Ireland to that made for England and Wales by the new section 3A inserted in the 1991 Act by clause 20.

Clause 22 and Schedule 4: Tobacco: minor and consequential amendments

242. Clause 22 gives effect to Schedule 4. Schedule 4 makes various minor and consequential amendments. These amendments include—

- limiting the application of sections 6(1) and 8 of the 2002 Act to Scotland;

- limiting the power of the Secretary of State under section 13(5) of the 2002 Act to take over the conduct of proceedings to proceedings in relation to offences committed in England and giving power to the Welsh Ministers to take over the conduct of proceedings in relation to offences committed in Wales;

- amending the definition of "appropriate Minister" for the purposes of the 2002 Act, to confer powers on the Welsh Ministers and DHSSPSNI to make regulations in relation to the new provisions about specialist tobacconists and displays and to transfer to them existing powers under section 4(3) of the 2002 Act (power to provide for exclusions from the section 2 prohibition on tobacco advertising); and

- provision for the procedure to be adopted in relation to regulations made by the Welsh Ministers and DHSSPSNI under the provisions of the 2002 Act as amended by the Bill.

243. Schedule 4 also amends section 8 (displays), section 9 (prohibition of free distribution), section 11 (brandsharing) of, and the Schedule (information society providers) to, the 2002 Act to give full effect to Directive 2000/31/EC of the European Parliament and Council of 8th June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce). It also repeals section 16(1A) of the 2002 Act (limitation of penalties for certain offences relating to information society services) to bring the penalties for offences covered by that provision into line with the penalties which apply generally for offences under the 2002 Act.

Pharmaceutical Services in England

244. These clauses introduce changes to the way in which PCTs determine applications by contractors to provide NHS pharmaceutical services and also introduce new provisions enabling PCTs to take action against contractors for breaches of the arrangements for providing those services.

245. In addition, the clauses amend current legislation concerning the provision of local pharmaceutical services (LPS) contracts enabling PCTs to provide services under LPS schemes in prescribed circumstances. Under existing legislation, PCTs can only commission such services.

246. These measures follow a Department of Health consultation in the autumn of 2008 on a series of proposals to amend the structure and legislation of NHS pharmaceutical services, following publication of the Government's White Paper *Pharmacy in England: Building on strengths, delivering the future* published in April 2008. A report of the outcome of that consultation concerning the primary legislation measures contained within this Bill was published on 16th January 2009 and is available on the Department of Health website.

Clause 23: Pharmaceutical needs assessments

247. Clause 23 creates a new duty in the NHS Act for all PCTs in England in respect of their assessments of pharmaceutical needs, commonly known as pharmaceutical needs assessments.

248. *Subsection (1)* requires PCTs, in accordance with regulations, to undertake assessments of needs for pharmaceutical services in their respective areas and to publish a statement of their first assessment of those needs and any subsequent revised assessment.

249. *Subsection (2)* requires regulations to make provision for certain matters relating to the procedures which PCTs must follow when undertaking their pharmaceutical needs assessments. Regulations must stipulate

- the minimum information requirements which each pharmaceutical needs statement must contain;
- the extent to which the pharmaceutical needs assessment is to take account of likely future needs for pharmaceutical services;
- the date by which each PCT must publish their first assessment; and
- the circumstances in which a PCT must undertake a new assessment.

250. For example, the regulations might stipulate that a pharmaceutical needs statement must contain information on the demography of the people in its area and any seasonal trends or variations as well as longer-term population projections and age profiles. It might also, for example, stipulate that PCTs must publish their first statement within six months of the regulations coming into force and that they must undertake a new assessment where important new health data, trends in disease or evidence of the effectiveness or ineffectiveness of certain types of service emerge.

251. *Subsection (3)* enables regulations to provide for additional matters or relating to pharmaceutical needs assessments. The additional matters may include the kinds of pharmaceutical services which the pharmaceutical needs assessment must relate to, for example, the provision of certain services such as reviews of patient medication, clinical support for patients starting medication to treat a long-term condition, advice and information to patients or other healthcare professionals. The regulations may also impose requirements on PCTs to consult specified persons about specified matters when undertaking their pharmaceutical needs assessment. The PCT may for example, be required by the regulations to consult local authorities, patient and community groups and local professional representative committees. The regulations may also prescribe the manner in which an assessment is to be made. The regulations may require the PCT to show, when publishing its pharmaceutical needs statement, how it has consulted interested parties. The regulations may also include a range of matters which a PCT must have regard to when making an assessment of pharmaceutical needs. Such matters may include for example—

- data on future disease trends;
- population forecasts;
- information on health concerns which may be specific to the PCT (such as asbestosis in mining areas); and
- how the PCT has taken into account the views and comments received as a result of consultation, whether it has accepted or rejected those views and, if rejected, the reasons why.

Clause 24: New arrangements for entry to pharmaceutical list

252. Section 129 of the NHS Act sets out various requirements under which regulations govern the provision of pharmaceutical services. Clause 24 amends section 129 of the NHS Act.

253. Section 129(2)(c) sets out the legislative criteria which a PCT must apply when considering applications from pharmaceutical contractors to be included on a PCT's pharmaceutical list for the provision of NHS pharmaceutical services or for changes to a contractor's listing following admittance. These criteria are often referred to as the "control of entry" test. The clause inserts new provisions regarding those criteria.

254. *Subsection (*2) of clause 24 amends the criteria in section 129(2)(c) to provide for circumstances where an application must be granted by a PCT and circumstances where an application may be granted by a PCT.

255. *Subsection (3)* then sets out the circumstances—

- in which a PCT must grant an application; and
- in which a PCT may grant an application.

256. Under new subsection (2A), a PCT must grant an application where it is satisfied, having first taken account of what is set out in the statement of its assessment of pharmaceutical needs, and any matters which are prescribed in regulations, that the need for the services or some of the services in the application is established and will be met through grant of the application.

257. Under new subsection (2B), a PCT may grant an application where it is satisfied, having first taken account of what is set out in the statement of its assessment of pharmaceutical needs, and any matters which are prescribed in regulations, that it would secure improvements or better access to pharmaceutical services in its area. The matters prescribed in regulations might include additional criteria such as improvements in access (for example through extended hours), in the choice and diversity of providers or of services in its area (for example, dedicated clinics at evenings or weekends to stop smoking or to review patients' medications), in innovation in the delivery of services or of services which meet the needs of specific groups of people in the PCT's area or local health conditions or diseases.

258. New subsection (2C) makes additional provision in cases where a PCT is satisfied that an application meets the criteria for grant of the application required under subsection (2B). First, new subsection (2C) provides that the regulations may set out the manner in which the PCT is to determine whether to grant the application. For example, a PCT might first seek views from local patient representative bodies and other key interested parties where it is minded to grant an application under new subsection (2B). Second, new subsection (2C)

provides that the regulations may stipulate certain matters which a PCT must or must not take into account when deciding whether or not to grant an application under new subsection (2B). For example, the regulations might make provision that a PCT must take account of the views of local patient representative bodies concerning the application in reaching its determination. Conversely, the regulations might make provision that a PCT must not take account of other matters in reaching its determination where such matters lead to the refusal of all applications (for example, on grounds of costs alone or of additional monitoring burdens for the PCT) where the criteria in new subsection (2B) are otherwise met.

259. *Subsections (4) (5) and (6)* of clause 24 modify the existing provisions which enable regulations to specify the circumstances in which two or more applications are considered together by the PCT.

260. *Subsection (4)* inserts a new subsection (3A) to provide that the regulations may prescribe the circumstances in which two or more such applications may be considered together by a PCT. *Subsection (5)* amends section 129(4) creating a general power to make provision for the case where two or more applications, taken individually, meet the test under new subsection (2A) or (2B), but taken together, do not.

261. *Subsection (6)* of clause 24 inserts a new subsection (4A) which allows regulations under subsection (4) to include, in particular, the provision mentioned in subsection (5), with or without modification. This new subsection ensures the wording in subsection (5) can be tailored to apply to both parts of the two part test under subsection (2A) and (2B).

262. *Subsection (7)* introduces a new provision which enables regulations to specify the circumstances in which, and the manner in which, a PCT can invite applications to be included in its pharmaceutical list. For example, this might be appropriate where a PCT has identified, in its first or subsequent statement of needs, areas where there are gaps in provision or where the PCT wishes to secure improvements in access to, or in the choice or quality of, services provided and wishes to invite applications from pharmaceutical contractors.

263. *Subsection (8)* inserts a new provision which requires PCTs to give reasons for decisions made in relation to all applications received under section 129 and provides that references to a "needs statement" in the clause are the most recently published statement, which will be the statement in force at the time the application is decided.

Clause 25: Pharmaceutical lists - minor amendment

264. Clause 25 corrects an apparent anomaly in section 129(6)(d) of the NHS Act. Section 129(6)(c) refers to a particular kind of application for inclusion in a pharmaceutical list and was not intended to affect the meaning of "such an application" in section 129(6)(d). The amendment makes clear that the provision in section 129(6)(d) for the inclusion of an applicant on a PCT's list for a fixed period of time may apply to any application made under section 129.

Clause 26: Breach of terms of arrangements: notices and penalties

265. Clause 26 inserts in Part 7 of the NHS Act a new Chapter 5A that concerns the issuing by PCTs of notices to contractors and the withholding of payments to contractors by PCTs.

266. This clause enables regulations to provide that where a contractor breaches a term of arrangements for providing NHS pharmaceutical services (for example, of a term of service, such as agreed quality standards or of performance in the provision of services) then PCTs will have the power to issue remedial notices, requiring corrective action to be taken or requiring the contractor to refrain from continuing with actions which have led to the breach, within a specified period of time. The regulations may also enable PCTs to withhold all or part of any payments due to the contractor for a prescribed period in view of such a breach. Powers to withhold payments could be used on their own or in conjunction with the issue of remedial notices.

267. *Subsection (2*) requires that any regulations under this section must include prescribed rights of appeal for the contractor against decisions made by the PCT under this section.

268. *Subsection (3)* provides definitions for this section.

Clause 27: LPS schemes: powers of Primary Care Trusts and Strategic Health Authorities

269. Clause 27 introduces changes to section 144 of, and Schedule 12 to, the NHS Act that will remove the restrictions in NHS legislation on PCTs providing local pharmaceutical services (LPS) or to other PCTs, in certain circumstances, for example, in the event of any emergency such as a flu pandemic or where there was no alternative provider. Where a PCT is a provider of local pharmaceutical services within its own it area is intended that the (LPS) commissioner must be the Strategic Health Authority.

Pharmaceutical services in Wales

270. These clauses introduce new provisions enabling Local Health Boards (LHBs) to take action against certain NHS contractors for breaches of the arrangements for providing those services. The clauses that relate to breaches of arrangements between LHBs and contractors relate to the providers of both pharmaceutical and ophthalmic services in Wales.

271. In addition, the clauses amend current legislation concerning the provision of local pharmaceutical services (LPS) contracts enabling LHBs to provide local pharmaceutical services (LPS) in prescribed circumstances. Under existing legislation, LHBs can only commission such services.

Clause 28: Pharmaceutical lists - minor amendment

272. Clause 28 corrects an apparent anomaly in section 83(6)(d) of the NHS (Wales) Act. Section 83(6)(c) refers to a particular kind of application for inclusion in a pharmaceutical list and was not intended to affect the meaning of "such an application" in section 83(6)(d). The amendment makes clear that the provision in section 83(6)(d) for the inclusion of an applicant on an LHB list for a fixed period of time may apply to any application made under section 83.

Clause 29: Breach of terms of arrangements: notices and penalties

273. Clause 29 inserts in Chapter 2 of Part 8 of the NHS (Wales) Act 2006 a new section 106A that concerns the issuing by LHBs of notices to certain NHS contractors and the withholding of payments to such contractors by LHBs.

274. This clause enables regulations to provide that where a contractor breaches a term of arrangements for providing NHS pharmaceutical services or arrangements for providing general ophthalmic services (for example, of a term of service, such as agreed quality standards or of performance in the provision of services) then LHBs will have the power to issue remedial notices, requiring corrective action to be taken or requiring the contractor to refrain from continuing with actions which have led to the breach, within a specified period of time. The regulations may also enable LHBs to withhold all or part of any payments due to the contractor for a prescribed period in view of such a breach. Powers to withhold payments could be used on their own or in conjunction with the issue of remedial notices.

275. *Subsection (2)* requires that any regulations under this section must include prescribed rights of appeal for the contractor against decisions made by the LHB under this section.

276. *Subsection (3)* provides definitions for this section.

Clause 30: LPS schemes: powers of Local Health Boards

277. Clause 30 introduces changes to Schedule 7 to the NHS (Wales) Act that will enable LHBs to provide local pharmaceutical services (LPS) in certain circumstances, for example, in the event of a national emergency. The circumstances in which LHBs are able to provide local pharmaceutical services (LPS) will be set out in regulations made by the Welsh Ministers.

Adult social care

Clause 31: Investigation of complaints about privately arranged or funded adult social care

278. Clause 31 gives effect to Schedule 5. Part 1 of Schedule 5 inserts a new Part 3A into the 1974 Act. Part 3A establishes a new scheme for the investigation by a Local

Commissioner of complaints about adult social care which is privately arranged or privately funded. References below to section numbers are to the sections as they will be numbered in the 1974 Act.

Schedule 5: Investigation of complaints about privately arranged or funded adult social care

Section 34A: Interpretation: "adult social care provider" and "adult social care"

279. Section 34A defines the terms "adult social care" and "adult social care provider" for the purposes of delineating the matters subject to investigation under the new scheme (set out in section 34B). The meaning of "adult social care" is defined by reference to Part 1 of the Health and Social Care Act 2008 (the 2008 Act). Section 9 of that Act states that social care "includes all forms of personal care and other practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstance, are in need of such care or other assistance". Such care falls within the scope of the new scheme if it is provided to persons aged 18 or over.

280. "Adult social care provider" is defined in subsection (3). Only persons providing adult social care which is a regulated activity within the meaning of Part 1 of the 2008 Act will be "adult social care providers" for the purposes of the new scheme. Section 8 of the 2008 Act allows for regulated activities to be prescribed in regulations made under that Act. Only activities that are prescribed will be regulated by the Care Quality Commission. If a service is not regulated by the Care Quality Commission it will not fall within the Local Commissioners' remit. It is the Government's intention to prescribe, for example, that provision of care home accomodation and the care provided to residents in a home will be regulated by the Care Quality Commission. Therefore a provider of these types of activity would come within the Local Commissioners' remit.

281. Subsections (4) and (5) provide that action taken on behalf of a provider will be treated as action by the service provider whether this is action taken by an employee, by a person with whom the provider has contracted to provide the service, or (subsection (5)) where the care is provided by means of a less formal arrangement with another person. The intention of these two subsections is to ensure that complaints about social care provided under any arrangements where the provider has delegated the service remain within the Local Commissioners' remit.

Section 34B: Power to investigate and Schedule 5A: Matters not subject to investigation

282. Section 34B sets out the matters that a Local Commissioner may investigate and the conditions that need to be satisfied before an investigation can take place. A Local Commissioner may investigate any matter relating to action taken by an adult social care provider in connection with the provision of adult social care. So as explained above, the new

scheme is limited to complaints about adult social care which is regulated by the Care Quality Commission.

283. Schedule 5A (inserted by paragraph 3 of Schedule 3) sets out matters which are not subject to investigation under the new scheme. Complaints about social care that already fall within the local authority statutory complaints procedure are excluded since these can be investigated by a Local Commissioner under the existing procedure in Part 3 of the 1974 Act. Complaints about NHS services (which may involve the provision of social care) are also excluded since these are for investigation by the Health Service Commissioner under the 1993 Act.

284. Section 34B(1)(b) requires one of two conditions to be met before an investigation can take place. Either a complaint has to have been made by someone who can complain (see section 34C) and in accordance with the procedure for making a complaint (set out in section 34D) or the matter has come to the attention of a Local Commissioner and in accordance with section 34E may be treated as though a complaint about the matter had been made directly.

285. Before proceeding to investigate a matter, a Local Commissioner must be satisfied either that the provider has had notice of the matter complained about and an opportunity to investigate and respond, or that it is not reasonable in the circumstances to expect the matter to be brought to the notice of the provider (subsection (5)). A Local Commissioner is able to use discretion to take a flexible approach and proceed with an investigation, if satisfied that it is not reasonable to expect the matter complained about to have first been brought to the attention of the service provider or investigated by the provider. The Government expects that in the majority of cases the complainant would raise the complaint with the provider first, but the scheme allows a person to taken the matter up directly with a Local Commissioner. This is because of the vulnerable nature of this group of service users, and allows for the possibility that a person might feel unable, through fear of reprisal or for some other reason, to take up the matter with the provider.

Section 34C: Who can complain and section 34D: Procedure for making complaints

286. Section 34C provides for the scheme to apply to members of the public who claim to have sustained injustice because of the service provider's action. It also allows someone to act on a person's behalf in making the complaint. Section 34D requires complaints to be made in writing. Complaints must be made within 12 months of the complainant first having notice of matter in question, or, if the person affected has died without having notice of the matter, within 12 months of the person's representatives (or such other person who is making the complaint) having notice of it. A Local Commissioner may disapply these requirements. For example, the requirement for the complaint to be made in writing may be disapplied where a complaint is made orally where the service user's particular circumstances make it difficult for them to put the complaint in writing. A Local Commissioner might also wish to disapply the 12-month time limit where the circumstances of the person affected have made it difficult for them or their representatives to raise the matter within that period.

Section 34E: Matters coming to attention of Local Commissioner

287. Under section 34E, matters that come to the attention of a Local Commissioner, without being raised by the person affected or his or her representatives, can be treated as though a complaint had been made about them directly. A Local Commissioner may investigate matters as though they had been raised by a complaint if they become aware of the matters either during an investigation under the existing scheme relating to local authorities (under Part 3 of the 1974 Act) or during an investigation of another matter under the new scheme. A Local Commissioner may only investigate a matter if it appears that a member of the public has or may have suffered injustice in consequence of the matter. The matter must also have come to the attention of the Local Commissioner before the person affected or their representatives have had notice of the matter, or within a permitted period of 12 months, although in the same way as in section 34D, the Local Commissioner can disapply the 12-month time limit.

Section 34F: Procedure in respect of investigations

288. Section 34F deals with the procedure for conducting an investigation. The adult social care provider concerned, and anyone alleged to have been responsible for taking or authorising the action complained about, must be allowed the opportunity to comment. This means that whoever carried out the action complained about, whether this is the provider himself, or someone else who has carried out the action on behalf of the provider, that person must be given an opportunity to comment. Investigations must be conducted in private. But otherwise it is for the Local Commissioner to decide how to conduct the investigation. The Local Commissioner may obtain information and make enquiries from any person as they see fit under subsection (4).

Section 34G: Investigations: further provisions

289. Section 34G gives a Local Commissioner various powers in order to facilitate their investigations. The Local Commissioner may require the adult social care provider, or any other person who in the Commissioner's opinion is able to provide information or documents relevant to the investigation, to provide such information or documents. For example, a local authority or the Care Quality Commission may have information or documents relevant to an investigation under Part 3A.

290. The Local Commissioner has the same powers as the High Court to compel the attendance and examination of witnesses and the production of documents. This means that anyone not complying with the Local Commissioner's requests may be in contempt of court and subject to the penalties associated with that. Subsection (9) provides that if any person obstructs an investigation, or is guilty of an act or omission in relation to an investigation which would constitute contempt of court in proceedings in the High Court, the Local Commissioner may certify this as an offence to the High Court. The High Court may then

deal with the person charged under subsection (9) as though they had committed the same offence in relation to the High Court.

Section 34H: Statements about investigations

291. This section provides for statements to be issued by a Local Commissioner when he decides not to investigate or to discontinue an investigation, and when an investigation is completed. If the Commissioner decides not to investigate or to discontinue an investigation, the statement must set out the Commissioner's reasons for that decision.

292. When a Local Commissioner has completed an investigation, the statement must set out the Commissioner's conclusions and any recommendations. The Commissioner may make recommendations for action which, in the Commissioner's opinion, the adult social care provider needs to take to remedy any injustice sustained by the person affected. Recommendations may also be aimed at preventing injustice being caused in the future as a result of similar action of the provider. For example, the Commissioner might recommend an apology to the complainant, compensation to be paid, a refund of charges or changes to be made to the services provided (possibly relating to the service user's facilities, accommodation, equipment or changes to how staff are managed or trained.

293. The Commissioner must send a copy of the statement to the complainant, the provider and, if someone else took the action complained of, to that person. The statement must identify the provider concerned unless the provider is an individual or doing so would identify an individual. It will then be for the Local Commissioner to decide whether it is appropriate for the individual to be identified. The statement must not identify the complainant or any other person (other than the provider) unless the Commissioner considers it necessary to identify that person.

294. The Local Commissioner may also send copies of the statement to the Care Quality Commission and any local authority. For example it is likely that this would occur in all cases where the statement draws attention to failings in the safety of services, or where there are implications for many service users, not only the person who has complained.

Section 34I: Adverse findings notices

295. Section 34I requires providers to consider any statement containing recommendations by a Local Commissioner and notify the Commissioner within the "required period" - one month of receiving the statement (or any longer period agreed in writing by the Local Commissioner) - of the action which the provider has taken or proposes to take. If by the end of that period, the Local Commissioner has not received this notification, or is satisfied before the period expires that the provider has decided to take no action, the Local Commissioner may require a provider to publish an adverse findings notice. The Commissioner may also do this in two other circumstances: firstly, if not satisfied with the action which the provider has taken or proposes to take; or secondly, if, after a further month following the end of the

"required period" (or any longer period agreed in writing by the Local Commissioner), the Commissioner has not received satisfactory confirmation that the provider has taken the proposed action.

296. Subsection (4) provides that an adverse findings notice, in a form agreed between the provider and a Local Commissioner, should include details of any action recommended in the Local Commissioner's statement which the provider has not taken, any supporting material required by the Local Commissioner, and an explanation of the provider's reasons for not having taken the recommended action (if the provider wishes). The adverse findings notice must be published by the provider in a manner directed by the Local Commissioner. The Local Commissioner might for example, require publication in a local newspaper or, if the provider has an internet site, on that site**.**

297. Under subsection (6), a Local Commissioner must publish an adverse findings notice if the provider fails to do so in accordance with subsections (4) and (5), or cannot agree the form of the notice with the Local Commissioner within one month of the date the notice was received (or longer if agreed in writing by the Local Commissioner). Subsection (7) requires the provider to reimburse the LGO on demand any reasonable expenses incurred by the Local Commissioner in performing the duty under subsection (6).

Section 34J: Publication of statements etc. by Local Commissioner

298. This section deals with the publication of statements or adverse findings notices. A Local Commissioner may publish all or part of a statement, further publish an adverse findings notice or publish a summary of a statement or adverse findings notice. In deciding whether to publish a statement the Commissioner must take into account the public interest as well as the interests of the complainant and of other persons. The Local Commissioner may also supply a copy of all or part of a statement or adverse findings notice to anyone who requests it, and charge a reasonable fee for this. Subsections (8) and (9) of section 34H apply to a Local Commissioner's publication of a statement or supply of any copy under this section. That means that, for example, the summary must not identify the complainant or any other person (other than the provider) unless the Commissioner considers it necessary to identify that person.

Section 34K: Disclosure of information

299. Section 34K restricts the disclosure by a Local Commissioner of information obtained during the course of an investigation. Information obtained must not be disclosed except for the purposes specified. Particular exemptions allowing disclosure of information include, for example, disclosure for the purposes of investigations and statements related to investigations under Part 3 or 3A of the 1974 Act, or for the purposes of a complaint being investigated by the Parliamentary Commissioner or the Health Service Commissioner.

Section 34L: Law of defamation

300. Section 34L confers absolute privilege for the purposes of the law of defamation on certain communications between a Local Commissioner and other parties and certain publications by a Local Commissioner. This means that these communications and publications are not actionable for slander or libel.

301. Communications between a Local Commissioner and an adult social care provider will be privileged. The publication of any matter by a Local Commissioner in communications with a complainant, the Parliamentary Commissioner, the Health Service Commissioner, a local authority or the Care Quality Commission will also be privileged. Privilege will also apply to the publication of statements, adverse finding notices, summaries and reports by a Local Commissioner.

Section 34M: Consultation with other Commissioners

302. Under section 34M, if a Local Commissioner thinks that any matters which are subject of the investigation include a matter that is potentially, or actually, the subject of another Ombudsman's investigation, the Commissioner is required to consult with that other Ombudsman. The other Ombudsmen this applies to are the Parliamentary Commissioner, the Health Service Commissioner, the Public Services Ombudsman for Wales, and the Scottish Public Services Ombudsman. Subsection (5) imposes a similar obligation on the Parliamentary Commissioner. If the Parliamentary Commissioner is conducting an investigation and considers that the complaint relates partly to a matter which could be the subject of investigation by a Local Commissioner, then they must consult with the Local Commissioner. (A similar obligation is placed on the Health Service Commissioner under the 1993 Act).

Section 34N: Collaborative working with other Commissioners

303. Section 34N applies if a Local Commissioner in conducting an investigation considers that the investigation raises a matter which could be the subject of investigation by the Parliamentary Commissioner or the Health Service Commissioner. A Local Commissioner may then, if the complainant consents, carry out a joint investigation with the Parliamentary Commissioner or the Health Service Commissioner, or both. Under subsection (3) a Local Commissioner may similarly collaborate in the investigation of a complaint being investigated by the Parliamentary Commissioner or Health Service Commissioner.

Section 34O: Disclosure of information by Local Commissioner to Information Commissioner and Section 34P: Disclosure of information by Local Commissioner to Care Quality Commission

304. Sections 34O and 34P allow a Local Commissioner to disclose to the Information Commissioner, or the Care Quality Commission, information that a Local Commissioner

receives as result of an investigation that may be relevant to the carrying out of the functions of those organisations. The disclosure of information to the Care Quality Commission enables a direct link to be made between a Local Commissioner's investigation and the regulation of the provider whose services have been the subject of that investigation. Under section 20 of the 2008 Act, the Secretary of State may impose requirements on regulated activities (as carried out by service providers) through regulations. The Care Quality Commission will determine whether the regulatory requirements have been complied with, and information from a Local Commissioner would be an indicator of potential non-compliance on which the Care Quality Commission would be able to act.

Section 34R: Review, recommendations, advice and guidance and Section 34S: Annual reports

305. Section 34R provides that every three years a Local Commissioner must review the operation of the provisions of Part 3A of the 1974 Act (the provisions of the new scheme). The review must be carried out in the same financial year as the Commission carries out a review of the provisions of Part 3 (already required under section 23(12) of the 1974 Act). A Local Commissioner may convey any recommendations or conclusions from this review to government departments or the Care Quality Commission. A Commissioner may also provide good practice advice or guidance to adult social care providers.

306. Section 34S provides that each Local Commissioner must prepare a report on the discharge of their functions for each financial year. The Commission must then prepare an annual report which must be laid before Parliament and which must be published along with the reports from the individual Commissioners.

Section 34T: Interpretation of Part 3A

307. Section 34T defines certain terms used in Part 3A.

Part 2 of Schedule 5

308. Part 2 of Schedule 5 makes a number of minor and consequential amendments to other Acts.

Disclosure of Information

Clause 32: Disclosure of information by Her Majesty's Revenue and Customs

309. Clause 32 applies to information held by the HMRC in connection with its functions relating to income tax.

310. *Subsection (2)* allows HMRC to disclose certain information relating to GPs and dental practitioners to the persons defined in *subsection (3).* The information disclosed will

be a summary of anonymised information relating to the earnings and expenses of these practitioners and will not extend to other details disclosed to HMRC as part of the tax assessment process such as matters unconnected with their professional activities.

311. *Subsection (3)* defines those persons to whom HMRC may disclose information covered by this clause. Those persons are the Secretary of State, Welsh Ministers, Scottish Ministers, the DHSSPSNI or persons providing services to them or exercising functions on their behalf.

312. *Subsection (4)* places restrictions on the format of the information disclosed by HMRC. The information must be summarised or presented as a collection of information. It must not be possible to identify, or link the information to, a particular individual.

313. *Subsection (5)* defines the terms dental practitioner and general medical practitioner for the purpose of this section.

PART 4 – GENERAL

Clause 33: Power to make transitional and consequential provisions etc

314. *Subsection (1)(a)* confers on the Secretary of State the power to make transitional or transitory provisions or savings in connection with the coming into force of any provision of the Bill. However, *subsection (1)(a)* is limited by the exclusions in *subsection (2). Subsection (3)* provides for appropriate transitional arrangements or savings to be made by the Welsh Ministers. *Subsection (4)* provides for appropriate transitional arrangements or savings to be made by DHSSPSNI. *Subsection (5)* provides that an order under the section may amend any enactment, and *subsection (12)* defines enactment as an enactment in or in an instrument made under a Measure or Act of the National Assembly for Wales or Northern Ireland legislation as well as an Act of Parliament. *Subsection (6)* provides for modifications by order of a provision brought into force to have effect until another provision comes into force.

315. Transitional arrangements are likely to be necessary in relation to commencement of various provisions of the Bill, including the provisions for suspension and in relation to tobacco and pharmaceutical services. Through transitional arrangements it will be possible to modify the application of the Bill to existing situations and to ensure transition from the old law and procedures to the new.

316. *Subsection (1)(b)* also confers on the Secretary of State power by order to make such supplementary, incidental, or consequential provision as he considers appropriate for the purposes of, in consequence of, or for giving full effect to, any provision of the Bill. This would, for example, enable amendments to be made to references in legislation to NHS trusts

to take into account the possibility created by provisions of the Bill of there being a new kind of NHS trust, a de-authorised NHS foundation trust.

317. By *subsections (5) and (9)(a)* orders of the Secretary of State may amend, repeal, revoke or otherwise modify any enactment contained in an Act of Parliament in which case they would be subject to approval by each House of Parliament under the affirmative resolution procedure. By *subsection (5) and (9)(b)* such orders of the Secretary of State, whether they amend any other legislation or not would be subject to the negative resolution procedure. The powers are additional to any other provision of the Bill.

Clause 34: Repeals and revocations

318. Clause 34 introduces and gives effect to Schedule 6, which contains repeals and revocations.

Clause 35: Extent

319. Clause 35 makes provision as to the extent of the provisions of the Bill. For further information on extent please refer to the Territorial Extent section of these notes.

Clause 36: Commencement

320. Clause 36 provides for the coming into force of the provisions of the Bill. *Subsection (1)* provides that the Bill when enacted, with certain exceptions, will come into force on a day appointed in an order made by the Secretary of State by statutory instrument. By *subsection (4)* different days can be appointed for different purposes or different areas.

321. The first exception is that, on the day on which the Bill receives Royal Assent, various provisions come into force by virtue of *subsection (5).* The provisions are the repeal of section 16(1A) of the 2002 Act (see paragraph 9(2) and (4) of Schedule 4) together with the associated repeals and revocations made by the Bill, and clause 36 itself, together with clauses 33 (power to make transitional and consequential provision etc), 35 (extent) and 37 (short title).

322. Secondly, for the purposes of making regulations, the following regulation-making powers also come into force by virtue of *subsection (6)* on the day on which the Bill receives Royal Assent: the power at clause 6 for the Secretary of State to make regulations to disapply the duty to publish quality accounts, those for regulations providing that no offence is committed in relation to a tobacco advertisement by specialist tobacconists in certain circumstances as inserted into the 2002 Act by clause 18, for making provision in relation to tobacco displays as inserted into the 2002 Act by clause 19, for prohibiting or imposing requirements in relation to sales of tobacco products from vending machines as inserted into the 1991 Act by clause 20, or for restricting sales from vending machines in Northern Ireland

as inserted into the 1991 (NI) Order by clause 21 and the provisions at paragraphs 11 and 12 of Schedule 4.

323. The third exception is in relation to some of the minor and consequential amendments made in relation to the tobacco provisions in Schedule 4 which are identified at *subsection (7).* These come into force at the end of the period of two months beginning on the day on which the Bill receives Royal Assent.

324. *Subsection (8)* provides for the section that introduces a provision of a Schedule mentioned in *subsection (5), (6)* or *(7)* to come into force for the purposes of the particular provision only.

325. The Welsh Ministers have power by order made by statutory instrument to bring into force on a day appointed by them provisions of the Bill which relate to Wales and are identified at *subsection (2).* Similarly DHSSPSNI has power by order made by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (S.I. 1979/1573 (N.I. 12) to bring into force on a day appointed by DHSSPSNI provisions of the Bill which relate to Northern Ireland and are identified at *subsection (3).* These powers at *subsections (2)* and *(3)* each benefit from the flexibilities provided by *subsection (4)* and respectively constitute further exceptions to the power at *subsection (1).*

326. Where amendments made by Schedule 3 (introduced by clause 17) relate to bodies operating in Wales, Scotland or Northern Ireland as well as in England, the Secretary of State is obliged to consult the Welsh Ministers, the Scottish Ministers or DHSSPSNI as appropriate before making an order bringing the amendments into force (see *subsections (9), (10) (11)* and *(12)*).

327. Insofar as the provisions of Schedule 3 relate to amendments to the NHS (Wales) Act, the Welsh Ministers are obliged to consult the Secretary of State before making an order bringing the amendments into force by virtue of *subsection (13).*

Clause 37: Short title

328. The Bill is to be known as the Health Act 2009.

PUBLIC SECTOR FINANCIAL COST AND MANPOWER IMPLICATIONS

329. The Government's view is that the Bill will have little overall effect on public sector manpower and financial cost to public expenditure. Further details on the financial implications of the provisions contained in the Bill are outlined below and under the heading *Summary of Impact Assessments*.

330. The provisions that will have a limited impact on public finance and/or public service manpower are those in relation to quality accounts, innovation prizes, TSAs for NHS bodies, the prohibition of display of tobacco products, changes to local pharmaceutical services (LPS) contracts and LGO's investigation into complaints about privately arranged or funded adult social care.

Quality accounts

331. The Government anticipates that the cost and public sector manpower impact of data collection for quality accounts will be zero, as the data collection should already be carried out as part of separate work on developing clinical quality metrics as part of the NHS Next Stage Review Quality Framework. The manpower involved in producing the quality account, after the data has been collected, will be variable and will depend on the size of the organisation and number and type of services provided. The Government estimates that a member of staff could take a total of between half a week to five weeks to analyse the data and produce the quality account.

Innovation prizes

332. For indicative purposes, The Government estimates that a total of up to £5million annually (from 2010/11) will be made available for the innovation prizes. The Government has set aside up to £1million for the administration of this scheme, which will also include related publicity and the hosting of an annual awards ceremony.

Trust special administrators for NHS bodies

333. The TSA regime will require support for the Secretary of State for Health. The government expects that the regime will be administered by the NHS Chief Executive and senior managers in the NHS Finance, Performance and Operations directorate within the Department of Health, resulting in an expected 96 hours in total being spent on each episode.

Tobacco

334. Monitoring and enforcing the prohibition on the display of tobacco products and any regulations governing the sale of tobacco from vending machines will be responsibility of local authorities, via trading standards. Trading standards currently ensure that retailers of tobacco products comply with existing legislation, including restrictions on tobacco advertising and age of sale restrictions for both sale from retailers and vending machines. The provisions in the Bill will change the compliance test used by trading standards when checking compliance with restrictions on the sale of tobacco, but the provisions will not increase the existing burden on trading standards on a continuing basis. There may be a small increase in cost for local authorities in the first year of implementation due to the need to educate and support retailers and trading standards on the changes in law.

Pharmaceutical Services (in England and Wales)

335. The exact costs resulting from proposals to create a duty on PCTs to prepare and to publish statements of pharmaceutical needs and to use these to assess applications to provide pharmaceutical services are not yet known, because the detailed regulations that will be brought forward to implement these proposals have not yet been prepared. However, the final Impact Assessment indicates an average cost to the NHS (excluding minimal one-off costs) of £1.8 million in the first year, £1 million in subsequent years and a further 5% reduction from the adoption of good practice in reviewing and refining such assessments. The Government assumes that there would initially be a 10% reduction in appeals, with a further 5% reduction after assessments of pharmaceutical needs are refined, and therefore reduced costs for PCTs and for the NHS Litigation Authority. The Government expects that existing PCT staff will spend more time on the preparation of statements of pharmaceutical needs. This is estimated at three months for a senior manager and one month for administrative support. Senior PCT board members will also need to sign-off the final statement prior to publication.

336. In respect of then applying these assessments to determine contractors' applications to provide pharmaceutical services, The Government intends that PCT's decisions, by virtue of being related to pre-existing statements of needs, become more transparent and consistent and that this may, in time, lead to some reduction in the time spent dealing administratively with such applications. However, it is not possible to estimate the exact effects at this stage, as these will depend on the detail contained in the regulations that will be needed to implement the proposal.

337. The exact costs resulting from proposals to introduce powers to enable PCTs in relation to England, and LHBs in relation to Wales, to take appropriate action against contractors on the grounds of inadequate performance or quality are not yet known, because the detailed regulations that will be brought forward to implement these proposals have not yet been prepared. However, the final Impact Assessment relating to the changes to pharmaceutical services in England models an illustrative scenario in which the NHS in England incurs an average cost of £600,000 each year.

338. Existing PCT and LHB staff will need to familiarise themselves with all new requirements. Where PCTs, in relation to England only, take action to remove a contractor, an illustrative scenario has been evaluated in which additional PCT staff time to the value of 25 days or £6,000 per appealed case will be incurred.

339. No additional implications for NHS staff have been identified in respect of appeals concerning remedial notices or withholding payments from contractors as it is anticipated that PCTs in relation to England, and LHBs in relation to Wales, would rarely use such measures against contractors and only where the grounds for action were serious and without ambiguity. An assessment in relation to England only has estimated that, with an expected 10% reduction in appeals to the NHS Litigation Authority concerning decisions on applications based on pharmaceutical needs assessments (see above), no implications for their

staffing have so far been identified, although there may be some increase in workloads if contractors wish to test the boundaries of the new regime.

340. In respect of the proposed changes to local pharmaceutical services (LPS) legislation, it is difficult to estimate the financial implications for PCTs in relation to England, and LHBs in relation to Wales, as local pharmaceutical service providers, especially where such contracts are only entered into in limited circumstances. Generally, PCT and LHB allocations should provide sufficient funding to cover the provision of pharmaceutical services in normal circumstances but in emergencies such as, for example, a flu pandemic, all PCT and LHB costs would be distorted and there may be extra minimal costs to, and staff demands on, PCTs and LHBs to meet such a need where there is no other suitable provider.

Adult social care

341. Establishing a complaints procedure for privately arranged or funded adult social care is likely to increase the workload of the LGO, who will be the body responsible for investigating such complaints. The Government estimates that the LGO would need to consider 800 to 1000 additional cases per year. Estimates for the set up costs for the LGO in 2009/10 are in the region of £500,000 to £770,000 and full year running costs from 2010/11 are estimated at approximately £1.3 million to £1.45 million.

SUMMARY OF IMPACT ASSESSMENTS

342. A separate Impact Assessment (IA) has been produced to accompany the Bill. The IA can be found on the Department of Health website at the following address—
http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/index.htm.
Copies can be obtained from the Printed Paper Office in the House of Lords.

NHS Constitution

343. The NHS Constitution will set out the principles and values of the NHS in England. It will set out the rights to which patients, public and staff are entitled, the pledges which the NHS is committed to deliver, and the responsibilities which the public, patients and staff owe to each other to ensure the NHS operates fairly and effectively.

344. The Constitution itself will not be in primary legislation (the rights contained already exist in law or will be implemented through secondary legislation). However, the Bill will create a duty on NHS bodies, primary care services and private and voluntary sector providers supplying NHS services to have regard to the Constitution. It will also place duties on the Secretary of State to consult on, to review, and to re-publish the Constitution at least every ten years; to review and to republish the explanatory guide at least every 3 years and to report on its impact.

345. An Impact Assessment covering both these clauses and the Constitution itself will be published shortly, alongside the Constitution. The legislative duties reinforce the benefits of the Constitution, reducing the likelihood that these benefits will be eroded over time.

346. Consideration of the Constitution by bodies providing NHS care may involve changes in planning and commissioning and an increased emphasis by bodies providing NHS care, public and staff to know their rights, pledges and responsibilities and appropriate redress. These may have both costs and benefits; there is currently insufficient data to make a realistic estimate.

347. The main direct costs associated with the legal duties to make available, to review, and to revise the NHS Constitution and Explanatory Guide are publication and staff costs. Reviewing the NHS Constitution will incur a cost every 10 years, and reviewing the Explanatory Guide will incur a cost at least every three years, in line with the legislative intent. Benefits are difficult to quantify, but putting a duty to review these documents will allow them to be kept up to date with legal and policy changes, to remain prominent in decision making by NHS staff, and will provide an opportunity to assess whether the benefits of the constitution and of its different elements exceed the costs.

Quality accounts

348. Provision of easily accessible information to all patients, the public, and others is intended to allow for providers of NHS healthcare to be held to account for the quality of services they provide. The Government expects that this will bring about benefits from improvements to the quality of those services, as providers react to public scrutiny and accountability.

349. The detail of the content of quality accounts will be specified in secondary legislation. The main cost is expected to be that of staff costs for producing quality accounts each year, alongside the potential costs of using a flexibility to determine local content and voluntary external validation of the reports. Any data mandated for inclusion in quality accounts is likely already to be collected for other purposes, so no further data collection costs are anticipated. The IA recognises risks of perverse incentives in the publication of such information, and highlights that this will be considered when regulations are made specifying the content of quality accounts.

Direct payments for health care

350. The IA describes the experience of individual budgets, including direct payments, in social care in England and in health and social care in other countries. The benefits derive from improved service user wellbeing through greater self-direction, leading to increased satisfaction and feeling of being in control, and lower costs through more planned care and a greater focus on prevention. Pilots will explore the possibility of using personal health budgets to give more autonomy and choice to patients with poorer access to health services,

and less successful outcomes, with a view to reducing health inequalities. Personal health budgets incur additional costs as the care planning process becomes more personalised, and oversight is necessary to ensure choices are safe and prudent, from the perspective both of patient and of the funding authority. The Government expects these costs to be justified by the benefits, but piloting is proposed in view of risks and uncertainties regarding how personal health budgets, including direct payments, can best be developed for different groups of people. The specific costs of piloting are justified by the information that will be gathered as to how the policy should best proceed and how it should be applied to different groups of people, thereby mitigating a large part of the uncertainty. The IA presents direct payments within the broader scope of the personal health budgets policy, as one potential model of delivery.

Innovation prizes

351. The main costs in relation to innovation prizes are likely to be the cost incurred by those competing for the prizes, together with the funding of the prizes themselves, and administration costs including the establishment of an expert panel to set the prizes. Social benefits are expected to be realised from the benefits of the solution to problems. It will be for the expert panel to devise challenges that are on the one hand likely to be solved and on the other hand promise social benefits that justify the effort that they are likely to induce.

Trust special administrators for NHS Bodies

352. Benefits of a regime for unsustainable NHS providers can be anticipated both in terms of improving the quality of care for patients in the affected area, and improving the efficiency with which that care is provided. There is also a potential benefit from incentivising underperforming providers to respond more actively to prior performance interventions due to the greater certainty of action if they fail to improve. The largest cost of the regime is likely to arise from administration costs of using external management to take the board functions of the organisation, produce a plan for resolution, and, potentially, to implement that plan.

Suspension of NHS and other health appointments

353. The IA indicates the largest benefit to introducing new powers of suspension to be the potential to avoid future untoward incidents. Under the status quo, where there is information that gives cause for concern about an individual continuing to hold office, there are risks of untoward incidents associated with leaving an unfit person in post, and risks of legal costs associated with removing a person from post inappropriately. Both these risks are mitigated by the introduction of the provisions in the Bill. Costs will be incurred in cases where a replacement is needed to cover the period of suspension.

Tobacco

354. The two main provisions relating to tobacco are described in separate IAs. The large monetised benefits described in the two IAs arise from life years gained by reducing the future take-up of smoking amongst young people; the benefits are presented as a range. They also take into account the fact that some of the averted smokers would have quit anyway at some point.

355. The main one-off cost associated with the provisions on display of tobacco products arises from the need to adjust shops so that tobacco is no longer visible, and the IA notes that the legislation will allow for some very low cost compliance options. The main ongoing costs are incurred due to the need to maintain a price list, and the opportunity cost to the exchequer from lost duty revenue.

356. The provisions relating to vending machines will be implemented via secondary legislation, but the IA shows that the main one-off costs will arise from fitting age-restriction devices to vending machines. Ongoing costs will centre around the time taken for staff to undertake age checks, and the opportunity cost to the exchequer from lost duty revenue.

357. Both policies are likely to see a marginal increase in enforcement costs during the initial years of implementation.

358. The IAs demonstrate that even on cautious assumptions the value of the health benefits that would be secured by the proposals are expected to greatly exceed the costs incurred.

Pharmacy services in England

359. The market entry IA projects improved health outcomes for patients as commissioning of services better reflects the needs of the local population. This is illustrated on the assumption that PCTs will wish to commission increased provision of smoking cessation services. Greater clarity in the contracting process will facilitate business planning and reduce the likelihood of legal challenge of PCT decisions. There will be costs to the PCT of conducting the pharmaceutical needs assessments required. If PCTs discover and address service needs they were previously unaware of, costs could also increase.

360. The provisions relating to remedial notices and withholding of payments give PCTs powers to address poor or inadequate performance. The bulk of the changes will be brought about in secondary legislation under existing powers; the IA presents an illustrative scenario of the potential costs and benefits arising from a reduction in the incidence of prescription errors. The Government thus expects the new proposals to bring benefits to service users by tackling poor quality and strengthening incentives for all providers to raise quality standards. The associated costs are likely to arise from PCTs acting against lower quality providers, and any associated legal costs for both PCT and provider. Contractors are expected to incur costs

in gathering and providing the information required by PCTs to assess the quality of their service.

361. The provisions that allow PCTs to provide local pharmaceutical services (LPS) themselves in situations of emergency or where a suitable alternative is lacking are likely to be implemented very rarely. PCT allocations should provide sufficient funding to cover the provision of pharmaceutical services in normal circumstances, but in emergencies such as, for example, an influenza pandemic, all PCT costs would be distorted and there may be extra costs to PCTs to meet such need. At this stage, the Department has not identified a significant impact arising from these proposals, as the use by PCTs of these new provisions would be expected to be of limited duration and only in exceptional circumstances. For this reason, an IA has not been prepared. However, the Government expects that the proposal will bring about benefits such that PCTs are able to take action, when appropriate and in the absence of any other suitable provider, to help secure continued access to medicines and other pharmaceutical services for their population in defined circumstances. In such circumstances, PCTs would be expected to have due regard for the cost-effectiveness of their actions.

Adult social care

362. General improvement in complaints handling is expected as a result of the provision, as well as resultant service improvements experienced by service-users. There are expected to be ongoing costs for independent sector care providers that do not currently have adequate complaints handling procedures. There will be costs to care providers who are the subject of a complaint referred to the LGO by a self-funding service user. There are expected to be ongoing costs to central government in respect of the cost to the LGO of handling a larger number of complaints.

Disclosure of information

363. The data disclosure provision does not represent a change in policy, but rather a change to the legal basis of a policy that has existed for many years. IAs are only required for those provisions in the Bill that change Government policy and are thus likely to increase or decrease costs to the public, private, or third sectors. Similarly, Equality IA screening has also been undertaken for this policy which concluded that a full Equality IA was not required as no policy, function, or process is being changed.

EUROPEAN CONVENTION ON HUMAN RIGHTS

Section 19 of the Human Rights Act 1998

364. Section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House of Parliament to make a statement about the compatibility of the provisions of

the Bill with the Convention rights (as defined in section 1 of that Act). Lord Darzi of Denham (Parliamentary Under-Secretary of State) has made the following statement—

> "In my view, the provisions of the Health Bill [HL] are compatible with the Convention rights".

Consideration of the European Convention on Human Rights

365. The Bill raises issues with regard to Articles 6 (right to a fair trial), 8 (right to respect for private and family life), 10 (freedom of expression), and 14 (prohibition of discrimination) of the European Convention on Human Rights and also Article 1 of the First Protocol to the Convention (protection of property).

366. The provisions for suspension of persons appointed to NHS and other health bodies in Schedule 3 inserted by clause 17 at Chapter 2 of Part 2 of the Bill may engage Article 6 of the Convention. Similarly the provision for suspension of directors when a TSA is appointed and for termination of office of directors when a trust is coming out of administration (Chapter 1 of Part 2 of the Bill) might also arguably engage Article 6. Some of the pharmaceutical services provisions at clauses 23 to 30 of Part 3 of the Bill may also engage Article 6 of the Convention. These include the market entry provisions which revise the "control of entry" test for practitioners who provide pharmaceutical services seeking to enter onto a pharmaceutical list at clauses 23 and 24 and the market exit provisions which provide PCTs or LHBs with explicit powers to act where there are concerns about the quality of services provided by a practitioner who provides pharmaceutical services in England or Wales, or, in Wales, also a practitioner who provides ophthalmic services (clauses 26 and 29 respectively).

367. As regards the suspension provisions at clause 17 of and Schedule 3 to the Bill and the provisions for suspension of directors when a TSA is appointed and for termination of the office of directors when a trust is coming out of administration at clause 13 in Chapter 1 of Part 2,, the Minister in charge of the Bill considers that Article 6 is not engaged by the provisions. Article 6 applies to a civil right, which may include rights arising from service as a civil servant, a right to continue to exercise a profession, or rights arising from an allowance payable to an office holder. However, appointees to the public office appointments to which the suspension provisions relate are not civil servants. Where such appointees are professionals the suspension or termination of office would not generally prevent them from exercising their profession. And generally, a suspended person would continue to hold office so would be unlikely by suspension to suffer pecuniary loss. A loss potentially arising from the effect of suspension or termination of office on a person's reputation would not be actionable by way of enforcement as a civil right, as there is no general civil right to a good reputation.

368. If Article 6 were engaged in relation to the suspension provisions at clause 17, the Minister in charge of the Bill considers that the procedures for suspension, including in cases not governed by regulations provision for review of suspension after three months, would be

fair. Where suspension powers were delegated to the Appointments Commission, if an appointee were to allege that a decision by the Appointments Commission to suspend him was not sufficiently independent, the appointee would be able to judicially review the decision. In relation to the provisions at clause 13, there would be consultation of the NHS Trust or foundation trust before a decision to trigger the TSA regime (which will result in suspension of the directors), and a fair procedure would apply before a decision to terminate the office of a particular director when a trust is coming out of administration. Both of those decisions would also be subject to judicial review. The right of appeal provided by judicial review in these circumstances would be a right which satisfies the requirements for appeal of Article 6. Therefore, the Minister in charge of the Bill considers that the provisions are compliant with Article 6.

369. Similarly, with regard to the pharmaceutical services provisions at Part 3 of the Bill, a decision by a PCT to refuse to admit a practitioner who provides pharmaceutical services to a pharmaceutical list and decisions taken by a PCT or LHB to impose a notice or withhold payments from pharmacy practitioners may arguably engage Article 6. However, such decisions would be subject to rights of appeal so satisfying the requirements of Article 6. In the case of a practitioner in England, a right of appeal against a decision of a PCT refusing admission to the pharmaceutical list is conferred by section 130 of the NHS Act. The regulation-making power in new section 150A inserted into the NHS Act by clause 26 requires that provision be made in the regulations for rights of appeal against decisions of PCTs to impose sanctions or withhold payments under that section. In the case of practitioners in Wales, the regulation-making power in new section 106A of the NHS (Wales) Act inserted by clause 27 requires that provision be made in the regulations for rights of appeal.

370. The suspension powers in Schedule 3 inserted by clause 17 of the Bill and the provisions for suspension of the directors when a TSA is appointed and for termination of the office of directors when a trust is coming out of administration (at clause 13 in Chapter 1 of Part 2) may also engage Article 8. The provision for complaints about adult social care at clause 31 in Part 3 of the Bill contain powers for obtaining and disclosing information and for publication of an adverse finding by a Local Commissioner, which may also engage rights to respect for private life protected by Article 8. Similarly the changes to the jurisdiction of the Health Service Commissioner made by the provision at clause 10 of Chapter 3 in Part 1 of the Bill to enable the Commissioner to investigate complaints about services in respect of which direct payments have been made may engage rights protected by Article 8. The provision at Part 3 of the Bill for disclosure of statistical, anonymised summary data on the income and expenses of GPs and dental practitioners by HMRC at clause 32 in Part 3 of the Bill may engage Article 8.

371. An appointee to a health body suspended under the provisions incorporated by clause 17 of the Bill would continue to receive benefits to which they were entitled by virtue of their office. Therefore, the Article 8 rights that might be affected by loss of employment would be unlikely to be engaged. Suspension would be unlikely otherwise to have consequences which

would affect the private life of a person suspended. If the rights were engaged, the procedures which the legislation provides for and the availability of appeal by way of judicial review would be fair. The public interest in preventing a person against whom serious allegations have been made from exercising public office would be balanced against the requirement for protection of the fundamental rights of the suspended person in a proportionate way so that any interference would be justified.

372. As to the provisions for suspension of the directors when a TSA is appointed, and for termination of the office of directors when a trust is coming out of administration (at clause 13 in Chapter 1 of Part 2 of the Bill), the Minister in charge of the Bill considers that suspension or termination of office in those circumstances would be unlikely to have consequences which would affect the private life of the person suspended or removed from office and therefore the rights would be unlikely to be engaged. If the rights were engaged, the procedures which would apply and the availability of a remedy by way of judicial review would be fair. In any event, the Minister in charge of the Bill considers that interference with any rights under Articles 8 would be justified to ensure that proper steps could be taken to deal with failing trusts and therefore in the interests of running a safe and effective health service.

373. If a Local Commissioner exercising powers under the provision at clause 31 of Part 3 of and Schedule 5 to the Bill in order to investigate complaints about social care interferes with the Article 8 rights of a provider, the Minister in charge of the Bill considers that any interference is compatible with Article 8. The powers of a Local Commissioner will enable the Commissioner to properly investigate complaints and encourage providers to carry out recommended action. The analysis would be similar in respect of the changes to the jurisdiction of the Health Service Commissioner made by the provision at clause 10 of Chapter 3 in Part 1 of the Bill. The Minister in charge of the Bill considers that the respective powers will pursue a number of legitimate aims including the protection of health and of the rights and freedoms of others and would be proportionate so that any interference would be justified.

374. The Minister in charge of the Bill considers that the provisions for disclosure by HMRC of statistical, anonymised summary data relating to the income and expenses of GPs and dentists at clause 32 in Part 3 of the Bill would be unlikely to impinge on an individual's right to respect for privacy protected by Article 8. The anonymised, generic form of the information for which the provisions provide would not lead to the identification of any individual. Even if it was considered that the proposed powers for HMRC to be provided with information or for further analysis by HMRC of the information for a non tax-related purpose would engage Article 8 they would be proportionate and justified in the interests of the economic well-being of the country as they are essential for financial planning for the delivery of primary medical care in the NHS.

375. The provisions at clause 19 of Part 3 of the Bill for prohibiting the display of tobacco products, regulating the display of their prices and regulating the display of such products and

their prices on websites may engage Article 10 (freedom of expression) of the Convention, which protects the freedom of commercial expression. The Minister in charge of the Bill is however satisfied that these provisions are compatible with the Convention. The main purpose of these provisions is to protect public health by protecting children and young people from the promotion of tobacco, with the aim of reducing the take up of smoking by them, and to provide an environment that supports smokers who are trying to quit. The protection of public health is an important counter-balance to unrestricted commercial expression. The proposed restrictions are within the margin of appreciation accorded to a state, justified by the considerable evidence as to the efficacy of the proposed restrictions and proportionate. Evidence from other countries which have introduced display bans show that the potential costs for retail outlets in complying with a display ban need not be high. Such potential costs and loss of profitability of the tobacco industry would be outweighed by potential public health gains in reductions in smoking, particularly among young people.

376. The provisions to enable the Secretary of State or a PCT to make direct payments for health care to patients at clause 9 of Chapter 3 in Part 1 of the Bill might be argued to confer an advantage on a citizen within the ambit of the Article 8 right to respect for private and family life. There might then be an issue as to whether any difference in treatment of patients with similar characteristics could arise between a patient within a pilot scheme and one outside the scheme who continues to receive NHS treatment by the traditional route, contrary to Article 14. Article 14 of the Convention prohibits discrimination in the enjoyment of rights under the Convention.

377. However the Minister in charge of the Bill considers that if Article 8 were engaged, and if there were a difference in treatment, that difference in treatment would be justified and would be proportionate for the protection of health and in the interests of the economic well-being of the country. The anticipated benefits in learning from schemes should be set against the risks of not operating such schemes in advance of possible national implementation. Piloting is expected to demonstrate, for example, which care groups are likely to benefit from health care direct payments (in terms of improved health and well-being outcomes), the types of support needed to ensure best use and management of direct payments and how best to operate a scheme. The risks associated with national implementation without piloting include waste of resources, lack of cogent guidance on administering and monitoring health care direct payments and imposing unnecessary burdens on patients. The Minister in charge of the Bill therefore is of the view that the provisions for pilot schemes are justified and proportionate.

378. The provisions for prohibiting or imposing requirements in relation to the sale of tobacco from vending machines at clauses 20 and 21 of Part 3 of the Bill may engage rights to the peaceful enjoyment of possessions or for possessions not to be subject to unnecessary controls protected by Article 1 of the First Protocol. Article 1 of the First Protocol may be engaged also by the provisions for appointing TSAs to deal with unsustainable NHS trusts and foundation trusts at clauses 13 to 16 of Chapter 1 of Part 2 of and Schedule 2 to the Bill, for suspension of persons appointed to NHS and other health bodies at clause 17 of Chapter 2

of Part 2 of and Schedule 3 to the Bill and for the market exit provisions relating to a practitioner who provides pharmaceutical services in England or Wales, or, in Wales, also a practitioner who provides ophthalmic services at clauses 23 to 30 of Part 3 of the Bill.

379. However, the Minister in charge of the Bill considers that prohibiting the display of tobacco products, or regulating the display of their prices, is unlikely to engage Article 1 of the First Protocol in respect of such products. Although the restrictions might make it harder for retailers to sell such products, the European Court of Human Rights has consistently held that a loss of future income does not engage Article 1 of the First Protocol[21]. Such prohibition or requirements could however engage rights to the peaceful enjoyment of the premises from which such products are sold, or of the equipment used by manufacturers for producing gantries for the display of tobacco products. Nonetheless, any such interference would be justified and proportionate for the reasons given at paragraph 376 above.

380. The powers for prohibition of or imposition of requirements in relation to the sale of tobacco products from vending machines at clauses 20 and 21 will not deprive owners of their machines or products. The use of such powers could however be expected to give rise to an interference with the right to peaceful enjoyment of the machines, and any goodwill in the business of supplying the machines, or amount to control on the use of the machines and tobacco products. Nonetheless, a state is entitled to enforce such laws as it deems necessary to control the use of property in accordance with the general interest, provided that the restrictions are not disproportionate.

381. These provisions are aimed at protecting public health. The policy objective is to reduce smoking take-up, prevalence and the number of cigarettes smoked by under 18s, as well as to support smokers seeking to stop smoking. While tobacco vending machines account for only 1% of the overall UK market in tobacco sales, evidence shows that a disproportionate number of young people under the minimum legal age for sale of tobacco obtain cigarettes from this source. Whilst a prohibition on the sale of tobacco from vending machines would impact on the business stability of tobacco vending machine companies, or the imposition of requirements would have a cost impact on them, these measures would be a proportionate means of protecting public health (with a net benefit in life years gained by smokers as against the costs of implementing requirements or a prohibition on the sale of tobacco products from vending machines).

382. Foundation trusts have greater freedoms than NHS trusts for example to invest, borrow, and generate income. When a foundation trust is de-authorised, to avoid potential interference with rights to the peaceful enjoyment of possessions or not to be deprived of possessions protected by Article 1 of the First Protocol, clause 14 of and Schedule 2 to the Bill (inserting new Schedule 10A) contain provision to enable a de-authorised foundation trust to continue to act in accordance with arrangements previously made between the trust

[21] See, for example, judgment of 19th December 1989, Mellacher and Others, A. 169, p. 25, (1990) 12 EHRR 391.

and a third party. The Secretary of State also has power to disapply relevant directions or guidance to de-authorised foundation trusts where necessary to protect third party rights. The Minister in charge of the Bill considers that these provisions will ensure that there is no interference with third party rights under Article 1 of Protocol 1 to the Convention.

383. It may be argued with regard to the provisions for suspension of appointees to NHS and other health bodies at clause 17 in Chapter 2 of Part 2 of and Schedule 3 to Bill that there is property in the right to exercise the functions of office from which an appointee might be suspended. The right to quiet enjoyment of such a possession might also need to be respected in the imposition of the proposed suspension provisions on existing appointees. However, the Minister in charge of the Bill considers that the proposed measures for control of any such right through suspension would be proportionate as indicated at paragraph 372 and strike a fair balance between the general interest of the community as regards the standards of conduct and competence of public office holders and the protection of an individual's fundamental rights.

384. Similarly, it might be argued that the provisions inserted by clause 13 in Chapter 1 of Part 2 of the Bill, for suspension of the directors when a TSA is appointed, and for termination of the office of directors when a trust is coming out of administration engage Article 1 of Protocol 1. Even if the rights were engaged, the Minister in charge of the Bill considers that the proposed measures would be proportionate and would strike a fair balance between the general interests of the community as regards the need to take effective steps to intervene in failing trusts and the protection of individual's fundamental rights.

385. Provision for pharmaceutical services in England at clause 26 and for pharmaceutical and ophthalmic services in Wales at clause 29 may indirectly impose restrictions in relation to the practise of a profession by placing conditions on the ability of pharmacists or ophthalmologists to provide services. PCTs in England or LHBs in Wales will have powers to impose sanctions on or withhold funds from underperforming pharmacies, (or, providers of ophthalmic services in Wales) leading ultimately to their removal from pharmaceutical lists or arrangements with LHBs. However, in exercising the powers a fair balance would be struck between the protection of any rights of pharmacists or ophthalmologists and the benefit to the general interest in monitoring the performance of pharmacies. The Minister in charge of the Bill considers that the proposed measures would be proportionate and strike a fair balance between the general interest of the community and the protection of an individual's property rights.

GLOSSARY OF TERMS AND ABBREVIATIONS

Terms used in the Notes

The Convention: the European Convention on Human Rights

Monitor: the Independent Regulator of NHS foundation trusts

Abbreviations used in the Notes

Abbreviation	Meaning
DHSSPSNI	Department of Health, Social Services and Public Safety in Northern Ireland
GP	General medical practitioner
HMRC	Her Majesty's Revenue and Customs
IA	Impact Assessment
LGO	the Commission for Local Administration in England
LHB	Local Health Board
Mental Health Act	Mental Health Act 1983 (c. 20)
NHS	National Health Service
NHS Act	National Health Service Act 2006 (c. 41)
NHS (Wales) Act	National Health Service (Wales) Act 2006 (c. 42)
PCT	Primary Care Trust
The 1993 Act	Health Service Commissioners Act 1993 (c. 46)
The 1991 Act	Children and Young Persons (Protection from Tobacco) Act 1991 (c.

	23)
The 1991 (NI) Order	Children and Young Persons (Protection from Tobacco) (Northern Ireland) Order 1991 (S.I 1991/2872 (N.I 25))
The 2002 Act	Tobacco Advertising and Promotion Act 2002 (c. 36)
The 2003 Act	Health and Social Care (Community Health and Standards) Act 2003 (c. 43)
The 2008 Act	Health and Social Care Act 2008 (c. 14)
TSA	Trust special administrator
UK	United Kingdom

HEALTH BILL [HL]

EXPLANATORY NOTES

These notes refer to the Health Bill [HL]
as introduced in the House of Lords on 15th January 2009
[HL Bill 18]

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