

HEALTH AND SOCIAL CARE BILL

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health and Social Care Bill as introduced in the House of Commons on 19 January 2011. They have been prepared by the Department of Health in order to assist the reader of the Bill and help inform debate on it.
2. These 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. Therefore, 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.

BACKGROUND AND SUMMARY

4. The Bill contains provisions on a range of policies. It contains 12 Parts and 22 Schedules. The Bill makes changes to a number of existing Acts, most notably the National Health Service Act 2006 (the ‘NHS Act’).
5. The Bill is intended to give effect to the policies requiring primary legislation that were set out in the White Paper *Equity and Excellence: Liberating the NHS*, (available in the Library of the House of Commons, and at www.dh.gov.uk) which was published in July 2010.

6. The main aims of the Bill are to change how NHS care is commissioned through the greater involvement of GPs and a new Commissioning Board; to improve accountability and patient voice; to give NHS providers new freedoms to improve quality of care; and to establish an economic regulator to promote efficiency. In addition, the Bill will underpin the creation of Public Health England, and take forward measures to reform health public bodies.

OVERVIEW OF THE STRUCTURE

Part 1 – The health service in England

7. Part 1 sets out a framework in which functions in relation to the health service are conferred directly on the organisations responsible for exercising them and the Secretary of State retains only those controls necessary to discharge core functions. The Secretary of State will continue to be under a duty to promote the comprehensive health service, but the focus of the role of the Secretary of State will shift to public health, and there will be a responsibility (with local authorities) to protect and improve public health.
8. Part 1 also establishes a new non-departmental public body to be known as the NHS Commissioning Board, accountable to the Secretary of State. The NHS Commissioning Board will have broad overarching duties to promote the comprehensive health service (other than in relation to public health) and to exercise its functions with a view to securing the provision of services for the purposes of that service.
9. Part 1 also makes provision for the constitution of commissioning consortia, which would be corporate statutory bodies, authorised to act by the NHS Commissioning Board. These bodies will be responsible for commissioning the majority of health services.
10. This part also contains related miscellaneous measures including the abolition of Strategic Health Authorities (SHAs) and Primary Care Trusts (PCTs), amendments to the Mental Health Act 1983 and pharmaceutical services expenditure.

Part 2 – Further provision about public health

11. Part 2 deals with a number of provisions relating to the public health service including the abolition of the Health Protection Agency, functions in relation to biological substances and radiation protection, the repeal of the AIDS (Control) Act 1987 and co-operation with bodies exercising functions in relation to public health.

Part 3 – Economic regulation of health and adult social care services

12. Chapter 1 makes provision for Monitor, the Independent Regulator of NHS

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Foundation Trusts to continue in existence, but to be known in legislation as “Monitor”. It outlines Monitor’s overarching duties and constitution.

13. Chapter 2 provides Monitor with powers to ensure that competition and patient choice operate effectively. Monitor would also be able to set or introduce new licence conditions for NHS healthcare providers
14. Chapter 3 allows for the protection of core health services through a process of defining designated services.
15. Chapter 4 provides Monitor with the necessary powers to run a system of licensing that will enable it to carry out the majority of its regulatory functions.
16. Chapter 5 sets out the proposed arrangements for Monitor to set prices for NHS services in conjunction with the NHS Commissioning Board.
17. Chapter 6 provides Monitor with powers to introduce failure arrangements in the health sector that will apply both to companies and NHS foundation trusts. Powers are also being taken to apply normal corporate insolvency procedures to foundation trusts.
18. Chapter 7 makes provision to ensure the continuity of designated services in the event that a provider fails, through either rescuing the provider as a going concern or by the transfer of designated and other services to another health provider or a number of different providers.
19. Chapter 8 deals with miscellaneous matters concerning Part 3 including the service of documents, electronic communications, interpretation and consequential amendments.

Part 4 – NHS foundation trusts and NHS trusts

20. Part 4 makes various changes to the provisions governing NHS foundation trusts. It removes various restrictions on foundation trusts that reflect changes to the role of Monitor introduced by Part 3 of the Bill. It provides for changes to foundation trusts’ internal governance arrangements and to the powers of governors. It repeals NHS trust legislation, and Monitor’s power to authorise new foundation trusts, from 1 April 2014. It also makes some amendments to the finance and accounting arrangements for foundation trusts and removes the cap on income from private patients. In addition, it makes some interim provisions specific to foundation trusts to cover the transitional period.

Part 5 – Public involvement and local government

21. Chapter 1 makes provision for the creation of a new national body, Healthwatch England, to be established as a statutory committee within the Care Quality Commission. It also provides for the establishment of local Healthwatch

organisations in each local authority area.

22. Chapter 2 deals with the health scrutiny functions of local authorities and makes provision for the establishment of health and wellbeing boards in each upper tier local authority area. It sets out their role in preparing the joint strategic needs assessment, the joint health and wellbeing strategy and in promoting integrated working between NHS, public health and social care commissioners. This chapter also contains provisions to make it possible for foundation trusts and commissioning consortia to be designated as Care Trusts.
23. Chapter 3 removes the current restrictions on those to whom the Health Service Commissioner (more commonly known as the Health Service Ombudsman) can send investigation reports and statements of reasons.

Part 6 – Primary care services

24. Part 6 makes changes to the NHS Act that are mainly required to revise, but not substantially change, the existing provisions with relation to medical, dental, ophthalmic and pharmaceutical services. This is as a consequence of the structural changes elsewhere in this Bill that create the NHS Commissioning Board, commissioning consortia and the public health service, and abolish PCTs and SHAs.

Part 7 – Regulation of health and social care workers

25. Part 7 makes various changes to the regulation of health and social care workers. It provides for the abolition of the General Social Care Council and the transfer of some of its functions to the Health Professions Council, which will be renamed the Health and Care Professionals Council to reflect its wider remit across health and social care.
26. It also makes changes to the funding and functions of the Council for Healthcare Regulatory Excellence (CHRE), which is to be renamed the Professional Standards Authority for Health and Social Care.
27. Provision is also made in this Part for the abolition of the Office of the Health Professions Adjudicator.

Part 8 – The National Institute for Health and Care Excellence

28. Part 8 re-establishes the National Institute for Health and Clinical Excellence (NICE) Special Health Authority as a non-departmental public body. It will also be re-named as the National Institute for Health and Care Excellence.
29. This Part also sets out how NICE will develop quality standards, give advice, guidance or provide information, and make recommendations on areas including medicines and treatment.

Part 9 – The Health and Social Care Information Centre

30. Chapter 1 sets out how the Secretary of State or the NHS Commissioning Board may prepare and publish information standards.
31. Chapter 2 re-establishes the Health and Social Care Information Centre Special Health Authority as a non-departmental public body. Its functions will relate to the collection, analysis and publication and or other dissemination of information relevant to the health service or adult social care at a national level.
32. Chapter 2 also sets out powers for the Information Centre to require information to be provided by health or social care bodies, and makes provision for the organisation to minimise the burden of central information collection.

Part 10 – Abolition of certain public bodies

33. Part 10 contains provisions that abolish the Alcohol Education and Research Council, the Appointments Commission, the National Information Governance Board for Health and Social Care, the National Patient Safety Agency and the NHS Institute for Innovation and Improvement. Section 250 of the NHS Act will be repealed, with a saving provision for the continuation of the Joint Committee on Vaccination and Immunisation as a statutory body.

Part 11 - Miscellaneous

34. Part 11 contains a number of miscellaneous provisions, including duties for bodies to co-operate, arrangements with devolved authorities, supervised community treatment and transfer schemes.

Part 12 – Final provisions

35. Part 12 deals with various technical matters such as consequential amendments, orders and regulations, financial provision, commencement, extent and the short title of the Bill.

TERRITORIAL EXTENT AND APPLICATION

36. Clause 280 sets out the territorial extent of the Bill.
37. Most of the provisions contained in the Bill extend to England and Wales only, but apply only to England. Some provisions apply only to Wales, others extend to the whole of the UK. Clauses covering the arrangements between the NHS Commissioning Board and Northern Ireland Ministers and Scottish Ministers extend

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to England, Wales and Northern Ireland or England, Wales and Scotland respectively.

38. Any amendment, repeal or reversal of legislation that is provided for in this Bill has the same extent as the original legislation.

Territorial application: Northern Ireland

39. Certain provisions of the Bill extend to Northern Ireland, in addition to England and Wales and, in most cases, Scotland.

40. Provisions in Part 2 that extend to Northern Ireland (as well as England, Wales and Scotland);

- abolish the Health Protection Agency (a body with a UK wide remit) and repeal the Health Protection Agency Act 2004 (clause 46)
- make provision for the Department of Health, Social Services and Public Safety in Northern Ireland (DHSSPS) to exercise biological substances functions jointly with the Secretary of State (clause 47);
- make provision for the Secretary of State to exercise radiation protection in relation to Northern Ireland (clause 48);
- confer functions on the DHSSPS in relation to radiation protection (clause 48), and provide for a UK wide duty of co-operation between bodies exercising functions in relation to health protection (clause 50).

41. Clauses 114 to 119 in Chapter 6 of Part 3, concerning special administration, extend to Northern Ireland (as well as England and Wales and Scotland) given that a relevant provider may include a company registered in Northern Ireland.

42. Clauses 198 (1), 206 (1) and clause 215 in Part 7, concerning regulation of health and social care workers, extend and apply to Northern Ireland (as well as England and Wales and Scotland), as they relate to bodies with functions in relation to Northern Ireland.

43. Clause 233 and Schedule 16 in Part 8, regarding changes to the National Institute for Health and Care Excellence (NICE), include consequential amendments to legislation that extends to Northern Ireland, in addition to England and Wales and Scotland.

44. Part 11 contains provision for the NHS Commissioning Board and the Northern Ireland Ministers to make arrangements with the NHS Commissioning Board to arrange for the provision of certain services, such as specialised services, for purposes of the Northern Ireland health service (clause 269). This provision extends to England and Wales and Northern Ireland.

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45. Clause 271 and Schedule 20 in Part 11 amend legislation relating to the health service in Northern Ireland to make consequential and other amendments, including provision for arrangements between Northern Ireland health bodies and health bodies in England.
46. Some of these provisions require the consent of the Northern Ireland Assembly through a legislative consent motion. Westminster will not normally legislate with regard to devolved matters in Northern Ireland without the consent of the Northern Ireland Assembly. As there are provisions in this Bill relating to such matters, the consent of the Northern Ireland Assembly is being sought for them through a legislative consent motion.

Territorial application: Scotland

47. Certain provisions of the Bill extend to Scotland, in addition to England and Wales and, in most cases, Northern Ireland.
48. Provisions in Part 2 that extend to Scotland (as well as England and Wales and Northern Ireland);
49. Clauses 114 to 119 in Chapter 6 of Part 3, concerning special administration extends to Scotland (as well as England and Wales and Northern Ireland), given that the law of insolvency is generally a reserved matter.
50. Clauses 198 (1), 206 (1) and clause 215 in Part 7, concerning regulation of health and social care workers extend and apply to Scotland (as well as England and Wales and Northern Ireland) as they relate to bodies with functions in relation to Scotland.
51. Clause 233 and Schedule 16 in Part 8, regarding changes to the National Institute for Health and Care Excellence (NICE), include minor and consequential amendments to legislation that extends to Scotland (as well as England and Wales and Northern Ireland).
52. Provision in Part 11 enables the NHS Commissioning Board to enter in to arrangements with Scottish health bodies that will enable the Board to arrange for the provision of certain services, such as specialised services, as part of the Scottish health service (clause 270). This provision extends to England and Wales and Scotland.
53. Clause 271 and Schedule 20 in Part 11 amend legislation relating to the health service in Scotland, (the National Health Service (Scotland) Act 1978) to make consequential and other amendments, including provision for arrangements between health bodies in Scotland and health bodies in England.
54. Some of these provisions fall within the terms of the Sewel Convention and therefore require a legislative consent motion by the Scottish Parliament. The effect of the

Sewel Convention is that Westminster will not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish Parliament. As there are provisions in this Bill relating to matters that trigger the Convention, the consent of the Scottish Parliament is being sought for them through a legislative consent motion.

Territorial application: Wales

55. A number of the provisions in the Bill apply in Wales as well as England, or apply in Wales only. The Welsh Assembly Government have been consulted on these provisions and have provided their consent where necessary.
56. Provisions in Part 1 of the Bill amend several sections of the Mental Health Act 1983 that extend and apply to England and Wales, as does the provision in Part 11 concerning supervised community treatment.
57. Provisions in Part 2 that extend and apply to England and Wales;
 - abolish the Health Protection Agency (a body with a UK wide remit) and repeal the Health Protection Agency Act 2004 (clause 46);
 - make provision for the Secretary of State to exercise biological substances and radiation protection functions in relation to Wales and (clause 47); and
 - provide for a UK wide duty of co-operation between bodies exercising functions in relation to health protection (clause 50).
58. Clauses 114 to 119 in Chapter 6 of Part 3, concerning special administration apply to a company in Wales which provides services to the health service in England.
59. Clauses 198 (1), 206 (1) and clause 215 in Part 7, concerning regulation of health and social care workers extend and apply to England and Wales (as well as Northern Ireland and Scotland) as they relate to bodies with functions in relation to Wales.
60. Provisions in Parts 8 and 10, regarding changes to the Department of Health's Arm's Length Bodies, extend and apply to England and Wales. The dissolution of the predecessor body to the National Institute for Health and Clinical Excellence applies to Wales, as that is established for England and Wales (clause 232), and related, minor and consequential amendments to legislation in Schedule 16 apply to Wales. In Part 10, the abolition of the Appointments Commission applies to Wales.
61. Clause 271 and Schedule 20 in Part 11 amend legislation relating to the health service in Wales, (the National Health Service (Wales) Act 2006) to make consequential and other amendments, including provision for arrangements between health bodies in Wales and health bodies in England.

COMMENTARY ON CLAUSES

62. This section provides explanation and comment, where necessary, clause-by-clause. The Bill largely amends the NHS Act, although, as explained below, it does also contain some freestanding provisions.

Part 1 – The Health Service in England

Provision of Health Services

Clause 1 - The Secretary of State and the comprehensive health service

63. This clause amends section 1 of the NHS Act, which contains the Secretary of State's duty to promote a comprehensive health service designed to secure improvement in the physical and mental health of the people of England, and in the prevention, diagnosis and treatment of illness. The amendments to section 1 made by this clause would leave intact this duty of the Secretary of State.
64. However, the clause removes the current duty on the Secretary of State in subsection (2) of section 1 to provide or secure the provision of services for the purposes of the health service. Instead, new subsection (2) imposes new duties on the Secretary of State for the purpose of the promotion of the comprehensive health service:
- a) to carry out his public health functions; and
 - b) to act with a view to securing the provision of services when exercising functions in relation to the NHS Commissioning Board ("the Board"), commissioning consortia (consortia) and local authorities (for example, when the Secretary of State sets the annual mandate for the Board under clause 19 or makes standing rules for the Board and consortia under clause 16).
65. The Bill thus draws a distinction between the Secretary of State's public health functions and his role in relation to the securing of services for the purposes of the NHS.
66. Currently, the Secretary of State is directly responsible for providing or securing the provision of all health services as set out in the NHS Act, a function which is largely delegated to Strategic Health Authorities and Primary Care Trusts (PCTs) under section 7 of the NHS Act. However, the new commissioning structure proposed by the Bill means that this would no longer be the case. Instead, the Secretary of State would have the duties described above. Direct responsibility for securing the provision of these services would be conferred on the Board and commissioning consortia by new section 1D of the NHS Act, inserted by clause 5 and new section 1E, inserted by clause 6 of the Bill.
67. The Secretary of State would however remain directly responsible, along with

local authorities, for securing the provision of public health services. *Subsection (2)(a)* sets out that the Secretary of State has a number of public health functions, and as *subsection (3)* indicates, these are set out in more detail in new section 2A, inserted by clause 7, new section 2B inserted by clause 8 and Schedule 1 to the NHS Act. The Secretary of State's public health functions include securing the provision of certain services (such as immunisation and screening), providing information regarding dangers to health, and advancing knowledge and understanding. This clause also contains a definition of the public health functions of local authorities, which are the functions under new section 2B of, and Schedule 1 to, the NHS Act.

68. *Subsection (4)* makes a consequential change to section 1(3) of the NHS Act, which is the provision which states that services provided or secured by the Secretary of State for the purposes of the health service must be free of charge, except where legislation expressly allows for charges to be made (for example, prescription charging). The amendment reflects the fact that the Secretary of State would no longer be responsible for the provision of services, so section 1(4) as amended will state that services provided as part of the health service in England must be free of charge (subject to the exception mentioned earlier). This consequential change does not signify any change to existing arrangements and services provided as part of the health service would remain free of charge, unless existing legislation allows otherwise.

Clause 2 - The Secretary of State's duty as to improvement in quality of services

69. This clause inserts new section 1A into the NHS Act. This new section creates a duty on the Secretary of State to act with a view to securing continuous improvement in the quality of individuals' healthcare.
70. Subsection (1) of new 1A details the duty on the Secretary of State to exercise the functions conferred on him/her by this Bill in a way that would secure continuous improvements in the quality of services provided as part of the health service. This includes both his/her public health functions (the prevention of illness, the protection or improvement in public health), and those functions that he exercises in relation to the NHS with the NHS Commissioning Board and commissioning consortia (the diagnosis and treatment of illness). Any service, for example screening, that is associated with both public health and the NHS, also comes within the ambit of this duty. The duty is therefore comprehensive. In discharging this duty, the Secretary of State must have regard to the NICE quality standard.
71. *Subsection (2)* of new 1A specifies that, in discharging this duty, the Secretary of State must focus on securing continuous improvement in the quality of outcomes achieved from health services. Clause 19 inserts new section 13D, which imposes a similar duty on the NHS Commissioning Board in relation to quality. In keeping with the policy set out in the White Paper *Equity and Excellence: Liberating the NHS*¹, the

¹ Copies are available in the Library, and from the DH website at <http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm>

outcomes are to focus particularly on the effectiveness, safety and patient experience aspects of healthcare (Subsection (3) of new 1A).

Clause 3 - The Secretary of State's duty as to reducing inequalities

72. This clause proposes to insert new section 1B (Duty as to reducing inequalities) into the NHS Act. This section outlines a further duty by which the Secretary of State must abide in exercising his functions under the Act.
73. This clause imposes a duty on the Secretary of State to consider the need to reduce inequalities in respect of the benefits that may be obtained from the health service, when exercising functions in relation to the health service in England. In other words, the Secretary of State must consider the need to reduce inequalities in the access to health services, and the outcomes achieved, when carrying out his functions. This includes the Secretary of State's functions in relation to the NHS and public health.

Clause 4 - The Secretary of State's duty as to promoting autonomy

74. This clause seeks to establish an overarching principle that the Secretary of State should act with a view to promoting autonomy in the health service. It identifies two constituent elements of autonomy: freedom for bodies/persons in the health service (such as commissioning consortia or Monitor) to exercise their functions in a manner they consider most appropriate (1C(a)), and not imposing unnecessary burdens from those bodies/persons (1C(b)). The clause requires the Secretary of State to act with a view to securing these aspects of autonomy in exercising his functions in relation to the health service, so far as is consistent with the interests of the health service.
75. This duty would therefore require the Secretary of State, when considering whether to place requirements on the NHS, to make a judgement as to whether these were in the interests of the health service. If challenged, the Secretary of State would have to be able to justify why these requirements were necessary.
76. The duty covers the arm's length body sector and commissioners and providers of NHS services. Although the Secretary of State would not have the same direct relationship with providers of NHS services as he currently has with NHS trusts, he would still have certain functions which impact on providers. For example, he would be able to require certain terms to be included in contracts entered into by the NHS Commissioning Board and consortia for the provision of NHS services by virtue of regulations made under clause 16.

77. This duty is intended to address the policy outlined in *Liberating the NHS: Legislative Framework and Next Steps*² to:

“enshrine the principle of autonomy at the heart of the NHS” [by] “maximising the autonomy of individual commissioners and providers and minimising the obligations placed upon them, in a way that is consistent with the effective operation of a comprehensive health service”

Clause 5 - The NHS Commissioning Board

78. This clause inserts a new section 1D into the NHS Act, which establishes a new body to be known as the NHS Commissioning Board (new section 1D, subsection (1)). The Board would be an independent body, which would hold commissioning consortia to account for the quality of services they commission, the outcomes they achieve for patients and for their financial performance. The Board would have the power to intervene where there is evidence that consortia are failing or are likely to fail to fulfil their functions. The specific functions of the Board, such as commissioning specialised services, are conferred elsewhere in the Bill.
79. Like the Secretary of State, the Board would be subject to the duty to promote the comprehensive health service (in subsection 1(1) of the NHS Act), except in relation to those services falling within the public health functions of the Secretary of State or local authorities (new section 1A, subsection (2)).
80. In order to fulfil this general duty, the Board would have two specific duties (new section 1D, subsection (3)):
- a) Firstly, it must commission services in accordance with the NHS Act (new section 1D(3)(a)). The services which the Board may be required to commission are described in new section 3B (inserted by clause 11) and these include services which can be more effectively commissioned at national level, such as specialised services, high secure services, prison health services and health services for the armed forces for example. The Board will also be responsible for commissioning primary care.
 - b) Secondly, when exercising functions in relation to commissioning consortia (for example, when issuing commissioning guidance under new section 14V inserted by clause 22, the Board must act with a view to securing the provision of services (new section 1D(3)(b)).
81. *Subsection (4)* introduces Schedule 1.

² Copies are available in the House library, and from the DH website at <http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm>

Schedule 1 - The NHS Commissioning Board: supplementary

82. This Schedule inserts a new Schedule in to the NHS Act which makes provision for the constitution and establishment of the NHS Commissioning Board. Paragraph 1 provides that the status of the NHS Commissioning Board is a non-Departmental public body that is not part of the Crown, nor regarded as a servant or agent of the Crown.
83. Paragraph 2 makes provision about the membership of the NHS Commissioning Board. It is to be comprised of:
- a) a chair appointed by the Secretary of State,
 - b) at least five other members also appointed by the Secretary of State, and
 - c) the chief executive and other members.
84. Paragraph 2(3) requires that the number of executive members must not exceed the number of non-executive members. In compliance with this paragraph, where there are resignations, suspensions or other departures of non-executive members, it may be necessary to appoint additional members or remove members from the board to ensure that the number of executives is less than the number of non-executives.
85. Paragraph 3(1) provides that the executive members be appointed by the non-executive members. Paragraph (2) requires that the appointment of the Chief Executive receives the approval of the Secretary of State. Paragraph (3) provides that the chief executive and the other executive members are employees of the NHS Commissioning Board.
86. Paragraph 3(4) requires that the Secretary of State appoint the first Chief Executive of the NHS Commissioning Board. The other remaining first executive members will therefore be appointed by the non-executive members.
87. Paragraph 4 makes provision about the terms of appointment and tenure of office of non-executive members which are equivalent to those for members of Monitor under Paragraph 4 of Schedule 4 to the Bill: the terms of their appointment will set out the detail of the basis on which non-executive members hold and vacate office. In subparagraph 4(2) provision is made to enable a non-executive member to resign at any time by giving notice to the Secretary of State and paragraphs 4(3) and 4(4) enable the Secretary of State to remove or suspend non-executive members from office on grounds of incapacity, misbehaviour or failure to carry out his or her duties as a non-executive member.
88. Paragraphs 4(5) and (4)(6) specify that the maximum term of appointment for non-executive members is 4 years and that a person who ceases to be a non-executive

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member is eligible for re-appointment.

89. Paragraph 5 sets out the procedural requirements to be complied with when the Secretary of State suspends a non-executive member of the NHS Commissioning Board under the power in sub-paragraph 4.
90. Paragraph 6 provides that the Secretary of State has power to appoint an interim Chair where the Chair is suspended. The NHS Commissioning Board will have no power to appoint an interim Chair but may choose in practice to appoint a deputy Chair (regardless of any suspension of the Chair).
91. Paragraphs 7(1) and (2) requires that the NHS Commissioning Board to pay to the non-executive members such remuneration, pensions, allowances or other gratuities as the Secretary of State may determine.
92. Paragraph 7(3) provides that, where a non-executive member of the NHS Commissioning Board ceases to be a non-executive member and the Secretary of State decides that there are exceptional circumstances for that person to receive compensation, the NHS Commissioning Board is required to make compensation payments of such amount as Secretary of State may determine with Treasury approval.
93. Paragraph 8 gives the NHS Commissioning Board powers to appoint its own employees.
94. Paragraph 9 provides that the NHS Commissioning Board can employ staff on such terms and conditions and pay such remuneration, pensions or allowances as it may determine. In common with the other arms-length bodies covered by this Bill (for example, NICE and the Information Centre), the Board would be required to seek the approval of the Secretary of State for its policies on the payment of remuneration, pensions and allowances to staff before making a determination under this paragraph.
95. Paragraph 10 provides that the NHS Commissioning Board may appoint committees and sub-committees, and pay remuneration and allowances to those members of a committee or sub-committee who are employees of the NHS Commissioning Board.
96. The NHS Commissioning Board may hold property on trust and paragraph 11 confers a power on the Secretary of State to appoint trustees to oversee the management of any property held on trust.
97. Paragraph 12 allows the NHS Commissioning Board to regulate its own procedure and make any arrangements it considers appropriate for the discharge of its functions. This power may, for example, remove the risk of a conflict of interest by preventing executive members from being involved in determining their own pay.
98. Paragraph 13 gives the NHS Commissioning Board the power to arrange for the

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exercise of any of its functions on its behalf by:

- a) any non-executive member,
- b) any employee (including any executive member), or
- c) a committee or sub-committee.

99. Paragraph 14 gives the Secretary of State power to require the Board to provide the Secretary of State with such information, in such form, and at such time or within such period, as the Secretary of State considers is necessary to delivery of the Secretary of State's functions in relation to health services.
100. Paragraph 15 requires that the NHS Commissioning Board, as a statutory body, must keep proper accounts and proper records in relation to the accounts (in such form as the Secretary of State may direct with the approval of the Treasury).
101. The NHS Commissioning Board sits within the Department of Health accounting and budgeting boundaries and the Department requires information to effectively and efficiently manage the Department's financial position against, for instance, Departmental Expenditure Limits. In addition, the Department has a responsibility to provide information on those bodies for which it is accountable in order to meet requirements that may be set by HM Treasury and others on both financial and non-financial matters.
102. Paragraph 16(1) requires the NHS Commissioning Board to prepare consolidated annual accounts in respect of each financial year. Consolidated annual accounts should contain the Board's own annual accounts and separately a consolidation of the Board's own annual accounts and the annual accounts of each commissioning consortium.
103. Paragraph 16(3) requires the NHS Commissioning Board to submit the consolidated annual accounts to the Secretary of State and to the Comptroller and Auditor General for audit to a timetable prescribed by the Secretary of State, who will remain accountable to HMT for the Department's Departmental Expenditure Limit. The Department's annual Resource Account must be prepared in accordance with the accounting rules and instructions set out by the Treasury in their annual Financial Reporting Manual (FRoM). In turn, the accounts of all bodies that are consolidated into the Department's Resource Account must be prepared in accordance with the same Treasury accounting framework. Secretary of State therefore requires powers to ensure that the NHS Commissioning Board's accounts, including the consolidation of its accounts with those of commissioning consortia, are prepared in accordance with the requirements set by HMT.
104. Paragraph 16(4) requires the Comptroller and Auditor General to examine the consolidated annual accounts of the NHS Commissioning Board and lay copies of the

accounts, along with a report on them, before Parliament.

105. Additional provision is made in paragraph 17 for the Secretary of State with the approval of the Treasury to require in-year ‘interim’ accounts and for the Secretary of State to direct that these are audited.
106. Paragraph 18 makes provision in relation to the NHS Commissioning Board’s seal.

Clause 6 - Commissioning consortia

107. As set out in *Equity and Excellence: Liberating the NHS*³, this Bill would create a comprehensive system of commissioning consortia. Their purpose would be to commission most NHS services, supported by and accountable to the NHS Commissioning Board.
108. This clause inserts a new section 1E into the NHS Act, that provides that there will be bodies to be known as commissioning consortia (consortia). Consortia will be established in accordance with Chapter A2 of Part 2 of the NHS Act (subsection (1) of new section 1(E) and will have the function (subsection (2)), of commissioning services and facilities for the purposes of the health service in accordance with the NHS Act.

Arrangements for provision of health services

Clause 7 - The Secretary of State’s duty as to protection of public health

109. This clause places a new duty on the Secretary of State for Health to protect public health through the insertion of a new section 2A into the NHS Act.
110. Subsection (1) of new section 2A requires the Secretary of State to take appropriate steps to protect the public in England from disease or other dangers to health. ‘Other dangers to health’ might include contamination, radiation (ionising or non-ionising), chemicals, poisons and the health effects of climate change (such as flooding and heat waves). The approach taken in the Bill is an ‘all hazards’ approach in that the Bill does not exhaustively list the dangers to health from which the Secretary of State must protect the public. This is to ensure that provision will continue to be effective as new threats to health emerge.
111. Subsection (2) of new section 2A lists some of the steps that the Secretary of State might take to protect public health. These include carrying out research into disease, providing laboratory services, providing information and advice to the public about

³ Copies are available in the Library, and from the DH website at <http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm>

dangers to and providing national vaccination and screening programmes. As well as vaccination and screening, the Secretary of State will also be able to provide other services for the prevention, treatment or diagnoses of illness, if the Secretary of State considers that an appropriate step to protect public health for example, the provision of treatment for tuberculosis. Many of these activities falling within this provision are currently carried out by the Health Protection Agency, which is abolished by clause 46.

112. Subsections (3) and (4) of new section 2A require the Secretary of State to consult the Health and Safety Executive (HSE) and have regard to its policies when taking steps to protect public health under subsection (1) in relation to a radiation matter in respect of which the HSE also has a function. This ensures consistency of action for example in a radiation incident.

Clause 8 – Duties as to improvement of public health

113. This clause concerns the duties and powers of the Secretary of State and of local authorities in relation to the improvement of public health. Improving health could include smoking cessation or weight loss services, for example, or providing advice and information to help people who want to adopt healthier behaviour.
114. The clause inserts a new section 2B into the NHS Act. The new section gives certain local authorities a duty to take appropriate steps to improve the health of the people who live in their areas (subsection (1)), and gives the Secretary of State the power to take appropriate steps to improve the health of the people of England (subsection (2)). The nature of the duty is that if a local authority considers a step appropriate to improve public health, they must take that step under the new provision, even if the activity had previously been carried out under other local authority powers. The local authorities who are subject to the duty are defined in subsection (5) – primarily county councils, London borough councils and unitary authorities (district councils where there is no county council). District councils in counties with a county council are not subject to the duty. This definition of local authority is applied in other clauses of the Bill.
115. Subsection (3) of the new section lists some of the steps to improve public health that local authorities and the Secretary of State would be able to take. These include carrying out research into health improvement, providing information and advice for example giving information to the public about healthy eating and exercise, providing facilities for the prevention or treatment of illness such as smoking cessation clinics, providing financial incentives to encourage individuals to adopt healthier lifestyles for example by giving rewards to people for stopping smoking during pregnancy and providing assistance to help individuals minimise risks to health arising from their accommodation or environment for example a local authority may wish to improve poor housing where this impacts on health.
116. Subsection (4) provides that the steps which local authorities may take making grants

or lending money to organisations or individuals - for example, voluntary sector organisations – when that would be an appropriate way of using resources to improve public health. For example, a local authority could choose to make a grant to an organisation that offered tailored health promotion advice to a black and minority ethnic community. The Secretary of State has existing grant-making powers that will continue (section 64 of the Health Services and Public Health Act 1968).

Clauses 9 and 10 - Duties and powers of consortia as to commissioning certain health services

117. This clause amends section 3 of the NHS Act to provide for the duties of commissioning consortia (consortia) in relation to commissioning certain health services.
118. Clause 10 inserts a new section 3A into the NHS Act which provides a power for consortia to commission such services or facilities as the consortium considers appropriate for the purposes of the health service that relate to securing improvement in the physical and mental health of persons for whom it has responsibility and the prevention, diagnosis and treatment of illness in these people.
119. Commissioning consortia will be the appropriate commissioner under the Act unless there is a duty on the Board to commission that service. Subsections (1) and (2) amend section 3 of the NHS Act to provide that consortia must arrange for the provision of the services and facilities in section 3(1) of the NHS Act to such extent as they consider necessary to meet the reasonable requirements of the persons for whom they have responsibility.
120. The persons in respect of whom consortia will be responsible for are set out in new section 3(1A) – that is those persons who are provided with primary medical services by a member of the consortium and under new section 3(1B), where regulations so provide, persons who have a prescribed connection with the consortium’s area - for example this could include people who live within the consortium’s area and are not registered with any GP practice; it is also likely to include people who are present in the consortium’s area and need access to emergency healthcare.
121. Subsection (1C) of clause 9 provides that regulations may provide that consortia do not have responsibility for certain people or cases that would otherwise meet the criteria in subsection (1A). It is intended that this power will be exercised, for example, to provide that people who are resident in Scotland but registered with a practice that is a member of a consortium and people who are receiving primary medical services as ‘temporary residents’ are not the responsibility of a consortium for these purposes.
122. Subsection (1D) sets out that consortia are not under a duty to commission a service or facility if the Board is under a duty to do so.

123. *Subsection (1)* of clause 10 provides a power for consortia to commission such services as it considers appropriate for the purposes of the health service that relate to securing the improvement in the physical and mental health of the persons for whom it has responsibility and the prevention, diagnosis and treatment of illness of these people. *Subsection (3)* sets out that sections 3(1A) to (1C) of the NHS Act will apply for the purposes of determining the persons for whom a consortium has responsibility.

Clause 11 - Power to require Board to commission certain health services

124. This clause inserts new Section 3B to the NHS Act and confers a regulation making power on the Secretary of State to require the NHS Commissioning Board to commission certain services as part of the health service, to such extent as it considers necessary to meet all reasonable requirements. The types of services that the NHS Commissioning Board may be required to commission are specified in this clause and it allow other services to be specified in the regulations.
125. Currently, most NHS services are commissioned by Primary Care Trusts (PCTs). It is intended that commissioning consortia (consortia) will commission most health services and the NHS Commissioning Board will have duties to commission certain other health services. Where the NHS Commissioning Board has this function, consortia will not be able to commission those services.
126. The NHS Commissioning Board would be responsible for the commissioning of primary medical, dental, ophthalmic and community pharmaceutical services, and this is set out in Part 6 of the Bill.
127. This clause provides that regulations may require the NHS Commissioning Board to commission certain services as part of the health service.
128. Firstly, regulations under new section 3A may require the NHS Commissioning Board to make arrangements for the provision of such dental services as are prescribed. The regulations may for example provide that the NHS Commissioning Board commission dental services other than those it is required to commission under Part 5 of the NHS Act (as amended by Schedule 4). Part 5 of the NHS Act refers to “primary dental services” and under this clause the NHS Commissioning Board could for example be required to arrange for the provision of “secondary dental services” such as community dental care and hospital dental services which Primary Care Trusts currently commission.
129. Secondly, regulations under new Section 3A may require the NHS Commissioning Board to commission health services for members of the Armed Forces and their families. The Ministry of Defence (MoD), through the Defence Medical Services (DMS), provides primary care services to all members of the armed forces and a small number of families resident in England. The NHS currently provides community services, and non-elective and elective secondary services, to the Armed Forces

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130. The NHS Commissioning Board will be responsible for arranging for the Armed Forces standard secondary services such as maternity services, elective (planned) surgery, and cancer services and community services such as wound management and district nursing.
131. Regulations under new section 3B will describe the types of services to be provided by the NHS Commissioning Board to members of the armed forces or their families.
132. Thirdly, regulations under new section 3B may require the NHS Commissioning Board to make arrangements for the provision of healthcare services to people detained in prisons in England or other accommodation of a prescribed description. The provision of primary care services for prisoners in England will be covered separately by the NHS Commissioning Board's functions in relation to primary care.
133. Lastly, regulations under new section 3B may require the NHS Commissioning Board to make arrangements for the provision of such other services or facilities as may be prescribed (subsection (1)(d)). It is intended that the services covered by this regulation making power will, for example, include services described as "specialised services" for rare conditions, which are currently commissioned nationally by Strategic Health Authorities rather than regionally by groups of Primary Care Trusts for each Strategic Health Authority region because of their low volume and high cost for example.
134. A service or facility may be prescribed under section 3B(1)(d) only if prescribed, the Secretary of State must consider it appropriate, taking into account the following factors:
 - a) the number of people who need to access those services;
 - b) the cost of providing those services;
 - c) the number of providers able to offer those services; and
 - d) the impact on consortia of having to fund those services.
135. The Secretary of State could take into account the fact that one or more of the factors here may not point towards the NHS Commissioning Board being the commissioner, for example, some specialised services may not be expensive but may be low volume. The Secretary of State would take a view on the weight of the factors to decide if the NHS Commissioning Board is the appropriate commissioner. The Secretary of State will be obliged to make arrangements with a view to securing that he receives advice appropriate for enabling him to determine which services should be commissioned by the NHS Commissioning Board under this section, including seeking advice from people or bodies with appropriate expertise and from the NHS Commissioning Board.

Clause 12 - Secure psychiatric services

136. High secure psychiatric services are provided to patients who are liable to be detained under the Mental Health Act 1983 and are judged to require treatment in conditions of high security on account of their dangerous, violent or criminal propensities. They are currently provided in England at three hospitals – Ashworth, Broadmoor and Rampton – which are each part of an NHS trust.
137. This clause amends section 4 of the NHS Act, which concerns the provision of high secure psychiatric services. The clause removes from the Secretary of State the duty to provide high secure services and places a duty instead on the NHS Commissioning Board to arrange for the provision of these services (*subsection (2)*). The clause stipulates that providers of high secure services must be approved for that purpose by the Secretary of State (*subsection (3)*).
138. This clause also gives the Secretary of State a power to give directions to providers of high secure services about their provision of high secure services (*subsection (3)*). It is intended that this power would be used in practice in a limited fashion in relation to issues such as safety and security, and children visiting high secure hospitals. The existing directions issued in relation to high secure services by the Secretary of State are the Safety and Security in Ashworth, Broadmoor and Rampton Hospitals Directions 2000 and the Visits by Children to Ashworth, Broadmoor and Rampton Directions 1999, which deal with risk assessment and safeguarding.
139. This clause enables the Secretary of State also to give directions to the NHS Commissioning Board about the way it exercises its functions in relation to high secure services (*subsection (3)*). It is intended that this power would be used in a limited manner to ensure that the National Commissioning Board in commissioning high secure services takes into account any conditions, which might be set by the Secretary of State, including directions to providers and ensuring that there is sufficient capacity to meet the demands of the criminal justice system.

Clause 13 - Other services etc. provided as part of the health service

140. This clause transfers responsibility for a number of public health activities from the Secretary of State, and confers a new duty on the Secretary of State to make arrangements for the supply of blood and human tissues. The clause amends section 5 of, and Schedule 1 to, the NHS Act, which provides for the Secretary of State to provide various health services and carry out other activity in relation to the health service.
141. *Subsections (3) to (9)* amend the provisions of Schedule 1 relating to children. The provisions transfer the Secretary of State's existing responsibilities for the medical inspection and treatment, dental inspection and treatment, and the weighing and measuring of school children. Responsibility is transferred to the local authorities which have a duty to improve public health under new section 2B. This would

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include school nursing services. In practice PCTs commission or provide these services now.

142. *Subsection (10)* inserts a new paragraph 7C of Schedule 1 and confers on the Secretary of State the duty to make arrangements for the collection, screening and supplying blood (and related services) and for facilitating organ or tissue transplantation services. The Secretary of State has responsibility for this under his existing functions under sections 2 and 3 of the NHS Act, but the new paragraph 7C ensures that the Secretary of State continues to have responsibilities for those arrangements despite the changes to those sections made by the Bill. As now, the functions will be performed by NHS Blood and Transplant, a Special Health Authority, rather than the Department of Health,
143. *Subsections (11) and (12)* amend paragraphs 9 and 10 of Schedule 1 so as to transfer to commissioning consortia the Secretary of State's existing responsibility for the supply of wheelchairs and other vehicles to people with a physical disability. In practice PCTs arrange these services now, and the Department's view is that the responsibility for those services is more consistent with consortia's other duties than with local authorities' health improvement duties.
144. *Subsection (13)* makes a consequential amendment to paragraph 12 of Schedule 1, which confers a power on the Secretary of State to provide a microbiological service (to help control the spread of infectious diseases). The power to provide such a service now falls under the Secretary of State's health protection duty under new section 2A; paragraph 12 will however continue to provide that he can carry on related activities and charge for such activity .
145. Finally, *subsection (14)* substitutes a new paragraph 13 of Schedule 1, which relates to the conduct of research into health-related matters by, or with the assistance of, the Secretary of State. The new paragraph 13 enables the NHS Commissioning Board, commissioning consortia and local authorities, as well as the Secretary of State, to conduct, commission or fund such research or assist others to do so. For example, this would enable the NHS Commissioning Board and commissioning consortia to assist valuable research designed to improve health care, by providing the NHS costs associated with research in the NHS, which are currently provided by Primary Care Trusts through the normal commissioning process." Local authorities would only be able to use the power in relation to their public health activities.

Clause 14 – Regulation as to the exercise by local authorities of certain public health functions

146. This clause inserts a new section 6C into the NHS Act, which gives the Secretary of State powers to make regulations requiring local authorities to exercise certain public health functions. In particular, the Secretary of State is able to specify the particular public health services, facilities or other steps that one, several or all local authorities must provide or take. The regulations would be subject to the affirmative procedure

and would therefore have to be approved by Parliament. The powers apply to local authorities which have the duty to improve public health under new section 2B of the NHS Act.

147. Subsection (1) enables the Secretary of State to make regulations requiring a local authority to exercise, in relation to their area any of the Secretary of State's public health functions – i.e. functions under section 2A (duty to take steps to protect public health), section 2B (power to take steps to improve public health) or Schedule 1 (e.g. providing contraceptive services).
148. Subsection (2) enables the Secretary of State to make regulations specifying the particular public health services, facilities or other steps that one, several or all local authorities must provide or take under their duty to improve public health (new section 2B) or their duties under Schedule 1 (e.g. arranging medical treatment of school pupils).
149. The Secretary of State could use this power to - for example - ensure long-term, national availability of a service or to respond to a serious local concern. If the Secretary of State provides in regulations that local authorities must undertake health protection activity, the Secretary of State would still be able to carry out that protection activity (subsection (3)).

Clause 15 - Regulations relating to EU obligations

150. This clause provides that the Secretary of State would have powers to confer functions by means of regulations and to direct the NHS Commissioning Board and commissioning consortia in respect of EU obligations connected to the health service. Under the current system, the Secretary of State has the power to delegate certain aspects of his functions relating to EU obligations to PCTs and Strategic Health Authorities, and to direct them in the exercise of these and other functions to ensure compliance with EU law. This clause makes new arrangements for the Board and consortia, in view of the abolition of PCTs and Strategic Health Authorities.
151. Subsection (1) of 6D gives the Secretary of State a power to require, by means of regulations, the Board or a consortium to exercise a specified EU health function. As subsection (2)(a) indicates, an “EU health function” refers to any function which may be exercised by the Secretary of State to implement EU obligations relating to the health service. For example, the Secretary of State might delegate to consortia the function of authorising patients in England to go to another EU state for their treatment under section 6B of the NHS Act. However, the Secretary of State may not require the Board or a consortium to exercise any functions relating to the making of subordinate legislation (such as regulations) for the purposes of implementing EU obligations. Subsection (2)(b) highlights that any such function must be specified in the regulations which impose the requirement on the Board or a consortium.
152. Further to the power to delegate some of his/her functions relating to EU obligations,

the Secretary of State may also direct the Board and consortia about the exercise of any of these delegated functions, as indicated in subsection (3). This would allow the Secretary of State to indicate to the Board and consortia the manner in which the delegated functions should be carried out in order to remain compliant with EU obligations. The Secretary of State could direct individual consortia in this way if necessary.

153. Subsection (4) gives the Secretary of State the power to direct the Board or consortia about the exercise of any of their other functions in order to secure compliance by the UK with EU obligations. This power is to allow the Secretary of State to address quickly any infractions which may be triggered by the actions of an individual consortium, but for which the Secretary of State ultimately remains responsible. Being able to act quickly in such a scenario is important to avoid the costs associated with full infraction proceedings being brought against the UK by the European Commission.

Clause 16 - Regulations as to the exercise of functions by the Board or consortia

154. This clause inserts new section 6E into the NHS Act. This section makes provision for the Secretary of State to establish “standing rules” which would impose requirements on the NHS Commissioning Board and commissioning consortia in the exercise of their functions. The requirements in the standing rules would be imposed by means of regulations, as outlined in subsection (1). The “standing rules” are intended to allow the Secretary of State to create a rules-based framework for commissioners. They would be generic, and it would not be possible for the Secretary of State to develop regulations affecting an individual consortium (subsection (8)). To a large extent their purpose is to allow some existing policies to be maintained in the context of the more limited powers of the Secretary of State under this Bill. In exercising the regulation making powers under this section, the Secretary of State would be bound by the duty inserted by clause 4 of the Bill to avoid unnecessary burdens on other bodies in the health system.
155. Subsections (2) to (7) of new section 6E outline the areas where the Secretary of State would have the power to make standing rules.
156. Subsections (2) and (3) of new section 6E are intended to allow the continuation of the existing arrangements for Continuing Healthcare (where the NHS is responsible for delivering a package of health and social care to individuals who have a primary health need) and the continuation of certain rights in the NHS Constitution, which are currently given legal effect through directions to PCTs. For example, the NHS Constitution contains a right for patients to make choices about their care, which is underpinned by directions. Subsection (2)(c) would allow this right to be underpinned by regulations instead, without any need to change the Constitution itself.
157. Subsection (4) of new section 6E provides a power to require certain matters to be included in the contracts that the Board or consortia use when commissioning services

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from providers. This includes specifying matters which must appear in commissioning contracts entered into by the Board or consortia, and requiring the Board to draft terms and conditions relating to those matters. Subsection (4) also indicates that regulations may require the Board or consortia to incorporate such terms and conditions into their commissioning contracts. For example, regulations could require the inclusion of contractual requirements on resilience planning in relation to incidents affecting the public in which the health service in England plays a front line or supporting role. A further example would be technical matters required commercially, such as payment terms and notice terms.

158. Subsection (5) of new section 6E lists a number of provisions which must be included in the regulations. Subsection (5)(a) states that the regulations must require the Board to draft terms and conditions that it considers appropriate for inclusion in commissioning contracts. The regulations must also allow the Board to require consortia to use such terms and conditions in their commissioning contracts ((5)(b)) and to draft model commissioning contracts ((5)(c)).
159. Under subsection (6) of new section 6E, the Board could be required to consult specified persons on any draft contracts that it produces.
160. Subsection (7) of new section 6E lists generic requirements which may be imposed on the Board or consortia by regulations, relating to the exercise of any of their functions. Subsection (7)(a) of new section 6E allows regulations to be drafted requiring the Board or consortia to provide specified information to specified persons in a specified manner (where “specified” means specified in the regulations). This power would allow the Secretary of State to require information to be provided to patients and the public.
161. Subsection (7)(b) of new section 6E allows for regulations that would secure compliance with EU obligations by specifying the manner in which the Board and consortia carry out their functions. This is complementary to clause 15.
162. Finally, (7)(c) of new section 6E allows for regulations to require the Board or consortia to do such other things, in the exercise of their functions, as the Secretary of State considers necessary for the purposes of the health service. This would support the Secretary of State in the effective discharge of his/her duty to promote a comprehensive health service. To help ensure that use of this relatively broad power is proportionate, and receives the proper scrutiny, regulations brought forward under subsection (7)(c) would be subject to the affirmative procedure in Parliament (as outlined in subsection (2) of this clause).
163. Subsection (9) of new section 6E specifies that if any regulations under this section come into force on any day other than the 1st of April, the Secretary of State must publish an explanation as to why, and lay that statement before Parliament. This is intended to create an expectation that any new regulations affecting the Board or consortia would be aligned with the Secretary of State’s annual mandate to the Board.

If this is not possible, and regulations must be introduced in the intervening period, the Secretary of State would be under a duty to explain why.

Clause 17 - Functions of Special Health Authorities

164. *Subsection (2)* of this clause substitutes subsection (1) of section 7 of the NHS Act. The new subsection allows the Secretary of State to direct a Special Health Authority to exercise any function relating to the health service in England. These functions can be functions of the Secretary of State or any other person. The Secretary of State already has powers to direct a Special Health Authority to exercise any of his/her functions relating to the health service. This provision would amend the power so that it relates to health service functions in general. This is because some of the functions currently exercised by existing Special Health Authorities, in particular the NHS Business Services Authority and the NHS Litigation Authority would be functions of the NHS Commissioning Board, or Commissioning Consortia in the new system. For existing Special Health Authorities (NHS Blood and Transplant, NHS Business Services Authority and the NHS Litigation Authority), there would be no need to re-issue the current directions specifying their functions and they would continue in force as if given under the new power.
165. If the Secretary of State directs a Special Health Authority to exercise a function of a person other than the Secretary of State, he must consult that person before giving the direction (new subsection (1A)).
166. New subsection (1B) would give the Secretary of State the power to confer new functions on a Special Health Authority, as specified in regulations. This would provide the Secretary of State with flexibility to respond to changes over time. These regulations would be subject to the affirmative resolution procedure to ensure that Parliament would be able to scrutinise any new functions that the Secretary of State wished to confer on a Special Health Authority.

Clause 18 - Exercise of public health functions of the Secretary of State

167. This clause inserts a new section 7A into the NHS Act and allows the Secretary of State to delegate, by arrangement, the Secretary of State's public health functions to the NHS Commissioning Board or commissioning consortia, or to local authorities which have a duty to improve public health (see new section 2B). "Public health functions" means functions under section 2A (duty to take steps to protect public health), section 2B (power to take steps to improve public health) or Schedule 1 (e.g. providing contraceptive services). Where functions are delegated to the Board under such arrangements, the Board may in turn delegate those functions to consortia (subsection (4)). The arrangements may include provision for the Secretary of State to provide funding to the Board or consortia in relation to the delegated functions (subsection (5)). The intention is to provide flexibility and efficiency in the way that public health services are delivered. The provision may be used, for example, to delegate responsibility to the Board for commissioning a national vaccination or

screening programme.

Further provision about the Board

Clause 19 - The NHS Commissioning Board: further provision

168. This clause inserts a new Chapter A1 into Part 2 of the NHS Act.
169. *Mandate to the Board.* This clause inserts new section 13A, which requires the Secretary of State to publish and lay before Parliament a document to be known as “the mandate” before the start of each financial year. Broadly, the mandate would set out the totality of what the Government expects from the NHS Commissioning Board on behalf of the public for that period. This would comprise a series of objectives that the Secretary of State thinks the Board should work to achieve (13A(2)(a)), and any other requirements that the Secretary of State considers necessary to ensure those objectives are met (13A(2)(b)). The objectives may relate to the current financial year or subsequent financial years (as set out in 13A(4)(a) and 13A(4)(b) . This is to allow the Secretary of State to set longer-term objectives for the Board, not necessarily tied to one particular year’s funding. For example, the Secretary of State might set the Board an objective of improving cancer survival rates by a certain percentage over a set number of years.
170. As subsection 13A(3) indicates, the Secretary of State must also specify in the mandate the Board’s financial allotment and resource allocation for the financial year, as defined in new subsections 223B and 223C respectively (as inserted by the clause). The Secretary of State may also specify any proposals as to the Board’s allotment and/or resource allocation for subsequent financial years, as outlined in 13A(4)(c) and 13A(4)(d). Such information may help the Board in planning how to achieve objectives which extend beyond the current financial year. Finally, the Secretary of State may also specify in the mandate any matters that are proposed to be considered in assessing the Board’s performance for that financial year (subsection 13A(5)). Such matters might include the achievement of the outcomes set out in the Outcomes Framework. The Secretary of State would not be able to specify in the mandate any objective or requirement which targets any individual commissioning consortium. This duty, in subsection 13A(6), mirrors that in relation to the standing rules in new section 6E(8) (inserted by clause 16).
171. Before specifying any objectives or requirements in the mandate, the Secretary of State would be under a duty to consult the Board and such other persons that he considers appropriate to ensure that the mandate would be effective (13A(8)). Once the mandate is published, the Board would be under an obligation to seek to achieve the objectives and comply with the requirements specified (as set out in 13A(7)).
172. As in new sections 223B and 223C (inserted by clause 20), “financial year” is defined as including the period from the day the Board is established to the following 31 March, as specified in 13A(9). In subsequent years, the “financial year” would run

from 1 April to 31 March, as defined in the NHS Act (section 275).

173. New section 13B establishes the rules around in-year changes to the mandate. The Secretary of State is under a duty to keep the NHS Commissioning Board's performance in achieving the objectives and requirements in the mandate under review (subsection (1)), which underpins the Secretary of State's responsibility to hold the Board to account.
174. Should the Secretary of State have to make any change to the allotment or resource allocation (as defined in new sections 223B and 223C respectively, as inserted by clause 16), that section of the mandate must be revised accordingly to reflect these changes. However, if the Secretary of State alters the objectives and requirements in the mandate, then he would not necessarily be required to revise the allotment and resource allocation.
175. As with both the allotment and the resource allocation, the Secretary of State may only make any other changes to the mandate if the Board agrees to the revision or if the Secretary of State feels that there are exceptional circumstances that make the revision necessary (subsection (3)). The Secretary of State may also revise the mandate following a parliamentary general election (subsection (3)(b)). After altering the mandate, the Secretary of State must publish the revised document, and lay the new version before Parliament with an explanation of the reasons for making the changes, as specified in subsection (4). This would ensure that the Secretary of State remained accountable to Parliament for any changes relating to the Board.
176. *General duties of the Board.* New Sections 13C, 13D, 13E, 13F, 13G, 13H, 13I, 13J and 13K confer some general duties on the NHS Commissioning Board.
177. *Duty as to effectiveness, efficiency etc* New Section 13C is a duty on the NHS Commissioning Board to exercise its functions in a way that is effective, efficient and economical.
178. *Duty as to improvement in quality of services.* New Section 13D puts the Board under a duty to exercise its functions in a way that will improve the quality of services provided as part of the health service. This also reflects the accepted definition of quality outcomes⁴ as comprising effectiveness, safety and patient experience. The Board must pursue this quality improvement objective with reference to two sets of guidance – a) “any document published by the Secretary of State for the purposes of this section”, i.e. the NHS Outcomes Framework; and b) the Quality Standards that the National Institute for Health and Care Excellence (NICE) produces (see Part 7, below). This duty mirrors the Secretary of State's duty to improve quality of services inserted by clause 2.

⁴For example see the NHS Outcomes Framework published by DH on 20 December 2010 - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122944

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179. *Duty as to promoting autonomy.* New section 13E requires the NHS Commissioning Board, in exercising its functions, to act with a view to securing, so far as is consistent with the interests of the health service, that any other person exercising functions in relation to the health service (such as commissioning consortia), or providing services for its purposes (such as foundation trusts) is free to exercise those functions, or provide those services, in the manner that it considers most appropriate, and is not subject to unnecessary burdens. This mirrors the duty placed on the Secretary of State under clause 4.
180. This duty would therefore require the NHS Commissioning Board, when considering how to exercise its functions in relation to consortia such as publishing commissioning guidelines, or when determining matters to be included in contracts with healthcare providers, to make a judgement as to whether these were in the interests of the health service. If challenged, the NHS Commissioning Board would have to be able to justify why these requirements were necessary.
181. The duty would cover those arm's length bodies in relation to which the NHS Commissioning Board has functions (such as NICE and the Information Centre) as well as commissioners and providers of NHS services. Although the NHS Commissioning Board would not have the same direct relationship with providers of NHS services as Strategic Health Authorities and Primary Care Trusts currently have with NHS trusts, it would still have certain functions which impact on providers. For example, it would be able to require certain terms to be included in contracts entered into either by the NHS Commissioning Board itself or by consortia for the provision of NHS services by virtue of regulations made under clause 16.
182. This duty is intended to address the policy outlined in *Liberating the NHS: Legislative Framework and Next Steps* to:
- “enshrine the principle of autonomy at the heart of the NHS” [by] “maximising the autonomy of individual commissioners and providers and minimising the obligations placed upon them, in a way that is consistent with the effective operation of a comprehensive health service”⁵
183. *Duty as to reducing inequalities, involving patients etc.* New Section 13F confers a duty on the NHS Commissioning Board to have regard to the need to reduce inequalities and involve patients in the exercise of its functions.
184. Subsection (1)(a) requires the NHS Commissioning Board to have regard to the need to reduce inequalities between patients with respect to their ability to access health services; the NHS Commissioning Board should seek to narrow inequalities in access to health services for individuals and groups of people from which they could derive significant benefit. For example, the Board could seek to narrow inequalities in ability to access through providing guidance to commissioning consortia on how

⁵ Copies are available in the House library, and from the DH website at <http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm>

services are communicated to specific groups, on opening hours, on reducing late presentation, where particular services are located in order to be more accessible to specific populations or on contract specifications between commissioning consortia and secondary care providers. It may also make use of reports from Healthwatch or other groups. However, it will be up to the NHS Commissioning Board to decide how it performs this duty.

185. Subsection (1)(b) requires the NHS Commissioning Board to have regard to the need to reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services; the NHS Commissioning Board should seek to narrow clinically unjustifiable inequalities in the outcomes of health care. For example, the Board could seek to improve the outcomes of care for specific groups through guidance to commissioning consortia on access issues, on appropriate referral practices for certain groups, on coordination of care, or through advising on contract specifications. As the NHS outcomes framework develops, and information on outcomes becomes more available by the protected characteristics of the 2010 Equality Act (for example by neighbourhood or by deprivation profile), it is expected that this will be increasingly helpful in guiding the NHS Commissioning Board's actions. However, it will be up to the NHS Commissioning Board to decide how it performs this duty.
186. Subsection (1)(c) requires the NHS Commissioning Board, in exercising its functions, to have regard to the need to promote the involvement of individual patients and their carers in decisions about their own care (shared decision-making) and management of their own care. It is intended that this will be achieved through effective involvement and engagement in its dialogue with consortia, and through commissioning and contract guidelines, and outcomes frameworks.
187. Subsection (1)(d) requires the NHS Commissioning Board to have regard to the need to enable patients to make choices with respect to aspects of health services provided to them. The NHS Commissioning Board will be responsible for championing effective involvement and engagement in decisions about healthcare by working with GP commissioners, local authorities, voluntary sector and patient-led support groups and Healthwatch. The Board will also develop and agree with the Secretary of State the guarantees for patients about the choices they can make. In addition, the Board will be responsible for commissioning, promoting and extending information to support meaningful choice over the care and treatment that people receive, where it is provided and who provides it (including personal health budgets). This information should include patient-reported experience and outcome measures.
188. *Duty to obtain appropriate advice.* New Section 13G provides that the NHS Commissioning Board must take the view of other healthcare professionals, so it can effectively discharge its functions.
189. *Duty to promote innovation.* New Clause 13H places a duty on the NHS Commissioning Board, in the exercise of its functions, to promote innovation in the

provision of health services by for example encouraging both innovative commissioning and the commissioning of innovative health services. This would be achieved, for example, through the NHS Commissioning Board developing commissioning guidelines for commissioning consortia as well as hosting some clinical commissioning networks where appropriate.

190. Innovation will originate primarily from the actions of commissioners and providers but we expect the NHS Commissioning Board will take a lead role in promoting innovation. The duty will support delivery of the NHS Commissioning Board's duty to secure continuous improvements in the quality of health care under clause 13D. This duty is similar to the duty that previously applied to Strategic Health Authorities.
191. *Duty in respect of research.* New Section 13I confers a duty on the NHS Commissioning Board, under which, in the exercise of its functions, it must have regard to the need to promote research on matters relevant to the health service and to promote the use in the health service of evidence obtained from research. The NHS Constitution confirms that the NHS is committed to the promotion and conduct of research to improve the current and future health and care of the population. To support this, the NHS Commissioning Board would be expected to promote the conduct of research and the use of evidence obtained from research when it exercises its commissioning and other functions. For example, through commissioning guidance, contracts and pricing structures, the Board will encourage providers to participate in research and to use research evidence to deliver and improve services. This is consistent with the general duty of the Board to exercise its functions with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, or the protection or improvement of public health.
192. *Duty to encourage integrated working.* New Section 13J is a general duty on the Board in exercising its functions to act with a view to encouraging commissioning consortia to work closely with local authorities in arranging for the provision of services and in particular through the use of joint arrangements with local authorities under section 75 of the NHS Act. The intention is that the NHS Commissioning Board should encourage consortia to work closely together with local authorities in arranging for the provision of services to secure and advance the health and wellbeing of the people of England.
193. *Duty to have regard to impact on services in certain areas.* New Section 13K requires the Board to have regard to the likely impact of its commissioning decisions on the provision of health services to persons living in areas of Scotland or Wales that are close to the border with England. It is the intention that consortia also have regard to the impact of their commissioning decisions on border areas.
194. *Public involvement and consultation by the Board.* New section 13L requires the NHS Commissioning Board to make arrangements with a view to securing public involvement and consultation in: (a) the planning of commissioning arrangements; (b)

the development and consideration of proposals for service change where they would have a significant impact on the range of services provided and / or manner in which they are provided; and (c) decisions affecting the operation of commissioning decisions. The duty only applies to the NHS Commissioning Board, as respects (a) health services which the NHS Commissioning Board commissions; and (b) the NHS Commissioning Board's plans, proposals or decisions.

195. *Information on safety of services provided by the health service.* Following abolition of the National Patient Safety Agency under clause 261, new section 13M would give the NHS Commissioning Board responsibility for the functions currently carried out by Agency in respect of reporting and learning from patient safety incidents . The intention is to ensure that patient safety is embedded into the health service through commissioning consortia and the contracts they agree with providers.
196. *Guidance in relation to processing of information.* New section 13N places a duty on the Board to publish guidance on information processing requirements, sometimes termed information governance requirements, in respect of patient information or other information obtained or generated in the course of the provision of the health service. These requirements may include confidentiality and information security and risk management practice, records management, data protection, disclosure of information and information quality. Subsection (2) requires registered persons who carry out activities connected to healthcare provision to have regard to the published guidance. Information processing is as defined in the Data Protection Act 1998 and covers any possible activity involving information obtaining, holding, recording, using or sharing.
197. *Business Plan* New Section 13O requires the NHS Commissioning Board to publish a business plan before the start of the financial year setting out how it is to exercise its functions over the coming three years with a view to achieving its statutory duties and the objectives and requirements set for it by the Secretary of State in the mandate.
198. *Annual Report* New Section 13P requires the NHS Commissioning Board to publish an annual report, as soon as practicable after the end of each financial year which should set out how, in its view, it has progressed against the proposals it made in its business plan for that year, its objectives and requirements set for it by Secretary of State in the Mandate, and its duties to improvement of quality under section 13D and as to the involvement of patients under 13L.
199. The Secretary of State will be under an obligation to review the annual report and publish a letter in response setting out how, in the Secretary of State's view, the NHS Commissioning Board have performed for the previous year against its statutory duties and the objectives and requirements set for it in the mandate. This letter should also be laid before Parliament.
200. *Establishment of pooled funds.* New Section 13Q allows the Board and one or more consortia to set up a pooled fund (which is made up of contributions by the bodies

establishing the fund), which can be used to make payments with the agreement of the bodies contributing to the fund, towards expenditure incurred in the discharge of any of their commissioning functions. This power is intended to assist the Board and consortia working together to discharge their functions, allowing them to share financial resources to meet expenditure requirements.

201. *Board's power to generate income.* New Section 13R confers on the NHS Commissioning Board a power to generate income for improving the health service. This enables the NHS Commissioning Board to do anything specified in section 7(2) of the Health and Medicines Act 1988. The NHS Commissioning Board would be under a duty to remain within the resource limits set by the Secretary of State under new section 223B and any income it generates could therefore reduce the funding required from public finances.
202. *Board's incidental powers: further provision.* New Section 13S gives the NHS Commissioning Board powers to enter into agreements, acquire and dispose of property and accept gifts (including property to be held on trust for the purposes of the Board).
203. *Exercise of functions.* New Section 13T confers a power on the NHS Commissioning Board to exercise any of its functions by or jointly with a Special Health Authority, a commissioning consortium or any other body specified in regulations. Regulations may specify which functions of the Board may not be exercised by or jointly with such bodies. Where functions are exercised jointly, this may be through a joint committee of the Board and the other body under arrangements agreed between them.
204. *Power to confer additional functions on the Board.* New Section 13U gives the Secretary of State the power to confer additional functions relating to the health service on the NHS Commissioning Board through regulations. These regulations would be subject to the affirmative procedure, and would enable the Secretary of State to provide for additional functions to be carried out by the Board if this were beneficial for the effective operation of the health service. Functions may only be conferred on the Board if it is connected to another function of the Board.
205. *Failure by the Board to discharge any of its functions.* New Section 13V confers powers on Secretary of State to intervene in cases of serious failure of the NHS Commissioning Board to carry out any of its functions.
206. The power enables Secretary of State to give the NHS Commissioning Board a direction if the Secretary of State considers they are failing or have failed to discharge their functions, or are failing or have failed to discharge their functions properly. The direction can direct the NHS Commissioning Board to discharge those functions in any manner and within any period specified in the directions. If the NHS Commissioning Board fails to comply with such a direction, the Secretary of State should be able to discharge the function which the direction relates to him/her self or to make arrangements for another person to discharge them on his behalf. This power

would only be exercised in extreme circumstances such as a significant failure by the NHS Commissioning Board or in the case of an emergency situation which prevented the NHS Commissioning Board from exercising its functions properly and provides a backstop to ensure Secretary of State is able to fulfil his duty to ensure a comprehensive health service.

207. *Permitted disclosures of information.* New section 13W sets out categories of information obtained by the NHS Commissioning Board that it is permitted to disclose.

Clause 20 - Financial arrangements for the Board

208. This clause inserts new sections 223B (Funding of the Board), 223C (Use of resources by the Board), 223D (Financial duties of the Board: general), 223E (Financial duties of the Board: use of resources), 223F (Financial duties of the Board: restriction on certain types of expenditure) and 223G (Power to establish contingency fund) into the NHS Act. Broadly, this clause outlines how the Secretary of State would fund the NHS Commissioning Board in its activities, and restrict its annual use of resources. It also sets out the general financial duties of the Board with regard to this allotment. The Secretary of State would specify annually in the mandate to the Board how much the Secretary of State will pay the Board in funding, and a limit to the amount of resource the Board can make use of in that financial year.
209. *Funding of the Board.* New section 223B provides that the Secretary of State must not pay sums exceeding the amount allotted to the Board for that year to enable it to perform its functions. The mandate to the Board will specify how much the Secretary of State must pay to the Board for each financial year (the allotment). Payment of the allotment would be subject to the Board keeping such records, pertaining to the funds, as the Secretary of State requires (new section 223B(6)). Further details of how allotments would be made by the Secretary of State in the mandate can be found in clause 19.
210. The Secretary of State would only be able to make a new allotment in any given financial year, either increasing or reducing the previously made allotment, under certain circumstances. Either the Board must agree to the change, or there must be exceptional circumstances, which the Secretary of State judges to necessitate a new allotment. Such exceptional circumstances might include a severe disease outbreak or unpredictable and substantial damage to infrastructure.
211. For new sections 223C to 223F “financial year” is defined as the period from the day the Board is established to the following 31 March (new section 223B(8)). In subsequent years, the “financial year” would run from 1 April to 31 March, as defined in the NHS Act (section 275).
212. *Use of resources by the Board.* New section 223C is concerned with the Board’s annual resource allocation. Under this section, the Secretary of State may give a

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direction that the Board's use of resources in a financial year must not exceed a specified amount, and this amount is known as the resource allocation. The resource allocation includes not only the Board's expenditure in the form of cash spending (that is, the cash spending that should be accounted for in that financial year, in line with resource accounting standards), but also consumption of other resources and the reduction in value of assets belonging to the Board (new section 223C(3)). For example, the reduction in value of a photocopier across the year, or the distribution of leaflets previously kept in storage would be counted as part of the Board's resource allocation.

213. As with the allotment, the Secretary of State may only vary the resource allocation within a financial year if the Board agrees that the change is necessary or the Secretary of State believes there to be exceptional circumstances which demand a variation of the allocation. This is outlined in (new section 223C(2)).
214. For sections 223C to 223F "financial year" is defined as the period from the day the Board is established to the following 31 March, as specified in new section 223B(8). In subsequent years, the "financial year" would run from 1 April to 31 March, as defined in the NHS Act (section 275).
215. *Financial duties of the Board: general.* Under new Section 223D(1) the NHS Commissioning Board will have an obligation to ensure its expenditure when performing its functions in that year does not exceed the aggregate of:
 - a) the amount allotted to it for that year in respect of those functions under new section 223B;
 - b) any sums received by it in that year under any provision of the NHS Act (other than sums received by it under new section 223B); and
 - c) any sums received by it in that year otherwise than under the NHS Act for the purpose of enabling it to defray such expenditure.
216. Category (b) will cover for example the power of the NHS Commissioning Board to generate its own income (see new section 13R) and category (c) could for example cover any money received by NHS Commissioning Board in order to comply with its freedom of information obligations. The Secretary of State has the power to determine by directions what will and what will not count when calculating whether the NHS Commissioning Board's expenditure has remained within the aggregate of the sums received and the amount allotted to it for that year. This system of setting not only a cash limit on the NHS Commissioning Board expenditure but also a limit on use of resources reflects the system for controlling government resources under the Government Resources and Accounts Act.
217. New section 223D(3) gives the Secretary of State a power to determine in directions the extent to which, and the circumstances in which, sums received by the NHS

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Commissioning Board under new section 223B but not yet spent must be treated for the purposes of this section as part of the expenditure of the Board, and to which financial year's expenditure they must be attributed.

218. *Financial duties of the Board: use of resources.* New Section 223E(1) places a duty on the NHS Commissioning Board to ensure its use of resources in a given financial year does not exceed the resource allocation specified by the Secretary of State under new section 223C, as set out in the mandate for that year. Subsection (2) gives the Secretary of State a power to give directions that specify what uses and descriptions of resources that must, or must not, be taken into account by the NHS Commissioning Board in its requirement to keep within its resource allocation for a financial year.
219. *Financial duties of the Board: restriction on certain types of expenditure.* Section 223F places a duty on the NHS Commissioning Board to ensure that its expenditure in a financial year on capital, on revenue and on prescribed matters relating to administration (as defined in regulations) do not exceed amounts specified by the Secretary of State in relation to that year. The Secretary of State may vary the amounts specified during that financial year and direct the Board about whether certain types of expenditure are capital expenditure or revenue expenditure for the purposes of this section.
220. *Power to establish contingency fund.* New Section 223G gives the NHS Commissioning Board a power to set up a contingency fund, using a proportion of the funds allotted to it by the Secretary of State, from which it can make payments to the Board or to commissioning consortium to enable them to discharge their commissioning functions or to enable a commissioning consortium to discharge its other functions exercisable by virtue of regulations under section 75 of the NHS Act.

Further provision about commissioning consortia

Clause 21 - Commissioning Consortia: establishment etc.

221. Establishment of commissioning consortia: This clause inserts Chapter A2 into Part 2 of the NHS Act, which makes further provision about commissioning consortia. New Sections 14A to 14D of the NHS Act make provision about the establishment of commissioning consortia.
222. *General duties of Board in relation to commissioning consortia.* New section 14A sets out the general duties of the Board in relation to commissioning consortia. Subsection (1) requires the Board to ensure that, at any time after the date specified in writing by the Secretary of State, all providers of primary medical services (for instance GP practices) in England are members of a consortium.
223. Subsection (2) requires the Board also to ensure that, from the date so specified by Secretary of State, the areas specified in each consortium's constitution cover the whole of England and do not coincide or overlap. This will ensure, for instance, that

there is no ambiguity as to which consortium is responsible for a person that is not registered with a GP practice or who needs access to emergency healthcare.

224. Subsection (3) sets out that a provider of primary medical services for the purposes of this Chapter is a person who is a party to a contract or arrangement that is described in subsection (4), in other words a person or organisation that holds a General Medical Services (GMS) contract, a Personal Medical Services (PMS) agreement or an Alternative Provider Medical Services (APMS) contract. By virtue of subsection (5), where a provider holds more than one such contract or arrangement, they must be a member of a consortium in respect of each contract or arrangement. Together, these subsections have the effect that all GP practices must be members of a consortium. Where two or more individuals practise as GPs in partnership, it is the partnership that is treated as a single provider of primary medical services, not the individuals in that partnership (subsection (6)). Similarly, where two or more individuals are parties to an arrangement in subsection (4) but are not a partnership they are to be treated as one person for these purposes.
225. *Applications for the establishment of commissioning consortia.* New section 14B makes provision for applications to be established as a consortium to be made to the Board (subsection (1)). Under subsection (2), an application may be made by two or more persons, provided that each of them is either a provider of primary medical services (a GP contract holder) or wishes to be so and they wish to be a member of a commissioning consortium. Under subsection (3), applications must include a copy of the consortium's proposed constitution, the name of the person whom the consortium wishes the Board to appoint as its accountable officer and such other information that the Board may specify. Any specification made by the Board for these purposes must be published. Subsection (4) provides for persons to become applicants or withdraw from being applicants at any time before the application is decided by the Board. Subsection (5) provides that with the agreement of the Board applicants can modify the proposed constitution at any time before the application is determined. Subsection (6) introduces Part 1 of Schedule 2 which makes provision about the constitution of a consortium.
226. *Constitution of a commissioning consortia:* Part 1 of Schedule 1A (inserted by Schedule 2 of this Bill), provides that a consortium must have a constitution (paragraph 1) and provides for certain arrangements and procedures which the consortium must set out in its constitution.
227. Paragraph 2 provides that the constitution must specify the name and members of the consortium and the geographical area that is relevant among other factors, to the consortium's commissioning responsibilities under subsection (1B) of revised section 3 of the NHS Act (e.g. in relation to people who are not registered with any GP practice) and the Health and Wellbeing Board(s) of which it must be a member.
228. Paragraph 3 provides that the constitution must specify the arrangements for the discharge of the consortium's functions, including functions in relation to determining

the remuneration and terms and conditions of its employees. Those arrangements may include the appointment of committees or sub-committees; the membership of these committees may include persons other than members of the consortium and its employees, such as members of the public.

229. Paragraph 4 provides that the constitution must include the procedures that the consortium will follow to make decisions and for dealing with consortium members' conflicts of interest.
230. Paragraph 5 provides that the provision made under paragraphs 3 and 4 must ensure that there is effective participation by each member of the consortium.
231. Paragraph 6 provides that consortia may include other matters in their constitutions over and above those matters required to be included under Part 1. Such provision should be consistent with the provisions of the Bill.
232. *Determination of applications.* New section 14C provides for the determination of applications by the Board. The Board must (under subsection (1)) grant an application for the establishment of a consortium if it is satisfied of the matters covered in subsection (2). These matters include:
- that the constitution complies with the requirements set out in Part 1 of Schedule 1A: for example that it sets out the name, members and area of the constitution, that it specifies the arrangements the consortium has put in place for the discharge of its functions, and the procedures for decision making, dealing with conflicts of interest and ensuring effective participation by members;
 - that each member of a consortium will be a provider of primary medical services (i.e. that they will be a GP practice) on the date of establishment of the consortium;
 - that the area of the consortium is appropriate;
 - that the Board considers it appropriate to appoint as the consortium's accountable officer the person proposed by the applicants; and
 - that the applicants have made appropriate arrangements to discharge the consortium's functions.
233. Regulations under subsection (2)(f) may set out other matters that the Board has to be satisfied about. Regulations under subsection (3) may set out factors that the Board must or may take into account when determining an application for establishment. Regulations under this subsection may also specify the procedure for the making and determination of applications.

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234. *Effect of grant of application.* New section 14D provides for the establishment of a consortium upon the grant of an application (under section 14C). The grant of an application for establishment has the effect that the consortium is established as a statutory body and the consortium's proposed constitution then has effect. This clause also introduces Part 2 of Schedule 1A which makes further provision about consortia.
235. Schedule 1A Part 2 makes further provision about consortia. Each consortium is to be a body corporate (paragraph 7) which may appoint employees on such terms and conditions (including remuneration) as they determine (paragraph 8). The Board may publish guidance for consortia on the determination of remuneration for employees. Regulations may be made under paragraph 8(3) requiring consortia to publish prescribed information in relation to the remuneration of their employees.
236. Consortia are to be granted the status of 'Employing Authorities' by amending the NHS Pension Scheme Regulations (after the passage of the Bill). This means that (like other NHS bodies such as foundation trusts) consortia would then be required to offer the NHS pension scheme to their employees, and would have to enrol their employees automatically in that scheme unless they opted out. Should any employees opt out, consortia would have the power under paragraph 8(5) to (7) to offer alternative pension arrangements or schemes should they wish. Foundation trusts already have this power.
237. Paragraph 9 sets out that each consortium must have an accountable officer, who may be either a member of the consortium or an employee. They may be the accountable officer for more than one consortium. If the accountable officer is not an employee of a consortium, the consortium may remunerate the accountable officer as they see fit. The accountable officer is responsible for ensuring the consortium complies with its financial obligations (under new sections 223I to 223K of the NHS Act) its requirements for accounting and audit (under paragraph 12 of this schedule (account and audit), its requirements for providing financial information to the Board (under paragraph 13). The accountable office is also responsible for ensuring that the consortium fulfils its duties to exercise its functions effectively, efficiently and economically under new section 14K, and its duties under new section 14L in relation to improvement in the quality of services. The accountable officer must also ensure that the consortia exercises its functions in a way which provides good value for money. Other obligations may be specified in a document published by the Board for these purposes.
238. Paragraph 11 of Part 2 enables a consortium to enter into externally financed development agreements. Such an agreement is certified by the Secretary of State, who may issue a certificate where he considers that the purpose or main purpose of the agreement is the provision of services or facilities in connection with the consortium's discharge of its functions; and a person proposes to make a loan or other form of finance for another party in connection with that agreement.
239. Under paragraph 12 a consortium must keep proper accounts and records, and prepare

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annual accounts for each financial year. The Board may direct a consortium, with the approval of the Secretary of State, to prepare a set of accounts in respect of a period or periods of time. Powers are conferred on the Board to direct consortia with the approval of the Secretary of State as to the form and content of accounts, the methods and principles by which they are prepared, and the timescales for submitting audited annual accounts and any other accounts including unaudited annual accounts. Annual accounts must be audited in line with the extant legislation. The Comptroller and Auditor General may examine a consortium's annual accounts and any related records, and any report on those accounts produced by an auditor or auditors. The provision specifies that a consortium is not required to prepare any accounts or records in respect of anything the consortium does as a trustee.

240. Paragraph 13 of Part 2 enables the Board to direct a consortium to supply it with information relating to its accounts, income or expenditure or its use of resources, within a specified period. The required information may include estimates of future consortium income, expenditure or use of resources.
241. Paragraph 14 is similar to that in Schedule 1, paragraph 14 and would require disclosure by all consortia to the Board of such information, in such form, and at such time or within such period, as the Secretary of State may require if the Secretary of State considers that information necessary for the purposes of the Secretary of State's functions in relation to the health service.
242. The paragraph would further require the Board to provide, to the Secretary of State, any information obtained from consortia under the power above.
243. Just as with the NHS Commissioning Board, commissioning consortia sit within the Department of Health accounting and budgeting boundaries and the Department requires information to effectively and efficiently manage the Department's financial position against, for instance, Departmental Expenditure Limits. In addition, the Department has a responsibility to provide information on those bodies for which it is accountable in order to meet requirements that may be set by HM Treasury and others on both financial and non-financial matters. Under this paragraph, it would not be possible for Secretary of State to request information from a single consortium or a group of consortia. The Secretary of State must exercise the power in the same way in relation to all consortia, for example by making the same request for information to all consortia.

Paragraph 15 clarifies that consortia also have the power under section 2 to acquire and dispose of property, enter into agreements including contracts, or accept gifts of property. Property in this sense means any possession - it is not limited to buildings or land.

244. *Variation of constitution.* New sections 14E and 14F make provision about the variation of a consortium's constitution. Under section 14E a consortium may apply to the Board for its constitution to be varied. Regulations may make provision about

the procedure to be followed when applying for a variation; the circumstances in which the Board must or may grant, or must or may refuse, an application; and factors the Board must or may take into account when deciding whether to grant or refuse an application.

245. Section 14F gives the Board powers to vary a consortium's constitution otherwise than on application by the consortium. The Board may change the area specified in a consortium's constitution, and may add any provider of primary medical services to, or remove any provider from, a consortium's list of members. Before exercising these powers the Board must consult the consortium and any other consortia affected. The powers can only be exercised if the consortium whose constitution is to be varied agrees to the change, or if the Board considers that it is necessary to make the variation to discharge its duties under section 14A (i.e. to ensure that every provider of primary medical services is a member of a consortium or to ensure that the areas specified in the constitutions of consortia together cover the whole of England)). Regulations may be made setting out further circumstances in which the Board may vary the constitution of a consortium, the circumstances in which those powers can be exercised and the procedure to be followed.
246. *Mergers, dissolution etc.*. New sections 14G and 14H make provision about the merger and dissolution of consortia. Section 14G allows consortia to apply to the Board to merge, i.e. for the consortia to be dissolved and for a new consortium to be established in their place. Any application under section 14G must include a copy of the proposed constitution of the new merged consortium, the name of the person whom the consortium wishes the Board to appoint as its accountable officer, and such other information that the Board may specify. Sections 14C and 14D, which make provision about the determination of applications and effect of grant of applications, also apply here.
247. Section 14H provides for a consortium to apply to the Board to be dissolved. Regulations under subsection (2) may make provision about the circumstances in which the Board must or may grant, or must or may refuse, applications under this section; the factors that the Board must or may take into account in determining whether to grant those applications; and the procedure for making and determining applications.
248. *Transfers in connection with variation, merger, dissolution etc.* Under section 14I, when variations, mergers or dissolution take place, the Board may make a scheme providing for the transfer of property or staff, or any associated rights and liabilities, of the consortium to the Board or to another consortium. Section 14I also introduces Part 3 of Schedule 1A which makes further provision about transfer schemes.
249. Part 3, paragraphs 16 to 20 of Schedule 1A sets out further details in respect of property and staff transfer schemes which may be made under new section 14I, clause 21. These schemes may transfer property, rights and liabilities, including those that could not otherwise be transferred, those arising after the making of the scheme, and

criminal liabilities (paragraph 16).

250. A property or staff transfer scheme may also make supplementary, incidental, transitional and consequential provision (paragraph 17). New rights can be created, or liabilities imposed, in relation to the property or rights transferred. Provision may be made in the scheme about the continuing effect of things the person (“the transferor”- the person from whom the things are being transferred) has done in respect of the things transferred. Provision may also be made about the continuation of things that are being done by, on behalf of or in relation to the transferor in respect of the things transferred. Provision may also be made for references to “the transferor” in legal instruments and documents to be treated as references to “the transferee” (the person whom the things are being transferred to).
251. A property scheme may make provision for the shared ownership or use of property (paragraph 18). A staff transfer scheme may make provision which is the same or similar to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) (paragraph 19). Either a property or staff transfer scheme may provide for the scheme to be modified by agreement after it comes into effect, and those modifications to have effect from the date when the original scheme comes into effect (paragraph 20).
252. *Guidance about the establishment of commissioning consortia etc.* Under section 14J the Board may publish guidance about how applications for establishment as a consortium (and applications to vary, merge or dissolve a consortium) should be made, including guidance as to the form, content and publication of constitutions. This would enable the Board, for instance, to issue guidance on how good governance principles (such as the Nolan principles of public life) might be reflected in a consortium’s constitution.

Clause 22 – Commissioning consortia: general duties etc.

253. Clause 22 inserts new sections 14K to 14Z9 into the NHS Act.
254. *General duties of consortia.* New sections 14K and 14L of the NHS Act are concerned with general duties of consortia.
255. *Duty as to effectiveness, efficiency etc.* Under new section 14K each commissioning consortium must exercise its functions effectively, efficiently and economically.
256. *Duty as to improvement in quality of services* New Section 14L places commissioning consortia under a duty to exercise their functions with a view to securing continuous improvements in the quality of services provided to individuals, particularly in relation to the outcomes from that care. This clause also reflects the accepted definition of quality (see, for example, the NHS Outcomes Framework published by

DH on 20 December 2010⁶) as comprising effectiveness, safety and patient experience. Subsection (4) requires consortia to have regard for these purposes to any guidance issued by the Board under new section 14V on how consortia should discharge their commissioning functions.

257. *Duty in relation to quality of primary medical services:* New section 14M specifies that each consortia must assist and support the Board in discharging its duty under 13D as to improvement in the quality of services in so far as that relates to securing continuous improvement in the quality of primary medical services. In this way, each consortium would support the continuous improvement in the quality of primary medical services provided by consortium members.
258. *Duties as to reducing inequalities, promoting patient involvement etc.* New section 14N sets out that consortia must in the exercise of their functions have regard to the need to reduce inequalities between patients in access to health services and in the outcomes achieved from health services. Section 14N also requires that consortia have regard to the need to promote the involvement of patients and their carers in decisions about the provision of health services and the need to enable patients to exercise choices in relation to the services provided to them.
259. *Duty to obtain appropriate advice:* New section 14O requires consortia to obtain appropriate advice from people with professional expertise in relation to physical and mental health. This could involve, for example, a consortium employing or otherwise retaining healthcare professionals to advise the consortium on commissioning decisions for certain services, or appointing professionals to any committee that the consortium may set up to support commissioning decisions.
260. *Public involvement and consultation by commissioning consortia:* New section 14P sets out requirements for public involvement (whether by consultation or otherwise). Consortia must make arrangements to involve individuals to whom services are being or may be provided in the commissioning process. Specifically, individuals must be involved in planning commissioning arrangements, in developing and considering proposals for changes in the commissioning arrangements where those proposals would have a significant impact on how services are provided or the range of health services available, and in decisions that would likewise have a significant impact. The Board may publish guidance for consortia on how to discharge their duties under this section, and consortia must have regard to any such guidance.
261. The Board has a duty to promote public and patient involvement in commissioning decisions. As such, new section 14P(3) gives the Board a power to issue guidance to commissioning consortia about how to carry out their duties in relation to public and patient involvement. The Board could, for instance, give guidance on effective ways

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http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122944

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of engaging and seeking views from members of the public, including how to engage people who do not regularly use healthcare services or are from disadvantaged communities. The Board could also give guidance to help consortia decide in what circumstances the duty to involve might most appropriately be met by providing information and in what circumstances a consortium should actively seek people's views through consultation.

262. *Arrangements with others.* New sections 14Q and 14R enable consortia to collaborate with each other, and with local health boards in particular circumstances.
263. *Arrangements by consortia in respect of the exercise of functions.* New section 14Q enables consortia to collaborate in respect of the exercise of their commissioning functions. Consortia may make arrangements under subsection (2)(a) for one consortium to take a role as lead commissioner and exercise commissioning functions on behalf of other consortia. Consortia may exercise their functions jointly. In exercising these powers, a consortium may make payments to other consortia, may make the services of its employees or other resources available to other consortia, and may establish pooled funds.
264. *Joint exercise of functions with Local Health Boards.* Regulations may be made under new section 14R to allow any prescribed functions of a consortium to be exercised jointly with a Local Health Board. Local Health Boards are the bodies responsible for commissioning and providing health services in Wales. Regulations may make provision for any such functions to be exercised by a joint committee of the consortium and the Local Health Board.
265. It should also be noted here that a consortium may provide advice or assistance to any public authority in the Isle of Man or Channel Islands, on such terms as the consortium considers appropriate (clause 272).
266. *Additional powers of consortia:* Additional powers for consortia are set out in new sections 14S and 14T.
267. *Raising additional income:* New section 14S enables consortia to raise additional income for improving the health service, provided that this does not interfere with the consortium's ability to perform its functions.
268. *Power to make grants:* New section 14T enables consortia to make grants, which may be subject to conditions, to voluntary organisations which provide or arrange to provide services which are similar to a consortium's functions.
269. *Board's functions in relation to consortia.* New sections 14U, 14V, 14W and 14X make provision for the Board to have functions in relation to assisting consortia.
270. *Responsibility for payments to providers.* New section 14U gives the Board the power to publish a document specifying the circumstances in which a consortium is liable to

make payments to a provider to pay for services provided under arrangements commissioned by another consortium. This provision would, for instance, enable the Board to specify that, where a person uses an urgent care service commissioned by a consortium other than the consortium that is ordinarily responsible for that person's healthcare, the cost of that service is charged to the latter consortium. The Board would not be obliged to adopt such arrangements. It could, for instance, decide that consortia should be left to agree mutual arrangements for sharing costs where patients from a number of different consortia use the same urgent care service. However, where the Board publishes such a specification, a consortium will be required to make payments in accordance with that document (subsections (2) and (3)). In those circumstances, no other consortium will be liable for the payment. Any sums payable by virtue of subsection (2) may be recovered under subsection (5) as a civil debt. Where the Board makes a specification it may publish guidance for the purpose of assisting consortia understand and apply it (subsection (6)).

271. *Guidance on commissioning by the Board.* Section 14V provides that the Board must publish guidance for consortia on the discharge of their commissioning functions (subsection (1)). Consortia must have regard to this guidance (subsection (2)). The Healthwatch England committee of the Care Quality Commission must be consulted before the Board publishes any guidance or any revised guidance containing significant changes (subsection (4)).
272. *Exercise of functions by the Board.* New section 14W provides that the Board may act on behalf of a consortium and arrange the provision of services and exercise related functions, if requested to do so by a consortium, in other words by mutual agreement between the Board and the consortium. Regulations may provide that the power does not apply to services or facilities of a prescribed description. Subsection (3) makes provision for terms as to payment to be agreed between the Board and consortia.
273. *Power of Board to provide assistance or support.* New section 14X sets out that the Board has the power to provide assistance or support to consortia (including financial assistance and making Board employees or other Board resources available to consortia). This assistance may be provided on such terms as the Board considers appropriate, including terms as to payment. The Board can impose restrictions on the use of any such assistance.
274. *Commissioning plans:* New section 14Y makes provision with regard to commissioning plans and reports. Section 14Y(1) stipulates that each consortium must prepare a plan before the start of each financial year to set out how it will exercise its functions. The plan must in particular explain how the consortium proposes to discharge its duties to seek continuous improvement in the quality of services (under new section 14L) and its financial duties (under sections 223I to 223K). This plan must be published and sent to the Board before a date specified by the Board.
275. Under subsection (8), the consortium must also send a copy of its plan to each relevant Health and Wellbeing Board – the effect of subsection (9) is that this is any

Health and Wellbeing Board whose area coincides with or includes some or all of the area specified in the consortium's constitution. When commissioning consortia send their commissioning plans to the NHS Commissioning Board, they will be under an obligation (subsection (4)(b)), to include a statement as to whether the relevant Health and Wellbeing Board(s) agree that their plans have due regard to the relevant joint health and well-being strategy or strategies. This means that consortia will need to discuss their plans in advance with Health and Wellbeing Boards to help ensure that they reflect joint strategic needs assessments and joint health and well-being strategies. The Health and Wellbeing Board will have a duty under subsection (4)(a) to give the consortium its view on whether the commissioning plan has taken account of the most recent joint health and well-being strategy. The Health and Well-being Board will be able to write formally to the NHS Commissioning Board and the commissioning consortium if, in its opinion, a consortium has not had adequate regard to the joint health and well-being strategy in developing its commissioning plans.

276. *Reports by commissioning consortia.* Under section 14Z, each financial year a consortium must prepare and provide to the Board an annual report on how it has discharged its functions in the previous financial year. The report must in particular explain how a consortium has fulfilled its duties to seek continuous improvement in the quality of services, and describe how the consortium has discharged its duties under 14P, involving patients and the public in commissioning decisions. The consortium must publish the report and present it at a public meeting. The Board can give directions, which may include further provision on the form and content of an annual report. For example, these directions could specify that the report include a review of joint arrangements with local authorities and the outcome of any consultations undertaken under the 14P.
277. *Performance assessment of consortia.* New section 14Z1 specifies that the Board must conduct an assessment of how well each consortium has discharged its functions during each financial year, including in particular how well it has discharged its duty to seek continuous improvement in the quality of services (under new section 14L) and its financial duties (under new sections 223I to 223K). In assessing performance, the Board must have regard to any relevant document published by the Secretary of State, which would include the NHS Outcomes Framework, and to any commissioning guidance published by the Board. Each financial year, the Board must publish a report containing a summary of the results of the performance assessments.
278. *Power to require documents and information etc.* New sections 14Z2 to 14Z5 are concerned with the Board's powers to require information. The Board can use the powers in section 14Z2 and 14Z3 to require documents, information and explanations where it has reason to believe that a consortium might have failed, might be failing or might fail to discharge any of its functions properly, or where it believes the area of a consortium is no longer appropriate (see new section 14Z2(1)).
279. New section 14Z3 provides that, where the conditions in section 14Z2 are met, the Board may require any information, documents, records or other items from a

consortium or any member or employee of the consortium who has possession or control of the item. When that information is stored on a computer, it must be provided to the Board in a legible form. The power does not include power to require the provision of personal records. By virtue of subsection (5) this power does not include the power to require the provision of personal records - personal records is defined by reference to the meaning in section 12 of the Police and Criminal Evidence Act 1984 and does not therefore include documentary and other records concerning an individual (whether living or dead) who can be identified from them and relating to his physical or mental health; to spiritual counselling or assistance given or to be given to him; or to counselling or assistance given or to be given to him, for the purposes of his personal welfare, by any voluntary organisation or by any individual who because of his office or occupation has responsibilities for his personal welfare; or by reason of an order of a court has responsibilities for his supervision.

280. *Power to require explanation.* New section 14Z4 sets out the Board's power, where the conditions in section 14Z1 are met, to require an explanation, either orally (at such time and place as the Board may specify), or written, regarding any matter relating to the consortium's exercise of its functions. That explanation can include an explanation of how the consortium is proposing to exercise its functions.
281. *Use of information.* Where the Board obtains information from a consortium in these ways, new section 14Z5 permits the Board to use this information in connection with any of its functions which relate to consortia.
282. *Intervention powers:* New section 14Z6 sets out the Board's powers to intervene in the operations of commissioning consortia.
283. *Power to give directions, dissolve consortium etc.* Under new section 14Z6, if the Board is satisfied that a consortium is failing or has failed to discharge any of its functions, or there is a significant risk that it will fail to do so, the Board has powers to:
- direct the consortium as to the discharge of its functions;
 - direct the consortium or the accountable officer to cease to perform any functions for a specified period;
 - terminate the accountable officer's appointment and appoint another person to be accountable officer
 - vary a consortium's constitution (including by varying its area, adding any GP practice to its list of members, or removing any GP practice from its list of members); or
 - dissolve that consortium.

284. Subsection (8) provides that, where a direction is given for the consortium to cease performing any specified functions, the Board may exercise those specified functions. Alternatively, the Board may direct that another consortium or the accountable officer of another consortium discharge those functions (providing the Board has consulted that consortium). Where the Board changes the constitution of a consortium or dissolves a consortium, it may make a scheme transferring any property, liabilities, or staff (as at Part 3 of Schedule 1A) of the affected consortium to the Board or another consortium. Subsection (9) sets out that where the Board exercises the function of a consortium under subsection (8), the consortium must cooperate with the Board. Subsection (9) also sets out that when a consortium's functions are being discharged by another consortium or the accountable officer of another consortium, the consortium whose functions are being discharged must co-operate with the other consortium or the accountable officer in question.
285. *Procedural requirements in connection with certain intervention powers.* New section 14Z7 provides for procedural requirements which the Board must follow before dissolving a consortium under new section 14Z6(7). The Board must consult with that consortium, any relevant local authorities, and any other persons the Board considers appropriate, and provide those persons with a statement explaining its proposed actions and reasons for them. The Board must, under subsection (3), publish a report in response to this consultation and, where it decides to exercise its power to dissolve a consortium, explain in the report its reasons for doing so (subsection (4)).
286. Subsection (5) of new section 14Z7 provides that regulations may be made as to the procedure that the Board must follow before exercising its powers to require information or explanation (under new sections 14Z3 or 14Z4) or before exercising the intervention powers in new section 14Z6. This will enable regulations to set out a clear, transparent set of triggers or criteria for different stages of intervention and to help ensure that the nature of the intervention is proportionate to the nature of the failure or risk.
287. Subsection (6) of new section 14Z7 provides that the Board must publish guidance setting out how it proposes to exercise its powers to require information or explanation and its powers of intervention, so as to ensure that the arrangements are clear and transparent.
288. *Permitted disclosures of information.* New section 14Z8 makes provision as to the circumstances when a consortium may disclose information obtained in the exercise of its functions.

Clause 23 Financial arrangements for consortia

289. This clause sets out the financial arrangements for commissioning consortia, inserting new sections 223H to 223L into the NHS Act. The Secretary of State will remain accountable to the Treasury for the Department of Health's Departmental Expenditure

Limit (DEL), the annual spending limit for a government department arising from its agreed, long term financial settlement with HM Treasury. The Department will allocate resources for NHS commissioning to the Board and hold the Board to account for living within its spending and resource limits. The Board will in turn allocate resources to consortia and hold them to account for living within their spending and resource limits.

290. *Means of meeting expenditure of commissioning consortia out of public funds.* .New section 223H sets out the Board's duties to make annual financial allotments to consortia and, over the course of the relevant financial year, allows consortia to draw down funding from this allotment to meet the consortium's expenditure. Subsection (1) sets out the latter duty. The funds that a consortium can draw down to meet its expenditure must not exceed the allotted amount. For these purposes, the funds that it draws down will be net of designated elements of pharmaceutical expenditure which are paid by the Board but which are treated as paid by the consortium because such expenditure arises from drugs, appliances or services ordered by GP practices that are members of the consortium.
291. Subsection (2) provides that, in determining a consortium's annual allotment, the Board may take into account the expenditure of the consortium during any previous financial year. This enables the Board to reduce a consortium's allotment to reflect any over-spends against its allotment in previous years, or conversely to increase that allotment to reflect any under-spends, provided that the Board keeps within its overall expenditure limit. Subsection (2) also enables the Board to take into account any amount that it proposes to hold as a contingency fund.
292. Subsection (3) provides for the Board to notify a consortium in writing of its annual financial allotment.
293. Subsection (4) allows the Board to make an in-year adjustment to a consortium's allotment, provided that it acts reasonably in line with general administrative law controls.
294. Subsection (5) provides that, where the Board allots an amount to a consortium or makes a new allotment, it must notify the Secretary of State.
295. Subsections (6) provides that the Board may direct that sums paid to a consortium as part of an increase in a consortium's allotment are spent in a certain way. The direction would apply only to the amount by which the allotment has increased, rather than the total allotment. The power might be used when for instance additional funds have been made available to make a specific service or therapy more widely available.
296. The Board may also give directions to a consortium regarding the payment of sums to the Board in respect of charges and other sums related to the valuation and disposal of assets. This would allow for monies from the sale of assets to be clawed back and therefore prevent consortia from selling assets and using the proceeds inappropriately,

for example by using the proceeds to fund a deficit. In practice, the monies would not be directly paid back to the Board, but the Board would deduct these amounts from the amount of capital funding provided.

297. *Financial duties of commissioning consortia: general.* Section 223I sets out the duty for consortia to break even on their commissioning budget, in other words to ensure that their expenditure in a financial year does not exceed the allotment given to them by the Board together with any other sums received by the consortium. The Board has powers of direction to determine whether or not specified sums count for these purposes as being received by a consortium (in other words whether or not this income is treated as increasing the amount that a consortium can spend in a financial year) and whether or not specified expenditure made by a consortium, or sums received by a consortium from its allotment but not yet spent, must be treated for these purposes as counting towards its expenditure.
298. New section 223I also specifies that the Secretary of State may make directions requiring consortia to use banking facilities specified in those directions for the purposes specified in those directions. It is a Treasury requirement that all NHS money is held in Government Banking Service accounts. However, under this Bill, the Secretary of State does not have general powers of direction over consortia. The Government needs to ensure that firstly, all allocations to consortia (and allocations to the Board) are held by consortia in a Government Banking Service (GBS) account, and secondly that this is the account in which consortia keep their allocation and that the monies allocated to consortia stay in GBS accounts until paid out (although there may be circumstances in which other commercial accounts may be held). This money is held in the GBS to offset the national debt.
299. *Financial duties of commissioning consortia: use of resources.* Section 223J sets out the duty for consortia to ensure that their use of resources in a financial year does not exceed an amount specified by the Board. The Board can vary a consortium's resource limit in-year, provided that it acts reasonably in line with general administrative law principles. A consortium's use of resources will differ from its cash expenditure during a financial year, for instance in so far as resources are consumed (e.g. a service is received) in a different year from that in which the payment for that service is made or in so far as there is a change in the value of assets belonging to the consortium. The Board may give directions specifying what uses of resources and what types of resources must (or must not) be taken into account in determining whether a consortium has lived within its resource limit.
300. *Financial duties of commissioning consortia: restriction on certain types of expenditure.* Section 223K gives the Board a power to specify separately the maximum amounts to be spent by a consortium on capital expenditure, on revenue expenditure, and on prescribed matters relating to administration. Administration costs will, for instance, include the cost of employing or engaging staff to carry out commissioning functions or the cost of paying for an external organisation to provide commissioning support. The Board can vary any of these specified sums, and can

determine by directions whether expenditure of a specified description should be treated as capital or revenue expenditure. For the purpose of calculating whether a consortium has stayed within these limits, expenditure is to be disregarded if it is met from sums other than those paid to it by the Board under section 223H (i.e. its allocation). This means that if a consortium raises money in other ways, it may spend this money without it counting against the relevant limits.

301. *Payments in respect of performance.* New section 223L gives the Board the power to make a payment to a consortium after the end of the financial year if it considers the consortium has performed well that year. Under subsection (7), the consortium may distribute any such payment among the GP practices in the consortium as it considers appropriate. This will enable the Board to reward consortia that achieve high-quality outcomes for patients and that perform well in terms of their financial duties and, in turn, for consortia to reward GP practices on the basis of their contribution to these service and financial outcomes.
302. Under subsection (2), the Board may make advance payments before the end of the financial year if it considers that the consortium is likely to perform well during that year. Under subsection (3), any advance payment would then be deducted from the amount awarded to the consortium after the end of the year to reflect its performance. Where an advance payment is made but no performance payment is awarded for that year, or the performance payment exceeds the advance payment, subsection (5) provides for the Board to make corresponding deductions from performance payments in a subsequent financial year.

Clause 24 - Requirement for primary medical services provider to belong to consortium

303. This clause inserts new provisions into section 89 and section 94 of the NHS Act. *Subsection (1)* inserts new subsections (1A) to (1E) into section 89 of the NHS Act (General Medical Services (GMS) contracts: other required terms) which enable regulations made under subsection (1) of that section, which prescribe matters that may be included as required terms of a GMS contract, to include a number of further specific matters that relate to the relationship between the GMS contract holder and the relevant commissioning consortium. These matters include a requirement to be a member of a commissioning consortium and to nominate an individual to act on behalf of the contract holder in its dealings with the consortium. *Subsection (2)* makes similar changes to section 94 of the NHS Act by inserting new subsections (3A) to (3E) into that section (Regulations about section 92 arrangements).

Further provision about local authorities' role in the health service

Clause 25 - Other health service functions of local authorities under the NHS Act

304. This clause enables the transfer to local authorities of primary care trusts' existing functions around dental public health, and extend to local authorities a duty to help

deliver and sustain good health among the prison population.

305. *Subsection (2)* of this clause amends section 111 of the NHS Act to provide for the transfer to local authorities of PCTs' existing functions in relation to dental public health (as set out in regulations made by the Secretary of State) (subsection (2)). This allows the Secretary of State to specify in secondary legislation the activity that local authorities should undertake to promote good dental public health – this might include oral health education campaigns, for example
306. *Subsection (3)* amends section 249 of the Act to extend to local authorities a duty to co-operate with the prison service with a view to improving the exercise of functions in relation to securing and maintaining the health of prisoners. The amendment would also enable the Secretary of State to make regulations enabling a local authority and the prison service to enter arrangements for the prison service to exercise local authority public health functions or for a local authority to exercise public health-related functions of the prison service.
307. In each case, the functions apply to local authorities which have a duty to improve public health under new section 2B of the NHS Act. The Department's view is that the functions are consistent with the new duties for health improvement.

Clause 26 - Appointment of directors of public health

308. This clause requires local authorities and the Secretary of State to appoint directors of public health (DsPH) and makes related provision. PCTs are currently required to appoint DsPH to provide local leadership and co-ordination of public health activity, but the clause would in effect transfer that requirement to local authorities. The intention is that the DPH role will become integral to the new duties for health improvement and health protection that this Bill proposes for local authorities. The provision applies to local authorities which have a duty to improve public health under new section 2B of the NHS Act.
309. The clause inserts a new section 73A into the NHS Act. Subsection (1) provides that each local authority must appoint a DPH, acting jointly with the Secretary of State. It then defines the responsibilities of DsPH as including:
- a) the new health improvement duties that the Bill would place on local authorities;
 - b) the exercise of any public functions or steps that the Secretary of State requires local authorities to exercise or take;
 - c) any public health activity undertaken by the local authority under arrangements with Secretary of State;
 - d) local authority functions in relation to planning for, and responding to,

emergencies that present a risk to public health;

- e) the local authority role in co-operating with police, probation and prison services in relation assessing risks of violent or sexual offenders; and
- f) other public health functions that the Secretary of State may specify in regulations (e.g. functions in relation to the Healthy Start programme).

310. DsPH would be local authority employees. Currently they are normally employed by PCTs, but in some cases they are effectively joint PCT/LA appointments. Local authorities would be able to dismiss their DsPH, but only after consulting the Secretary of State (although the Secretary of State's agreement would not be necessary) (subsections (5) and (6)).
311. Where the Secretary of State considers a DPH has failed or may be failing to carry out certain aspects of the director's responsibilities then the Secretary of State may require the local authority to take certain action. The responsibilities in question are the director's responsibilities for the exercise of the Secretary of State's public health functions which have been conferred on the local authority by regulations or agreement, and for the taking of any health improvement steps which the local authority is required to take by regulations. The action which the Secretary of State may require consists of reviewing and investigating the DPH's performance, considering any steps that may be necessary (including any that the Secretary of State may require the local authority to consider) and then reporting back to the Secretary of State on the action it has taken. See subsections (3) and (4).

Clause 27 - Exercise of public health functions of local authorities

312. This clause inserts a new section 73B into the NHS Act and applies to local authorities which have a duty to improve public health under new section 2B of the NHS Act. Subsection (1) and (2) requires such local authorities to have regard to documents that the Secretary of State publishes for the purposes of the section, when exercising their public health functions; in particular this power would be used to require local authorities to have regard to the Department's proposed public health outcomes framework. The public health outcomes framework will set out the Government's goals for improving and protecting the nation's health and for narrowing health inequalities through improving the health of the poorest, fastest. Subsection (3) also provides that the Secretary of State may publish guidance to local authorities relating to their public health functions.
313. Subsection (4) and (5) requires DsPH to publish annual reports on the health of their local population and that local authorities publish that report. The reports are intended to help DsPH account for their activity and to chart progress over time.

Abolition of Strategic Health Authorities and Primary Care Trusts

Clause 28 - Abolition of Strategic Health Authorities

314. This clause abolishes Strategic Health Authorities, and repeals Chapter 1 of Part 2 of the NHS Act, which makes provision for Strategic Health Authorities.

Clause 29 - Abolition of Primary Care Trusts

315. This clause abolishes Primary Care Trusts and repeals Chapter 2 of Part 2 of the NHS Act, which makes provision for Primary Care Trusts.

316. The commissioning functions currently undertaken by Primary Care Trusts are intended to fall to other health bodies such as Commissioning Consortia, the NHS Commissioning Board, or by local authorities. Commissioning consortia will be responsible for commissioning the great majority of health services, while the NHS commissioning board will be responsible for commissioning services that cannot be solely commissioned by consortia, such as national specialist services, and GP services. PCT responsibilities for local health improvement will transfer to local authorities, who will employ Directors of Public Health jointly appointed with the Public Health Service.

317. Following this transfer of responsibilities, Primary Care Trusts will no longer have commissioning responsibilities in the NHS. As explained in the explanatory note for clause 20, the government intends for PCTs to retain commissioning responsibility until April 2013, as consortia become developed and established. Once consortia are able to take on their commissioning responsibilities, it is intended that Primary Care Trusts will be abolished- this should occur in April 2013.

Functions relating to mental health matters

318. These clauses make a number of changes to the Mental Health Act 1983 (the 1983 Act) in the light of the abolition of PCTs and Strategic Health Authorities and the other proposals in White Paper *Equity and Excellence: Liberating the NHS*⁷.

Clause 30 - Approval functions

319. This clause amends the 1983 Act to provide new ways in which the Secretary of State's approval functions under that Act may be exercised. At present, the Secretary of State's approval functions are delegated to Strategic Health Authorities, by means of directions given by the Secretary of State under section 7 of the NHS Act.

⁷ Copies are available in the Library, and from the DH website at <http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm>

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

320. The Secretary of State has two approval functions. Under section 12 of the 1983 Act, the Secretary of State may approve doctors (“section 12 doctors”) as having special experience in the diagnosis or medical treatment of mental disorder. The Secretary of State is also responsible for approving doctors and other professionals as approved clinicians for the purposes of the Act.
321. Certain decisions under the 1983 Act may only be taken by people who have been approved in this way. For example, an application cannot be made to detain a patient under the Act unless it is supported by two medical recommendations, one of which is given by a section 12 doctor. Similarly, only an approved clinician can be the “responsible clinician” in overall charge of the case of a patient detained under the Act.
322. The clause inserts three new sections into the 1983 Act.
323. New section 12ZA allows the Secretary of State to arrange for one or both of the approval functions to be exercised by anyone else who is willing to enter into an agreement to do so. Such an agreement might cover the approval function in general, or only to a more limited extent. For example, there could be agreements with different people in relation to different parts of the country, or (for approved clinicians) in relation to the approval of people from different professions.
324. An agreement could be for a fixed period, or could specify how decisions about the termination of the agreement will be made. However, it would not be possible for the agreement to give the other party a contractual right to go on exercising the approval function against the Secretary of State’s wishes. The Secretary of State would be able at any time to issue an instruction requiring the other party to stop approving people (either at all, or to a specified extent). The agreement could include provision for the Secretary of State to pay the other party compensation if this happened.
325. The other party would also have to comply with other instructions given by the Secretary of State. It would be for the Secretary of State to decide how these other instructions should be given, but they would have to be published. In practice, at least for approved clinicians, it is likely that these instructions would include rules about things such as the professions from which approved clinicians may be drawn, the competencies they must possess, and the training they must undertake before being approved. At present, these matters are dealt with in directions to Strategic Health Authorities.⁸ (There are no equivalent directions in respect of section 12 doctors, but the Strategic Health Authorities have themselves agreed and published their expectations of candidates for approval.)

⁸ The Approved Clinician (General) Directions 2008, available at www.dh.gov.uk/en/Healthcare/Mentalhealth/InformationontheMentalHealthAct/DH_106657

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326. Agreements under the new section 12ZA could include arrangements for Secretary of State to make payments to the other party. The Secretary of State could also make payments to other people in connection with the exercise of approval functions under the agreement. For example, the Secretary of State would be able to agree to meet the costs of another body exercising the approval function, but also directly pay a third party to give expert advice to that body.
327. While the new section 12ZA allows for other people to exercise the approval functions by agreement, the new section 12ZB enables the Secretary of State to require the NHS Commissioning Board or any Special Health Authority to exercise those functions. The Secretary of State could require the Board or a Special Health Authority to exercise one or both of the approval functions, and (as in section 12ZA) that could apply to the function generally, or to a more limited extent.
328. It would also be possible for approval functions to be exercised concurrently both by the Board or a Special Health Authority under section 12ZB and by another person under section 12ZA.
329. Like a party to an agreement under section 12ZA, the Board or Special Health Authority would have to comply with instructions given by the Secretary of State. The Secretary of State would have to publish those instructions. The Secretary of State would be able to end (or vary) the requirement on the Board or Special Health Authority at any time, which would in turn end (or vary) the Board or authority's power to approve people.
330. Where the Secretary of State had required the Board or a Special Health Authority to exercise an approval function, that function would be treated as a function under the NHS Act. That would mean, for example, that the Secretary of State would have to take that function into account when allocating funding to the Board or the authority. As in section 12ZA, the Secretary of State would also be able to make payments to a third party in connection with the exercise of the approval function by the Board or a Special Health Authority.
331. New section 12ZC gives the Secretary of State and people exercising approval functions under sections 12ZA and 12ZB the power to disclose information in connection with those functions, whether or not they would otherwise have a power to do so. In addition, it would allow information to be shared between those people (although not with third parties) even if that would not normally be allowed under the common law of confidentiality. Provided other legal requirements (such as data protection legislation) were complied with, this might, for example, allow one approving body to pass on to another approving body information it had received from, or about, an applicant, without having to obtain that applicant's consent.
332. Although sections 12ZA and 12ZB give the Secretary of State new ways in which to arrange for these approval functions to be exercised, there would be nothing to prevent the Secretary of State deciding to exercise them directly through the

Department of Health.

333. The clause also makes a number of consequential changes to the 1983 Act and other legislation to recognise the effects of the new sections 12ZA and 12ZB. In particular, it amends section 139 of the 1983 Act under which people who bring legal cases about the exercise of functions under the 1983 Act have generally to show that the person they are complaining about acted in bad faith or without reasonable care. They also generally have to obtain permission from the High Court before bringing proceedings (or, in a criminal case, the consent of the Director of Public Prosecutions). Those rules do not apply now to cases against the Secretary of State, Strategic Health Authorities or other NHS bodies, and the effect of the amendment is that they would similarly not apply to cases against people exercising approval functions by agreement with the Secretary of State under section 12ZA. The same would also be true in respect of cases against the Board and Special Health Authorities as a result of a separate amendment made by this Bill.
334. Nothing in this clause affects the exercise of approval functions under the 1983 Act in Wales.

Clause 31 - Discharge of patients

335. This clause amends sections 23 and 24 of the 1983 Act, which deal with the discharge of patients from detention, supervised community treatment and other compulsory measures under that Act. It removes certain powers from the Secretary of State, the Welsh Ministers and some NHS bodies in respect of patients of independent hospitals.
336. Section 23 currently gives the Secretary of State the power to discharge from detention people who are detained in registered establishments (which, in effect, means independent hospitals). This power has its roots in long-abolished arrangements under which the Secretary of State was responsible for registering and regulating independent hospitals. The Secretary of State also has the power to discharge from supervised community treatment patients whose responsible hospital is a registered establishment. In both cases, the Secretary of State's power is exercisable in relation to Wales by the Welsh Ministers. Section 23 similarly allows NHS trusts, NHS foundation trusts, Local Health Boards (in Wales), Special Health Authorities and PCTs to discharge patients of registered establishments from detention or supervised community treatment, but only where the NHS body concerned has commissioned the service the patient is receiving from that registered establishment.
337. The clause removes all these powers from the Secretary of State, the Welsh Ministers and these various NHS bodies. It does not affect the powers under section 23 of other people (including the patient's responsible clinician and the managers of the registered establishment itself) to discharge patients. Nor does it affect patients' rights under Part 5 of the 1983 Act to apply to an independent Tribunal for their discharge. The clause also makes a number of consequential changes to the 1983 Act and other

legislation to reflect the abolition of these discharge powers.

Clause 32 - After-care

338. This clause amends section 117 of the 1983 Act. That section places a duty on PCTs (in England), Local Health Boards (in Wales) and local social services authorities (in both England and Wales) to provide after-care for people who have been detained in hospital for treatment for mental disorder under the Act. They must provide such after-care, in co-operation with relevant voluntary agencies, until such time as they are satisfied that the person is no longer in need of such services, or (where applicable) for at least as long as the person remains on supervised community treatment under the Act.
339. As it stands, section 117 is a free-standing duty. Case-law⁹ has established that after-care services required by this duty are provided under section 117 itself, not under the legislation under which most social services and NHS services are provided. Case-law¹⁰ has also established that, in most cases, the duty falls on the local social services authority and PCT (or Local Health Board) for the area in which the person was resident before being detained (whether or not that body is responsible for other aspects of the person's health or social care.). If there is no such area, the duty falls on the authorities for the area to which the person is sent on leaving hospital.
340. The main effect of this clause is to transfer the duty on PCTs under section 117 to commissioning consortia. As now, the duty will fall in the first place on the commissioning consortium for the area in which the person was resident before being detained. However, the new section 117(2G) inserted into the 1983 Act by this clause would allow the Secretary of State to make regulations conferring the duty instead on another commissioning consortium or on the NHS Commissioning Board.
341. Those regulations could, for example, be used to ensure that the commissioning consortium responsible for section 117 after-care for a patient was the same consortium that was responsible for commissioning other health services for the person in question under the NHS Act. (At present, the PCT responsible for section 117 after-care is not always the same as the PCT responsible for other aspects of a patient's health care, especially where the patient moves while already in receipt of after-care.) These regulations could also be used to deal with cases where a person's after-care needs included services of the type that the Board, rather than consortia, was responsible for commissioning under provisions earlier in this Bill. In those cases, the regulations could say that it was the Board, rather than any individual consortium, which was responsible for commissioning such services as part of the person's after-care under section 117.

⁹ *R. v Manchester City Council Ex p. Stennett* [2002] UKHL 34; [2002] 4 All E..124

¹⁰ *R. v Mental Health Tribunal, ex p. Hall* [1999] 1 CCLR 383, 390

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342. The clause also amends section 117(2) to make clear that where the duty to secure after-care falls on a commissioning consortium (or the Board) and a local social services authority, the duty on the consortium in question (or the Board) continues until it (rather than it and the local social services authority together) is satisfied that after-care is no longer required. Likewise, the duty on the local social services authority continues until it (rather than it and the consortium or Board) is satisfied that after-care is no longer required.
343. The effect of new subsection (2D) is to make clear that the duty on a consortium (or the Board) is to commission, rather than provide, after-care. It also removes from commissioning consortia and the Board the express duty to arrange after-care in co-operation with relevant voluntary organisations (there is to be no such express duty on consortia or the Board when commissioning other types of NHS care).
344. New subsection (2E) means that commissioning consortia are only required to commission services as part of after-care under section 117 if they could commission those services under the NHS Act itself. In other words, it makes clear that the after-care services for which commissioning consortia would be responsible are health (rather than social) services.
345. New subsection (2F) means that the duty on consortia (and the Board) under section 117 is to be regarded as being a duty under section 3 of the NHS Act. As a result, references in legislation to services under section 3 of the NHS Act (or the NHS Act generally) will automatically include references to services commissioned by consortia (or the Board) under section 117. In practical terms, that means that various provisions of the NHS Act will apply to services commissioned by consortia (and the Board) under section 117 without needing to refer explicitly to section 117. For example, it would be possible for the new “standing rules” about commissioning to apply to services commissioned by consortia (or the Board) under section 117. Similarly, it would mean that consortia’s duty under section 82 of the NHS Act to co-operate with local authorities and others would apply to its arrangements for after-care under section 117.
346. Subsection (2F) also says that references in legislation to services provided under section 117 are to be read in light of the rule described in the previous paragraph that such services commissioned by consortia (and the Board) are to be regarded as commissioned under section 3 of the NHS Act. One practical effect of that is that it is no longer necessary to say in section 117(2C) that references in the 1983 Act to after-care services provided under section 117 include services which are provided by means of direct payments under section 12A of the NHS Act. The effect of subsection (2F) is that those references to after-care under section 117 will now automatically include services provided by means of direct payments under the NHS Act in lieu of services commissioned by consortia (or the Board). The clause amends 117(2C) accordingly.
347. This clause does not change the way that section 117 applies to Local Health Boards

and local social services authorities in Wales. Nor, except to the limited extent described above, does it change the way that section 117 applies to local social services authorities in England. However, the Law Commission is currently reviewing adult social services legislation generally, including section 117 insofar as it applies to social services. Its recent consultation document¹¹ invited comments on a number of possible changes to section 117.

Clause 33 - Provision of pocket money for in-patients

348. This clause abolishes the power of the Secretary of State in section 122 of the 1983 Act to make payments to in-patients in mental health hospitals in respect of their occasional personal expenses, where they cannot meet those expenses themselves. In England, this power is currently delegated to PCTs by means of directions under section 7 of the NHS Act. It is primarily used to provide small personal allowances for patients who have been transferred from prison to hospital under section 47 of the 1983 Act and who are therefore not eligible for social security benefits.
349. Commissioning consortia and the NHS Commissioning Board would still be able to arrange for such payments to be made to NHS patients under the NHS Act. And the Secretary of State would be able to make regulations requiring such payments to be made, using the power to make “standing rules” introduced earlier in this Bill.
350. The clause also removes this power entirely in Scotland (where it has no practical significance). This change does not affect the powers of the Scottish Ministers to make pocket-money payments under Scottish mental health legislation. This clause does not affect the position in Wales, where the Secretary of State’s powers are exercisable by the Welsh Ministers. Indeed, it amends section 122 to confer the power directly on the Welsh Ministers.

Clause 34 - Transfers to and from special hospitals

351. This clause abolishes the power of the Secretary of State (and the power of Welsh Ministers) under section 123 of the Act to direct that a patient detained in a high secure psychiatric hospital be transferred to another high secure hospital, or to any other hospital. This power is rarely used. This change would not affect the power of the managers of high secure hospitals themselves to arrange the transfer of patients by agreement with the managers of the receiving hospital.
352. The clause also removes references to section 123 elsewhere in the 1983 Act and in the Health Act 1999. But it says that the repeal of section 123 would not affect the validity of the detention of anyone who had previously been transferred under section

¹¹ Adult Social Care, Consultation Paper No. 192, The Law Commission (2010). For more information on this project visit www.lawcom.gov.uk/adult_social_care.htm

123, nor prevent the recapture of anyone who escaped from custody while being transferred under that section.

Clause 35 - Independent mental health advocates

353. This clause transfers from the Secretary of State to local authorities the duty to arrange independent mental health advocate (IMHA) services. IMHAs provide help and support for people subject to the 1983 Act.
354. As it stands, section 130A of the 1983 Act places a duty on the Secretary of State to make arrangements to enable qualifying patients to have access to an independent mental health advocate. Qualifying patients are defined in section 130C. They include most of those liable to be detained under the 1983 Act, all patients on supervised community treatment, all patients subject to guardianship and a few others who are being considered for certain specified treatments for a mental disorder.
355. The Secretary of State currently delegates the duty to commission IMHA services to PCTs, by means of directions under section 7 of the NHS Act. This clause places the duty on local social services authorities instead. It inserts a new subsection into section 130C of the 1983 Act setting out the rules for deciding which local social services authority would be responsible for which qualifying patients.
356. The clause also amends Schedule 1 to the Local Authority Social Services Act 1970 to make local social services authorities' new role in respect of IMHAs a social services function for the purposes of that Act. In particular, that would allow the Secretary of State to issue directions and statutory guidance to local social services authorities about the exercise of this function.
357. IMHA arrangements in Wales are a devolved matter, and the National Assembly for Wales has recently passed legislation amending the provisions in the 1983 Act which deal with IMHA services Wales. In doing so, the Assembly also made some consequential amendments to the provisions as they apply in England. The changes made by this clause are to sections 130A and 130C of the 1983 Act as amended by the Mental Health (Wales) Measure 2010, which received Royal Approval on 15 December 2010. Those amendments are not yet in force. If they were still not in force when the amendments made by this clause were brought into effect, some minor transitional modifications to the 1983 Act would be required. The Bill allows such modifications to be included where necessary in commencement orders bringing specific parts of the Bill into force (see clause 278(5)).

Clause 36 - Patients' correspondence

358. This clause amends section 134 of the 1983 Act, which deals with the correspondence of patients detained in hospital under that Act. Section 134(1)(a) allows the managers of a hospital to refuse to put a detained patient's correspondence in the post if the intended recipient has made a written request not to receive correspondence from the

patient in question. This clause amends that section so that it will no longer be possible for such a request to be made to the Secretary of State (or, therefore, to the Welsh Ministers). It will continue to be possible for requests to be made to the managers of the hospital in which the patient is detained or to the approved clinician in overall charge of the patient's case.

359. Although the Department of Health cannot recall having received any such request in recent years, the clause ensures that any request made to the Secretary of State (or the Welsh Ministers) before this change takes effect would remain valid.

Clause 37 - Notification of hospitals having arrangements for special cases

360. This clause amends section 140 of the 1983 Act, which requires PCTs to notify local social services authorities in their area of the hospitals at which arrangements are in place for mental health patients to be admitted urgently, or for the provision of accommodation designed to be especially suitable for mental health patients under the age of 18.
361. This clause transfers that duty from PCTs to commissioning consortia.

Emergency powers

362. Clauses 38 and 39 amend the NHS Act to make provision in relation to emergencies affecting the health service. The provisions are in addition to the provisions of the Civil Contingencies Act 2004 relating to emergencies and civil contingency planning by health service and other public bodies.

Clause 38 - Role of the Board and consortia in respect of emergencies

363. This clause inserts a new section 252A into the NHS Act and sets out the role and responsibilities of the NHS Commissioning Board and commissioning consortia in relation to assuring NHS emergency preparedness, resilience and response. Emergency preparedness enables organisations within the health service and communities to respond to an emergency in a coordinated, proportionate, timely and effective manner.
364. Subsection (1) confers duties on the Board and each consortium to ensure they are properly prepared for emergencies which might affect them. Similar duties would be imposed on each NHS provider as a term of their contracts with the Board or consortia to provide NHS services. Subsections (2) and (4) provide that the Board also has duties to take steps to secure that consortia and providers of NHS services are properly prepared for emergencies. Subsections (3) and (5) provide that these duties include a responsibility for monitoring compliance by consortia and NHS providers with their duties relating to emergency preparedness under this section and, in the case of NHS providers, under the terms of their service contracts with the Board or consortia. Subsection (6) allows the Board to coordinate the responses between

commissioning consortia and service providers to emergencies that might affect those bodies. Subsection (7) allows the Board to arrange for any other person or body to exercise its functions in relation to securing the preparedness of consortia and NHS providers.

365. Subsection (8) requires that all relevant service providers must appoint an individual to be responsible for ensuring that the provider is properly prepared for any relevant emergency, that the provider complies with any requirements relating to emergency preparedness in its service contracts with the Board or consortia, and that the Board is provided with information so that it can carry out its duties to secure preparedness and monitor compliance with emergency preparedness obligations. The person appointed would be known as an “accountable emergency officer”.
366. Subsection (9) defines the terms “relevant emergency” and “relevant services provider”, used in the new section 252A. “Relevant emergency” is defined so that the emergencies to which the duties under this section apply include any emergency which might affect the body in question, whether by increasing the need for services it commissions or provides, or in any other way. The provisions therefore apply in relation to an emergency where the body may be asked to assist other NHS bodies or public authorities responding to that emergency, as well as one which directly affects their local NHS services.

Clause 39 - Secretary of State’s emergency powers

367. Section 253 of the NHS Act confers on the Secretary of State the power to give directions to any body or person exercising functions under the Act (other than NHS foundation trusts), where he considers it necessary by reason of an emergency to do so in order to ensure that a service under the Act is provided. This clause amends the section so as to extend the Secretary of State’s powers and make them consistent with the new framework for the health service provided for by the Bill. For example, under the Bill, unlike the existing position under section 8 of the NHS Act, the Secretary of State will not have a general power to give directions to NHS bodies about how they exercise their functions. .
368. *Subsection (2)* amends section 253 so that the Secretary of State can give a direction under the section where he considers it is appropriate, not just necessary, to do so by reason of an emergency. In addition, the effect of the amendment is that the power is not limited to giving directions to ensure that a service is provided. *Subsection (3)* provides that the Secretary of State’s power to direct applies to all NHS bodies except Local Health Boards (which are Welsh NHS bodies) – i.e. it covers the NHS Commissioning Board, commissioning consortia, Special Health Authorities NHS trusts and NHS foundation trusts. The power also applies to the National Institute for Health and Care Excellence (NICE), the Health and Social Care Information Centre (the Information Centre) and any provider of NHS services.
369. *Subsection (4)* substitutes new subsections (2) and (2A) of section 253 and specifies

how the direction-making powers may be exercised. A distinction is made between NHS bodies, NICE and the Information Centre, on the one hand, and a provider of NHS services on the other. In relation to NHS bodies, NICE and the Information Centre, the Secretary of State may direct the body: about the exercise of any of its functions; to cease to exercise its functions; to exercise its functions concurrently with another body; or to exercise the functions of another body under the NHS Act. In relation to providers, the power is more limited and the Secretary of State can direct the provider: about the provision of NHS services by the provider; to cease to provide services or to provide additional services. This ensures that the Secretary of State may give directions to both NHS bodies and providers of NHS services not only regarding their own activities but also to ensure coordination between bodies in exercising their activities in times of emergency. *Subsection (5)* allows Secretary of State to direct the Board to exercise the Secretary of State's powers of direction.

370. *Subsection (6)* removes the exclusion of NHS foundation trusts from the Secretary of State's powers emergency powers. *Subsection (7)* amends the NHS Act so that directions under this provision can be given either in writing or by regulations, as with many other directions under the NHS Act.

Miscellaneous

Clause 40 – New Special Health Authorities

371. This clause inserts new section 28A after section 28 of the NHS Act. This new section relates to orders under section 28, which pertain to the establishment of Special Health Authorities. Section 28A proposes limitations to section 28, which would allow the Secretary of State to establish a Special Health Authority for a specific function, but only for a time-limited period. The time limit is intended to maintain a stable system architecture by ensuring that when a Special Health Authority is required for a specific purpose, it does not continue to exist once that purpose has been met. This section would only apply following the coming into force of clause 17 of the Bill (as outlined in subsection 28A(1)).
372. *Subsection (2)(a)* of new section 28A specifies that any order establishing a new Special Health Authority once the Bill is in force must include provision for the abolition of that Authority on a specified day. As outlined in subsection 28A(3), this day must be within a period of 3 years from the day the Special Health Authority is established. This means that all new Special Health Authorities established once the Bill is in force would be time limited to a maximum of 3 years. The establishment order must also make provision for the transfer of the staff, property and liabilities of the Authority following its abolition.
373. Orders under section 28 could be altered in line with the power to vary orders and directions in section 273(1) of the NHS Act, to change the day on which the Special Health Authority is to be abolished to an earlier or later date (28A(4)(a)). If an order is varied to provide for the abolition of a Special Health Authority on a later date, this

must be no more than 3 years from the date on which the Special Health Authority would have been abolished had it not been for the variation, as outlined in 28A(5). Any such order would be subject to the affirmative Parliamentary procedure, in order to discourage the proliferation of Special Health Authorities. Orders under section 28 may also be altered to make different provision as to the transfer of officers, property and liabilities of the Authority (28A(4)(b)).

Clause 41 - Primary care services: directions as to exercise of functions

374. This clause inserts new powers to give directions into the NHS Act. *Subsection (1)* inserts a new section 98A into the NHS Act to provide a power of direction, in respect of those functions of either the Secretary of State or the Board that relate to the provision of primary medical services, to be exercised by the Secretary of State in respect of the Board and by the Board in respect of commissioning consortia. This would both permit the delegation of functions by directions and allow for the directions to set out how the functions (including delegated functions) should be exercised by the Board or the commissioning consortia.
375. Subsection (1) of section 98A provides that the Secretary of State may direct the Board to exercise on his behalf his functions relating to the provision of primary medical services. Subsection (2) of section 98A provides that the Secretary of State may direct the Board as to how it is to exercise any functions relating to the provision of primary medical services that it is directed to exercise. The Secretary of State has retained a number of functions that relate to the setting of the detail that must be included in primary medical services contracts and the various fees and allowances that attach to those contracts. It is envisaged that as the Board's role in commissioning primary medical services develops it may be appropriate for the Board to take responsibility for some of the more detailed operational aspects currently set by the Secretary of State. For example, it may be more appropriate for the Board to determine the rules under which contractors receive support with the cost of locum cover, a matter currently set out in directions under section 87 of the NHS Act.
376. Subsection (5) of section 98A permits regulations to set out functions that the Board cannot direct a consortium to exercise on the Board's behalf (for example, it is likely that regulations would prescribe the function of entering into primary medical services contracts as a function that cannot be delegated).
377. Subsection (6) of section 98A permits the Board to provide information to the consortium where that information is required by the consortium to exercise any function that the Board has directed it to exercise. The supply of information would be limited to that which the Board considered necessary to enable the consortium to perform the function effectively.
378. Subsections (7), (8) and (9) of section 98A require the commissioning consortium to report to the Board on matters that come to its attention as a result of undertaking the Board's functions and permit the Board to consider those matters when exercising its

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primary medical services functions, such as issues relating to a contractor's performance under its contract.

379. *Subsection (2)* of this clause inserts a new section 114A into the NHS Act to provide a power of direction in respect of the exercise by the Board of the Secretary of State's functions relating to the provision of primary dental services. This would both permit the delegation of functions by directions and allow for the directions to set out how any functions (including any functions delegated to it) were to be exercised by the Board.
380. Subsection (1) of the new section 114A provides that the Secretary of State may direct the Board to exercise on his behalf his functions relating to the provision of primary dental services.
381. Subsection (2) of section 114A provides that the Secretary of State may direct the Board as to how it is to exercise any functions relating to the provision of primary dental services (including any functions delegated to it).
382. *Subsection (3)* of this clause inserts new section 125A into the NHS Act to provide a power of direction in respect of those functions of either the Secretary of State or the Board that relate to the provision of primary ophthalmic services, to be exercised by the Secretary of State in respect of the Board and by the Board in respect of commissioning consortia, a Special Health Authority or such other body as may be prescribed. This would both permit the delegation of functions by directions and allow for the directions to set out how the functions (including delegated functions) should be exercised by the Board, the commissioning consortia, the Special Health Authority or any prescribed body.
383. Subsection (1) of section 125A of the Act provides that the Secretary of State may direct the Board to exercise on his behalf his functions relating to the provision of primary ophthalmic services.
384. Subsection (2) of section 125A of the Act provides that the Secretary of State may direct the Board as to how it exercises any function relating to the provision of primary ophthalmic services (including any functions delegated to it).
385. Subsection (3) of section 125A of the Act provides that the Board may direct a commissioning consortium, a Special Health Authority or other prescribed body to exercise on its behalf the Board's functions relating to the provision of primary ophthalmic services.
386. Subsection (4) of section 125A of the Act provides that the Board may direct a consortium, a Special Health Authority or other prescribed body about the exercise of any functions relating to the provision of primary ophthalmic services (including any function delegated to it).

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387. Subsection (5) of section 125A of the Act permits regulations to set out functions that the Board cannot direct a consortium, a Special Health Authority or such other body as may be prescribed to exercise on the Board's behalf.
388. Subsection (6) of section 125A of the Act permits the Board to provide information to the consortium, a Special Health Authority or such other body as may be prescribed where that information is required by the consortium, Special Health Authority or other prescribed body to exercise any function that the Board has directed it to exercise. The supply of information would be limited to that which the Board considered necessary to allow the function to be performed effectively.
389. Subsections (7), (8) and (9) of section 125A of the Act require the body directed to report to the Board on matters that come to its attention as a result of undertaking the Board's functions and permit the Board to consider those matters when exercising its primary ophthalmic services functions, such as issues relating to a contractor's performance under its contract.
390. *Subsection (4)* of this clause inserts a new section 168A into the NHS Act to provide a power of direction in respect of the exercise by the Board of the Secretary of State's functions relating to the provision of pharmaceutical services or local pharmaceutical services. This would both permit the delegation of functions by directions and allow for the directions to set out how any functions (including any functions delegated to it) were to be exercised by the Board.
391. Subsection (1) of section 168A of the Act enables the Secretary of State to direct the Board to undertake certain functions in relation to the provision of pharmaceutical services or local pharmaceutical services, such as maintaining pharmaceutical lists or setting up local pharmaceutical services on his behalf.
392. Subsection (2) of section 168A of the Act enables the Secretary of State to direct the Board about the exercise of any functions in relation to the provision of pharmaceutical services or local pharmaceutical services (including any functions delegated to it).

Clause 42 - Charges in respect of certain public health functions

393. This clause sets out when the Secretary of State or local authorities would be able to charge for steps taken in the exercise of their public health functions – i.e. their functions under new sections 2A and 2B of the NHS Act inserted by clauses 7 and 8. The clause inserts a new section 186A into the NHS Act. Any service which is provided under section 2A or 2B is a service provided as part of the comprehensive health service and so must be provided free of charge, unless specific provision is made for a charge in legislation (see section 1(3) of the NHS Act).
394. The new section would allow the Secretary of State to charge an appropriate amount for any health protection step taken by the Secretary of State under his duty to protect

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public health (section 2A), including charges for any services or facilities provided. However, this power to charge would not include services or facilities that are provided to an individual in order to protect that individual's health – vaccination or screening, for example (see subsection (2)). These provisions are intended to ensure an approach consistent with existing position for NHS services, which are generally free of charge to patients.

395. Subsection (4) of the new section allows the Secretary of State to make regulations specifying the steps to improve public health that local authorities would be able to charge for under section 2B. Subsection (4) also allows the Secretary of State to specify the health protection steps that local authorities would be able to charge for under section 2A (by virtue of regulations under section 6c(1)).
396. The Secretary of State would be able to specify particular services for which a charge may be made, or particular circumstances in which such services could be charged for, and to specify the maximum amount of any charge, or how the charge is calculated. Some existing services for which local authorities charge under current legislation would now fall within the new duty to improve health, and so the new section would enable the Secretary of State to allow local authorities to continue to charge, in appropriate cases, while maintaining the general position that services under the NHS Act are free of charge.

Clause 43 - Pharmaceutical services expenditure

397. This clause makes provision for the arrangements for pharmaceutical services expenditure by inserting new section 165A and new Schedule 12A into the NHS Act.

New Section 165A

398. Subsection (1) and (2) provides that the Board must give the Secretary of State such information in relation to the pharmaceutical remuneration paid to persons providing pharmaceutical services or local pharmaceutical services that the Secretary of State requires. To enable the Secretary of State to discharge his duties in section 164 and 165 of the NHS Act the Secretary of State may require that the Board must notify the Secretary of State of both the expenditure for which consortia are to be liable by virtue of determinations and apportionments under Schedule 12A and the rest of the expenditure by the Board on the commissioning of pharmaceutical services under Part 4 of the NHS Act. Subsection (3) makes further provision about pharmaceutical remuneration in Schedule 12A to the NHS Act.

Schedule 12A

399. Paragraph 1 defines 'drugs' by reference to Section 126 so that the definition includes listed appliances (such as stoma care products) as well as drugs and defines 'pharmaceutical remuneration' so that it includes both contractors who provide NHS pharmaceutical services and contractors who provide NHS local pharmaceutical

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services (which would be provided under direct contracts with the Board).

400. Paragraph 2 sets out the arrangements for how pharmaceutical remuneration is to be apportioned amongst commissioning consortia.
401. Paragraph 2(1) provides that the Board must determine the elements of pharmaceutical remuneration which will be apportioned to consortia in relation to the relevant financial year. This could, for example, include the drug costs attributable to the prescriptions that the GPs in a given commissioning consortium issue.
402. Paragraph 2(2) provides that the elements of pharmaceutical expenditure to be apportioned each financial year, which the Board has determined under paragraph 2(1), are to be referred to as 'designated elements'.
403. Paragraph 2(3) requires the Board to notify each commissioning consortium of its determination of the designated elements of pharmaceutical remuneration on which the apportionment to consortia during the financial year is based.
404. Paragraph 2(4) provides that the Board must apportion the sums paid by it amongst all commissioning consortia for each designated element as the Board thinks appropriate. For example, the Board could determine that the drug costs for prescriptions written in Scotland but dispensed in England are to be shared across all consortia in an equitable way. This would reflect existing arrangements whereby such costs are shared equitably across all PCTs (since such costs cannot be attributed to an individual PCT and will not be capable in future of being attributed to an individual consortium).
405. Paragraph 2(5) provides that when the Board is apportioning the sums paid by it to commissioning consortia under sub-paragraph (4), the Board may, in particular, take into account the financial consequences of the prescriptions issued by members of each consortium. If the Board does this, it will mean that consortia will be responsible for the financial consequences of prescribing decisions made by the GP practices in the consortium in the same way that they are responsible for the financial consequences of referral decisions. This will provide incentives for consortia to work with practices in the consortium to look in the round at how to achieve the best overall health outcomes from the resources available.
406. Paragraph 2(6) provides that the Board may deduct the amount of pharmaceutical remuneration it has apportioned to a consortium from the sums it would otherwise pay to the consortium under section 223H and where it does so it must notify the consortium.
407. Paragraph 2(7) provides that the Secretary of State may issue directions to the Board specifying that a particular element (or elements) of pharmaceutical remuneration should not be included in the determination the Board makes under sub-paragraph 2(1). For example, the Secretary of State might direct the Board that the cost of dental

prescriptions are not to be included in the Board's determination.

408. Paragraph 2(8) provides that the Board, when determining the overall allocation to a commissioning consortium under section 223H, must take account of the effect of this Schedule. Thus when determining the amount to be allotted under section 223H, the Board must take account of pharmaceutical needs, alongside other relevant healthcare needs, where designated elements of pharmaceutical remuneration are apportioned to commissioning consortia.
409. Paragraph 2(9) provides that, for the purposes of Sections 223I, 223J, 223K(2) and Schedule 1A paragraph (10), the amount of pharmaceutical remuneration apportioned by the Board for a given financial year and notified to consortia under paragraph 2(6) is to be treated as expenditure of the consortium which arises as a consequence of the performance of its functions in the relevant year.
410. Paragraph 3 provides that the Board may require reimbursement of elements of pharmaceutical remuneration which are not designated elements under paragraph (2) or other remuneration of a prescribed description. The Board would, for example, under sub-paragraph (2), be able to require reimbursement from an NHS Trust or NHS Foundation Trust for the costs of the drugs prescribed by one of its employees (or any such costs incurred in the course of the delivery of services arranged by that person) which are dispensed in the community by a pharmaceutical contractor. Sub-paragraph (3) provides that any such sums due can be recovered summarily as a civil debt.
411. Paragraph (4) provides that the Board may, with the express consent of the Secretary of State, delegate its functions under this Schedule to a Special Health Authority or arrange for its functions to be exercised by another person. This would, for example, enable existing arrangements to continue if so desired whereby the National Health Services Business Services Authority makes payments to contractors for the provision of pharmaceutical services on behalf of PCTs.

Clause 44 - Secretary of State's annual report

412. This clause inserts new section 247B into the NHS Act. This section would require the Secretary of State to publish an annual report relating to the performance of the comprehensive health service in England, which is to be laid before Parliament. This is the first time that a specific requirement for an annual report of this kind has been proposed, and it is intended to ensure that the performance of the comprehensive health service is subject to the appropriate Parliamentary scrutiny.
413. This report would cover both those aspects of the health service commissioned by the NHS Commissioning Board and commissioning consortia, as well as those public health services for which the Secretary of State and local authorities are responsible. It may, for example, include an assessment as to the extent to which the comprehensive health service had achieved progress in the outcomes set out in the Outcomes

Framework.

Clause 45 - Amendments related to Part 1 and transitional provision

414. This clause gives effect to Schedules 4, 5 and 6.

Schedule 4

415. This Schedule makes a number of amendments to the NHS Act as a result of the changes made to the health service architecture elsewhere in this Bill.
416. **Part 1 (The health service in England) of Schedule 4** makes amendments to Part 1 of the NHS Act primarily as a result of the abolition of Strategic Health Authorities and Primary Care Trusts, the establishment of the NHS Commissioning Board and commissioning consortia and changes to the Secretary of State's role in Part 1 of the Bill.
417. Paragraph 1 substitutes section 2 of the NHS Act. Currently, section 2 of the NHS Act empowers the Secretary of State to provide such services as he considers appropriate for the purpose of discharging his/her duties under the Act (section 2(1)(a)), and to do anything which is calculated to facilitate, or is conducive or incidental to the discharge of such duties (section 2(1)(b)). Section 2(1)(a) would no longer be necessary because the Secretary of State would no longer be under a duty to provide services. The new section 2 inserted by this clause therefore confers power on the Secretary of State, the Board and consortia to do anything which is calculated to facilitate, or is conducive or incidental to the discharge of their functions.
418. Paragraph 2 amends section 6 of the NHS Act so that instead of applying only to the Secretary of State, it applies in addition to the NHS Commissioning Board and commissioning consortia. Section 6 allows for health services to be procured outside of England, and also for functions to be performed outside England in certain circumstances, such as transfers of patients across borders.
419. Paragraphs 3 and 4 amend sections 6A and 6B of the NHS Act. These sections deal with reimbursement of the cost of services provided in another EEA state and prior authorisation for the purpose of seeking treatment in another EEA state. The changes reflect the fact that services will in future be commissioned by the NHS Commissioning Board and commissioning consortia, or in relation to public health, provided by the Secretary of State and local authorities.
420. References to Strategic Health Authorities and Primary Care Trusts are removed from sections 8 (Secretary of State's directions to health service bodies), 9 (NHS contracts) and 11 (Arrangements to be treated as NHS contracts) of the NHS Act by paragraphs 5, 6 and 7 respectively. Paragraph 6 adds the NHS Commissioning Board and commissioning consortia into the definition of "health service body" in section 9 of the NHS Act, meaning that contracts entered into by those bodies with other health

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service bodies will be treated as NHS contracts for the purposes of the NHS Act. Paragraph 7 adds the NHS Commissioning Board into the list of persons in section 11(1) of the NHS Act. This means that certain arrangements which it enters into in relation to ophthalmic and pharmaceutical services will be treated as NHS contracts.

421. Paragraph 8 amends section 12 of the NHS Act to reflect the fact that the Secretary of State will no longer be a provider of NHS services, but may be providing services in accordance with public health functions. Section 12 allows the Secretary of State to make arrangements with any person or body to secure or assist in the securing of any of the services he or she is under a duty to provide. This includes arrangements with voluntary organisations, and will in future include the Board and consortia.
422. Paragraph 9 inserts new section 12ZA into the NHS Act, which makes special provision about commissioning arrangements made by the NHS Commissioning Board and commissioning consortia. For example, it allows those bodies to make their facilities and employees available to service providers.
423. Paragraphs 10 to 13 amend sections 12A, 12B, 12C and 12D of the NHS Act (inserted by the Health Act 2009) to allow the NHS Commissioning Board and commissioning consortia rather than the Secretary of State to make monetary payments to patients in lieu of providing them with health care services. These are known as 'direct payments' or 'personal health budgets'. The amendment to section 12B allows the regulations governing the rules around administration of such payments to apply to the NHS Commissioning Board and commissioning consortia instead of Primary Care Trusts.
424. **Part 2 (NHS Bodies) of Schedule 4**, consisting of paragraphs 14 to 22 of Schedule 4 to the Bill, makes a series of amendments to Part 2 of the NHS Act (which deals with NHS bodies). Paragraph 14 amends section 28 (special health authorities). Subsection (5) of that section provides that on dissolution of a Special Health Authority, criminal liabilities may be transferred to an “NHS body”; subsection (6) defines “NHS body”, but is omitted by paragraph 14. The provision is omitted as a new definition of “NHS body”, which does not include Strategic Health Authorities and Primary Care Trusts, but includes the NHS Commissioning Board and commissioning consortia, is inserted into section 275 of the Act by paragraph 129 of Schedule 4 to the Bill.
425. Paragraph 15 amends section 67 (effect of intervention orders) which makes provision regarding the effect of an order made under section 66. Section 66 enables the Secretary of State to make an intervention order where an NHS body (other than a foundation trust) is not performing its functions adequately or at all, or where there are significant failings in the way it is being run. Section 66 is amended by paragraph 8 of Schedule 20 to the Bill, so that it applies only to NHS trusts and Special Health Authorities. Paragraph 15 of Schedule 4 to the Bill amends section 67 consequentially so as to remove the references to Strategic Health Authorities and Primary Care Trusts. References to the NHS Commissioning Board and commissioning consortia are not inserted, as they are subject to separate powers

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provided for in Part 1 of the Bill.

426. Paragraph 16 amends section 70 (transfer of residual liabilities), which provides that on dissolution of certain bodies, the Secretary of State must ensure that all their liabilities are dealt with by being transferred to the Secretary of State or an NHS body. Paragraph 15 removes the references to a Strategic Health Authority and a Primary Care Trust, as those bodies are abolished by the Bill. The provision is not extended to the NHS Commissioning Board (as it may only be abolished by amendment of primary legislation) nor commissioning consortia (Part 1 of the Bill deals with the dissolution of those bodies).
427. Paragraph 17 amends section 71 (schemes for meeting losses and liabilities in respect of certain health service bodies) so as to remove references to Strategic Health Authorities and Primary Care Trusts and insert references to the NHS Commissioning Board and commissioning consortia. This enables the Secretary of State to provide in regulations that the Board and consortia are eligible to participate in such schemes or may administer such schemes.
428. Section 73 (directions and regulations) of the NHS Act makes provision relating to directions and regulations made under the provisions specified in subsection (1). Paragraph 18 of Schedule 4 to the Bill removes sections 14, 15, 19 and 20 from the list in subsection (1), as those sections relate only to Strategic Health Authorities and Primary Care Trusts and are repealed by the Bill.
429. Paragraphs 19 and 20 omit Schedules 2 and 3 to the NHS Act, as they deal with the constitution of Strategic Health Authorities of Primary Care Trusts, bodies abolished by the Bill.
430. Paragraph 21 amends paragraph 15 of Schedule 4 to the NHS Act, which deals with NHS trusts. Sub-paragraphs (2) and (3) of paragraph 15 provide that an NHS trust may provide high secure psychiatric services only where approved by the Secretary of State. Those provisions are omitted, as the Bill makes new provision requiring any provider of such services to have approval – see clause 12.
431. Schedule 6 to the Act provides for the Secretary of State to make regulations or give directions about Special Health Authorities transferring staff to, making staff available to, and furnishing information to, various bodies. Paragraph 22 of Schedule 4 to the Bill removes Strategic Health Authorities from the list of bodies to which those provisions apply.
432. **Part 3 (Local Authorities) of Schedule 4** amends Part 3 (Local Authorities and the NHS) of the NHS Act.
433. Paragraph 23 amends section 74 by removing references to a Strategic Health Authority and a Primary Care Trust and inserting references to the Board and commissioning consortium so that the expression ‘public body’ in the Local

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Authorities (Goods and Services) Act 1970 (c.39) includes the Board and a commissioning consortium.

434. Paragraph 24 amends 76 by removing references to a Strategic Health Authority and a Primary Care Trust and inserting references to the Board and a commissioning consortium so that a local authority can make payments to those bodies towards expenditure incurred or to be incurred by the body in connection with its performance of prescribed functions.
435. Paragraph 25 amends section 77 by removing the references to Primary Care Trusts.
436. Paragraphs 26 and 27 amend sections 80 and 81 by removing references to Strategic Health Authorities and Primary Care Trusts and inserting references to the Board and a commissioning consortium. The amendment of section 80 gives the Board and a commissioning consortium powers to supply goods and services to local authorities and such public bodies as the Secretary of State may determine. The amendment also requires the Board and a commissioning consortium to make certain services available to local authorities so far as is reasonable necessary and practicable to enable local authorities to discharge their functions relating to social services, education and public health. Section 81 is amended so that the conditions of supply under section 80 apply to the Board and a commissioning consortium.
437. **Part 4 (Medical services) of Schedule 4** makes consequential amendments to Part 4 of the NHS Act. In particular, the Board is placed under a duty to secure the provision of primary medical services in England under section 83 of the NHS Act and may make such arrangements as it considers appropriate to meet all reasonable requirements in this area including arrangements for the performance of a service outside England. The Board will be unable to provide primary medical services itself as a result of the changes to section 83. Sections 89 and 94 are amended to clarify that any consequential changes made to a GMS contract or a PMS agreement as the result of the establishment of commissioning consortia may be imposed by virtue of existing provision in section 89(2)(d) and section 94(3)(f) of the NHS Act. Provision is also included to clarify that transitional provision may be made in connection with the commencement of the amendments to section 92 of the NHS Act for the Board to direct a Primary Care Trust to exercise its functions relating to section 92 (Personal Medical Services) arrangements during the interim period between the abolition of Strategic Health Authorities and the abolition of Primary Care Trusts. A new subsection (3)(ca) is inserted into section 94 of the NHS Act which clarifies, for consistency with section 84(4)(b), that section 92 arrangements can include services performed outside England. Section 95 is omitted. Provision is also made in section 97 for the Board to recognise Local Medical Committees for an area.
438. **Part 5 (Dental services) of Schedule 4** makes consequential amendments to Part 5 of the NHS Act. In particular, the Board is placed under a duty to secure the provision of primary dental services in England under section 99 of the NHS Act and may make such arrangements as it considers appropriate to meet all reasonable requirements in

this area including arrangements for the performance of primary dental services outside England. The Board will be unable to provide primary dental services itself as a result of changes to section 99. Section 107 of the Act is amended to enable the Board to enter into arrangements for the provision of primary dental services instead of Strategic Health Authorities. Provision is also included to clarify that transitional provision in connection with the commencement of the amendments to section 107 of the NHS Act may be made for the Board to direct a Primary Care Trust to exercise its functions relating to section 107 (Personal Dental Services) arrangements during the interim period between the abolition of Strategic Health Authorities and the abolition of Primary Care Trusts. A new subsection (3)(ca) is inserted into section 109 of the NHS Act which clarifies, for consistency with the new section 99(1A) of the Act, that section 107 arrangements can include services performed outside England. Section 110 is omitted. Provision is also made for the Board to recognise Local Dental Committees for an area.

439. **Part 6 (Ophthalmic services) of Schedule 4** makes consequential amendments to Part 6 (Ophthalmic Services) and Part 9 (Charges for optical appliances) of the NHS Act. In particular, the Board is placed under a duty to provide a sight testing service and other ophthalmic services and may make such arrangements as it considers appropriate to meet all reasonable requirements in this area including arrangements for the performance of ophthalmic services outside England. The Board will be unable to provide primary ophthalmic services itself as a result of the changes to section 115 of the NHS Act. Provision is also made for the Board to recognise Local Optical Committees formed for an area. Section 180 of the Act is amended to include new provision for the Board to direct a Special Health Authority or such other body as may be prescribed to exercise the Board's functions under that section and to omit subsection (10) of that section which is not consistent with the funding arrangements for the Board. The title of section 180 is also amended to clarify that this section relates to payments for both the cost of optical appliances and sight tests.
440. **Part 7 (Pharmaceutical services) of Schedule 4** makes consequential amendments to provisions in Part 7 of the Act in respect of pharmaceutical services. In particular, provision is made for the Board to commission pharmaceutical services for England. The Board cannot provide pharmaceutical services itself. Further amendments are made to section 129 of the Act regarding the preparation and publication of pharmaceutical lists of NHS contractors. The Board will be required to prepare such lists by reference to the area in which the premises from which the services are provided are situated. Under section 150A of the Act as amended, the Board may remove a pharmaceutical services contractor from a list if they breach their terms of service by, for example, a repeated failure to open in accordance with contracted hours. Section 132 of the Act is amended to require the Board to prepare lists of medical and dental practitioners who are authorised by it to provide pharmaceutical services by reference to an area of a prescribed description. The disqualification provisions in sections 151 to 162 of the Act are also amended to enable the Board to make decisions and take action (such as suspension or removal from a list) in fitness to practise matters. Provision is also made for such matters to be referred to the First Tier Tribunal for national disqualification. Provision is made for the Board to

recognise Local Pharmaceutical Services Committees for an area. Transitional provision is included in Schedule 11 for the continuation of pilot schemes and in Schedule 12 for the continuation of Local Pharmaceutical Services (LPS) schemes and for such schemes to be treated as if they had been established by the Board. The Secretary of State may continue to establish LPS schemes and, in prescribed circumstances, the Board will be able to provide local pharmaceutical services itself.

441. **Part 8 (Charging) of Schedule 4** makes amendments to Part 9 of the NHS Act by removing references to Primary Care Trusts and Strategic Health Authorities.
442. Paragraph 92 amends section 176 by inserting a reference to the Board to ensure that regulations under subsection (1), which provide for the making and recovery of charges for relevant dental services, may provide for sums otherwise payable by the Board to persons providing relevant dental services to be reduced by the amount of the charges.
443. Paragraph 94 amends section 180 by inserting references to the Board so that the Secretary of State must provide by regulations for payments to be made by the Board to meet or contribute to the costs incurred in respect of optical appliances and sight tests. The amendment also inserts new subsection (6A) to enable the Board to direct a Special Health Authority, or such other body as may be prescribed, to exercise any of the Board's functions under regulations under section 180.
444. Paragraph 96 amends section 183 by removing references to Primary Care Trusts and inserting references to the Board and a commissioning consortium so that regulations may provide for the payment by those bodies of travelling expenses to prescribed descriptions of persons.
445. Paragraphs 97 and 98 amend sections 185 and 186 by removing references to Primary Care Trusts and inserting references to the Board, a commissioning consortium and a local authority so that regulations may provide for the making and recovery of charges by those bodies in respect of more expensive supplies and repairs and replacements of appliances or vehicles in certain cases.
446. Paragraph 99 amends section 187, which enables the Secretary of State to make regulations to provide for charges in respect of services or facilities for the care of pregnant women, women who are breastfeeding and young children, or other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness. This covers certain "community health services" arranged at present by Primary Care Trusts under section 3(1) of the NHS Act. The amendment ensures that the Secretary of State may continue to make provision for charges for these kinds of services, whether arranged by commissioning consortia under section 3(1) (as amended clause 9), or by local authorities under their new health improvement powers (new section 2B inserted by clause 8).

447. **Part 9 (Fraud etc.) of Schedule 4.** Paragraph 102 amends section 195 as a result of changes made to section 2 of the NHS Act. Paragraph 103 amends section 196 by removing references to Strategic Health Authority and Primary Care Trusts and inserting references to the Board and a commissioning consortium in the definition of an ‘NHS body’ for the purposes of sections 195(3) and 197(1). Paragraphs 103, 104 and 105 amend sections 196, 197 and 210 by substituting the references to ‘NHS contractor’ with references to ‘health service contractor’.
448. **Part 10 (Property and finance) of Schedule 4.** Paragraph 106 amends section 213 by removing the reference to a Primary Care Trust as a ‘relevant health service body’ and inserting references to commissioning consortium and the Board as ‘relevant health service bodies’ who the Secretary of State may provide for the transfer of trust property to and from.
449. Paragraph 107 amends section 214 which contains a power for the Secretary of State to transfer all trust property by order from any special trustees to certain health service bodies. The amendment makes provision for the Board and commissioning consortium to be included as bodies to who all trust property can be transferred and removes the references to Primary Care Trusts.
450. Paragraph 108 amends section 215 as a result of the amendment to section 214. Paragraph 109 amends section 217 by removing references to Schedules 2 and 3 to the NHS Act which relate to Primary Care Trusts and Strategic Health Authorities. Paragraph 110 amends section 218 by removing references to Primary Care Trusts and Strategic Health Authorities.
451. Paragraph 111 amends section 222 which contains a power for the Secretary of State to exclude, by way of directions, specified descriptions of activities that NHS Bodies (other than Local Health Boards) undertake in order to raise money. This power has been amended to enable (a) the NHS Commissioning Board to make directions excluding specified descriptions of activities in relation to a commissioning consortium and (b) the Secretary of State to make directions excluding specified descriptions of activities in relation to any other NHS body (other than Local Health Boards).
452. Paragraph 112 amends section 223 by inserting a reference to the Board so that the Board also has powers to form and invest in companies. Paragraph 110 inserts new section 223A to apply section 223 to a commissioning consortium.
453. Paragraph 113 omits section 224 which concerns the funding of Strategic Health Authorities. Paragraphs 114 and 115 amend sections 226 and 227 to remove the references to Strategic Health Authorities so that the sections only apply to Special Health Authorities. Paragraph 116 omits sections 228 to 231 which concern the funding of Primary Care Trusts.
454. Paragraph 117 amends section 236 replaces the reference to the Secretary of State

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with a reference to the ‘prescribed commissioning consortium’ so that a consortium must pay remuneration and reasonable expenses under section 236 rather than the Secretary of State. The amendment also omits the reference to a Primary Care Trust and inserts a reference to arrangements made by the Board or a commissioning consortium in section 236(2)(b) which sets out when payments may not be made to a medical practitioner.

455. Paragraph 118 omits Schedule 14. Paragraph 119 amends Schedule 15 by removing references to Primary Care Trusts and Strategic Health Authorities and by removing the requirement for the Secretary of State to prepare summarised accounts.
456. **Part 11 (Public involvement and scrutiny) of Schedule 4.** Paragraph 120 omits sections 242A and 242B which allow regulations to require Strategic Health Authorities to involve health service users in prescribed matters. Paragraph 121 amends section 246 to remove reference to regulations under section 12A(4) because that subsection is being omitted.
457. **Part 12 (Miscellaneous) of Schedule 4.** Paragraph 122 amends section 256 by substituting references to Primary Care Trusts with references to the Board or a commissioning consortium so that those bodies they have power to make payments towards expenditure on community services.
458. Paragraph 123 amends section 257 by substituting the reference to a Primary Care Trust with reference to the Board and a consortium as a result of amendments made to section 256.
459. Paragraph 124 amends section 258, which confers a regulation making power on the Secretary of State to provide for any functions exercisable by Primary Care Trusts, Strategic Health Authorities, Special Health Authority or Local Health Board in relation to the provision of certain facilities to be exercisable by the body jointly with one or more NHS body (other than an NHS Foundation Trust), by substituting references to Primary Care Trusts and Strategic Health Authorities with references to the Board and a commissioning consortium.
460. Paragraph 125 amends section 259 as a result of amendments made to the provisions relating to primary medical services (Part 4 of the NHS Act). Paragraph 126 omits section 268.
461. Paragraph 127 amends section 270 by inserting references to the Board, a commissioning consortium or a local authority to ensure the Registrar General may provide information to those bodies in addition to the Secretary of State.
462. Paragraph 128 inserts a reference to the Board in section 273 to ensure that a direction under this Act by the Board must be given by an instrument in writing.
463. Paragraph 129 inserts a new definition of “NHS body” to section 275 and makes

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transitional provision to ensure the definition includes a reference to Primary Care Trusts until they are abolished.

Schedule 5

464. This Schedule makes a number of consequential amendments to other Acts. Most of the consequential amendments in this Schedule address references to ‘Primary Care Trusts’ and ‘Strategic Health Authorities’, removing references to those bodies and inserting references to commissioning consortia, the NHS Commissioning board and local authorities as necessary.
465. The following amendments make more substantive changes to other Acts:

Act	Amendment
<i>National Assistance Act 1948 (c.29), section 24</i>	This amends the definition of “NHS accommodation” in light of amendments to section 117 of the Mental Health Act 1983, removing references to Primary Care Trusts.
<i>Mental Health Act 1983 (c.20), sections 19, 23, 32, 39, 134, 139 and 145</i>	<p>Amendments to sections 19, 23 and 32 remove references to Primary Care Trusts.</p> <p>The amendment to section 39 removes references to Primary Care Trusts and inserts references to commissioning consortia and the NHS Commissioning Board for the purposes of requiring them to provide information under section 39. The NHS Commissioning Board will only be required to provide information in relation to services or facilities the provision of which the Board arranges.</p> <p>The amendments to sections 134, 139 and 145 remove references to Strategic Health Authorities and Primary Care Trusts and inserts references (where appropriate) to commissioning consortia and the NHS Commissioning Board.</p>

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Act	Amendment
<p><i>Disabled Persons (Services, Consultation and Representation) Act 1986 (c.33) sections 7 and 11.</i></p>	<p>The amendment to section 7 removes the reference to a Primary Care Trust and inserts a reference to commissioning consortia.</p> <p>The amendment to section 11 removes the duty on the Secretary of State to lay reports before Parliament on the development of health and social care services for persons with mental illness and for persons with learning disabilities.</p>
<p><i>Freedom of Information Act 2000 (c.36) Part 3 of schedule 1</i></p>	<p>The amendment inserts references to commissioning consortia and the NHS Commissioning Board as ‘public authorities’ for the purposes of the Act.</p>
<p><i>Health and Social Care (Community Health and Standards) Act 2003 (c.43) section 45</i></p>	<p>The amendment removes the reference to regulations under section 12A(4) of the NHS Act, reflecting the changes to section 117 of the Mental Health Act 1983.</p>
<p><i>Mental Capacity Act 2005 (c.9, sections 35, 64 and Schedule A1</i></p>	<p>The amendment to section 35 makes local authorities, instead of the Secretary of State, responsible for making arrangements to enable independent mental capacity advocates to represent and support specified persons.</p> <p>The amendment to Schedule A1 removes references to Primary Care Trusts and Strategic Health Authorities and inserts references to a local authority as the supervisory body if the relevant person is ordinarily resident in England. There are also minor changes to the situation in Wales as regards the determination of who is a supervisory body. The reference to the Welsh Ministers, in contrast to the references in the Act to the National Assembly for Wales, is necessitated by devolution.</p>
<p><i>Safeguarding Vulnerable Groups Act 2006 (c.47) sections 6, 17, 21 and 59</i></p>	<p>The amendment removes references to Strategic Health Authorities and Primary Care Trusts and inserts references to commissioning consortia and the NHS Commissioning Board in section 17.</p> <p>The amendment also removes references to section 12A(4) of the NHS Act, reflecting the changes to section 117 of the Mental Health Act 1983.</p>

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Act	Amendment
<p><i>Health and Social Care Act 2008 (c.14) sections 30, 39, 46, 48, 49, 54, 59, 64, 70, 72, 97, 153</i></p>	<p>The amendment removes references to Strategic Health Authorities and Primary Care Trusts and where appropriate, inserts references to commissioning consortia and the NHS Commissioning Board.</p> <p>The amendment to sections 30 and 39 requires the Care Quality Commission ('CQC') to give notice to certain NHS bodies if it takes action against a registered provider.</p> <p>The amendment to section 54 inserts a reference to the NHS Commissioning Board and commissioning consortia so that they are not included in the definition of 'English NHS Body' for the purpose of section 54(1) which relates to the CQC's power to undertake studies designed to enable it to make recommendations for improving the management of an English NHS body.</p> <p>The amendment to section 59 means that the Secretary of State will not have the power to confer additional functions on the CQC relating to improving the economy, efficiency and effectiveness and the financial or other management or operations of certain NHS bodies.</p>

Schedule 6

466. This Schedule is concerned with the transitional arrangements for the establishment of commissioning consortia and the exercise of functions by consortia during the 'initial period'. The initial period is defined in paragraph 1(2) as the period beginning with the commencement of section 21 and ending on a day specified by the Secretary of State for the purposes of section 14A of the 2006 Act (the date from which the Board must ensure every provider of primary medical services is a member of a consortium and that the areas specified in the constitutions of consortia cover the whole of England). It is envisaged that this 'initial period' will run from 1 April 2012 to 31 March 2013. Initial applications are applications made during the initial period.
467. During the initial period, the Secretary of State may (under paragraph 2) direct the Board to exercise any of the functions of the Secretary of State that relate to Primary Care Trusts, but not including the Secretary of State's powers or duties to make orders or regulations. This will, for instance, enable the Secretary of State to arrange for the Board to hold Primary Care Trusts to account for their performance during 2012/13.
468. Paragraph 3 of the Schedule makes provision for the conditional establishment of consortia during the initial period in any cases where the Board is not fully satisfied as to the matters set out in new section 14C, in other words the matters as to which it

would normally have to satisfy itself before granting an application for establishment. Regulations may be made authorising the Board in these circumstances to grant initial applications, but allowing the Board to give a direction that the consortium exercise some of its functions in a certain way or to direct the consortium not to exercise specified functions. If the regulations authorise the Board to give such a direction they may also authorise or require the Board to exercise any functions specified on behalf of the consortium, or arrange for another consortium to exercise those functions. Regulations may also make provision requiring the Board to keep any conditions or directions under review and make provision about how the Board varies or removes any conditions or directions imposed.

469. Paragraph 3(6) enables regulations to be made making modifications to the 2006 Act as far as it applies to consortia established on the grant of an initial application. These regulations may provide that the Board's power to dissolve a consortium (in new section 14Z6) applies where a consortium established with conditions fails to comply with those conditions. The regulations may also make provision about the factors that the Board must or may take into account when exercising these powers, and the procedures to be followed. Paragraph 3(12) provides that, where a conditionally established consortium ceases to be subject to any conditions or directions, it is deemed to have been established on an application granted under new section 14C.
470. Paragraph 4 of the Schedule provides that, where a consortium is established, the Board may direct it to exercise only some of its functions during the initial period. PCTs will retain commissioning responsibilities until 31 March 2013. This power of direction is necessary to avoid consortia having concurrent statutory responsibility for commissioning functions that remain with PCTs during the initial period. This means that, where consortia commission services for patients during the initial period, they will be doing so on behalf of PCTs (see paragraph 6 of the Schedule) rather than through exercising the consortium's own statutory functions
471. Paragraph 5 of the Schedule provides that a consortium may in the initial period, while it is carrying out limited functions, undertake preparatory work to help it prepare to exercise its functions after the end of the initial period (even if that consortium has had conditions imposed on it by a direction from the Board).
472. Paragraph 6 provides that, during the initial period, a Primary Care Trust can make arrangements with a consortium under which the consortium carries out functions of the PCT on the PCT's behalf. This will allow consortia to carry out, on behalf of PCTs, commissioning functions very similar to those for which they will be responsible in their own right from April 2013 onwards. These arrangements are intended to support a smooth transition from PCT commissioning to consortia commissioning. However the legal responsibility for the commissioning will remain with the PCT.

Part 2 – Further provision about public health

Clause 46 – Abolition of the Health Protection Agency

473. This clause abolishes the Health Protection Agency (HPA) and repeals the Health Protection Agency Act 2004. Abolishing the HPA is part of the Government's policy of creating a new system for the protection and improvement of public health.

Clause 47 - Functions in relation to biological substances

474. This clause confers new UK-wide functions in relation to biological substances (see subsection (7) for the definition of 'biological substances'). These are functions currently carried out by the Health Protection Agency. Functions relating to biological substances include standardising and controlling biological medicines like vaccines or blood products to ensure their safety and effectiveness.
475. *Subsection (1)* imposes a number of specific duties on the Secretary of State and the Department of Health, Social Services and Public Safety in Northern Ireland (DHSSPS) acting jointly in relation to biological substances. *Subsection (7)* provides the definition of 'appropriate authority'.
476. *Subsection (2)* provides the Secretary of State and the DHSSPS with general powers by which their functions in relation to biological substances may be discharged.
477. *Subsections (3) to (5)* provides for a reciprocal duty of co-operation between the Secretary of State and DHSSPS on the one hand and any person or body exercising biological substances functions similar to those of the Secretary of State and the DHSSPS on the other. The duty of co-operation applies irrespective of whether those functions are exercised in relation to the UK or overseas.
478. *Subsection (6)* allows the Secretary of State and the DHSSPS to charge for their activity in relation to biological substances, including on a commercial basis.

Clause 48 – Radiation protection functions

479. This clause confers functions in relation to protecting the public from radiation. These are functions currently carried out by the Health Protection Agency.
480. This clause applies in relation to Wales, Scotland and Northern Ireland. It does not apply in relation to England (see subsection (10)). Provision for protecting the public in England from radiation is made at new section 2A of the NHS Act (Secretary of State's duty as to protection of public health) as inserted by clause 7.
481. *Subsection (1)* imposes a general duty in relation to protecting the public from radiation on the 'appropriate authority'. Under subsections (8) and (9) the appropriate authority in relation to Wales is the Secretary of State; the appropriate

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authority in relation to Scotland is the Secretary of State where the matter is not devolved and the Scottish Ministers where it is; and the appropriate authority in relation to Northern Ireland is the Secretary of State where the matter is not devolved and the Department of Health, Social Services and Public Safety in Northern Ireland where it is.

482. *Subsection (2)* lists some of the steps the appropriate authorities may take to protect the public against radiation.
483. *Subsection (3)* provides the appropriate authority with a general power to do things which it considers appropriate to facilitate the discharge of the duty under subsection (1) or is incidental or conducive to it, including providing technical services for measuring and assessing levels or amounts of radiation.
484. *Subsection (4)* enables the appropriate authority to charge for their activity in relation to radiation protection, including on a commercial basis.
485. *Subsections (5) and (6)* require the appropriate authority to consult the Health and Safety Executive or the Health and Safety Executive for Northern Ireland and have regard to its policies when taking steps in relation to a radiation matter in respect of which the HSE also has a function.

Clause 49 – Repeal of the AIDS (Control) Act 1987

486. This clause repeals the AIDS (Control) Act. The Act allows the collection of information about numbers of HIV cases and deaths, but for some time laboratories and clinics have voluntarily reported more accurate and relevant data than the Act calls for. As a result, the Department of Health has not used the Act for several years and now regards it as redundant.
487. For consistency, the AIDS (Control) (Northern Ireland) Order 1987 will also be revoked.

Clause 50 - Co-operation with bodies exercising functions in relation to public health

488. This clause requires co-operation between the Secretary of State and other people or organisations engaged in public health protection activity. This could include circumstances when the Secretary of State's activity takes place overseas and co-operation between the Secretary of State and other organisations is required to help control the spread of infectious disease or the release of harmful chemicals into the environment. The intention is to make sure that the system works in a co-ordinated and coherent way to deal with threats to public health.
489. The clause inserts a new section 247A into the NHS Act. New section 247A imposes a reciprocal duty of co-operation on all individuals or organisations, including the

Secretary of State, who carry out health protection functions similar those of the Secretary of State under new section 2A of the NHS Act.

490. Under *subsections (3) to (5)*, the Secretary of State and individuals or organisations would be able to charge for the costs of their co-operation, on a costs recovery basis, when it is requested.

Part 3 - Economic Regulation of Health and Adult Social Care Services

Chapter 1 – Monitor

491. Monitor is currently the independent regulator of foundation trusts. It is responsible for determining whether NHS trusts are ready to become foundation trusts, ensuring foundation trusts comply with the conditions of their authorisations, and supporting their development. This Bill turns Monitor into an economic regulator for all NHS-funded health services. As an economic regulator, Monitor's overarching duty would be to protect and promote the interests of people who use health care services, by promoting competition where appropriate and through regulation where necessary. It would have three core functions: promoting competition where appropriate; setting or regulating prices; and supporting the continuity of services. To support its functions, Monitor would have the power to licence providers of NHS-funded care. These clauses draw upon precedents from the utilities, rail and telecoms industries, tailoring them to the particular circumstances of the health sector.
492. The Department of Health, working with the Department for Communities and Local Government, is considering the proposed role for Monitor in regulating adult social care services with respect to potential anti-competitive behaviour or provider failure, ensuring that such a role does not duplicate existing functions. The Bill allows for Monitor's remit to be extended to include adult social care should this work identify a case for regulation.
493. Schedule 7 outlines the structure and governance of Monitor, which would remain as a non-departmental public body. The provisions are designed to ensure consistency with the other non-Departmental public bodies in the health sector, such as the National Institute for Health and Care Excellence. There are some exceptions, where the particular nature of Monitor's role requires a different approach. These exceptions are explained in the commentary below.

Clause 51 - Monitor

494. This clause provides that Monitor continues to exist, but ceases to be known as the Independent Regulator of NHS Foundation Trusts. Instead, the formal name would be 'Monitor', and the organisation would carry out the duties and functions of an economic regulator for the NHS-funded health sector, as specified in later clauses. The clause also gives effect to the Schedule explained below.

Schedule 7 - Monitor

495. This Schedule provides details of the membership of Monitor and the process for appointments, including the appointment of the chief executive. These governance arrangements are designed to be consistent with those proposed for the other health non-Departmental public bodies such as the National Institute for Health and Care Excellence.
496. Paragraphs 1 and 2 detail the membership and appointment of the chair, chief executive and other members of Monitor. The chief executive and other executive members would be appointed by the non-executive members, with the consent of the Secretary of State. The number of non-executive members would have to be equal to or exceed the number of executive members. The non-executive members could not appoint more than five executive members without the consent of the Secretary of State. This is intended to keep Monitor's Board at an appropriate size and to ensure that any additional members would be appropriately justified.
497. Paragraph 3 details how long non-executives may hold office. It provides that the Secretary of State can suspend or remove a non-executive member from office, on the grounds of incapacity, misbehaviour, or failure to carry out duties.
498. Paragraph 4 provides for what is to happen when a non-executive member is suspended from office. The suspension must be for an initial period of not more than six months. It requires the Secretary of State to provide the individual with notice of the suspension, and states the process for review.
499. Paragraph 5 states the arrangements for appointing an interim chair when a chair is suspended. The Secretary of State would have the power to do this.
500. Paragraph 6 requires that Monitor must pay to non-executive members such remuneration and allowances as the Secretary of State may determine. It also provides for Monitor to make arrangements for pensions, allowances and gratuities to be paid to non-executive members or former non-executive members. These arrangements would be for Monitor to determine with the approval of the Secretary of State.
501. Paragraph 7 provides Monitor with powers to employ staff on such pay, terms and conditions as it may determine, following approval of the Secretary of State as to its policy on the remuneration, pensions etc of employees.
502. Paragraph 8(2) applies where a person appointed as chair of Monitor is a member of a public sector pension scheme under section 1 of the Superannuation Act 1972. It provides that the Minister for the Civil Service can decide whether time as chair of Monitor can count as years of service for that pension scheme. Paragraph 8(3) provides that employment with Monitor is among the kinds of employment to which such a pension scheme can apply.

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503. Paragraph 9 gives Monitor the power to appoint committees and sub-committees, and to pay remuneration and allowances to their members if they are not members or employees of Monitor.
504. Paragraph 10 allows Monitor to regulate its own procedure and states that any vacancy amongst the members would not affect the validity of its actions.
505. Paragraph 11 requires Monitor to act effectively, efficiently and economically in exercising its functions and provides power to arrange for any of its functions to be exercised on its behalf by certain persons.
506. Paragraph 12 enables Monitor to engage and pay individuals to contribute to particular cases or types of cases. For example, Monitor could employ someone with specialist skills needed only for a short period.
507. Paragraph 13 gives Monitor the power to temporarily borrow money by overdraft (with the consent of the Secretary of State). Other than this arrangement and powers to borrow money in relation to financial mechanisms to support continuity of services, Monitor would not be allowed to borrow money.
508. Paragraph 14 allows Monitor to obtain and compile information in order to be able to take informed decisions in exercising its functions. This could include the commissioning or supporting of research.
509. Paragraph 15 gives Monitor the power to do anything it needs to in order to exercise its functions.
510. Paragraph 16 allows the Secretary of State to fund Monitor's activities to the extent that he considers necessary.
511. Paragraph 17(1) requires Monitor to prepare a set of accounts in each financial year which consolidates the annual accounts of all foundation trusts. Paragraph 17(2) enables the Secretary of State to direct Monitor to prepare a set of interim accounts which consolidates any interim accounts prepared by foundation trusts. Overall, this paragraph sets out the arrangements necessary to ensure that the Secretary of State would receive whatever information in respect of foundation trusts he required to permit him to fulfil his statutory duties in respect of the Department's own consolidated Resource Accounts.
512. Paragraphs 17(3) and (4) give the Secretary of State the power, subject to HM Treasury approval, to specify the form and content of the consolidated annual and interim accounts; to specify the accounting methods to be used in preparing those accounts; and to set the timescales in which the accounts must be prepared.
513. Paragraph 17(7) provides that any consolidated accounts (both annual and interim) prepared by Monitor under this paragraph, should be audited by the Comptroller and

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Auditor General. Monitor is also required to act with a view to securing that foundation trusts comply promptly with requests from it or from the Secretary of State relating to accounts, and facilitate the preparation of accounts by the Secretary of State.

514. Paragraph 17(9) provides that from a date to be specified by the Secretary of State under Part 4 (accounts: variations to initial arrangements), when all the responsibilities imposed on Monitor by this paragraph (i.e. the preparation of consolidated interim and annual accounts) will be transferred to the Secretary of State, this paragraph is not to apply.
515. Paragraph 18 requires Monitor, in its capacity as a non-Departmental public body, to prepare its own annual accounts in the form and with the content, and using methods and principles, determined by the Secretary of State with HM Treasury's approval.
516. Paragraph 19 provides that Monitor must prepare annual accounts in respect of each financial year, and then sets out arrangements for the audit of Monitor's annual accounts by the Comptroller and Auditor General.
517. Paragraph 20 enables the Secretary of State to require Monitor to produce interim accounts in addition to its annual accounts, and to have these audited by the Comptroller and Auditor General. The Secretary of State could require copies of these accounts to be laid before Parliament.
518. Paragraph 21 provides that Monitor must publish an annual report on how it has exercised its functions, and in particular how it has promoted economy, efficiency and effectiveness. Monitor would need to lay a copy before Parliament and send a copy to the Secretary of State. Monitor would also be required to provide further information to the Secretary of State as he requires.
519. Paragraph 22 requires Monitor to respond to recommendations made by the Parliamentary Committees about the exercise of its functions.
520. Paragraphs 23 and 24 are standard provisions that replicate those currently in the NHS Act, covering the use of Monitor's seal and its non-Crown status.

Clause 52 - General duties

521. This clause provides for Monitor's principal overarching duty and certain other general duties. Its main duty is to exercise its functions so as to protect and promote the interests of people who use health care services, by promoting competition where appropriate and through regulation where necessary. It is intended that 'protect' be interpreted as ensuring that the interests of people who use health services are not diminished; whilst 'promote' is intended to mean furthering their interests.
522. *Subsection (2)* provides that Monitor, in carrying out this duty, must consider the

likely future demand for health services.

523. Under *subsection (3)* Monitor, in performing its functions would have to promote the economic, efficient and effective provision of NHS services.
524. The Secretary of State has a duty in section 1(1) of the NHS Act to promote a comprehensive health service, and *subsection (4)* requires Monitor to exercise its functions in a manner consistent with this. This means that Monitor should not take any action that is not consistent with the promotion of the comprehensive health service.
525. *Subsection (5)* provides that Monitor's duties do not cover the supply of goods to providers of health care services where those goods are to be provided as part of the health care service. This would mean, for example, that Monitor's duties would not include the supply of pharmaceuticals and medical devices by a manufacturer or supplier to a provider of health care services, but they would include the supply of those pharmaceuticals or medical devices by such provider in the course of providing health care services.
526. The definition of health care in *subsection (7)* is the same as that used in the Health and Social Care Act 2008 (section 9). Health care services provided for the purposes of the NHS exclude public health services provided by the Secretary of State or local authorities.

Clause 53 - Power to give Monitor functions relating to adult social care services

527. This clause allows the extension of Monitor's duties to include adult social care to be achieved through regulations. The clause also defines adult social care, to exclude children's services. Subject to the outcome of the joint review by the Department of Health and the Department for Communities and Local Government, the Government anticipates that these regulations would be limited to potential anti-competitive practice and/or provider failure.

Clause 54 - Matters to have regard to in exercise of functions

528. This clause provides a list of the considerations to which Monitor must have regard when carrying out its specific functions. These matters are key priorities for the health sector, with some applying only to NHS-funded services, and others relevant across the sector. These matters are to ensure that Monitor would exercise its functions in a way that is consistent with these priorities.
529. *Subsection (1)(a)* to (e) requires that Monitor gives regard to patient safety, continuous improvement in quality and efficiency in NHS services, and access to those services.
530. The desirability of securing continuous improvement in the quality of NHS-funded

services is included to ensure that Monitor's actions would not inadvertently impede the duties of other bodies in the system to act with a view to improving quality (namely the Secretary of State and the NHS Commissioning Board). When taking any action, Monitor would need to take into account the importance of improving quality.

531. Subsection (1)(f) to (i) concerns the best use of resources, promoting investment by providers of health care, the need to promote research, and education and training.
532. Subsection (1)(j) to (l) states that Monitor must also have regard to various functions that the Secretary of State and the NHS Commissioning Board will exercise. Specifically, this subsection requires that Monitor must take account of the duty of the NHS Commissioning Board to secure the provision of NHS services, and the duty of both the NHS Commissioning Board and the Secretary of State to secure improvements in the quality of healthcare.

Clause 55 - Conflicts between functions

533. This clause places requirements of transparency upon Monitor in the case of conflict between its general duties. Under *subsection (1)*, Monitor would be required to take steps to secure that such conflicts are resolved in the manner it considers best.
534. *Subsection (2)* is designed to ensure that, whilst retaining certain foundation trust-specific functions during the transition to the new regulatory system, Monitor would make appropriate arrangements to mitigate and manage potential conflicts of interest between those functions and the new functions given to it as economic regulator of health care services for the purposes of the NHS, so that it was able to treat all providers equally.
535. *Subsection (3)* of this clause states that in exercising its functions around competition, licensing - in relation to securing the continuity of designated services - and in respect of pricing, Monitor must ignore its functions in respect of imposing transitional licence conditions on certain foundation trusts under Chapter 4 of this Part.
536. There are additional requirements for cases of particular significance. *Subsection (5)* states the types of cases which would be subject to these extra requirements: those involving a major change to Monitor's activities, or likely to have a significant impact upon patients, for example. In these cases Monitor would have to publish a statement about the particular conflict that arose, and how it decided to resolve it. The clause also requires Monitor to do this for any other such conflict that it considers 'of unusual importance'.
537. Every year, Monitor would have to include in its annual report a summary of how it has resolved any conflicts between its general duties.

Clause 56 - Duty to review regulatory burdens

538. This clause requires Monitor to keep its exercise of functions under review to ensure that it does not impose or maintain unnecessary burdens, having regard to best regulatory practice. It is based on section 72 of the Regulatory Enforcement and Sanctions Act 2008. The purpose of *subsection (1)* is to ensure that Monitor would only impose regulation that was necessary and proportionate, and that this would be reviewed over time. This means that where developments over time rendered a particular regulatory burden no longer necessary, that it would be removed. For example, as more providers entered the market and more efficient competition developed, regulatory burdens could be lessened for certain services or providers.
539. The remainder of this clause stipulates the manner in which Monitor is required to publish a statement, reporting upon its actions over the year and setting out its plans for the following year. Monitor would then be required to have regard to its statement when carrying out its functions. Monitor would be able to revise the statement, but would have to publish revisions as soon as practicable.

Clause 57 - Duty to carry out impact assessments

540. This clause stipulates that Monitor must either carry out an impact assessment, or publish a statement explaining why it is not necessary to do so, before it implements a proposal. This only applies to particularly significant proposals, which are set out in *subsection (1) (a) to (e)*. For example, an impact assessment would be likely to be necessary for proposals involving a major change to Monitor's activities, or proposals likely to have a significant impact on patients.
541. *Subsections (2) and (3)* state that this action is not required in certain circumstances – firstly, where Monitor carries out competition functions concurrently with the Office of Fair Trading, and secondly, where Monitor feels the situation is too urgent to delay intervention.
542. *Subsections (5) to (7)* state what the impact assessment must consist of and how it must be published. It would have to explain why an additional intervention by the regulator was necessary, rather than Monitor using its competition powers under the Competition Act 1998 and the Enterprise Act 2002, under Chapter 2 of this Bill. It would also have to describe how the proposed action would secure the discharge of Monitor's duties. Beyond these requirements, Monitor would be able to decide what else the assessment should include, whilst taking account of general guidance on impact assessments as appropriate.
543. *Subsection (8)* restricts Monitor to implementing the proposal only when it has considered any representations made by anyone affected by it (if any are made). Monitor would also be prevented from using the requirements of this clause to replace any other obligations it had to consult about a particular issue.

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544. *Subsection (10)* stipulates the way in which Monitor would be required to report upon the assessments it had carried out in each financial year.
545. The duty to carry out impact assessments is modelled on that of OFCOM.

Clause 58 - Information

546. This clause stipulates that Monitor may use any of the information it collects from providers to support any of its regulatory functions.

Clause 59 - Failure to perform functions

547. This clause gives power to the Secretary of State to direct Monitor when he considers that it is failing, or has failed, to perform its functions. It is intended that this would only be used in exceptional circumstances. Similar powers of intervention would exist for other non-Departmental bodies including the Care Quality Commission and the NHS Commissioning Board.

Chapter 2 – Competition

548. This Chapter provides Monitor with powers intended to ensure that competition operates effectively in the market for health care services. Monitor is given concurrent powers with the Office of Fair Trading (“the OFT”) to apply the Competition Act 1998, which would allow Monitor to investigate practices by individual organisations or groups of organisations that might restrict competition, such as actions to exclude competitors from providing services or agreements to restrict patient choice. It also provides for Monitor to have concurrent functions with the OFT under Part 4 of the Enterprise Act 2002 as they relate to health care services provided in England. This Chapter also makes provision about requirements as to good procurement practice for commissioners, mergers involving NHS foundation trusts, reviews by the Competition Commission and the cooperation of Monitor and the OFT.

Clause 60 - Functions under the Competition Act 1998

549. This clause provides Monitor with concurrent functions with the OFT under Part 1 of the Competition Act 1998 (“the 1998 Act”) in relation to the provision of health care services in England. The 1998 Act is generally applied and enforced by the OFT but in a number of regulated industries, such as telecommunications, gas, electricity, water and sewerage and railway services, concurrent powers with the OFT are in place for sectoral regulators, such as the Office of Communications which regulates the telecommunications sector (see section 371 of the Communications Act 2003).
550. Chapter 1 of Part 1 of the 1998 Act prohibits undertakings from reaching certain agreements and decisions and carrying out concerted practices that prevent, restrict or distort competition. For example, it prohibits organisations from reaching agreements to fix prices; limit or control production, or share markets except where an exemption

applies. Chapter 2 prohibits undertakings from abusing a dominant position in a market. For example, it prohibits organisations with a dominant position from imposing unfair purchase or selling prices or other unfair trading conditions, limiting production, markets or technical development to the prejudice of consumers, or applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.

551. The Chapter 1 and Chapter 2 prohibitions are modelled on Articles 101 and 102 of the Treaty on the Functioning of the European Union which prohibit agreements that prevent, restrict or distort competition, and abuse of a dominant market position.
552. Monitor would have concurrent powers with the OFT to conduct investigations where it had reasonable grounds for suspecting that either of these two prohibitions – under either UK or EU law – had been infringed in the provision of health services in England.
553. Monitor would also have concurrent powers to impose remedies for breaches of the prohibitions, as stipulated in sections 32 to 41 of Part 1 of the 1998 Act. Under sections 32 and 33 of that Act, Monitor would be able to issue directions to undertakings to bring an infringement to an end. For example, Monitor might direct an undertaking to change its conduct, for example to cease particular sales or pricing practices which restricted competition. Under section 36, Monitor would have the power to issue fines following an infringement.
554. There are some functions of the OFT under the 1998 Act which Monitor would not share. The OFT is responsible for issuing guidance on appropriate levels of penalties for infringements of the prohibitions in the 1998 Act and for making procedural rules to be followed under that Act. This is because the OFT is responsible for issuing this type of guidance and making regulations on the application of the 1998 Act for the economy as a whole, which is designed to secure consistent application of that Act.

Clause 61 - Functions under Part 4 of the Enterprise Act 2002

555. This clause gives Monitor concurrent functions with the OFT under Part 4 of the Enterprise Act 2002 (“the 2002 Act”), in respect of the provision of health care services in England. These powers would enable Monitor to make market references to the Competition Commission. Similar provisions have been made in relation to the other sectoral regulators, such as the Office of Communications (see section 370 of the Communications Act 2003).
556. The clause enables Monitor to make market references to the Competition Commission if it has reasonable grounds for suspecting that any features of a market prevent, restrict or distort competition. For example, Monitor might refer a market to the Competition Commission if there were barriers to competition which required more detailed investigation or problems which it could not address using its licensing

and other powers.

557. Under section 134 of the 2002 Act, after receiving a market reference the Competition Commission must investigate it and publish a report within two years. If it decides that there is an adverse effect on competition, it also decides upon the action to be taken to remedy this.
558. *Subsections (4) and (5)* of this clause also include provision requiring Monitor and the OFT to consult each other before exercising these functions under the 2002 Act and are designed to avoid duplication by prohibiting both Monitor and the OFT from exercising these functions if the other has already done so in relation to a particular matter.
559. This clause also applies section 117 of the 2002 Act so that Monitor is included (so far as relating to functions exercisable by it by virtue of this clause), in the list of persons and bodies set out in subsections (1)(a) and (2), to whom it is an offence to knowingly or recklessly supply false or misleading information. Sanctions available to the courts in respect of this offence are set out in section 117 of that Act.
560. Functions of the OFT in sections 166 and 171 of the 2002 Act are not to be exercised concurrently with Monitor. Section 166 requires the OFT to keep a register of undertakings. Sectoral regulators are required to notify the OFT of any undertakings to be included in the register and so need not keep a register themselves. Clause 171 requires the OFT to publish guidance about market investigation references. This duty is to remain with the OFT so that guidance is consistent across different sectors.

Clause 62 - Competition functions: supplementary

561. This clause makes a number of supplementary provisions relating to how Monitor should apply its competition functions.
562. *Subsection (1)* states that the concurrent nature of Monitor's powers means that there could be no valid objection that its actions under these powers should have been carried out by the OFT.
563. *Subsections (2) and (3)* make provision about the relationship between Monitor's competition functions and its general duties. Chapter 1 of this Part makes provision about Monitor's general functions and matters to which Monitor would have to have regard in exercising its functions. Those functions do not apply where Monitor is carrying out its concurrent competition functions under this Chapter unless they are functions to which the OFT is also entitled to have regard.
564. *Subsection (4)* adds Monitor to the list of regulators in the Company Directors Disqualification Act 1986 with powers to apply to a court to make a company director disqualification order, when the director's organisation had committed a breach of Part 1 of the Competition Act 1998. The Company Directors Disqualification Act

1986 specifies the issues courts should consider when assessing whether to issue a disqualification order against a director following a breach of competition law. These include whether the person's conduct contributed to the breach, and whether he or she had reasonable grounds to suspect the breach and took no steps to prevent it.

565. The OFT already has the power to apply to a court to disqualify directors in healthcare and other industries following a breach of the Competition Act 1998. The sectoral regulators with concurrent powers (including the Office of Communications, the Office of Gas and Electricity Markets and the Office of Water Services) also have this power. This power enables Monitor to apply competition law and appropriate sanctions in health care alongside the OFT.
566. *Subsections (5) to (7)* make modifications to the Competition Act 1998 and the Enterprise Act 2002 to include Monitor in provisions of that Act which are relevant to Monitor's concurrent powers and which apply to other sectoral regulators with concurrent powers.

Clause 63 - Requirements as to good procurement practice, etc.

567. This clause enables the Secretary of State to make regulations imposing requirements on the NHS Commissioning Board and commissioning consortia in order to ensure good procurement practice and to protect choice and competition with regard to health care services. Where a contract is for goods and services, *subsection (2)* provides that the regulations will only apply where the value of the part of the contract for services is greater than the value of the goods. This is intended to ensure that the regulations would only capture contracts that are primarily for services rather than goods.
568. *Subsection (3)* provides that the regulations may include specific procedural requirements to ensure that commissioners carry out fair and transparent practices. The regulations could also address conflicts of interest where a commissioning consortium was responsible for commissioning a service that its practices had an interest in delivering. *Subsection (4)* allows for regulations to provide for exemptions in relation to particular arrangements.

Clause 64 - Powers in relation to requirements imposed under section 63

569. This clause makes provision for what may be included in regulations made under the previous clause about Monitor's powers to investigate and remedy breaches of the regulations. Monitor may be given the power to investigate following a complaint by an interested party. It may also be given powers to require commissioners to provide information during an investigation, including requiring commissioners to provide explanations for documents.
570. Under *subsection (3)* the regulations could confer on Monitor powers to declare, in specified circumstances, that an arrangement for the provision of services was ineffective and to direct the Board, or a consortium, to put the provision of services

out to tender. *Subsection (4)* provides that those powers would only be exercisable in circumstances where there has been a sufficiently serious breach of the regulations.

571. Where Monitor deems a particular arrangement for service provision to be ineffective, it is void. But this would not affect any right acquired or liability incurred under the existing arrangement for service provision.
572. *Subsection (6)* provides that regulations may give Monitor a further power to direct the NHS Commissioning Board or a commissioning consortium to take steps to prevent failures to comply with the regulations under the previous clause, or to remedy any breaches of the regulations. This includes the power to require a commissioner to remedy a failure to comply, or modify a tendering process.
573. *Subsections (7) and (8)* make provision about actions brought for a failure to comply with the regulations. In the event of loss or damage caused by a failure to comply with a requirement imposed by the regulations, a person affected would be able to bring an action, unless the regulations restricted this. Regulations may also provide for a specified defence to such an action.
574. There are circumstances in which it may be possible for a person to bring an action under both the regulations made under the previous clause and the Public Contracts Regulations 2006 (S.I. 2006/5). In those circumstances, any person bringing an action under the Public Contracts Regulations 2006 is precluded from bringing an action under regulations made under the previous clause in relation to the same matter.

Clause 65 - Mergers involving NHS foundation trusts

575. This clause applies Part 3 of the Enterprise Act 2002, which sets out the general merger control regime for enterprises in the UK, to certain foundation trusts. This clause provides that the merger control regime in Part 3 of the Enterprise Act 2002 would apply to foundation trusts which are not enterprises for the purposes of that regime in relation to mergers between foundation trusts or between NHS foundation trusts and other organisations. This means that the OFT and the Competition Commission would be responsible for reviewing mergers involving all foundation trusts whether or not they are enterprises.

Clause 66 - Reviews by the Competition Commission

576. This clause stipulates that the Competition Commission must review the development of competition in relation to NHS service provision, and the way in which Monitor carries out its functions in this area.
577. Before conducting a review, the Commission would have to publish a notice giving details of what was to be considered in the review. The Commission would have to publish a completed report of the review within 12 months of that notice and send a

copy to the Secretary of State, Monitor and the NHS Commissioning Board.

578. The Commission must consider whether one or more matters under review has adversely affected or might be expected to adversely affect the public interest. Where the Commission concludes that it has or may, the report would have to include recommendations to the Secretary of State, Monitor and the Board as to how the situation could be remedied. Each of the three parties would be required to respond to the Commission in light of the recommendations, and to do so within six months of the date of publication of the report.
579. *Subsection (8)* requires that during the review process Monitor provides the Commission with certain information and assistance.
580. For the purposes of the law of defamation, absolute privilege would attach to a report under this clause.
581. *Subsections (9) and (10)* make provision about when the reviews must be carried out. The first review would have to begin in 2019 and each subsequent review would have to take place within 7 years of the previous review.
582. *Subsection (12)* makes consequential changes to paragraph 19A of Schedule 7 to the Competition Act 1998 which makes provision about the procedural rules about the Commission's general functions which are relevant to reviews.

Clause 67 - Reviews under section 66: considerations relevant to publication

583. This clause requires that in the production of a report, the Commission must have regard to the need to avoid publishing, as far as practicable and bearing in mind how necessary the information is for the purposes of the report, information that it believes would be contrary to the public interest or commercial or personal information that it believes might significantly harm legitimate business interests or an individual's interests.

Clause 68 - Co-operation with the Office of Fair Trading

584. This clause requires that Monitor and the OFT co-operate in their functions under the Competition Act 1998 and the Enterprise Act 2002. Specifically, they would have to share relevant information that would enable and assist the other to exercise its functions and provide such other assistance as the other may require.

Chapter 3 – Designated Services

585. One of Monitor's new core functions under this Bill would be to support commissioner's duties with regards to the continuity of certain specified services, for the purposes of the NHS, in the event of provider failure, by means of a special administration regime. These services would be known as "designated services".

Local commissioners would lead the process of defining which services would be designated for each provider.

Clause 69 - Designation of services

586. This clause provides for commissioners (commissioning consortia, the NHS Commissioning Board or the Secretary of State where he exercises his power under section 13V of new Chapter A1 of the NHS Act) to make an application to Monitor for services to be designated and therefore subject to the special administration regime in the case of provider failure and to additional regulation to ensure their continued provision. This is intended to be similar to other engagement processes run by other regulators in other sectors (such as the energy sector).
587. *Subsection (2)* provides that a commissioner may only apply for a service to be designated if a consultation of the relevant persons has been carried out and if the criterion in *subsection (3)* has been met. That criterion is that there would be likely to be a significant adverse impact on the health of those for whom the commissioner is responsible for arranging services if the service was no longer provided, or that this would be likely to cause a failure to prevent or ameliorate such adverse impact. The relevant persons a commissioner would be required to consult are specified in *subsections (9), (10) and (11)*. Relevant persons differ depending on who the commissioner is and include any person who the commissioner considers appropriate, which might include potential providers of NHS services.
588. The determination as to whether the criterion would be met for a service should in practice be based on an assessment of evidence of patient needs and local provision, and therefore done principally by local professionals with local knowledge. Commissioners would be expected to demonstrate this evidence to Monitor when applying for a service to be designated and would be required to provide copies of consultation responses they had received regarding the question of whether to designate the service. As provided for later in this Chapter, Monitor would have to provide guidance on the tests to be used when designating services.
589. In addition to commissioners' overarching duties on effectiveness, efficiency and continuous quality improvement under Part 1, *subsection (4)* of this clause requires commissioners, in designating services, to have regard also to (i) the current and future need for the provision of the service, (ii) whether the removal of the service would significantly reduce equality of access to the service and (iii) any other matter that may be specified in Monitor's guidance.
590. *Subsection (6)* requires Monitor to grant an application for designation if it is satisfied that the criterion in *subsection (3)* is met and if the commissioner has consulted as required under *subsection (2)*. Under *subsection (7)* Monitor must then give notice of the designation of the service to the commissioner and every relevant person, and explain the right of appeal.

Clause 70 - Appeals to the Tribunal

591. This clause allows a provider of a service to make an appeal to the First-tier Tribunal against a decision by Monitor to designate that service. Under *subsection (4)* the First-tier Tribunal may confirm or overturn the decision.
592. *Subsection (2)* states that an appeal can only be made if the provider has already made a complaint under the following clause about the designation and received notification from Monitor of its decision on the complaint. *Subsection (3)* specifies the grounds on which an appeal can be made.

Clause 71 - Reviews and removals of designations

593. This clause requires commissioners to review their designated services to ensure that they continue to meet the criterion for designation. Reviews would have to take place within a period of between one and ten years after either designation or each subsequent review. Monitor would be required to give guidance, as provided for later in this Chapter, on the carrying out of such reviews. This may include guidance on when, within the one to ten year period, they should be carried out.
594. This clause also allows a commissioner to apply to Monitor for the removal of the designation, whether or not as a result of a review. *Subsection (4)* provides that the commissioner may only make that application if it has consulted the relevant persons and it is satisfied that the criterion for designation no longer applies. The relevant persons are the same as those specified for the purposes of the clause on designation of services and might include potential providers of NHS services.
595. *Subsection (6)* requires Monitor to grant the commissioner's application if satisfied both that the criterion for designation no longer applied and that the commissioner had consulted the relevant persons. *Subsection (7)* requires Monitor to give notice to the commissioner and the relevant persons if the application is granted.
596. *Subsection (8)* provides that Monitor may also remove the designation following a complaint by a provider of the designated service, if satisfied that the criterion for designation no longer applied and if Monitor has consulted the commissioner that made the application for designation. Such complaints provide the gateway to appeals to the First-tier Tribunal, under the previous clause. *Subsection (9)* specifies the period during which such a complaint could be made. *Subsection (10)* requires Monitor to notify the provider, the commissioner and the relevant persons of a removal of a designation.

Clause 72 - Designations affecting more than one commissioner

597. This clause places a requirement on the NHS Commissioning Board to make arrangements for facilitating agreement between commissioning consortia about whether to apply for designation of a service and about which consortium is to apply

for designation. *Subsection (2)* provides that where commissioning consortia fail to reach such an agreement, the NHS Commissioning Board may intervene to determine the matter. *Subsection (3)* confers a power on the Secretary of State to make regulations to make provision about such a determination.

Clause 73 - Guidance

598. This clause requires Monitor to publish guidance on applications for designation of services, on reviews of designations, and on removal of designations. Guidance may develop the principles for designation further, for instance setting out how the designation process will work and giving examples of the types of service or cases when it might be expected that a service would be designated. *Subsection (2)* requires Monitor to consult certain relevant persons, as specified in *subsection (3)* and to agree the guidance with the NHS Commissioning Board before publishing it.
599. *Subsection (5)* allows Monitor to revise the guidance and requires it to re-publish where it has done so (before publishing it would have to go through the consultation and Board approval process under *subsection (2)*). This would enable Monitor to develop the guidance based on experience of how previous designation processes have operated or the outcomes of any national reviews of designated services.

Chapter 4 – Licensing

600. These clauses provide Monitor with the necessary powers to run a licensing regime. The licence would be the mechanism which would enable Monitor to carry out the majority of its regulatory functions, giving it the ability to collect information, set prices, promote competition and support the continuity of designated services. Monitor would determine the licence conditions that it would be necessary to impose on providers to enable effective regulation of NHS health care services, and would have a set of enforcement powers so that providers complied with the requirements of the licence.
601. The Care Quality Commission currently registers providers of health and adult social care services to provide assurance that they meet essential levels of quality and safety. It will continue to exercise this role. Monitor on the other hand would need to license providers of NHS services as a mechanism for delivering its economic regulatory functions such as setting prices, promoting competition and supporting continuity of services.
602. Monitor and the Care Quality Commission would need to work closely together on some issues. However, their remits would be distinct: the intention is that Monitor would carry out economic regulation while the Care Quality Commission is responsible for assuring essential standards of quality and safety. The two organisations would be under a duty to co-operate, with an equal duty to share information and provide for a joint licensing process.

Licensing requirement

Clause 74 - Requirement for health service providers to be licensed

603. It is common in regulated sectors (for example, electricity supply and gas distribution) to require providers to hold licences, and to deliver regulatory control via a licensing process. The scope of Care Quality Commission registration remains unchanged from the Health and Social Care Act 2008. This clause specifies which providers would be required to hold a licence issued by Monitor.
604. *Subsection (1)* stipulates that providers of health care services for the purposes of the NHS would have to hold a licence. This would not include services provided for public health purposes.
605. *Subsection (2)* also provides a mechanism for a case where two or more legal persons are involved, in different capacities, in providing a service. It provides that, in this situation, regulations may set out who will be treated as the service provider for the purposes of licensing. It is intended that this would be the person responsible for ensuring the service complies with the licensing requirements laid out in this (and any other relevant) legislation. This is based on section 10(2) of the Health and Social Care Act 2008, where the same provision is made for the purposes of registration with the Care Quality Commission.

Clause 75 - Deemed breach of requirement to be licensed

606. The effect of this clause would be that a licence holder would be in breach of the requirement to hold a licence if it had not also registered with the Care Quality Commission where necessary. The intention is that providers who need to be registered with both regulators would be able to apply via a joint licensing application process overseen by both Monitor and the Care Quality Commission. However, current providers would only have to apply for something that they did not already have – for instance, providers who were already registered with the Care Quality Commission would not have to re-register as part of the joint licensing process. Specific provision is made later in this Chapter about the requirements and processes that would apply to existing foundation trusts, which at present are already authorised by Monitor under current legislation.

Clause 76 - Exemption regulations

607. This clause provides the power for the Secretary of State to make regulations subject to the negative resolution procedure, exempting providers of NHS services from the requirement to hold a licence. Exemptions are designed to target licensing at those parts of the health sector where the sort of regulation that can be delivered via a licence is necessary (for example, where regulation of competition, pricing or to support continuity of services is necessary). The intention is to ensure that regulatory burden would not be imposed where it was not needed, keeping the system targeted

and proportionate. For example, GPs providing only traditional primary care ‘gatekeeper’ services might be exempted as, initially at least, they might not require sector-specific competition regulation or additional regulation to support the continuity of services. This approach is consistent with that adopted in other regulated sectors, such as electricity. Exemptions could be granted to individuals, groups of providers, or for certain types of health services.

608. It would be for the Secretary of State to grant an exemption under such regulations. *Subsection (4)* provides that before making exemption regulations, the Secretary of State would have to give notice to Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England (established in Chapter 1 of Part 5). It is common practice in other regulated sectors for the Secretary of State to have the ability to define classes of exemptions, and to make exemptions by order. That established model has been followed closely in this clause. However, the clause does stipulate broad parameters for the way in which the exemptions can be set. For example, *subsection (2)* provides that the regulations may specify that a particular exemption could apply generally (for example to a whole group of providers) or more specifically (for example to a subset of that group) and that it could apply indefinitely or subject to such period as specified in either the regulations or by the exemption.
609. Exemptions could also be granted subject to specific conditions which could include those listed in *subsection (3)*. For example a provider may have to inform the regulator if it planned to substantially expand or change the nature of the services that it offered, so that the regulator could determine whether the grant of the exemption to that provider was still appropriate.

Clause 77 - Exemption regulations: supplementary

610. This clause provides a mechanism for the Secretary of State to revoke or withdraw licensing exemptions. The exemption regulations themselves could be revoked or amended under *subsections (1) and (2)*, in relation either to an individual provider or a whole group of providers, to withdraw an exemption. Exemptions could be withdrawn in accordance with the relevant exemption regulations or if the Secretary of State considered it inappropriate for the exemption to continue. Under *subsection (1)* exemptions could also be withdrawn at the request of an individual provider to whom the exemption was granted.
611. Under *subsection (3)*, an exemption could be withdrawn by a direction made by the Secretary of State for a particular provider within a group, whilst the exemption remained in place for the rest of that group. Exemptions could be withdrawn where a person made a request, in accordance with the relevant exemption regulations, or if the Secretary of State considered it inappropriate for the exemption to continue.
612. When the exemption revocation or withdrawal was not for an individual provider at their request, the Secretary of State would have to consult Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England about

the proposed withdrawal, and give notice of the proposal in accordance with *subsections (5) and (6)*. The notice would have to state the Secretary of State's proposal and reasons for it, and specify a period during which representations can be made. The clause also specifies how the notice would have to be delivered in different circumstances: either by giving a copy to an individual provider, or by publishing the notice to bring it to the attention of an affected group of providers.

Licensing procedure

613. These clauses provide for the procedure for applying for a licence, and for Monitor in granting, refusing or revoking a licence.

Clause 78 - Application for licence

614. This clause states that providers seeking a licence must apply to Monitor, who could require such information from them as required and may specify the form in which any such application must be made.

Clause 79 - Licensing criteria

615. This clause requires Monitor to set and publish the criteria that a provider must meet in order to be granted a licence. *Subsection (3)* requires that these criteria would have to be approved by the Secretary of State. *Subsection (2)* provides that Monitor could revise these criteria, but would have to publish the revised version. This is intended to enable Monitor to adapt the licence as the market developed over time. The core licensing provisions made in this clause and the previous clause are based on provisions in the Electricity Act 1989. However, to ensure that the licensing process in the health sector would, from its outset, be as robust as it could be, the additional step of requiring the Secretary of State's approval of the initial set of criteria for granting licenses has been added.

Clause 80 - Grant or refusal of licence

616. This clause stipulates the process once an application for a licence has been made to Monitor. Where Monitor was satisfied that the provider had met the published criteria, it would have to approve the provider's application and, in accordance with *subsection (3)*, would have to issue the licence to the applicant. If it was not satisfied that the criteria were met, the application would have to be refused.
617. *Subsection (4)* provides that licences would be subject to both standard licence conditions and any special licence conditions. Further details about these conditions are found in later clauses. *Subsection (4)* also allows Monitor to set transitional licence conditions for foundation trusts designated as subject to transitional intervention measures (see "transitional provision" under this Chapter).

Clause 81 - Application and grant: NHS foundation trusts

618. Under this section an existing foundation trust would be automatically granted a licence by Monitor without needing to make an application. This is because these organisations have already been through a robust authorisation process in order to gain foundation trust status under Chapter 5 of Part 2 of the NHS Act, and have been granted Terms of Authorisation. This provision for the automatic granting of licences is designed to limit the regulatory burden on foundation trusts.

Clause 82 - Revocation of licence

619. This clause provides Monitor with the powers to revoke a licence, either because the licence holder has requested this, or because the provider has failed to comply with a licence condition. A revocation provision is common to regulatory regimes that rely on a licence to deliver regulatory functions. It is intended that Monitor would only revoke a licence on the application of a provider of designated services if it were satisfied that it was appropriate to do so having regard to the obligations on the licence holder to provide those services. It is also intended that before revoking a licence for failure to comply with a condition of it, Monitor would first consider whether it could address the situation using its licence enforcement powers.

Clauses 83, 84, 85 - Representations, notice and appeals

620. The first of this group of clauses requires Monitor to give the relevant provider advance notice when it proposes to either refuse or revoke a licence and to state the reasons for its intended course of action. This notice would also have to specify the period within which the provider could make written representations to Monitor, allowing them the opportunity to make a case against Monitor's proposal if they wished to. This period would have to be at least 28 days.
621. The second of these clauses specifies that once Monitor had reached a decision to either refuse or revoke a licence, it would have to notify the relevant provider of the right of appeal. The clause also stipulates when Monitor's decision to revoke a licence becomes final. This would be: if an appeal is brought, when the appeal is concluded or abandoned; when the provider declares its intention not to appeal; or, the day after the day that the period for bringing an appeal ended.
622. The third of these clauses provides the process for appeals to the First-tier Tribunal against a decision of Monitor to refuse a licence application or revoke a licence. The Tribunal is the leading appeals Tribunal in the UK, run by the Tribunals Service and established by Parliament under the Tribunals, Courts and Enforcement Act 2007. It has been chosen because it is also used for Care Quality Commission registration appeals and for other appeals relating to care standards and mental health issues (and as such has expertise in health and social care) and because it is also used for appeals against decisions by other regulators including the Office of Fair Trading and the Environment Agency. *Subsection (2)* specifies the possible grounds for appeal as an

error of fact, a legal error, or unreasonableness. The Tribunal might either confirm Monitor's decision, direct that Monitor's decision is not to have effect, or send the case back to Monitor for reconsideration.

Clause 86 - Register of licence holders

623. Monitor is required by this clause to keep and publish a register of licence holders, as the Care Quality Commission is required to do under the 2008 Act. The register should contain such information as Monitor thinks necessary to keep the public informed about licence holders, including details of every licence granted or revoked. These provisions are intended to create transparency so the information would be available to the public for inspection at Monitor's offices or available on request. However, there might be occasions on which it was not appropriate to release certain information to the public. The clause therefore allows regulations to be made setting out what information should not be accessible. This follows the procedure for the register kept by the Care Quality Commission (see section 38 of the Health and Social Care Act 2008).

Licence conditions

624. These clauses specify the different licence conditions that Monitor can set. Standard conditions would apply to all providers, or to all providers of a certain type (either those providing a particular service, or those in a particular geographic area). Special conditions are intended to meet unique requirements for individual providers. Creating different types of conditions means that providers would have some certainty over what a licence would entail (standard conditions) whilst Monitor retained sufficient flexibility to tailor licences as appropriate (special conditions).

Clause 87 - Standard conditions

625. This clause requires Monitor to set and publish the standard licence conditions. Standard conditions might include basic requirements necessary to support the regulator in exercising its functions, such as submitting the information about service provision that Monitor would need to set prices effectively.
626. Before determining the first set of standard conditions, Monitor would have to publish its draft standard conditions and consult the persons listed in *subsection (8)*, which include the Secretary of State and the NHS Commissioning Board.
627. *Subsections (2) to (6)* allow Monitor to set different standard conditions for different types of licences by reference to the nature of the provider, the services provided or the area in which services are provided. The intention is to seek to achieve a level playing field for providers by giving Monitor sufficient flexibility to set different licence conditions in these circumstances so as to establish a consistent regulatory framework for different types of provider, be they foundation trusts, PLCs, charities, Community Interest Companies or other provider types. *Subsections (4) to (6)* also

impose appropriate constraints on Monitor's ability to set differential licence conditions relating to the nature of the provider. In particular, different conditions might be necessary so that the burdens to which different licence holders were subject as a result of holding a licence were broadly consistent.

628. The Secretary of State is given the power in *subsection (10)* to reject Monitor's proposed first set of standard conditions, as a whole rather than as individual conditions.

Clause 88 - Special conditions

629. The power to include special licence conditions under *subsection (1)* is designed to address specific concerns and is intended for use in exceptional situations, where the degree of differentiation possible in the standard conditions is not sufficient. For example, where a licence condition might only need to apply to a specific provider due to it having an exceptional service, or where a condition might be needed to address a specific financial or governance issue particular to a provider.

630. Monitor would be able to include a special condition (or modify an existing one) if the applicant or licence holder consented. If that party did not agree and Monitor still wanted the special condition or modification to be included in the licence, it would need to make a reference to the Competition Commission for an investigation by it, in a similar way as occurs in relation to special licence conditions in the gas, electricity and water sectors.

631. Before including a special condition, or modifying one, Monitor would have to comply with the notice requirements in *subsections (2) to (5)*.

Clause 89 - Limits on Monitor's functions to set or modify licence conditions

632. This clause specifies the purposes for which Monitor is empowered to set or modify licence conditions. Monitor would only be able to set licence conditions for the purposes of its regulatory functions specified in *subsection (2)*.

Clause 90 - Conditions: supplementary

633. *Subsection (1)* provides, by way of example, a list of conditions that Monitor might include in licences. These include a requirement for licence holders to pay to Monitor such fees as Monitor may determine in respect of the exercise of its licensing functions and a requirement to charge for services in accordance with the national tariff (see Chapter 5). *Subsection (7)* gives Monitor the power to apply time restrictions to conditions, either by indicating when a condition should take effect or when it should end.

634. *Subsections (3) and (4)* make further provision about conditions under *subsection (1)(c)*, which gives one provider access to another provider's services (defined by

clause 135 to include facilities). It is intended that this would be used to give new entrants to the market access to existing infrastructure or equipment that it would be uneconomic to re-provide. There is precedent for this in other regulated sectors – for instance similar access provisions have been introduced in relation to access to postal facilities and telephone exchanges, as well as in the water and electricity sectors. In these circumstances, Monitor would have to have regard to the practicability of a comparable service being installed and of requiring this access, the investment made by the provider in the service, and the need to promote competition.

Clause 91 - Modification of standard conditions

635. Provision is made in this clause for modification of standard licence conditions in all providers' licences or in licences of a particular description. Before making such a modification, Monitor would have to comply with the notice requirements set out in *subsections (2) to (5)* which require Monitor to notify its intention to modify standard licence conditions and offers the opportunity for relevant licence holders to object.
636. Under *subsection (6)(a)* Monitor could make the modification if it received no objections from relevant licence holders.
637. In order for Monitor to be able to make the modification where it did receive such objections, the proportion of licence holders objecting would have to be less than proportions specified by the Secretary of State in regulations - which would be subject to the affirmative resolution procedure - made under *subsections (7) and (9)*. Two proportions would be specified: a proportion of affected providers who were objecting (the "objection percentage"), and a proportion of affected providers who were objecting, weighted according to their share of supply (the "share of supply percentage"). This process is designed to balance the desirability of providers having a say in the design of the licence with Monitor's need to be able to modify standard conditions. This approach has been adopted in other sectors, most notably gas and electricity.
638. Other provisions of this clause deal with the situation where Monitor modified the standard licence conditions. *Subsection (10)* provides that, firstly, Monitor would have to publish the modifications. Secondly, Monitor would be given the power to make modifications to other conditions in a licence that might be required as a consequence. Thirdly, Monitor would also be required to make the same modifications to future licences. The latter two requirements are intended to ensure consistency across licences.

Clause 92 – Modification references to the Competition Commission

639. Under *subsection (2)* Monitor could make a reference to the Competition Commission when the applicant or licence holder refused to accept a proposal to include or modify a special licence condition. Under *subsection (4)* a reference could also be made where Monitor was unable to modify the standard licence conditions because too

many licence holders objected to the conditions. This is the case in other regulated sectors such as the water, electricity and gas sectors.

640. A reference to the Competition Commission would require it to investigate whether there was an issue that needed addressing because it was operating, or was expected to operate, against the public interest. The Commission would be required to consider whether a special condition or standard condition could remedy or prevent the problem. Under *subsection (6)* the Commission would be required to take into consideration Monitor's general duties and the matters to which it must have regard under Chapter 1 of this Part.
641. If one part of a standard licence condition were modified under this procedure, *subsection (7)* provides that the remainder of the condition would still be valid as a standard licence condition.
642. *Subsection (5)* of this clause also gives effect to Schedule 8 and defines who are the "relevant persons" for the purposes of notices under specified provisions of that Schedule.

Schedule 8 - References by Monitor to the Competition Commission

643. This Schedule is based on sections 12 to 14A of the Electricity Act 1989.

Variation of reference

644. Under paragraph 1, where Monitor has made a reference to the Competition Commission it would be able to change what is included in that reference by giving notice to the Commission. The Commission would be obliged to accept the variation.

Monitor's opinion of public interest etc

645. Paragraph 2 is intended to enable Monitor to assist the Competition Commission by identifying in a reference or variation of a reference, any aspects of the referred matter that might have an adverse effect on the public interest, and by suggesting any alterations to licence conditions to avoid or remedy these effects.

Publication etc of reference

646. As soon as practical after making a reference or varying a reference, a copy would have to be sent to relevant persons and published by Monitor.

Information

647. This paragraph requires Monitor to provide relevant information and assistance to the Commission whenever the Commission investigated a reference. The Commission

would be required to take the information supplied into account.

Time limits

648. Under this paragraph, a reference to the Competition Commission would have to give a specific notice period – not longer than six months from the date of the reference – within which the Commission would have to report on the reference. The Commission’s report would only have effect if made before the period stated in the reference or at the end of an extended period where special reasons existed for extending the period. An extension could be for no more than a month and could only be made once. Monitor would have to send notice of the extension to the relevant persons, and publish the notice.

Reports on references

649. When reporting on a reference, the Commission would have to present its conclusions, including details of any aspects it concludes might have negative impacts on the public interest. There should also be explanations as to how the adverse effects that had been identified could be remedied or prevented by changes to the licence conditions.
650. This paragraph requires that a conclusion in a report would have to have the agreement of at least two thirds of the group assigned to the investigation. Should a member of the group disagree with a conclusion, a statement would have to be included in the report if that person so wished, explaining why that person disagreed. Monitor would have to receive a copy of a report on a reference and, in turn, send a copy to the Secretary of State, the NHS Commissioning Board and a copy to the relevant persons within 14 days.

Changes following report

651. This paragraph concerns any report of the Commission on a reference that contains conclusions indicating that one or more matters are unfavourable to the public interest, that they could be prevented or minimised and suggesting changes to achieve this. Where this was the case, Monitor would have to make the necessary changes to resolve the matter. Before doing so, Monitor would have to publicise the proposed changes to the relevant persons, explaining why it is taking such action and giving the period – of at least 28 days from the date of publication - within which comments on the changes could be made. Once Monitor had considered the responses, it would have to notify the Commission, specifying the changes that were to be made.

Competition Commission’s power to veto changes

652. There would then be a four week period from the date of Monitor’s notice to the Commission during which the Commission could veto the changes. If the Commission did not veto the changes, Monitor would have to make them. During this

period, the Commission could direct Monitor not to make the changes set out in the notice, or not to make some of the changes. The Commission would have to give notice of the changes Monitor proposed and its reasons for directing Monitor not to make them, allowing time for representations to be made on the proposed changes. In this situation, the Commission would itself have to make such changes to the relevant matters as it thought necessary to remedy the expected adverse effects on the public interest.

653. In undertaking this task, the Commission would have to take into account the matters to which Monitor must have regard.
654. Once the changes had been made, the Commission would have to publish the fact that the changes had been made and why it had made them.

Disclosure

655. This paragraph requires the Commission, before making a report or giving notice in relation to its power to veto Monitor's proposed changes, to ensure that no information harmful to the public interest is included in the report or notice. Likewise, no sensitive commercial information, or personal information related to any person concerned in the matter, should be included. All information disclosed would have to be necessary for the purposes of the report.

Powers of investigation

656. A number of investigative and enforcement powers under specified sections of Part 3 of the Enterprise Act 2002 would apply for the purposes of references by Monitor to the Commission.

Clause 93 - Modification of conditions by order under other enactments

657. This clause provides that the Office of Fair Trading, the Competition Commission and the Secretary of State, as relevant authorities, can modify standard conditions or conditions of a particular licence, by an order made under various specified provisions of the Enterprise Act 2002. This provision is designed to ensure that the licensing regime would be consistent with competition law and enforcement powers in that Act and to enable the relevant authorities to modify conditions to remedy or prevent adverse effects on competition. The inclusion of a provision of this type is consistent with other regulatory regimes. These provisions mean that the modifications could be made if:

- where one or more enterprises was or may have ceased to be a distinct enterprise, one of them was a provider of licensable services;
- where one or more enterprises would or might cease to be a distinct enterprise,

one of them was a provider of licensable services; or

- a feature of a market which relates to the commissioning or provision of services for the purposes of the NHS, prevents, restricts or distorts competition.

Enforcement

658. These clauses provide Monitor with the necessary powers to enforce its licensing requirements. Whilst the joint licensing regime would be overseen by both Monitor and the Care Quality Commission, the two organisations would have separate responsibilities regarding enforcement, although they would be obliged to share information about relevant enforcement actions taken. Monitor's enforcement powers are modelled on the set of civil sanctions for regulatory regimes laid down in Part 3 of the Regulatory Enforcement and Sanctions Act 2008.

Clause 94 - Power to require documents and information

659. *Subsection (1)* provides Monitor with a power to require persons listed in *subsection (2)* to provide to Monitor any information that it needs to carry out its regulatory functions, which are specified in *subsection (4)*. This is the broadest of the enforcement powers because it applies to commissioners, applicants for licences, licensees, providers exempted from holding a licence or providers operating without a licence when they should have one. It is intended to allow Monitor to obtain the information it needs to operate effectively and fulfil its functions. For example, Monitor could require a provider to submit information about its financial situation to support regulatory work to protect continuity of services, or about its prices to support tariff calculation.

660. Information might also be needed from providers who are currently exempted from licensing – for example, if Monitor and the NHS Commissioning Board decided to extend the scope of tariff pricing to a new service, and needed information on the prices of these services to do so.

Clause 95 - Discretionary requirements

661. 'Discretionary requirements' are obligations which Monitor could place upon a provider of NHS services in response to it breaching a licence condition, or failing to hold a licence when it is required to, and upon any person for failure to provide information to Monitor under the previous clause. They would act as both an incentive to a person to comply, as well as a means of rectifying any problems that arose as a result of a person's action or failure.

662. The types of discretionary requirements that Monitor could impose are outlined in *subsection (2)*. They are:

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

- a monetary penalty of such amount as Monitor may determine, up to 10% of turnover of the person in England (‘variable monetary penalty’);
- action to stop the breach in question, or make sure it did not happen again (‘compliance requirement’). An example of this might be a requirement that a provider cease plans to dispose of an asset that was needed for the provision of a designated service;
- action to restore the position to what it was before the breach occurred (‘restoration requirement’). For example, Monitor could require that a provider re-open a designated service that it had closed inappropriately or without regulatory approval.

663. The Secretary of State is given power by regulations to prescribe how turnover would be calculated for the purposes of the limit on variable monetary penalties (*subsection (4)*).

664. *Subsection (3)* provides that Monitor would not be able to impose discretionary requirements on a provider in relation to the same breach on more than one occasion.

665. *Subsection (5)* provides that a penalty imposed under this section that was not paid in full would accrue interest, but the total amount of interest charged could not exceed the amount of the penalty itself.

Clause 96 - Enforcement undertakings

666. ‘Enforcement undertakings’ are not sanctions imposed by Monitor but are settlements offered by a provider to rectify a breach (being a breach of licence conditions, providing services without holding a licence where a licence is required, or failing to provide Monitor with information).

667. Monitor could choose whether to accept the offered settlement, based on whether it was likely to constitute an appropriate remedy. Enforcement undertakings could be used in the same circumstances as discretionary requirements (see above). Having scope in the system for enforcement undertakings offers a positive behavioural incentive as it encourages providers to take responsibility for proposing solutions to problems, and thus to be proactive about remedying licence breaches.

668. Various types of enforcement undertaking are specified in *subsection (3)*:

- action to stop the activity in breach of the licence, or make sure it does not happen again;
- action to restore the position to what it would have been before the breach occurred, so far as is possible;

- action to benefit any licence holder or commissioner affected by the breach, which could be payment of money; or
- other action as may be specified in regulations.

669. Once Monitor had accepted an enforcement undertaking, it could only impose a discretionary requirement or revoke a licence if the licensee failed to comply with the undertaking, or any part of it. *Subsection (5)* provides that where a provider had partially complied with an undertaking, Monitor would have to take these actions into account when deciding whether to take further enforcement action.

Clause 97 - Further provision about enforcement powers

670. This clause gives effect to Schedule 9, which provides further detail about both discretionary requirements and enforcement undertakings.

Schedule 9 - Further provision about enforcement powers

Part 1 - Discretionary requirements

Procedure

671. The procedure for discretionary requirements follows that laid down in section 43 of the Regulatory Enforcement and Sanctions Act 2008.
672. This paragraph requires Monitor to give notice to a person of its intention to impose a discretionary requirement upon them. The notice would have to provide certain details stipulated at paragraphs (a) to (d), including the grounds for the proposal to impose the requirement, and the notice period within which written representations may be made by the provider, which must be at least 28 days.
673. Monitor would be able to shorten the notice period (to a minimum of five days) for a compliance or restoration requirement. This would only be possible where Monitor considered a shorter period was necessary to avoid or minimise further breaches of licence conditions. For example, a shorter period might be necessary to require a provider of designated services, who had stopped providing those services, to restore provision of them.
674. Having given notice, where Monitor decided to impose a requirement, a second and final notice would have to be given to the provider. It would have to include information about why the requirement was being imposed, the implications of failure to comply with the requirement, details of how any monetary penalty is to be paid, and explain the rights of appeal.
675. The notice would have to be given within five years of the breach occurring if

Monitor wished to impose a fine.

676. Appeals about the imposition of a discretionary requirement could be made to the First-tier Tribunal. During an appeal, the duty to fulfil the discretionary requirement(s) being appealed would be suspended. There would be a number of grounds for appeals:

- that the decision was based on a factual error;
- that the decision was wrong in law;
- that the amount of a variable monetary penalty was unreasonable;
- that action required by Monitor was unreasonable (in the case of either compliance requirements or restoration requirements);
- that the decision was unreasonable for any other reason.

677. There are a number of actions that the First-tier Tribunal could take following the appeal, including confirmation or rejection of the requirement in question, or a variation of it. It could also take steps that Monitor could take in relation to a breach or remit the decision to Monitor.

Non-compliance penalties

678. These paragraphs give Monitor the power to impose a monetary penalty (a “non-compliance penalty”) on a person who fails to comply with a compliance or restoration requirement, and to determine the amount of the monetary penalty. When proposing to impose such a penalty, Monitor would have to serve a “non-compliance notice” on the person concerned. This would have to include details of the monetary penalty and how and when it was to be paid, the grounds for imposing the penalty, the consequences of failing to pay the penalty and the appeals process.

679. The period for payment could not be less than 28 days from the day after the date that the notice was received. If the person on whom the notice was served complied with the compliance requirement within that period the payment would cease to be due. If the payment remained due and was not paid within the specified payment period, Monitor could increase the penalty by no more than 50%.

680. The grounds on which a person served with a non-compliance penalty could appeal to the First-tier tribunal are set out in paragraph 5(2). Penalties would be suspended whilst an appeal was in progress. The Tribunal could confirm, change or withdraw a non-compliance penalty, or remit the decision to Monitor for reconsideration.

Recovery of financial penalties and payments of penalties etc. into Consolidated Fund

681. Both variable monetary penalties and non-compliance penalties would be recoverable summarily as a civil debt. In addition, Monitor would have to pay money it received from penalties into the Consolidated Fund.

Part 2 – Enforcement undertakings

Procedure

682. These paragraphs stipulate that Monitor must consult upon and then publish a procedure for entering into enforcement undertakings. It would be able to revise that procedure but it would have to publish any revision. Monitor would also have to publish details of each enforcement undertaking it accepted.

Variation of terms

683. The terms of an enforcement undertaking could be modified when both Monitor and the person giving it agreed to do so. This is intended to provide the flexibility to alter the agreement if necessary, for example if for legitimate reasons accepted by the regulator a provider took longer to carry out a remedial measure than was originally planned and agreed.

Compliance certificates

684. Monitor would have to issue a compliance certificate when it was satisfied that a person has complied with an enforcement undertaking given by them. Certificates could be applied for at any time by persons who had given an enforcement undertaking.
685. An appeal to the First-tier Tribunal could be made against a decision of Monitor to refuse an application for a compliance certificate, on the grounds that the decision was based on an error in fact, was wrong in law, or was unfair or unreasonable. The Tribunal could confirm Monitor's decision or decide that it did not have effect.

Inaccurate, incomplete or misleading information

686. If Monitor is satisfied that information supplied by a person in relation to an enforcement undertaking was inaccurate, misleading or incomplete, the person is treated as having failed to comply with the undertaking and Monitor must revoke any compliance certificate given to that person.

Clause 98 - Guidance as to use of enforcement powers

687. This clause requires Monitor to consult on and publish guidance about the way in which it will exercise its powers to impose discretionary requirements and to accept

enforcement undertakings (*subsection (1)*). *Subsection (5)* provides that Monitor would then have to have regard to the published guidance in exercising those powers. Guidance is intended to provide licensees with certainty as to the enforcement action Monitor would take in particular circumstances.

688. *Subsection (4)* provides that the guidance must include details of when Monitor was likely to impose a discretionary requirement and when it may not impose one, how it would decide the amount of variable monetary penalties, and how decisions could be appealed.

Clause 99 - Publication of enforcement action

689. *Subsection (1)* provides that Monitor must include information in its annual report on discretionary requirements imposed and enforcement undertakings accepted that it has taken during the financial year that the report covers. Under *subsection (2)* Monitor would not be able to include information if it was satisfied that publication of it would or might significantly harm the legitimate business interests of the licence holder concerned.

690. *Subsection (3)* provides that Monitor is not to include in the report information about discretionary requirements that were imposed but then overturned on appeal.

Clause 100 - Notification of enforcement action

691. This clause provides that Monitor must notify the NHS Commissioning Board, affected commissioning consortia and other relevant regulators of discretionary requirements imposed by it and of enforcement undertakings accepted by it. This is designed to ensure that information about provider performance, which may be relevant to the duties and functions of commissioners and other regulators, would be shared appropriately.

Transitional provision

Clause 101 - Designation of NHS foundation trusts during transitional period

692. This clause empowers Monitor to designate foundation trusts on whom it would be able to impose additional licence conditions for a limited period. *Subsection (1)* provides that in order to identify such trusts, Monitor would first set and publish criteria, after consultation with a number of specified parties (*subsection (2)*). It would then assess each foundation trust against these criteria and submit to the Secretary of State a notice as to which trusts should be designated for these purposes. *Subsection (3)* provides that the designation of a foundation trust authorised before the commencement of this Chapter may not come into effect until the Secretary of State has given his approval, which must be within 28 days of receiving the notice from Monitor.

693. Where an NHS Trust was authorised to become a foundation trust after the commencement of this Chapter, Monitor would be able to designate it without the approval of the Secretary of State (*subsection (6)*).
694. In each case, a designated foundation trust would be subject to any transitional licence conditions imposed on it under the next clause for two years from the date of its designation, unless Monitor removed its designation before the end of that period because it was satisfied that the published criteria no longer applied (*subsection (9)*). Once Monitor removed a designation it would not be able to re-impose it. *Subsection (10)* provides for the Secretary of State to extend this two-year period by an order which is subject to the affirmative resolution procedure.

Clause 102 - Imposition of licence conditions on designated NHS foundation trusts

695. *Subsection (2)* allows Monitor to impose transitional licence conditions on a foundation trust designated under the previous clause, where it is satisfied that such conditions are appropriate for reducing a significant risk that the trust will fail to fulfil its principal purpose (see section 43(1) of the NHS Act). *Subsection (3)* provides that any such conditions would remain in place until the trust's designation expired, although Monitor would be able to modify them under *subsection (4)*.
696. *Subsection (5)* provides Monitor with compliance powers that it can use if satisfied that a designated foundation trust is in breach of a transitional licence condition during the period of its designation (*subsection (7)*). For example, Monitor could place requirements on the trust to do or not to do specified things, or remove or suspend one or more directors or governors of the trust.
697. *Subsection (8)* provides that *subsection (5)* does not prevent Monitor from imposing discretionary requirements or accepting enforcement undertakings in relation to transitional licence conditions imposed under *subsection (2)*.
698. *Subsection (12) repeals section 52 of the NHS Act (failing NHS foundation trusts)*.

Chapter 5 – Pricing

699. These clauses provide Monitor with powers to set prices for NHS services, subject to the agreement of the NHS Commissioning Board, in order to promote competition and maximise productivity.

Clause 103 - Price payable by commissioners for NHS services

700. This clause sets out how prices would be specified and used for the payment of health care services provided for the NHS. In relation to services covered by the national tariff (see the next clause) it allows for those services to be provided at a standard price or a maximum price, with flexibility to negotiate below that price.

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701. In relation to services not covered by the national tariff and, as such, not subject to standard or maximum prices, the price payable would be determined by rules set out in the national tariff to cover such circumstances.
702. The commissioners who would have an interest in pricing are those that are responsible for arranging provision of health care services for the purpose of the NHS. This would include the NHS Commissioning Board, commissioning consortia, and the Secretary of State where section 13V of the NHS Act (inserted under Part 1 of this Bill) applies.

Clause 104 - The national tariff

703. This clause requires Monitor to publish “the national tariff”, a document that makes provision about pricing of health care services. That document would have to:
- specify the range of health care services to which it will apply;
 - specify the methodology that had been employed by Monitor to produce price levels;
 - specify the resultant price levels for those services;
 - provide rules for determining prices for services not specified as being covered by a national tariff;
 - provide for rules under which providers and commissioners could make modifications to the national tariff prices; and
 - include guidance as to the application rules included in the national tariff.
704. The national tariff would be able to specify different prices according to whether a service was a designated service (under Chapter 3 of this Part) or in relation to different types of provider. Prices specified in the national tariff would not be able to include prices for public health services.
705. The national tariff would have effect for such period as specified in the tariff or until a new edition of the tariff took effect.
706. Monitor would have to have regard to the mandate set by the Secretary of State (published under section 13A of the NHS Act, inserted under Part 1 of this Bill) when setting its national tariffs.

Clause 105 - Consultation on proposals for the national tariff

707. This clause requires that agreement must be reached between Monitor and the NHS

Commissioning Board regarding:

- services for which the national tariff would apply;
- the rules governing local modification of national prices;
- the pricing methodology;
- the prices themselves; and
- the rules on setting prices not covered by the national tariff.

708. If agreement could not be reached, independent arbitration would be used to facilitate agreement.
709. Before publication of the national tariff, Monitor would have to notify all commissioners, licence holders and others it considered appropriate – for example providers in the market not currently providing NHS services - of the proposed national tariff document. The notice would also have to be published and would specify the consultation period within which objections could be made (which may not be less than 28 days after publication).
710. At the time of publication of the first national tariff, licence holders may not yet exist. Therefore those who provide health care services for the NHS would be treated as if they were licence holders.

Clause 106 - Responses to consultation

711. This clause sets out the process for commissioners and licence holders to challenge the methodology used to set prices. Where an objection were made, the tariff could only be published where either the conditions in *subsection (2)* of this clause were met or, if they were not met, where Monitor had made a reference to the Competition Commission.
712. The conditions in subsection (2) are that the percentage of commissioners or licence holders who objected to the pricing methodology (“the objection percentage”) and the percentage of licence holders, weighted by their share of supply, who objected to the pricing methodology (“the share of supply percentage”) were both less than percentages prescribed by the Secretary of State in regulations..
713. This clause also gives effect to a Schedule which makes provision about the procedure for these types of references which is different from the procedures applicable to the Competition Commission under the Competition Act 1998 in relation to other types of reference.

Schedule 10 - Procedure on references under section 106

714. This Schedule outlines the procedure for the Competition Commission in relation to references made by Monitor regarding the national tariff.
715. In making a reference to the Competition Commission, Monitor would have to outline its reasons for the proposed pricing methodology. After the reference had been made an objector to the methodology would be subject to certain time limits in making representations on that reference. Monitor would be able to reply to these representations but would also be subject to specified time limits.
716. The Chairman of the Commission would have to select a group to carry out its functions to consider any such reference, make a determination and give directions to Monitor in relation to it. Paragraph 3(1) to (6) makes provision about the constitution of the group. Sub-paragraph (7) provides that a decision of the group would only be effective if all members were present when the decision was made and two of the three members were in favour of the decision.
717. Paragraph 4 makes provision about the timetable for references. The group would have to make a determination within 30 working days of the last date on which a reply to representations on the reference could be made by Monitor. Under certain circumstances this deadline could be extended by the group (by not more than 20 working days and not more than once). The extension would need to be notified to Monitor, the NHS Commissioning Board and the objectors.
718. Paragraph 5 provides that the Commission could also disregard representations of commissioners where those matters were not raised during the consultation period or matters raised by Monitor in response to objections that it did not include in the reference, if it felt this was necessary in order to reach a determination.
719. Paragraphs 6 to 8 make provision to enable the Commission to require information in order to help it make its determination. The information could take the form of documents, evidence at oral hearings or written statements. Paragraphs 10 and 11 make provision relating to evidence, including provision about default. A failure to provide information or the provision of false information could result in the provider of the information being found in contempt of court. However, no person could be compelled to provide information that it would not be forced to under civil proceedings in the High Court.
720. The Competition Commission could also make rules on the procedure to be followed in making determinations on references under the clause on consultation responses. In particular, this could include time limits applied to the oral evidence.
721. The costs of making a determination on a reference under this Part would have to be paid, in accordance with an order made by the group, by the unsuccessful party. If the pricing methodology needed to be changed, Monitor would pay the costs incurred by

the Commission. If the Commission determined that the methodology could be implemented without changes objectors would have to pay the costs incurred by the Commission (those costs could be apportioned where there was more than one objector).

Clause 107 - Determination on reference under section 106

722. This clause makes provision about the Competition Commission's role following a reference. After a reference following objections to the pricing methodology, the Competition Commission would have to make a determination as to whether the pricing methodology was appropriate, having regard to the matters to which Monitor must have regard in relation to pricing methodology, and taking into account both any representations made by licence holders and anything that Monitor did not consider when proposing the methodology (although only where Monitor would have been entitled to consider it but was unable to at the time).
723. If the Commission determined that Monitor had set the pricing methodology appropriately, Monitor would be able to use that method for the purpose of the national tariff.
724. The Commission would be able to determine that Monitor had not set the pricing methodology appropriately only in the circumstances set out in *subsection (4)*. Those circumstances are where Monitor had failed to have regard to matters relating to pricing methodology to which it was required to have regard or where the decision had been based on an error of fact or was wrong in law. In those circumstances the Commission would have to refer the methodology back to Monitor with the reasons for its decision.
725. The adjudication process that would be used by the Competition Commission in making its determination is based on the process used in the energy sector for code modification appeals under section 173 of the Energy Act 2004.

Clause 108 - Changes following determination on reference under section 106

726. When the Commission had referred the matter back to Monitor, Monitor would have to make the necessary changes to deal with all the issues raised in the determination. Monitor would then be able to implement the revised methodology unless the Competition Commission exercised its power of veto.

Clause 109 - Power to veto changes proposed under section 108

727. Within 28 days of receiving the revised pricing methodology from Monitor, the Commission would be able to direct Monitor not to implement the proposed changes or not to implement changes specified in the direction. The Commission would have to inform Monitor and the NHS Commissioning Board of this decision and make the necessary changes to the pricing methodology itself. The power of veto is intended to

give the Commission the opportunity to prevent Monitor from making changes that do not adequately deal with the Commission's determination on a reference.

Clause 110 - Local modifications of prices of designated services: agreements

728. This clause specifies the process for a provider of a designated service and the commissioner to agree modification of price levels in the national tariff if the standard or maximum price did not allow it to cover costs even with an efficient service. This is intended, for example, to allow providers to negotiate an exceptional subsidy to the tariff price where pricing levels do not cover costs.
729. Where the provider and commissioner agreed locally, the local provider would have had to present an evidence-based case that the modification was needed. When agreement on the need for a subsidy had been reached, Monitor would have to approve the agreement only if it was satisfied that it would be uneconomic for the provider to continue to provide services without it.
730. Where an agreement is made, Monitor would have to give notice in accordance with *subsections (6) to (8)*.

Clause 111 - Local modifications of prices of designated services: applications

731. This clause deals with situations in which agreement to a local modification between the commissioner and provider has not been reached. In such circumstances, the provider in question would be able to apply to Monitor for a local modification. This application would have to include evidence on why the modification was needed. Monitor would then make a decision on whether it would be uneconomic for the provider to continue to provide the service without the modification. Monitor would then be able to grant the application and determine the price of the designated services. Monitor would have to give notice of any such decision in accordance with *subsections (6) to (8)*.
732. If the NHS Commissioning Board did not agree with the decision of a subsidy, it could consult on whether the service concerned should be de-designated, and the process for de-designation of services (specified in Chapter 3 of this Part) would apply. The modified price would apply until the service is de-designated.

Clause 112 - Correction of mistakes

733. If a mistake were found in the national tariff so that the tariff did not reflect what was agreed between Monitor and the NHS Commissioning Board or what was determined by arbitration, corrections could be made. Monitor would have to notify all commissioners, licence holders and other persons as it considered appropriate of the mistake and the correction and specify the date on which the correction would take effect (which could be before the notification).

Chapter 6 – Insolvency and health special administration regime

734. These clauses make provision for regulations to establish a special administration regime for health as an alternative to ordinary insolvency procedures under the Insolvency Act 1986. The intention is that where a provider of designated services fails, a special administration regime would provide for continuity of those services. In other sectors of the economy delivering essential public services (for example, the transport and utilities sectors) special administration regimes are in place, as an alternative to normal corporate insolvency procedures, to ensure the continuity of those services where a provider fails.
735. Foundation trusts are outside of the scope of the Insolvency Act 1986. This Chapter therefore also makes provision for the application of normal corporate insolvency procedures, by regulations, to foundation trusts.

Clause 113 - Application of insolvency law to NHS foundation trusts

736. This clause removes the existing (and non-operational) failure arrangements set out in sections 53 to 55 of the NHS Act and obliges the Secretary of State to make secondary legislation as soon as is practical to apply existing corporate insolvency procedures to foundation trusts. Those procedures are company voluntary arrangements, administration and winding up as set out in Parts 1, 2 and 4 of the Insolvency Act 1986 respectively, and schemes of arrangement and reconstruction set out in Part 26 of the Companies Act 2006.
737. This would assist in ensuring a level playing field between foundation trusts and other providers, and the procedures could facilitate the rescue of a failed foundation trust (for example, through administration or a voluntary arrangement with creditors) or enable the affairs of a trust to be wound up in the best interests of its creditors (for example, through voluntary or compulsory liquidation). Introducing an effective failure regime would allow for orderly market exit. It would also mean that trust directors would be under similar obligations to company directors since offences that may be prosecuted under the insolvency legislation would be applied through regulations and disqualification proceedings could be taken against directors who were held responsible for misconduct.
738. Health special administration, provided for in the rest of this Chapter, would provide an alternative insolvency resolution process to ensure the continuity of designated services if a foundation trust (or any other provider of designated services) were to fail. Normal insolvency processes would therefore only be appropriate to deal with the failure of a foundation trust that was providing wholly non-designated services.
739. Introducing these procedures would also facilitate the commencement of health special administration in appropriate cases (for example, where steps are taken by a creditor to initiate ordinary insolvency and Monitor intervenes to seek a health special administration order from the court) and, in keeping with existing insolvency law and

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practice, these procedures may also provide appropriate exit routes from health special administration.

740. *Subsection (2)* inserts a new section 55A to the NHS Act. This new section specifies that the procedures which would be applied by the regulations are company voluntary arrangements, administration, winding up and other provisions as set out in Parts 1, 2, 4 and 6 of the Insolvency Act 1986 respectively, and schemes of arrangement and reconstruction and related provisions as set out in Part 26 of the Companies Act 2006.
741. The new section also provides that these corporate insolvency procedures may be applied to foundation trusts with any necessary changes, for example to reflect the unique legal status, structure and constitution of those bodies as public benefit corporations.
742. Given the technical nature of insolvency law and the public interest in dealing with the failure of a foundation trust, *subsection (6)* of the new section requires the Secretary of State to consult before making regulations. Regulations made under these provisions would be subject to the affirmative resolution procedure in Parliament.
743. *Subsections (3) and (4)* of the new section provides that insolvency rules would be made in the normal way under section 411 of the Insolvency Act 1986 to support the regulations and make them workable in practice.

Clause 114 - Health special administration orders

744. This clause specifies what is meant by a health special administration order, which is the order that Monitor would be able to seek from the court if a foundation trust or company providing designated services (which may include those in the independent sector) failed.
745. An application for a health special administration order could only be made by Monitor and would only apply to providers of designated services. Where the court made such an order, a health special administrator would be appointed and would be required to exercise his functions as specified in *subsection (4)*.
746. Under *subsection (4)*, the health special administrator would be obliged to manage the affairs, business and property of the provider to achieve the objective of health special administration (see next clause) as quickly and efficiently as reasonably practical. In doing so, the administrator would have to ensure that the provider continued to comply with the requirements and conditions of the Care Quality Commission's provider registration regime (provided for in Part 1, Chapter 2 of the Health and Social Care Act 2008). The health special administrator would also be required to act in a manner which, insofar as it was consistent with the objectives of a health special administration, protected the interests of the creditors of the provider as a whole, and, subject to those interests, the interests of members (where the provider was a

company).

747. *Subsection (5)* establishes that a health special administration order would only apply to the affairs and business of a non-GB company (that is, a company incorporated outside Great Britain) which are carried on in Great Britain and to its property in Great Britain. This is consistent with a number of existing special administration regimes (for example, those in rail and energy).

Clause 115 - Objective of a health special administration

748. This clause specifies the objective of health special administration, which is to ensure the continuity of the provision of designated services.
749. That objective may be achieved by either rescuing the provider as a going concern (for example, a provider could exit health special administration in a viable commercial form) and/or the transfer of all or some of the designated services (the designated services and related assets are transferred to one or more other providers).
750. Similar to special administration regimes in other sectors, the clause provides for a hierarchy in these two possible outcomes. The health special administrator would be required to work towards a rescue as a going concern and, as specified in *subsection (5)*, would only be able to make transfers to the extent that:
- a rescue was not reasonably practicable at all or without the transfer of some services,
 - a rescue would not achieve the objective of health special administration or would not do so unless services were transferred,
 - transfers would produce a better result for creditors as a whole, or
 - in the case of a company, transfers would produce a better result for members so long as this does not prejudice the interest of creditors.

Clause 116 - Health special administration regulations

751. This clause requires the Secretary of State to make regulations setting out the detail of the health special administration regime. The regulations are to be known as “health special administration regulations” and would be subject to the affirmative resolution procedure. These provisions are designed so that health special administration can be based on existing insolvency law and practice. The regulations may apply, with modifications, the administration procedure set out in Part 2 of the Insolvency Act 1986. Modifications would be likely to be needed to make provision for the continuity of designated services and in the application of that procedure to foundation trusts.
752. *Subsection (3)* enables the regulations to provide that a special health

administration order may also be made where the Secretary of State presents to the court a public interest winding-up application against a provider. This is consistent with existing special administration regimes, for example that provided for in the Energy Act 2004.

753. *Subsections (5) and (6)* provide that the regulations may also modify this Chapter, the Insolvency Act 1986 or any other enactment relating to that Act and section 242 of the NHS Act, which makes provision about involvement and consultation duties in relation to foundation trusts.
754. *Subsection (7)* provides that the power to make rules under section 411 of the Insolvency Act 1986 applies for the purpose of giving effect to the special health administration regime. This is consistent with other insolvency regimes where the rules make provision to make the scheme workable in practice.
755. *Subsection (9)* specifies that the regulations would be subject to consultation.

Clause 117 - Transfer schemes

756. This clause allows for the health special administration regulations to make provision about transfers in relation to designated services. A transfer scheme would allow designated services and related assets to be transferred to one or more other providers to ensure the continuity of those services in order to achieve the objective of health special administration.
757. *Subsection (2)* states that the health special administration regulations could in particular require a transfer scheme to be agreed by Monitor and the provider who would take over the provision of the delegated services, and allow Monitor to modify a transfer scheme with the consent of the affected parties.
758. Further detail about what may be included in a transfer scheme under the regulations is given in *subsection (3)*.

Clause 118 - Indemnities

759. This clause enables the health special administration regulations to make provision about Monitor's power to provide appropriate indemnities from the risk pool to the health special administrator and other persons in respect of liabilities incurred or loss or damage sustained in connection with the exercise of the health special administrator's functions. Such indemnities are a feature of existing special administration regimes (for example those in the utilities and transport sectors).

Clause 119 - Modification of this Chapter under the Enterprise Act 2002

760. This is a technical provision that would allow the Secretary of State to make consequential amendments under specified sections of the Enterprise Act 2002 to the provisions of this Chapter. This is designed to allow for future changes to the health special administration regime to ensure that it was in line with changes in the insolvency legislation.

Chapter 7 – Financial Assistance in Special Administration Cases

761. These clauses require Monitor to set up effective mechanisms for providing financial assistance to health special administrators, appointed to protect the continued provision of designated services in the event of the failure of a provider of designated services. The intention is that this financial assistance would be funded by the providers and commissioners of designated services rather than current failure arrangements that rely on funding from the Secretary of State.
762. It is intended that the financial assistance could be used by a health special administrator to cover operating costs during health special administration associated with ensuring the continuity of designated services. This could include (i) any indemnities for the health special administrator and other relevant persons in respect to liabilities incurred, or loss or damage sustained in connection with the exercise of the health special administrator's powers and duties; (ii) continuing costs of operating designated services; and (iii) costs of restructuring the provider to ensure a sustainable future organisation. These restructuring costs could include, but are not limited to, staff redundancy, renegotiation of service contracts, restructuring of debts or payments made to a new operator to establish a viable provider.
763. The proposed financial mechanisms are not intended to provide funding for organisations experiencing temporary liquidity issues, nor are they intended to provide funding for providers of designated services which are unprofitable due to market factors or special service requirements. Funding for these issues should take the form of commercial loans or be provided through adjustments made to tariff and non-tariff income respectively. Neither should the financial mechanisms set up under this clause provide cover in relation to non-designated services, as such services should be dealt with through a normal administration process.

Establishment of mechanisms

Clause 120 - Duty to establish mechanisms for providing financial assistance

764. This clause would place Monitor under a duty to establish effective financial mechanisms to support the operation of the health special administration regime provided for in the previous Chapter.
765. Monitor would have the power to decide which financial mechanisms would best fit

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the risks of failure and to establish such financial mechanisms and would be able to provide different mechanisms for different providers or different types of providers. As specified by *subsection (2)*, these mechanisms could include, but not be limited to:

- providers and commissioners of designated services being required to contribute to a collective insurance scheme or ‘risk pool’; or
- providers being required to purchase their own insurance to cover such liabilities on failure as are specified by Monitor,

and could provide for Monitor to recover the costs of setting up and running any such mechanism.

766. The financial mechanisms would be exempt from any provisions of the Financial Services and Markets Act 2000.
767. An order commencing this provision would be able to provide for Monitor to comply with this duty by a specified date. This is intended to ensure that the financial mechanisms would be in place in time for the commencement of the health special administration regime.

Clause 121 - Power to establish fund

768. This clause allows Monitor to establish and maintain a fund for the purposes of providing financial assistance to health special administrators and would require Monitor to secure the prudential management of such a fund.
769. The clause specifies certain requirements relating to the management of the fund. Monitor would be required to appoint at least two fund managers (which could be individuals or firms). Monitor would not be able to appoint an individual or firm as a fund manager unless it was satisfied:
- in the case of an individual, that the individual had the appropriate knowledge and experience for managing the investments and is not disqualified under the Financial Services and Markets Act 2000, or
 - in the case of a firm, that arrangements were in place to ensure that any individual who would exercise the firm’s fund manager functions would, at the time of doing so, have the appropriate knowledge and experience for managing the investments.

Applications for financial assistance

Clause 122 - Applications

770. This clause provides the process by which a health special administrator would be

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able to make an application for financial assistance from Monitor.

771. The clause allows Monitor to specify the form of the application and the supporting evidence required. Monitor would then be required to either grant or refuse the application.
772. *Subsection (3)* requires that Monitor notifies a successful applicant of the purpose for which the financial assistance must be used, and the conditions attached, and *subsection (4)* requires that the health special administrator may not use the assistance for any other purpose and must observe the conditions.
773. *Subsection (6)* obliges Monitor to notify an unsuccessful applicant of its reasons for refusing an application.
774. The health special administrator would be able to request a re-consideration of any refusal and Monitor would be able to request information from the applicant for those purposes. The reconsideration of the application would need to be carried out by individuals other than those who made the original decision to refuse the application.
775. Following reconsideration of an application, Monitor would have to notify the applicant of its decision. Monitor would then have to follow the process provided in *subsection (3)* in notifying a successful applicant and the notice requirements in *subsection (6)* where the applicant was unsuccessful.
776. Financial assistance would only be granted for the period during which a provider is in special administration but could be granted for shorter periods.

Clause 123 - Grants and loans

777. This clause prescribes the circumstances in which Monitor would be able to give financial assistance in the form of loans or grants in response to an application from a health special administrator. *Subsection (1)* provides that Monitor may only grant financial assistance if it is necessary to enable a provider to continue to provide designated services or to secure viable business to secure a provider's long term future where there is no other source of funding available.
778. *Subsection (3)* provides that Monitor would be able to make any such grant or loan in whatever manner, and on whatever terms, it considered appropriate, subject to *subsection (2)*, which provides that those terms would have to include a term requiring the whole or a part of the grant to be repaid to Monitor if there were a contravention of the other terms.

Charges on commissioners

Clause 124 – Power to impose charges on commissioners

779. This clause gives the Secretary of State the power to make regulations that would allow Monitor to require commissioners to pay charges for the protection of designated services.
780. *Subsections (2) and (3)* specify what would have to be included in the regulations, which includes provision about how the charge would be calculated. The charge could be fixed in the regulations or determined by reference to criteria set in the regulations. The regulations would also have to set out to whom the charge was to be paid and when. Where a charge would be set using criteria, the regulations would have to require Monitor to consult before imposing the charge. Where a charge were not paid when it was due, regulations would have to provide for interest to be payable on that amount and allow for any unpaid balance, including interest to be recoverable as a civil debt.
781. Where the charge was payable to a provider, Monitor would be able to require the provider to pay that amount in accordance with the regulations.
782. *Subsection (5)* requires that the Secretary of State must consult Monitor and the NHS Commissioning Board before making the regulations.
783. *Subsection (6)* states that the regulations under this section may apply, with modifications, the provisions on consultation later in this Chapter. This would provide for a consultation on the commissioner charge and require Monitor to calculate the amount each commissioner is to pay under the charge and to notify commissioners of that amount and when it will become payable for each financial year the service is designated.

Levy on providers

Clause 125 - Imposition of levy

784. Under this Chapter Monitor would have the power to impose levies on providers of designated services in order to raise money for financial assistance to health special administrators.
785. *Subsection (2)* requires that before the beginning of each financial year and before determining the levies to be imposed for the financial year, Monitor would have to estimate:

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

- the amount of funds needed to cover the risk of failure of providers of designated services in the forthcoming financial year;
- the amount to be collected from providers and commissioners in each financial year; and
- any surplus funds remaining at the end of that financial year.

786. *Subsection (3)* requires Monitor, before the imposition of any levy, to determine (i) the methodology for establishing the rate of the levy; (ii) the time period the levy would cover; and (iii) when the levy would be payable. Where a determination concerned the methodology for establishing the rate, notice would have to be given including an explanation of the charges.

Clause 126 - Power of Secretary of State to set limit on levy and charges

787. This clause allows the Secretary of State, subject to the approval of HM Treasury, to limit the amount raised by Monitor through a provider levy and commissioner charge. This power would be exercised by order. The intention is that this power would be used in exceptional circumstances, if the size of the financial mechanisms were excessively large.

788. The Secretary of State would be obliged to lay the order before Parliament, in order to inform Parliament of the intervention.

Clause 127 - Consultation

789. This clause requires Monitor to consult on the methodology by which the provider levy and commissioner charge would be determined. The clause specifies details about the consultation process, such as the persons to whom Monitor would have to send a notice of its proposals on the levy, and the length of the consultation period.

Clause 128 - Responses to consultation (and Schedule 8)

790. This clause details how Monitor would be required to handle objections to the methodology raised in response to the consultation. Where an objection was made Monitor would not be able to give notice about amounts payable unless the conditions in *subsection (2)* of this clause were met or, where they were not met, Monitor had made a reference to the Competition Commission.

791. The conditions in *subsection (2)* under which Monitor would be able to go ahead and give notice about amounts payable are that the percentage of providers objecting to the methodology (the “objection percentage”) and the percentage of providers objecting to the methodology, weighted by their share of supply (the “share of supply percentage”) are both less than the percentages prescribed by the Secretary of State in

regulations.

792. A reference to the Competition Commission would have to be designed to require the Competition Commission to investigate and report on certain matters, specified in *subsection (4)*. Those matters are whether Monitor had failed to give sufficient weight to the matters it would be required to have regard to under Chapter 1 of this Part, and if so whether that failure did or might operate against the public interest and whether that could have been remedied or prevented by changes to the proposals.
793. Schedule 8 applies, subject to the modifications set out in *subsection (5)*, to references made under this section. The Schedule sets out the requirements and processes surrounding the reference to the Competition Commission and the Competition Commission's determination of any appeal. The Schedule is explained in greater detail under Chapter 4 of this Part, since it also provides the process for references to the Competition Commission about licence conditions.

Clause 129 - Amount payable

794. This clause requires Monitor to calculate the amount each provider is to pay under the levy and to notify the provider of that amount and when it will become payable for each financial year the levy is imposed. The amount payable could be apportioned where the provider's liability was only for part of the year. That amount could also be zero.
795. *Subsections (4) and (5)* allow Monitor to adjust the amount payable by a provider if Monitor judges that the risk of the provider going into health special administration has changed since the start of the financial year or since it last adjusted the amount. Before making an adjustment, Monitor would have to give notice in accordance with *subsection (6)*.
796. *Subsections (8) and (9)* require Monitor to recalculate the amount payable where a provider to request a recalculation because it reasonably believes that the amount has been miscalculated (as long as the request relates to the current financial year).
797. *Subsection (10)* specifies how Monitor would be able to recover unpaid levies. It would also allow Monitor to claim interest on the unpaid levies as a civil debt through section 17 of the Judgements Act 1838.

Supplementary

Clause 130 - Investment principles and reviews

798. This clause requires Monitor to publish a statement on the principles governing the decisions about investments for the purposes of providing financial assistance to the health special administration regime (*subsection (1)*). Under *subsection (2)* Monitor would have to review that statement annually, revising it if necessary. If Monitor

revised the statement, it would have to re-publish it.

799. *Subsection (3)* provide that Monitor must publish a review of the operation of the health special administration procedure and the financial mechanisms supporting it.
800. *Subsections (4) to (6)* specify the purposes of the review, what it would be required to cover and what information, such as commercially sensitive information, must be left out. For example, subsection (4) requires that the statement would cover a review of the performance of the financial mechanisms in the previous year and an assessment of how Monitor would ensure that the mechanisms would be effectively managed over the following years in order to undertake its statutory function.

Clause 131 - Borrowing

801. This clause allows Monitor to take out loans or arrange overdrafts in order to exercise its functions to provide financial assistance.
802. *Subsection (2)* provides that Monitor would not be able to borrow beyond a borrowing limit specified by the Secretary of State by order (such an order would be subject to the negative resolution procedure).

Clause 132 - Shortfall or excess of available funds, etc.

803. This clause allows the Secretary of State to provide financial assistance to Monitor, if satisfied that the financial mechanism established by Monitor to provide funds to health special administrators is not generating sufficient funds and this is preventing the mechanism from operating effectively. What this would mean in practice is that in exceptional circumstances the Secretary of State would be able to top up the financial mechanisms to ensure the continuity of designated services.
804. The clause also provides that the Secretary of State would be able to direct Monitor to transfer funds to the Secretary of State if satisfied that the funds generated by a financial mechanism exceeded the level necessary or if the financial mechanism had been dormant or wound up. The intention of this power is to ensure that excess funds do not go unused.

Chapter 8 – General

Clause 133 - Service of documents

805. Details are provided in this clause of how notices required under this Part should be delivered, including details of when a notice is to be treated as having been delivered.

Clause 134 - Electronic communications

806. This clause provides that Monitor may send notices in electronic form, if the

person to be notified has given permission to receive notices electronically and has provided an email address. Monitor would be able to impose requirements about how notices are to be sent electronically; and it would have to publish whatever requirements it imposed.

Clause 135 - Interpretation and consequential amendments

Schedule 11 – Part 3: minor and consequential amendments

807. This clause gives effect to the Schedule, which contains consequential amendments, most of which reflect the change of Monitor’s statutory name.

Part 4 – NHS Foundation Trusts and NHS Trusts

808. This Part amends Chapter 5 of Part 2 of the NHS Act, which makes provision for NHS foundation trusts.

809. It removes various restrictions on foundation trusts and regulation specific to them and makes changes to the authorisation of foundation trusts, in light of the proposals in Part 3 for Monitor to become an economic regulator and to license all providers of NHS services. It repeals NHS trust legislation, and Monitor’s power to authorise new foundation trusts, from 1 April 2014, as the Government intends all NHS trusts to become foundation trusts. It clarifies the duties on governors and directors and introduces new powers for governors. It makes amendments to the financing and accounting arrangements of foundation trusts. In addition, it makes amendments to the process of foundation trust mergers and enables acquisitions, separations and dissolution of foundation trusts. It repeals provision about de-authorisation, preventing foundation trusts being returned to NHS trust status, and allows Monitor to operate the failure arrangements for foundation trusts, ahead of their replacement by the new failure arrangements set out in Part 3 of the Bill. In the longer-term, when most of Monitor’s specific functions in relation to foundation trusts will be repealed, there will be a specific role for Monitor in maintaining an adapted register of foundation trusts, and also allows Monitor to establish a panel to advise foundation trust governors.

Governance and management

Clause 136 – Governors

810. This clause makes changes to the powers of foundation trust governors as specified in Schedule 7 to the NHS Act and clarifies the collective duties on them. It is intended to strengthen foundation trusts’ internal governance given that the Bill would reduce specific oversight of foundation trusts by Monitor, with future controls operating through regulatory licensing and clinically-led NHS commissioning on all providers.
811. *Subsections (1) and (8)* rename the board of governors the “council of governors” in

order to avoid confusion between it and the board of directors. The term is already used in practice by some foundation trusts.

812. The Bill retains minimum requirements on the composition of the council of governors, including the existing requirement for there to be a majority of elected governors. *Subsection (2)* removes the existing requirement for the council of governors to include a member appointed by a Primary Care Trust, reflecting the abolition of Primary Care Trusts elsewhere in the Bill. *Subsection (3)* provides that a foundation trust can specify in its constitution any other organisation that is entitled to appoint a member or members of the council of governors. This would enable foundation trusts to tailor their governance to local circumstances.
813. *Subsection (4)* sets out the duties of the council of governors, making explicit the duties on governors that are implicit in the NHS Act through their election and existing powers. *Subsection (5)* provides that foundation trusts will be required to take steps to ensure that governors are equipped with the skills and knowledge they require. *Subsection (6)* gives governors an additional power to hold directors of the trust to account by enabling them to require directors to attend a meeting for the purposes of obtaining information about the performance of the trust or its directors, and to vote on issues concerning their performance. *Subsection (7)* requires the trust to include in its annual report details of any such meetings.

Clause 137 – Directors

814. This clause specifies some of the duties on directors of foundation trusts. *Subsection (1)* places a general duty on the directors of foundation trusts to promote the success of the trust.
815. *Subsections (2) and (3)* set out the specific ways in which duties to avoid conflicts of interest, to declare any interest in a proposed transaction and not to accept benefits from third parties apply in relation to foundation trust directors. By virtue of their office in public sector organisations, foundation trust directors are subject to certain duties that reflect administrative law principles. These are similar to specific duties on directors of other organisations, such as those on company directors which are set out in the Companies Act 2006. These general duties include, among others, a duty to act within powers, a duty only to exercise powers for the purposes of which they are conferred, a duty to exercise reasonable care, skill and diligence and a duty to act in accordance with the constitution of the organisation. However, in relation to conflicts of interest and accepting benefits, the Bill specifies the ways in which these duties apply to foundation trust directors, creating certain exceptions to administrative law principles, for example by permitting a conflict of interest if sanctioned in accordance with the trust's constitution.
816. In order that governors of foundation trusts have the information they require to discharge their duties, *subsection (4)* requires directors to send their governors

agendas for, and minutes of, their meetings.

Clause 138 – Members

817. This clause requires a foundation trust to take steps to ensure that the membership of any public and patient constituencies is representative of those eligible for membership of the trust because, under subsequent clauses, Monitor would lose the power to ensure this through terms of authorisation. Paragraph 3(1)(a) of Schedule 7 to the NHS Act defines a public constituency as comprising “individuals who live in any area specified in the constitution as the area for a public constituency” while paragraph 3(1)(c) of that Schedule provides that the patient constituency, which is optional for foundation trusts, includes “individuals who have attended any of the corporation’s hospitals either as a patient or the carer of a patient within a period specified in the constitution”.
818. *Subsection (2)* requires a foundation trust to have regard to the population it serves in deciding on the geographic areas to be eligible for its public constituency and any patient constituency. For example, if a foundation trust serves patients from a wide area – if for instance it is a regional centre of expertise or a tertiary referral centre – the effect would be to require the trust to give consideration to creating a patient constituency if it decided against including the whole area in its public constituency.

Clause 139 – Accounts: initial arrangements

819. This clause, and the following clause on variations to initial arrangements, make changes to the accounting requirements of foundation trusts. These clauses link with paragraphs in Schedule 7 to the NHS Act and specify Monitor’s responsibilities in relation to the production of foundation trust accounts. They reflect changes to government accounting rules, allow the Secretary of State to fulfil his functions and remove an aspect of Monitor’s role which is specific to foundation trusts.
820. This clause specifies the initial arrangements for foundation trust accounts, amending the existing provisions in paragraphs 24 and 25 of Schedule 7 to the NHS Act under which Monitor has powers to direct foundation trusts on form, content and other matters relating to foundation trust accounts.
821. The clause requires Monitor to seek the approval of the Secretary of State, rather than of HM Treasury, on foundation trust accounting matters. This would enable the Secretary of State to ensure that the accounting directions issued by Monitor were in line with the accounting framework that the Department of Health must follow in preparing its accounts, set out by HM Treasury in their Financial Reporting and Accounting Manual.
822. From 2011/12 foundation trusts will move within the Department’s accounting boundary under the cross-Government “clear line of sight” initiative (following the Constitutional Reform and Governance Act 2010) and will be fully consolidated into

the Department's resource account. Therefore, foundation trust accounts will, in future, need to be produced to the same standards and timescales as those of the Department and other organisations in the Department's "group". As the Department must produce its accounts in accordance with HM Treasury guidance, subject to any agreed divergence, foundation trust accounts would also continue to be consistent with HM Treasury accounting guidance.

823. The clause creates a power for Monitor to direct foundation trusts to produce accounts for periods other than a financial year, such as in-year accounts that may be required by the Department or Government.
824. The clause also gives Monitor powers to ensure that accounts are produced on a timely basis, early enough to be consolidated into the Department's resource account to meet wider Government reporting deadlines.
825. These powers would apply for a transitional period during which Monitor would be responsible for setting foundation trust accounting policy, subject to the Department's agreement and in providing a consolidation of foundation trust accounts to the Department.
826. *Subsection (6)* removes the requirement for foundation trusts to lay accounts before Parliament independently. As with other NHS bodies that are consolidated into the Department's resource account, the route of accountability for the spending of these organisations will be through the Department's resource account.

Clause 140 – Accounts: variations to initial arrangements

827. This clause provides that after a transitional period, the powers and duties relating to the production of foundation trust accounts would transfer to the Secretary of State. The proposed change to Monitor's role to become economic regulator for all providers (the subject of Part 3 of the Bill) means that it would not be appropriate for Monitor to have an ongoing and specific role in foundation trust accounts when this would not be the case for other providers.
828. The enactment of this clause, by order of the Secretary of State, would bring the interim accounting arrangements to an end, as stated in *subsection (7)*.
829. This clause amends paragraphs 24 and 25 of Schedule 7 to the NHS Act (as previously amended by the previous clause on accounts: initial arrangements) to substitute the Secretary of State for the regulator in respect of those powers and duties relating to the form, content, timing and other matters concerning the accounts of foundation trusts. The clause requires the Secretary of State to seek the approval of HM Treasury in those cases where the regulator had been required to seek the approval of the Secretary of State.

Clause 141 – Annual report and forward plan

830. This clause specifies new requirements relating to Monitor's existing power to determine the content of foundation trusts' annual reports and allows the transfer of powers over annual reports and forward plans to the Secretary of State.
831. *Subsection (1)* requires foundation trusts to include in their annual reports information on the pay and remuneration of directors and expenses of governors and directors, in line with the requirements on other public sector organisations and those already set out in Monitor's current code of governance. *Subsection (3)* requires Monitor to consult before imposing significant new requirements regarding the contents of annual reports.
832. *Subsection (3)* provides that in future, the power to determine the content of foundation trusts' annual reports could move from Monitor to the Secretary of State, who would need to set out such requirements in secondary legislation, mirroring the existing requirements on charities. The timing of this change would be for the Secretary of State to decide, but it is anticipated that this would be at a time at which the requirements on the content of foundation trust annual reports had stabilised.
833. *Subsection (4)* provides that foundation trusts would have a duty to send their forward plans to the Secretary of State, rather than to Monitor as they do at present. Alongside provisions on accounts, this is to ensure the Department of Health has the information it needs to manage against its financial controls, since the spending of foundation trusts counts towards the Department's spending. *Subsection (6)* provides that foundation trusts' forward plans would no longer be included on the register of foundation trusts, but the public would retain the existing right to request, free of charge, a copy of the latest information as to the forward planning of a trust from the organisation concerned, as is provided for in paragraph 22(1)(e) of Schedule 7 to the NHS Act.

Clause 142 – Meetings

834. This clause requires foundation trusts to hold annual meetings of the trust's membership, similar to the existing requirements on other types of organisations and on foundation trusts to hold, in public, general meetings of the council of governors. *Subsection (1)*, which inserts a new paragraph 27A into Schedule 7, gives the membership of a foundation trust a role in relation to considering the organisation's annual report and accounts. This is intended to increase the accountability of governors and directors to the members and to promote transparency about the trust's performance.
835. *Subsection (1)* provides that the membership of the trust, at the annual meeting, must be able to vote on constitutional amendments affecting the role of governors, similar to the scrutiny of other changes by governors.

836. *Subsection (2)* clarifies that the existing requirement on the council of governors to hold a general meeting to consider the trust's annual accounts and report in no way prevents the governors holding a general meeting more than once a year if they wish to do so. *Subsection (3)*, inserting a new paragraph 28A, enables the trust, if it wishes, to combine the annual meeting of the membership with a general meeting council of governors.

Clause 143 – Voting

837. This clause inserts a new paragraph into Schedule 7 to the NHS Act. This would give the Secretary of State, in light of new decision-making powers for foundation trusts in subsequent clauses, a regulation-making power to alter the associated voting arrangements for directors, governors and members of foundation trusts provided for in this Bill.
838. Existing voting provisions unaffected by this Bill, such as the majority of governors required to remove a non-executive director, would be beyond the scope of this power. In general, beyond provisions on the appointment of non-executive directors by governors, specific voting arrangements for foundation trusts have not been provided for in detail in primary legislation and this clause is intended to ensure that the new voting provisions can be modified if necessary. Under this clause, the Secretary of State could, for example, change the size of a majority required for approving mergers or for making changes to the constitution of a foundation trust, or specify that such a majority should be of those eligible to vote as opposed to those actually voting.
839. *Subsection (2)* provides that any regulations made under this clause would be subject to the affirmative resolution procedure.

Foundation trust status

Clause 144 – Authorisation

840. This clause changes the nature of foundation trust authorisation to a one-off test, ahead of the repeal of provisions on authorisation under a later clause. Under current legislation, Monitor sets terms of authorisation when authorising an NHS Trust to become a foundation trust, and these terms form the basis of Monitor's foundation trust-specific regulatory regime. Under Part 3 of this Bill, Monitor would in future issue licences to providers with conditions attached, and all providers would be regulated on the basis of such conditions. An NHS trust wanting to become a foundation trust after implementation of Monitor's licensing regime (proposed for 1 April 2012) would still need to meet the standards necessary to be authorised by Monitor as a foundation trust, but rather than receiving ongoing terms of authorisation, would undergo a one-off test to gain authorisation.
841. This clause therefore amends the NHS Act to change the application process for NHS

trusts wishing to become foundation trusts and to remove ongoing terms of authorisation. *Subsection (4)* removes Monitor's discretion to give an authorisation on particular terms, and subsection (5) removes Monitor's ability to vary those terms of authorisation. *Subsections (6) and (8)* make consequential changes which would remove the requirement for a copy of the authorisation to be on the register and available for public inspection as this would no longer be a live document.

842. *Subsection (2)* repeals the requirement in section 33(2)(a) of the NHS Act to describe the goods and services to be provided in an application for foundation trust status and for Monitor to be satisfied that an applicant can provide them. This information is currently required to set the terms of authorisation. In future, Monitor as the economic regulator would be able to use its licensing regime to require a provider to provide a particular service. The existing powers under which Monitor can use terms of authorisation to ensure the provision of a particular service would therefore no longer be required. Monitor's existing foundation trust-specific powers to enter and inspect a foundation trust's premises would also no longer be required given its proposed new functions as economic regulator of all providers of NHS services, so *subsection (7)* repeals section 49 of the NHS Act which enabled it to exercise such a power.

Clause 145 – Bodies which may apply for foundation trust status

843. This clause removes the ability for organisations other than NHS trusts to apply for foundation trust status using section 34 of the NHS Act. There is little prospect of any organisation other than an NHS trust applying to become a foundation trust (no other type of organisation has ever applied using Section 34) and Section 34 is therefore considered unnecessary. Section 34 would be repealed when the licensing regime is implemented (proposed for 1 April 2012). The clause also makes consequential amendments to the NHS Act, for example removing powers for Monitor to authorise such trusts. If an organisation were to submit an application prior to the repeal of section 34, subsections (4) to (7) would enable Monitor to consider the application and authorise the organisation as a foundation trust.

Clause 146 – Amendment of constitution

844. This clause gives foundation trusts powers to amend their constitutions without seeking external permission. The Bill retains the existing requirement on foundation trusts to have a constitution and continues to require trusts' constitutions to include certain information. However, as Monitor in its proposed new role as economic regulator would no longer give additional supervision to foundation trusts, this clause transfers responsibility for approving changes to a foundation trust's constitution from Monitor to the council of governors and board of directors of the foundation trust. *Subsection (2)*, among other things, requires that foundation trusts inform Monitor of any amendments they decide to make to their constitutions, since Monitor would continue to act as the registrar of foundation trusts, so would be responsible for maintaining on the foundation trust register the constitutions of such organisations.

Clause 147 – Panel for advising governors

845. This clause gives Monitor the power to establish a panel to consider questions brought by governors about the appropriateness of actions taken by their foundation trust. The panel is intended to provide a source of independent advice to governors which, at present, they receive informally from Monitor. Its purpose in providing advice is to help governors to fulfil their role of holding non-executive directors to account for the performance of the board. *Subsection (2)* provides that questions can only be referred to the panel if a majority of the council of governors agree. Decisions of the panel would not be binding on the trust, but a court or tribunal could take the panel's determination into account if considering a question previously considered by the panel. *Subsections (3) and (4)* enable the panel to regulate its own procedures in order to ensure its independence from Monitor. However, the Secretary of State would have the power, under *subsection (10)*, to make regulations about the membership of the panel in the event that the arrangements made by the panel proved problematic in practice or to ensure the panel's independence from Monitor. For example, if the panel decided to appoint members for life, this power would allow the Secretary of State to introduce term limits.

Finance

Clause 148 – Financial powers etc.

846. This clause amends powers relating to the financial matters of foundation trusts.
847. The changes are in two broad areas. Firstly, the Secretary of State's powers to give financial assistance to foundation trusts would be restricted and would be governed by guidance required under legislation. Secondly, the taxpayer investment in foundation trusts would no longer be managed through foundation trust-specific statutory controls but instead through conditions to be applied to loans, public dividend capital and guarantees of payments under externally financed development agreements. This would enable the management of the taxpayer investment, through the application of these conditions, by an operationally independent banking function to be established by the Department of Health. This is intended to protect the taxpayer investment in foundation trusts from material increases in risk that may arise as a result of such events as deteriorating financial performance or significant structural changes. As the conditions would be set to trigger only in exceptional circumstances they would not affect the operational freedoms of foundation trust.
848. *Subsections (1) and (2)* remove the Secretary of State's powers to give financial assistance to foundation trusts in the form of public dividend capital, grants or other payments. This would restrict the Department to providing financial assistance to foundation trusts in the form of loans and to providing a guarantee of payments under an externally financed development agreement. The Government intends these will come into effect only after the establishment of mechanisms to provide financial assistance to ensure continuity of services under special administration in Part 3.

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as introduced in the House of Commons on 19 January 2011*

Subsection (3) requires the publication of an annual report detailing all loans outstanding, loan transactions during the year and the terms under which those loans were let.

849. As part of the move away from statutory controls on foundation trusts, the prudential borrowing code currently produced by the regulator and the borrowing limits that are calculated using that code would no longer be required. *Subsection (4)* therefore removes the powers for the regulator to revise the prudential borrowing code and *subsection (10)* removes the limit imposed on foundation trust borrowing by the code.
850. *Subsection (8)* requires the Secretary of State to produce guidance on his powers to issue loans and set terms for public dividend capital conferred under sections 40 and 42 of the NHS Act, as amended by this Bill. The guidance would set out criteria to be applied when setting the terms and conditions of financing issued under section 40 and those which would be applied to existing public dividend capital under section 42(3) of the NHS Act.
851. The guidance would cover terms and conditions for loans, public dividend capital and guarantees of payment that fall into two categories. Firstly, it would cover those terms and conditions that relate directly to the financing itself, for example the interest or dividend payable by foundation trusts on the financing, or the requirement to repay public dividend capital. Secondly, it would cover those conditions that do not directly apply to the financing, which would be designed to highlight material changes in the risks to the taxpayer investment and would be consistent with the terms that any lender would apply to financing. These may include the following and similar conditions:
- achievement of financial metrics, such as debt service cover, to give confidence of a foundation trust's ongoing ability to service debt;
 - limits on additional indebtedness or preferring other creditors;
 - restrictions on the use of assets to secure debt;
 - restrictions on the disposal of assets;
 - restrictions on material structural changes, for example, mergers, separations and acquisitions;
 - restrictions on material change of business; and
 - restrictions on investments or giving of guarantees.
852. *Subsection (7)* of this clause sets out those powers of foundation trusts which would be subject to such terms as above. These terms may be applied to existing or new

public dividend capital under subsection (3) of section 42 of the NHS Act.

853. *Subsection (9)* repeals a provision that relates to Monitor's existing foundation trust-specific role. As economic regulator, Monitor would have powers under Part 3 that would allow it to protect property required for the delivery of designated services.
854. *Subsection (11)* amends section 50 of the NHS Act to require foundation trusts to pay to Monitor fees associated with Monitor's two continuing foundation trust-specific functions, namely maintaining the foundation trust register and establishing an advice panel (its fee charging powers in respect of its functions as economic regulator are addressed in the explanatory notes on the economic regulator).

Functions

Clause 149 – Goods and services

855. This clause amends section 43 of the NHS Act on authorised services to remove mentions of ongoing terms of authorisation, since terms of authorisation would no longer exist under changes proposed by the earlier clause on foundation trust authorisation.
856. *Subsection (1)* retains the current position that the principal purpose of a foundation trust is to provide goods and services for the health service in England and that a foundation trust may provide goods and services for any purposes related to the provision of health care. To make the principal purpose clear to governors and directors, *subsection (5)* requires a foundation trust to include the principal purpose in its constitution.

Clause 150 – Private health care

857. This clause repeals the restriction on the amount of income a foundation trust can earn from private charges, otherwise known as the "private patient income cap".
858. The cap, which was introduced in 2003, has the effect that a foundation trust cannot earn in any financial year a higher proportion of its total income from private charges than it derived from private charges in the financial year 2002-03 (the year before the first foundation trusts were authorised). For example, as no mental health foundation trust derived income from private charges in 2002-03, their cap was 0%. This was increased to 1.5% by section 33 of the Health Act 2009. The Bill does not repeal the provisions of section 44 of the NHS Act which allow foundation trusts to make charges to NHS patients for the provision of accommodation, such as a private room, and additional services, such as an ancillary service like the provision of a television.

Clause 151 - Information

859. This clause transfers from Monitor to the Secretary of State the power to require

information from foundation trusts necessary for the Secretary of State to exercise his functions effectively. Whilst foundation trusts sit within the Department of Health accounting and budgeting boundaries the Department will need information from foundation trusts in order to carry out its functions. These functions include financial management against Parliamentary estimates, Departmental Expenditure Limits and other controls, financial reporting to HM Treasury and those wider reporting requirements made of all Government Departments for both financial and non-financial matters.

860. This information is currently collected and provided to the Department by Monitor under the terms of authorisation of foundation trusts. Given the proposed change to Monitor's remit, it would no longer be consistent with its new role for it to continue to collect information on behalf of the Department when it would not have a similar role for other healthcare providers. Therefore, this clause requires foundation trusts to provide the required information directly to the Department.

Clause 152 – Significant transactions

861. This clause provides that a foundation trust may designate in its constitution certain transactions as “significant transactions” which cannot proceed unless a majority of governors agree to them. Foundation trusts would be able to decide which transactions they want to designate as significant, strategically or financially: for example, they could provide that this included any contract valued over a certain amount or over a particular percentage of the trust's turnover. As the definition of a “significant transaction” would need to be specified in the constitution of the trust, it would have to be agreed by a majority of the council of governors and of the board of directors. Trusts could choose not to specify any transactions as “significant transactions”, but this would need to be stated in the constitution, ensuring the agreement of the governors.

Mergers, acquisitions, separations and dissolution

Clause 153 – Mergers

862. This clause, and the subsequent ones enabling other types of organisational change, brings the legislation for foundation trusts more in line with legislation on other types of organisations. The clause amends the process specified in the NHS Act for foundation trusts to merge with each other or with NHS trusts. The amendments remove the specific discretion that Monitor currently has in relation to mergers involving foundation trusts and some of the information requirements needed alongside an application. Monitor's licensing powers under Part 3 would allow it to set license conditions giving it a role in organisational changes, which impacted on the provision of designated services.
863. *Subsection (2)* introduces a new requirement for the approval of the majority of the

governors of the foundation trusts for such an application to be made.

864. An application for such a merger would still have to be made to Monitor, but *subsection (5)* provides that Monitor's foundation trust-specific role in relation to such mergers would be limited to granting the application that would effect the change, which it would be required to do if it were satisfied that the necessary preparatory steps had been taken.

Clause 154 – Acquisitions

865. This clause makes explicit provision for a foundation trust to acquire another foundation trust or an NHS trust. The clause enables an acquisition of a foundation trust to occur without the acquiring foundation trust being required to dissolve.
866. A joint application, by the acquiring and target organisations, would have to be made to Monitor, who would be required to grant the application if it were satisfied that the necessary preparatory steps had been taken. *Subsection (2)* requires that such an application could only be made with the approval of the majority of the governors of each of the foundation trusts involved.
867. The provision for a foundation trust to acquire an NHS trust would be removed when the NHS trust legislation was repealed.

Clause 155 – Separations

868. This clause makes explicit provision for a foundation trust to separate into two or more foundation trusts.
869. An application would have to be made by the foundation trust to Monitor for the separation, who would be required to grant the application effecting the change if it was satisfied that the necessary preparatory steps had been taken. *Subsection (2)* requires that such an application could only be made with the approval of the majority of the governors of the foundation trust.

Clause 156 – Dissolution

870. This clause makes provision for a foundation trust, with no remaining liabilities, to dissolve.
871. An application would have to be made by the foundation trust to Monitor who would be required to grant the application, and make the order to effect the administration of the dissolution, if it were satisfied that the foundation trust had no liabilities and that the necessary preparatory steps had been taken.

Clause 157 – Supplementary

872. This clause extends the supplementary provisions in the NHS Act in relation to mergers involving foundation trusts, so that it now covers mergers, acquisitions, separations and dissolutions.
873. The clause makes provision for Monitor to make an order to dissolve a foundation trust and to effect mergers and separations in which a new foundation trust is (or trusts are) created. The clause requires that such orders would have to specify the properties and liabilities to be transferred, and to where.

Failure

Clause 158 – Repeal of de-authorisation provisions

874. This clause removes sections 52A to 52E and Schedule 8A of the NHS Act (inserted by the Health Act 2009), which provide for the de-authorisation of foundation trusts. The effect of de-authorisation would be to revert a foundation trust to being an NHS trust, which would no longer be appropriate given the intention that all NHS Trusts are to become foundation trusts and the associated repeal of the NHS Trust model. The clause also removes references to sections 52A to 52E, in force only for certain purposes, and Schedule 8A from other parts of the NHS Act.

Clause 159 – Trust special administrators

875. This clause and subsequent clauses amend existing provisions on foundation trust failure (in Part 2, Chapter 1 of the Health Act 2009) which have not yet been used. They would adapt the failure regime for foundation trusts to create a transitional failure regime which is consistent with the end-state special health administration regime proposed by Chapter 6 of Part 3 of this Bill and which can operate until that end-state regime is in place.
876. This clause amends the trust special administration provisions (sections 65A to 65O of the NHS Act as amended by the Health Act 2009) to allow a foundation trust to have a trust special administrator appointed without the need for de-authorisation, and to replace the Secretary of State's role in appointing trust special administrators with a role for Monitor. These amendments make the transitional foundation trust failure regime consistent with the proposed end-state special health administration regime which would be operated independently of the Secretary of State.
877. This clause amends section 65D of the NHS Act (as amended by the Health Act 2009) to:
- Change the test Monitor must meet to trigger the trust special administration regime to a technical insolvency test, since the original test is based on Section 52 of the NHS Act, which will not be in place during the intended life-span of

these transitional failure arrangements.

- Replicate for Monitor the powers the Secretary of State has in section 65B of the NHS Act to appoint a trust special administrator to a foundation trust without de-authorising that foundation trust, and to take control of the body for a temporary period, during which the trust special administrator 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).
- Replicate the trust special administrator's powers in relation to NHS trusts for foundation trusts by enabling the trust special administrator to carry out the functions of the council of governors and the board of directors, who would be suspended whilst the trust special administrator is in post.

Clause 160 – Procedure etc.

878. This clause amends the process of trust special administration in relation to foundation trusts in order to give Monitor the role in the regime that the Secretary of State has had for NHS trusts in sections 65F (producing a draft report), 65H (consultation requirements), 65I (producing the final report) and 65J (the power to extend the deadline) of the NHS Act.
879. *Subsection (2)* amends section 65F of the NHS Act (inserted by the Health Act 2009) so that during the period of appointment, the trust special administrator would be required to produce a report stating the action which he recommends Monitor (rather than the Secretary of State) should take in relation to the foundation trust.
880. *Subsections (3), (4), (5) and (7)* amend sections 65H and 65J of the NHS Act to replicate the Secretary of State role for NHS trusts with a Monitor role for foundation trusts. The amendments will allow Monitor to direct the trust special administrator to obtain a written consultation response or to hold a meeting with any person (section 65H) and to allow Monitor to extend the deadlines in producing the draft report, the consultation stage or producing the final report (section 65J).
881. *Subsection (6)* amends section 65I of the NHS Act so that it would be Monitor rather than the Secretary of State that received the trust special administrator's final report on a Foundation Trust.

Clause 161 – Action following final report

882. This clause amends section 65K of the NHS Act so that for foundation trusts only, it would be Monitor rather than the Secretary of State that would make a decision as to what action to take in the light of the final report. New subsections (4), (5) and (6) of section 65K specify Monitor's powers to dissolve a foundation trust and transfer any liabilities to the Secretary of State or another foundation trust at the outcome of the

failure regime. What would happen in practice would be that should Monitor decide to dissolve a foundation trust, it would need to first gain the approval of the Secretary of State. If the Secretary of State approved the dissolution, Monitor could issue an order under subsection (4) to dissolve the foundation trust. However, if the Secretary of State were to refuse Monitor's application, then Monitor would need to decide on an alternative action to take in relation to the foundation trust within 20 working days from receiving written notification of the Secretary of State's refusal.

883. The clause also amends section 65L of the NHS Act so that for foundation trusts only, it would be Monitor, rather than the Secretary of State, that was able to bring a foundation trust out of administration. In addition, the clause removes subsections (3) to (5) of that section, as they refer to NHS trusts created by the de-authorisation of a foundation trust, which would no longer be possible.
884. This clause would also enable Monitor to appoint or remove any governor or director in order to ensure that the foundation trust coming out of administration had the correct number as set out in Schedule 7 to the NHS Act. This mirrors the power the Secretary of State had in the original legislation in relation to NHS trusts created through the de-authorisation of a foundation trust.

Clause 162 – Sections 159 to 161: supplementary provision

885. This clause amends sections 65M and 65N so that for foundation trusts only, it would be Monitor, rather than the Secretary of State, that would be able to replace a trust special administrator and issue guidance to the trust special administrator on how the regime applies to foundation trusts.
886. This clause requires Monitor in its foundation trust registrar role to file all relevant orders, notices and publications in relation to this regime with the papers relating to the foundation trust in administration.
887. This clause also includes a number of consequential amendments to references to these provisions in other legislation

Clause 163 – Repeal of Chapter 5A of Part 2 of the NHS Act

888. This clause provides for the repeal of the trust special administrator provisions once the health special administration regulations are commenced (Part 3, Chapter 6 of this Bill).

Abolition of NHS trusts

Clause 164 – Abolition of NHS trusts in England

889. This clause makes provision to abolish NHS trusts in England and the legislative framework that provides for them on 1 April 2014. This reflects the

Government's intention, set out in *Liberating the NHS: Legislative Framework and Next Steps*, to support all NHS trusts to become foundation trusts within three years. Given the expectation that there will be no NHS trusts on 1st April 2014, *subsection (1)* abolishes the NHS trusts established under section 25 of the NHS Act and *subsection (2)* repeals Chapter 3 of Part 2 of the NHS Act.

890. *Subsection (4)* provides that the Secretary of State may by Order change the date on which the NHS trust legislation is repealed, in the event that he considers there will still be NHS trusts in existence on 1st April 2014.
891. There is one exceptional circumstance under which the Government intends that an organisation could remain as an NHS trust after the NHS trust legislation is repealed. Under what is described as a franchise agreement, an independent sector franchisee assumes many of the risks and rewards of ownership, and is required to deliver agreed outcomes in return for a share of the trust's surpluses. There is one known proposed franchise agreement at an advanced stage where the arrangement is incompatible with the NHS trust becoming a foundation trust before April 2014. The Department of Health is planning to avoid further such cases. *Subsection (5)* therefore provides the legislative basis that would enable an NHS trust whose functions are exercised under a franchise agreement to remain an NHS trust after the repeal of the NHS trust legislation in exceptional circumstances.
892. Schedule 12 to the Bill makes the necessary consequential amendments to the NHS Act, and other relevant Acts.

Clause 165 – Repeal of provisions on authorisation for NHS foundation trusts

893. This clause repeals sections 33 and 35 of the NHS Act (which enables an NHS trust to apply to become, and be authorised as, a foundation trust) which will no longer be needed once all NHS trusts have become foundation trusts. It also makes associated changes.
894. *Subsection (2)* repeals the provision enabling applications by NHS trusts to become foundation trusts. *Subsection (3)* repeals Monitor's power under section 36 of the NHS Act to authorise an NHS trust to be a foundation trust, as the powers would not be needed when all NHS trusts are foundation trusts. The clause also amends the title of section 36 from "effect of authorisation" to "Status etc of NHS foundation trusts", recognising that organisations would not be authorised as new foundation trusts following the repeal of section 33. *Subsection (7)* retains the powers necessary to enable NHS trusts in franchise agreements to apply for foundation trust status after April 2014.

Part 5 – Public involvement and local government

Chapter 1 – Public involvement

Healthwatch England

Clause 166 - Healthwatch England

895. This clause amends Schedule 1 to the Health and Social Care Act 2008 (“the 2008 Act”) and establishes Healthwatch England as a statutory committee of the Care Quality Commission (CQC); and makes provision about Healthwatch England’s purpose, its exercise of functions and other related matters. The system for making appointments to the Healthwatch England committee will be set out in regulations. Healthwatch England will be a national body representing the views of users of health and social care services, other members of the public and Local Healthwatch organisations.
896. *Subsection (4)* inserts new sections 45A and 45B into Chapter 3 of Part 1 of the Health and Social Care Act 2008. New section 45A (1) to (4) provide the functions to be performed by Healthwatch England. Healthwatch England will advise and provide information to Local Healthwatch organisations on their functions. Healthwatch England will also advise the Secretary of State, NHS Commissioning Board, Monitor, the English local authorities and the Care Quality Commission on views of users of health and social care services and their experience of such services. Healthwatch England will also advise these persons and provide information to them on the views of Local Healthwatch organisations and other persons on the standards of services and whether or how they could or should be improved.
897. The function under new Section 45A(3) could include informing the NHS Commissioning Board of concerns Healthwatch England has identified from feedback from Local Healthwatch organisations about problems with the commissioning of maternity services across England. Section 45A(5) requires the Secretary of State, NHS Commissioning Board, Monitor, and the English local authorities to inform Healthwatch England how they have responded, or intend to respond, to advice given by Healthwatch England. The Care Quality Commission is required by section 45A(7) to publish details of how it has arranged for Healthwatch England to perform its functions. Healthwatch England is also required by section 45A(8) to have regard to such aspects of government policy as directed by the Secretary of State.
898. New section 45B(1) requires Healthwatch England to report to the Care Quality Commission on the views of users of health and social care services and their experiences of such services and on the views of Local Healthwatch organisations and other persons on the standard of services and whether or how they could or should be improved. It also requires Healthwatch England to publish a report on how it has discharged its functions during the year. Section 45B(2) requires Healthwatch England to lay before Parliament its report on how it has discharged its functions and

send a copy to the Secretary of State. Section 45B(3) allows Healthwatch England to publish other reports at other times about matters relating to health and social care as it sees fit. When writing a report on how it has discharged its functions Healthwatch England must exclude, as far as it is practical, information that relates to an individual's private affairs that, if published, could seriously and prejudicially affect that individual's interests.

899. *Subsections (5) to (7)* of this clause enable the Secretary of State to direct Healthwatch England if it fails to fulfil the functions as set out in 45A. If Healthwatch England fails to comply with the direction, the subsections enable the Secretary of State to carry out the function to which the direction relates or arrange for someone else to carry out the function.
900. *Subsections (8) and (9)* of this clause insert new subsections (1A) and (2A) in section 83 of the 2008 Act. New subsection (1A) has the effect that the duty on the Care Quality Commission to make a report on the way it has exercised its functions does not apply in relation to the functions exercised by Healthwatch England under section 45A. New subsection (2A) has the effect that the Care Quality Commission's report must separately set out Healthwatch England's report made to it on the matters mentioned in 45A(3).

Local Healthwatch organisations

Clause 167 – Establishment and constitution

901. This clause provides for the establishment and form of Local Healthwatch organisations. Local Involvement Networks will cease to exist. Local Healthwatch organisations will continue the functions of Local Involvement Networks as well as gaining additional functions.
902. Local Healthwatch organisations (LHW) will be based in local authority areas and funded by local authorities.
903. *Subsection (4)* inserts new Schedule 16A in the Local Government and Public Involvement in Health Act 2007 (the 2007 Act), which in turn makes further provisions as to the form and functions of a Local Healthwatch organisation. The clause introduces Schedule 13.

Schedule 13 - Local Healthwatch organisations

904. This schedule inserts Schedule 16A – Local Healthwatch organisations. It gives details of further provision about Local Healthwatch organisations such as about its organisational structure including status, membership and accounts.
905. Paragraph 1 of new Schedule 16A, creates Local Healthwatch organisations as bodies corporate, making provision for matter such as the organisational structure which

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

includes status, membership and accounts. It also states that Local Healthwatch organisations will not be regarded as agents of the Crown.

906. Paragraph 2 of new Schedule 16A enables the Secretary of State to make regulations about the membership of Local Healthwatch organisations.
907. Paragraph 3 of new Schedule 16A enables Local Healthwatch organisations to appoint employees, and to determine the terms and conditions of those staff.
908. Paragraph 4 of new Schedule 16A grants Local Healthwatch organisations general powers in connection with their exercise of functions, including entering agreements, co-operating with other English public authorities and providing training. It requires them to exercise functions in an effective, efficient and economic manner.
909. Paragraph 5 of new Schedule 16A enables Local Healthwatch organisations to appoint committees and sub-committees, with members sitting on them who are not members of the Local Healthwatch organisations. For example, if a Local Healthwatch organisation is looking into local maternity services, it could form a sub-committee with this as its focus. Subparagraph (3) allows Local Healthwatch organisation to pay such members remuneration and allowances.
910. Paragraph 6 enables a Local Healthwatch organisation to arrange for a member, employee, committee or sub-committee, or other person to perform its functions on its behalf. This also allows Local Healthwatch organisations to make a payment of remuneration or other amounts for performing these functions.
911. Paragraph 7 of new Schedule 16A provides the accounting process for Local Healthwatch organisations. It requires them to keep accounts and prepare annual accounts. These are to be produced every financial year. Local Healthwatch organisations must send copies of their annual accounts to the Secretary of State and the Comptroller and Auditor General. This paragraph also imposes a duty on the Comptroller and Auditor General to examine, certify and report on the annual accounts and to lay copies before Parliament.
912. *Subsections (5) and (6)* of this clause make consequential amendments to section 65H of the NHS Act and to section 4 of the Health and Social Care Act 2008. The amendments ensure that in the consultation requirements for de-authorisation of NHS foundation trusts, the trust's special administrator must request a written response from Local Healthwatch organisations, if directed by the Secretary of State. Additionally, the amendments ensure that the Care Quality Commission in performing its functions must have regard to views expressed by Local Healthwatch organisations, as opposed to those expressed by Local Involvement Networks, about the provision of health and social care services in their areas.

Clause 168 – Activities relating to local care services

913. This clause amends section 221 of the 2007 Act to ensure that, as Local Involvement Networks are replaced by Local Healthwatch organisations, the duty is retained on local authorities to make contractual arrangements for the involvement of the public in the commissioning, provision and scrutiny of health and social care services.
914. *Subsection (3)* adds to the list of activities mentioned in section 221(2) which are to be performed by Local Healthwatch organisations by virtue of section 222(2) for which a local authority must contract. This includes reaching views on certain matters, making those views known to the Healthwatch England committee of the Care Quality Commission, and giving advice and information to users of local health and social care services.

Clause 169 – Local authority arrangements

915. This clause sets out the arrangements that a local authority must make with a Local Healthwatch organisation.
916. *Subsection (2)* inserts a new section 222(2) into the 2007 Act to ensure that Local Healthwatch organisations carry out the activities previously undertaken by Local Involvement Networks, as currently specified in section 221(2) of that Act.
917. *Subsection (3)* amends section 222(3) of the 2007 Act allowing a local authority to directly contract with a Local Healthwatch organisation, or to retain the current arrangements of contracting with a host organisation to make the arrangements under section 221.
918. *Subsection (5)* substitutes section 222(5) of the 2007 Act allowing for section 221 arrangements to make provisions for Local Healthwatch organisations to cooperate with one another across boundaries.
919. *Subsection (6)* inserts new subsections (7A) and (7B) into section 222 of the 2007 Act. New section (7A) places a duty on local authorities to ensure that their Local Healthwatch arrangements are operating effectively and are providing value for money. Subsection (7B) requires the local authority to publish a report of its findings in seeking to meet these two objectives.
920. *Subsections (8) to (11)* make consequential amendments to section 223 of the 2007 Act under which the Secretary of State has the duty to make regulations requiring section 221 arrangements to include particular provision or to require particular provision to be included in the Local Involvement Network arrangements. The amendments ensure that the duty applies in relations to Local Healthwatch organisation arrangements instead.

Clause 170 - Independent advocacy services

921. This clause requires local authorities to make arrangements for the provision of independent advocacy services for complaints relating to the provision of health services, transferring this duty from the Secretary of State.
922. *Subsection (1)* inserts new section 223A into 2007 Act to require local authorities to make arrangements for the provision of independent advocacy services. Local authorities may commission either a Local Healthwatch organisation or other provider to deliver such services. The categories of NHS complaints in respect of which such services must be provided are mentioned in *subsection (2)* of new section 223A. *Subsection (5)* of new section 223A provides that local authorities must have regard to the principle that, as far as practically possible the provision of services should be independent of any person who is the subject of a complaint, or involved in investigating or adjudicating on such a complaint.
923. *Subsection (7)* of this clause enables the Secretary of State to make regulations to require a provider of independent complaints advocacy services to have in place insurance cover against any claims that could be made against the provider for negligence whilst providing those services.

Clause 171 - Requests, rights of entry and referrals

924. *Subsections (1) to (8)* amend sections 224 and 225 of the 2007 Act the effect of which is to allow the Secretary of State to make regulations to impose a duty on health and social care services-providers to:
- respond to requests for information from Local Healthwatch organisations
 - respond to reports or recommendations made by Local Healthwatch organisations
 - allow Local Healthwatch organisations to enter and view premises (if all criteria are met and exclusions do not apply).
925. *Subsections (9) to (12)* amend section 226 of the 2007 Act, which imposes duties on local authority overview and scrutiny committees, including the acknowledgement of receipt of a referral by a Local Involvement Network of organisation on a matter relating to social care services. The effect would be that those duties apply in relation to referrals by Local Healthwatch organisations instead.

Clause 172 – Dissolution and transfer schemes

926. This clause provides for the dissolution of Local Healthwatch organisations and for transfer schemes to be made if needed by inserting new section 226A into the 2007 Act. This gives the Secretary of State the power to dissolve a Local Healthwatch

organisation on his own initiative or if both the Local Authority and Healthwatch England make an application to this effect, if the Secretary of State is satisfied that the circumstances require it. Furthermore, new section 226A (3) allows the Secretary of State on dissolution to make a scheme to transfer property rights and liabilities to the new Local Healthwatch organisation established in the place of the previous organisation.

Clause 173 – Annual reports

927. This clause makes consequential amendments to the 2007 Act. The effect of these amendments would be to require Local Healthwatch organisations to produce annual reports each financial year. This includes the requirement for the report to be prepared by 30 June following the end of each financial year and copies of it to be made publicly available. There must also be a requirement for the person preparing the report, in deciding the manner in which it is appropriate for the report is to be made publicly available, to have regard to any guidance issued by the Secretary of State.
928. *Subsection (5)* adds the Healthwatch England committee of the Care Quality Commission (CQC) to the list of bodies, mentioned in 227(4) of the 2007 Act, that the report must be sent to as specified in 227(2) of the 2007 Act.

Clause 174 – Transitional arrangements

929. This clause enables local authorities to begin the transfer of arrangements to Local Healthwatch organisations, where local authorities wish to directly contract with these organisations, upon commencement of the amendments made to the 2007 Act. The Secretary of State under *subsection (2)* may make a scheme to transfer property, rights and liabilities from the current persons with whom arrangements under section 221 have been made to the new Local Healthwatch organisations. *Subsection (4)* enables the Secretary of State's scheme to require a local authority to pay compensation to the persons from whom property, rights and liabilities are being transferred and enables the scheme to enable the Secretary of State to determine the amount or require the local authority to do so.

Chapter 2 – Local Government

Scrutiny functions of local authorities

Clause 175 - Scrutiny functions of local authorities

930. This clause amends section 244 of the NHS Act. The amendments have the effect that the existing regulation-making powers in section 244 apply in relation to local authorities rather than in relation to local authority health overview and scrutiny committees. The amendments enable regulations under section 244 to authorise the local authority to arrange for an overview and scrutiny committee to discharge the

health scrutiny functions.

931. *Subsection (2)* of this clause amends subsection (2) of section 244 of the NHS Act so that the regulation-making power it confers applies in relation to a local authority instead of an overview and scrutiny committee of a local authority. Local authorities will no longer be required to have health overview and scrutiny committees, but will continue to have oversight and scrutiny powers, which they may discharge how they see fit. For example, local authorities may choose to continue to operate their existing overview and scrutiny committees, or may choose to put in place other arrangements such as appointing committees involving members of the public. The regulation making powers will continue to enable provision to be made on the matters on which an NHS body is required to consult the local authority. Current scrutiny powers enable local authorities to request NHS bodies to attend before them to answer questions and to provide information. The amendments to subsection (2) will enable the regulations under subsection (2) to be extended to cover GP consortia, the NHS commissioning board and all providers of NHS funded services, including independent sector providers.
932. *Subsection (3)* inserts new subsections (2ZA), (2ZB), (2ZC) and (2ZD) into section 244 of the NHS Act. This enables regulations under subsection (2) to set out the circumstances in which certain matters can be referred to the Secretary of State, Monitor, or the NHS Commissioning Board.
933. New subsection (2ZA) sets out the additional provision which may be made where regulations by virtue of subsection (2)(c) of section 244 make provision as to matters on which local NHS bodies must consult the local authority. This includes the conferring of powers on the Secretary of State to give directions to the NHS Commissioning Board and on the NHS Commissioning Board to give directions to a commissioning consortium.
934. New subsection (2ZB) sets out details of the powers of directions that may be conferred under new section (2ZA). New subsection (2ZC) enables regulations under new section (2ZA) to either disapply any provision of section 101 of the local Government Act 1972 to the local authority's discharge of the function of making referrals, or apply such provision with modification as necessary to the discharge of such function. For example, this would allow the regulations to prevent the local authority from appointing a committee to discharge the functions of making such referrals (under section (2ZA)).
935. New subsection (2ZD) enables regulations under the amended section 244 to authorise a local authority to arrange for its functions, under the regulations, to be discharged by an overview and scrutiny committee.
936. *Subsection (4)* inserts a definition of "NHS body" and "relevant NHS provider" into section 244. Subsection (5) inserts a definition of member in relation to NHS

foundation trusts.

937. *Subsection (8)* amends section 9F of the Local Government Act 2000 to remove the requirement on local authorities to have health overview and scrutiny committees and to make clear that the prohibition on overview and scrutiny committees discharging particular functions does not extend to functions conferred by virtue of regulations under new subsection (2ZD). This would allow local authorities to arrange for overview and scrutiny committees to take on the scrutiny functions under section 244.

Joint strategic needs assessments and strategies

Clause 176 – Joint strategic needs assessments

938. This clause amends section 116 of the Local Government and Public Involvement in Health Act 2007, so that a local authority and commissioning consortia that have a boundary within or overlapping or coinciding with that local authority's have a duty to prepare a joint strategic needs assessment. The joint strategic needs assessment is:

“a process to identify the current and future health and wellbeing needs of a population in a local authority area.”¹²

939. It may also address needs around wider determinants of health, such as housing or leisure services, though this would be a local decision.
940. *Subsection (2)* amends subsection (4) of section 116 of the 2007 Act so that the duty to prepare an assessment of relevant needs is transferred from each partner PCT to each partner commissioning consortium of the local authority.
941. Subsection (3) amends subsection (6) of section 116 of the 2007 Act which sets out when there is a relevant need for the purposes of section 116. The amendments replace references to a partner PCT with references to partner commissioning consortia. They also widen the scope of the joint strategic needs assessment to require it to cover both the current and future needs of the local population, and not only current needs.
942. *Subsection (4)* amends subsection (7) of section 116 of the 2007 Act to replace references to “the partner PCT” with references to the “partner commissioning consortium”.
943. *Subsection (5)* amends subsection (8) of section 116 of the 2007 Act so that the duty to co-operate transfers from each partner PCT to each partner commissioning consortia of the local authority.

¹² *Joint Strategic Needs Assessment Guidance* (Department of Health 2007)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081097

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

944. *Subsection (6)* inserts a new subsection (8A) into section 116 of the 2007 Act to enable the local authority and commissioning consortium to consult externally when preparing the joint strategic needs assessment.
945. *Subsection (7)* substitutes a definition of “partner PCT” with a definition of “partner commissioning consortium” and makes consequential amendments to the definition of “relevant district council”.

Clause 177 – Joint health and wellbeing strategies

946. This clause inserts new sections 116A and 116B into the Local Government and Public Involvement in Health Act 2007. New section 116A imposes a duty on local authorities and commissioning consortia to produce a joint health and well-being strategy to meet the needs identified in the joint strategic needs assessment.
947. New section 116B imposes a duty on consortia, the local authority and the NHS Commissioning Board (in relation to its local commissioning responsibilities) to have regard to the joint strategic needs assessment and joint health and wellbeing strategy when carrying out their commissioning functions.
948. The clauses do not specify the form the joint health and wellbeing strategy should take. They require it to address the needs identified in the joint strategic needs assessment, and require the local authority and partner consortia to have regard to the Secretary of State’s mandate under section 13A of the NHS Act when preparing the strategy. For example, the strategy could be high level and strategic, focusing on the interface between the NHS, social care and public health commissioning, rather than being a detailed study of all the commissioning across health and social care in the local authority area. The joint health and wellbeing strategy is not limited in its scope and could potentially include wider health determinants such as housing, if the Health and Wellbeing Board wishes to consider this.
949. Subsections (1) and (2) of new section 116A have the effect that where an assessment of relevant needs is prepared under section 116, the local authority and each partner commissioning consortia must prepare a strategy for meeting those needs.
950. Subsection (3) requires the local authority and its partner commissioning consortia to consider how the needs in the joint strategic needs assessment could more effectively be met through the use of flexibilities available under section 75 of the NHS Act, such as pooled budgets, when preparing the joint health and well-being strategy.
951. Subsection (5) requires the local authority to publish the joint health and well-being strategy.
952. Subsection (6) enables the local authority and partner commissioning consortia to include in the strategy their views on how arrangements for the provision of health-related services could be more closely integrated with arrangements for the provision

of health services and social care services in the area.

953. Subsection (1) of section 116B places a duty on a local authority, and each partner commissioning consortia to have regard to the most recent needs assessment and strategy when exercising relevant functions. Subsection (2) defines a relevant function for the purposes of subsection (1). Subsection (3) places a duty on the NHS Commissioning Board to have regard to the most recent needs assessment and strategy in discharging their local commissioning functions.

Health and Well-being Boards: establishment

Clause 178 – Establishment of Health and Wellbeing Boards

954. This clause requires each upper tier local authority to establish a Health and Wellbeing Board in its area (*subsection (1)*).
955. The clause also sets out their minimum membership (*subsection (2)*). This includes the director of children's services, the director of adult social services and the director of public health. There must be at least one elected representative, which may be the elected mayor or leader of the council, or a councillor nominated by them (*subsections (3) and (4)*). The Local Healthwatch organisation and a relevant commissioning consortium of the local authority must also appoint representatives (*subsections (5) and (6)*). A commissioning consortium may, with the consent of the Health and Wellbeing Board, be represented by the representative of another commissioning consortium within the local authority area (*subsection (7)*).
956. *Subsection (8)* enables the board to appoint additional persons as members. The local authority will also be able to invite other people, or appropriate persons to become members, for example local voluntary groups or service providers (*subsection (1)(g)*). *Subsection (9)* requires the local authority to consult the health and wellbeing board before appointing additional persons after the board has been established. *Subsection (10)* requires each relevant commissioning consortium to cooperate with the health and wellbeing board in the exercise of the board's functions.
957. *Subsection (11)* provides that the Health and Wellbeing Board is a committee of the local authority and is to be treated as if it were appointed under section 102 of the Local Government Act 1972.
958. *Subsection (12)* enables regulations to be made to disapply legislation which applies in relation to committees appointed under section 102 of the Local Government Act 1972 or to provide for such legislation to apply with modifications in relation to Health and Wellbeing Boards. This could be used to govern the arrangements which the health and wellbeing boards could make to discharge their functions, including the establishment of joint committees, or application of maximum terms for board members.

Health and Well-being Boards: functions

Clause 179 –Duty to encourage integrated working

959. This clause imposes a duty on the Health and Wellbeing Board to encourage integrated working between commissioners of NHS, public health and social care services for the benefit of the health and wellbeing of the local population. The Health and Wellbeing Board must provide advice, assistance or other support to commissioners of NHS, public health and social care in order to encourage the developing of agreements to pool budgets or make lead commissioning arrangements under section 75 of the NHS Act.
960. *Subsection (1)* requires the Health and Wellbeing Board to encourage persons who arrange for the provision of health and social care services in its area to work in an integrated manner to secure and advance the health and wellbeing of the people in the area.
961. *Subsection (2)* requires the Health and Wellbeing Board (in particular) to provide advice, assistance or other support for the purpose of encouraging arrangements under section 75 of the NHS Act. These are arrangements under which NHS bodies and local authorities agree to exercise specified functions of each other.
962. *Subsection (3)* enables the Health and Wellbeing Board to encourage persons who arrange for the provision of services related to wider determinants of health (“health-related services”), such as housing, to work closely with the Board; while *subsection (4)* allows the Board to encourage such persons to work closely with the commissioners of health and social care services. *Subsection (6)* defines health services, health-related services and social care services for the purposes of this clause.

Clause 180 – Other functions of Health and Wellbeing Boards

963. This clause makes provision about the functions of Health and Wellbeing Boards.
964. *Subsection (1)* requires the functions of commissioning consortia and local authorities of preparing joint strategic needs assessments and joint health and wellbeing strategies to be discharged by the Health and Wellbeing Board.
965. *Subsection (2)* enables the local authority to delegate any of its functions to the Health and Wellbeing Board. This will provide the flexibility to enable the Health and Wellbeing Board to discharge a local authority’s function of joining up with other local authority commissioners, for example to consider wider determinants of health, such as housing, that affect the health and wellbeing of the population.
966. *Subsection (3)* enables a Health and Wellbeing Board to inform the local authority of its views on whether the authority is discharging its duty to have regard to the joint

strategic needs assessment and joint health and well-being strategy in discharging relevant functions.

967. *Subsection (4)* prevents the local authority from delegating its scrutiny function (under section 244 of the NHS Act) to the Health and Wellbeing Board.

Health and Well-being Boards: supplementary

Clause 181 - Participation of the NHS Commissioning Board

968. This clause provides for participation of the NHS Commissioning Board in the Health and Wellbeing Board's activities. The NHS Commissioning Board will be required to send a representative to participate in the preparation of the joint strategic needs assessment and joint health and wellbeing strategy. It will also be required, upon request of the health and wellbeing board, to send a representative for the purpose of discussing a matter in relation to its local commissioning responsibilities – for example primary medical services commissioning. This could also involve taking part in discussions to improve joint working.
969. *Subsections (1) and (2)* have the effect that where a Health and Wellbeing Board is preparing an assessment of relevant needs under section 116 of the Local Government and Public Involvement in Health Act 2007 or a strategy under section 116A of that Act, the NHS Commissioning Board must appoint a representative to participate in the preparation of the assessment or strategy.
970. *Subsections (3) and (4)* have the effect where a Health and Wellbeing Board is considering a matter that relates to the NHS Commissioning Board's exercise or proposed exercise of commissioning functions in relation to the Health and Wellbeing Board's area, then if the Health and Wellbeing Board so requests, the NHS Commissioning Board must appoint a representative to participate in the consideration of that matter.
971. *Subsection (5)* enables the NHS Commissioning Board to appoint as its representative someone other than a member or employee of the Board, subject to the agreement of the Health and Wellbeing Board.
972. *Subsection (6)* defines "commissioning functions" in relation to the NHS Commissioning Board.

Clause 182 - Discharge of functions of Health and Wellbeing Board

973. This clause makes further provision about how the functions of Health and Wellbeing Boards could be discharged across local authority boundaries by enabling them to arrange for their functions to be exercised jointly.

Clause 183 – Supply of information to Health and Wellbeing Boards

974. This clause allows a Health and Wellbeing Board to require the provision of information from certain persons, for example, the Local Healthwatch organisation represented on the Board and the commissioning consortia so represented. For example, this could be used to support the analysis within the joint strategic needs assessment or the development of the joint health and wellbeing strategy. *Subsection (3)* requires the information supplied to be used only for the purpose of enabling or helping the Health and Wellbeing Board to exercise its functions.

Care Trusts

Clause 184 – Care Trusts

975. This clause amends Section 77 of the NHS Act to make it possible for NHS foundation trusts or commissioning consortia and local authorities to form Care Trusts, if they decided locally that this was the best way to meet the needs of their local populations. The clause also makes amendments that abolish the direct role of the Secretary of State in the process of forming or disbanding a Care Trust.
976. Care Trusts provide opportunities for close integrated working across health and social care services, provision for which is made in Section 77 of the NHS Act.
977. *Subsections (1), (11) and (12)* make changes to subsections (1), (10) and (12) of Section 77 of the NHS Act to make it possible for foundation trusts and commissioning consortia to be designated as Care Trusts. Current legislation makes no provision for Care Trusts to be formed with any NHS partners other than Primary Care Trusts and NHS trusts. Provisions in other parts of this Bill for the abolition of Primary Care Trusts and for all NHS trusts to become NHS foundation trusts would mean that Care Trusts, in their current form, would cease to exist without these changes. Inclusion of NHS foundation trusts and commissioning consortia in subsection (10) of Section 77 would ensure that forming the Care Trust would not affect any of their core functions, rights or responsibilities. In addition, new subsection (5D) enables the parties to agree to act separately or jointly in respect of duties imposed by Section 77 on the NHS body and local authorities.
978. *Subsections (1), (2) and (5) to (7)* make amendments to subsections (1) and (5) of Section 77 of the NHS Act. Subsections (2) and (5) in particular introduce new subsections (1A) and (5A), (5B), (5C) and (5D). These changes end the direct involvement of the Secretary of State in the process of forming or disbanding a Care Trust arrangement. This would include removing the Secretary of State from any direct involvement in specifying the area in question. The decision to form or disband a Care Trust would be for local bodies and they would make the designation themselves. Subsection (4) makes amendments to subsection (4) of Section 77 which enables the designated NHS body to also be able to perform the health related functions of the local authority in agreed areas of that local authority even though it

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may not exercise NHS functions in that area. In future the 'area' served by the Care Trust will be agreed by the NHS body and local authority in the Care Trust arrangement rather than by Secretary of State and this will be influenced by the scope of their partnership agreement and the areas which the NHS body and local authority cover.

979. Repealing subsections (2) and (3) of section 77 of the NHS Act removes the requirement to make a joint application to the Secretary of State for designation as a Care Trust. Subsection (1)(c) to (f) provides that the NHS body and the local authority wishing to form a Care Trust must satisfy themselves that the Care Trust arrangement would lead to an improvement in the health or care outcomes for their local populations. Subsection (2) requires them to publish and consult on their reasoning and the proposed Care Trust governance arrangements. Regulations would prescribe the manner and form of the consultation, when a consultation must commence, how long the consultation period must be and what actions must happen after consultation. This could include publishing the date on which the Care Trust designation would begin (or end in the case that it were disbanded) and the names of the bodies involved in the Care Trust.
980. Subsections (2) and (5) (in particular, new subsections (1B) and (5B)) provide that having decided to form or disband a Care Trust, the NHS body and the local authority would have to notify interested parties. The prescribed persons to be notified would include the NHS Commissioning Board, Monitor, lead elected member of the local authority and the Care Quality Commission. In addition, if local Health and Wellbeing boards are established, notification would be extended to cover those organisations.
981. The intention is that the NHS and health related functions of the local authority should be exercised together as far as possible in order to provide or commission integrated services. The policy to split commissioning and provision within Primary Care Trusts by March 2011 will mean that existing Care Trusts that have a commissioning and provision function will need to change their functions locally - becoming either commissioning or provider organisations, but not both.
982. *Subsections (13) to (15)* are saving provisions. Subsection (13) ensures that that the requirement to consult (see new subsection 1A) before being designated as a Care Trust would not apply to Care Trusts that have already gone through the process under the current legislative requirements. Care Trusts that have already met the current requirements would not have to fulfil any additional requirements to enable them to remain as Care Trusts.
983. *Subsections (14) and (15)* ensure that an NHS Trust or Primary Care Trust which became a Care Trust prior to the commencement of the new provisions but then decided to cancel the arrangement after commencement, would still need to notify the Secretary of State, who will amend its establishment order to remove the words 'Care Trust' from its title. These provisions would remain in force until the point when

Primary Care Trusts are abolished and NHS trusts became NHS foundation trusts. This is because the name of a Primary Care Trust or NHS trust is set out in its establishment order and can only be amended by an order made by the Secretary of State. In future, the intention is to remove the requirement (by repealing subsection (6) of Section 77) that the NHS body must include the words “Care Trust” in its title or branding in order to form a Care Trust.

Chapter 3 – The Health Service Commissioner for England

Clause 185 – Disclosure of reports etc. by the Health Service Commissioner

984. This clause amends section 14 of the Health Service Commissioners Act 1993 to allow the Health Service Commissioner for England, more commonly known as the Health Service Ombudsman, to share her complaints investigation reports and statements of reasons with such persons as she thinks appropriate. The recipients of such reports and statements of reasons would, in practice, largely be part of the NHS in England.

Part 6 – Primary Care Services

Clause 186 - General medical services: minor amendments

985. This clause makes some minor changes to sections 86 (Persons eligible to enter into General Medical Services (GMS) contracts), 89 (GMS contracts: other required terms) and 93 (Persons with whom agreements may be made under section 92) of the NHS Act to improve consistency and as an aid to interpretation.

Clause 187 - Persons eligible to enter into general dental services contracts

986. This clause amends section 102 of the NHS Act to provide for amendments to the organisational types and the background of persons who are permitted to enter into a general dental services (GDS) contract. The clause extends slightly the range of organisational arrangements whilst continuing to provide for the professional dental nature of GDS providers through new rules on what constitutes acceptable control of a contracting body.
987. *Subsections (1) and (2)* amend section 102(1) and (2) to provide that, whilst a GDS contractor must always include a dental practitioner, in future any person would be able to be part of a limited liability partnership (LLP) or a company limited by shares providing GDS.
988. *Subsections (3), (4) and (5)* permit those entering into a GDS contract to arrange their affairs as an LLP, provided that at least one member is a dental practitioner, or falls within a defined group of people within the NHS. This extends the existing provisions which allow dental bodies corporate to enter into a GDS contract, as well

as individual dentists and dental partnerships.

Clause 188 - Arrangements under section 107 of the NHS Act

989. This clause amends section 108 of the NHS Act to provide amendments which relate to the organisational types and the background of persons who are permitted to enter into a section 107 arrangement (a PDS agreement). This paragraph removes certain restrictions in relation to the people and organisations that can be party to a PDS agreement.
990. *Subsections (2) and (3)* amend section 108(1), adopting the approach used in the amendment to section 102(1), to allow the Board to make section 107 (PDS) agreements with a company limited by shares or a limited liability partnership, provided that at least one member is a dental practitioner, or falls within a defined group of people within the NHS, and that such a person has the power to ensure that the partnership's affairs are conducted in accordance with wishes.
991. *Subsection (5)* omits current section 108(2) as the section is no longer required as a consequence of the amendment to section 108(1).
992. *Subsection (6)* omits the definition of qualifying bodies, following the adoption of the nomenclature "company limited by shares" and inserts a definition of "dental corporation".

Clause 189 - Payments in respect of costs of sight tests

993. This clause amends section 180(3) of the NHS Act (payments in respect of costs of optical appliances).
994. *Subsection (2)* amends subsection (3) of section 180 by inserting a new paragraph (za) which introduces a new reference to the Board and clarifies the existing payment powers that underlie current practice.
995. *Subsection (3)* inserts new subsection (3A) into section 180 to clarify the level of repayments which may be made. The clarification is in line with existing practice.

Clause 190 - Pharmaceutical needs assessments

996. This clause makes amendments to the arrangements for preparing pharmaceutical needs assessments (PNAs).
997. *Subsection (1)* amends section 128A of the NHS Act to provide that the responsibility for developing, updating and publishing local PNAs is transferred from PCTs to Health and Well-being Boards (HWBs) in local authorities.
998. *Subsections (2) to (5)* amend sections 24, 24A, 242 and 242A to put it beyond doubt

that, pending the abolition of PCTs, PCT duties in relation to their plans for improving health and consultation as effects pharmaceutical services are treated as having been discharged by compliance with the requirements in section 128A for consultation on their assessment of needs for pharmaceutical services.

Clause 191 - Control of entry on pharmaceutical lists

999. This clause amends the control of entry provisions in section 129 of the NHS Act which govern the right to be included on the pharmaceutical list in order to provide pharmaceutical services.
1000. *Subsection (2)* amends subsection (2)(c) of section 129 of the NHS Act to provide that the Board is to be responsible for determining applications for market entry in England (inclusion in the pharmaceutical list or additional premises) in line with the relevant pharmaceutical needs assessment (“PNA”) as prescribed in regulations.
1001. *Subsection (3)* inserts a new subsection (2ZA) into section 129 of the NHS Act which provides that the Secretary of State and such other persons as may be prescribed in regulations are not to be included in a pharmaceutical list.
1002. *Subsection (4)* amends subsection (2A) of section 129 of the NHS Act consequential to the establishment of the Board and the requirement to have regard to a PNA prepared in respect of a particular area before granting an application.
1003. *Subsection (5)* substitutes subsection (2B) of section 129 of the NHS Act so as to define the relevant area by reference to the area to which an application relates. The intention is that regulations will make provision for the relevant area to be linked to the area of the PNA as currently published and updated by PCTs and in future by HWBs.
1004. *Subsections (6) and (7)* amend section 129 of the NHS Act consequential to the amendments at subsections (4) and (5).
1005. *Subsection (8)* makes amendments to subsection (6)(g) of section 129 of the NHS Act to put it beyond doubt that regulations under section 129 may provide for the removal of a person from the pharmaceutical list for reasons that are not connected to a person’s fitness to practise, and are not the grounds specified in subsection (6)(d), but rather are other grounds prescribed in regulations. The intention is that, for consistency with the amendments made to section 130 of the NHS Act, any appeals against decisions to remove a person from a list on other prescribed grounds are to be made to the Secretary of State (that is, in practice, to the National Health Service Litigation Authority).
1006. *Subsections (9), (11) and (12)* amend subsection (10B) of section 129 and section 136 of, and Schedule 12 to, the NHS Act consequential to the responsibility for PNAs transferring to HWBs and as a consequence of PNAs being carried out by reference to

“relevant areas” as defined in section 129 of the NHS Act.

1007. *Subsection (10)* amends section 130 of the NHS Act so as to ensure that appeals against the Board’s determination of an application for inclusion in the pharmaceutical list are heard by the First Tier Tribunal only if they are on fitness to practise grounds. The amendments also provide that if the First Tier Tribunal does allow an appeal, it would not have to re-determine the application but can remit the matter back to the Board. Appeals on other grounds are to be made to the Secretary of State. It is intended that the current position whereby the Secretary of State’s functions relating to hearing appeals on pharmaceutical list matters are delegated to the National Health Service Litigation Authority will be maintained.

Clause 192 - Lists of performers of pharmaceutical services and assistants etc.

1008. This clause makes provision for the Board to establish lists of Local Pharmaceutical Service (LPS) performers and those who assist pharmaceutical contractors in the provision of pharmaceutical services.
1009. *Subsection (1)* omits sections 146, 149 and 150 of the NHS Act which make provision for the compilation and publication of lists of LPS performers and those who assist pharmaceutical contractors in the provision of services.
1010. *Subsection (2)* inserts new sections 147A and 147B into the NHS Act which introduce composite regulation making powers in respect of, among other things, the compilation and publication of lists of LPS performers and those who assist pharmaceutical contractors in the provision of pharmaceutical services.

New Section 147A

1011. Subsection (1) of section 147A provides that the Board is to maintain and publish one or more lists of those who assist pharmaceutical contractors or who are LPS performers.
1012. Subsection (2) of section 147A enables regulations to make provision for persons of a prescribed description (such as pharmacist managers and employees or pharmacy technicians) not to assist in the provision of pharmaceutical services which the Board arranges nor to perform local pharmaceutical services unless the person is included in a list prepared by virtue of regulations made under subsection (1).
1013. Subsection (3) of section 147A makes detailed provisions carried forward from sections 146 and 149 in respect of other matters that may be included in the regulations about such lists. These matters include how such lists are to be published and maintained, the criteria for inclusion in a list, how applications are to be made and the supporting information that is required, the grounds for admittance, refusal, or suspension from the list and corresponding appeal rights.

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1014. Subsection (4) of section 147A enables regulations to be made to cater for the situation where a person who is entered on a contractual pharmaceutical list under section 129 may also be required to be entered on a performers' list. For example, a partner in a limited liability partnership who is entered in the contractual pharmaceutical list may also be a LPS performer and therefore may be required to apply to be entered on the relevant LPS list. The regulations may also provide that approval for the purposes of entry to a LPS performer's list may similarly be treated as approval for the purposes of entry to a pharmaceutical assistants' list and vice versa.
1015. Subsections (5) and (6) of section 147A enable regulations to make provision in respect of conditional entry to a pharmaceutical performers' or assistants' list and to specify the purposes for which such conditions may be imposed.
1016. Subsections (7) to (9) of section 147A enable further provision to be made in respect of regulations relating to the suspension or removal of a person from a list and for appeals against decisions to suspend or remove a person from a list or to impose conditions.
1017. Subsection (10) of section 147A enables regulations to be made which authorise the disclosure of information to the Board in cases where regulations are made relating to the grounds on which a person may be suspended or removed from a list and the procedure to be followed in such cases.

New Section 147B

1018. Section 147B of the Act makes further provision about regulations under section 147A.
1019. Subsection (1) of section 147B enables regulations to make provision for persons of a description prescribed in regulations to not employ or engage a person to assist in the provision of pharmaceutical services unless that person is included in a list mentioned in subsection (2).
1020. Subsection (2) of section 147B sets out the lists in which a person would need to be included. These include the lists in section 147A and also medical, dental or ophthalmic lists.
1021. Subsection (3) of section 147B enables regulations to require that persons providing pharmaceutical services and those assisting in the provision of pharmaceutical services must both be included in lists prepared by the Board.

Other matters

1022. Subsection (3) of this clause amends the heading of Chapter 5 of the Act.

1023. Subsection (4) of this clause amends section 159 of the NHS Act consequential to the amendments of this paragraph of Schedule 4.
1024. Subsection (5) of this clause provides for transitional arrangements to preserve the effect of any regulations made under section 146 or 149 of the NHS Act despite the repeal of those sections.

Part 7 – Regulation of Health and Social Care Workers

1025. Part 7 contains provisions relating to three distinct changes:
- a) the abolition of the General Social Care Council and the transfer of some functions to the Health Professions Council;
 - b) reforms to the governance and functions of the Council for Healthcare Regulatory Excellence, which is to be given new powers to accredit voluntary registers; and,
 - c) the abolition of the Office of the Healthcare Professions Adjudicator.
1026. Schedule 14 makes further provision in these areas. Unless otherwise stated, the following terms used in this Part have the meaning set out below:
- ‘the Council’ refers to the body currently known as the Health Professions Council which will be renamed the Health and Care Professions Council by the Bill;
 - ‘the Authority’ refers to the Professional Standards Authority for Health and Social Care (which will be the new name of the Council for Healthcare Regulatory Excellence);
 - ‘the 2001 Order’ refers to the Health Professions Order 2001, which will be renamed the Health and Social Work Professions Order 2001 by the Bill;
 - ‘the 2002 Act’ refers to the National Health Service Reform and Health Care Professions Act 2002;
 - ‘the 1999 Act’ refers to the Health Act 1999; and
 - ‘the 1983 Act’ refers to the Mental Health Act 1983.
1027. *Abolition of the General Social Care Council and transfer of its functions.* The following clauses deal with the abolition of the General Social Care Council and the transfer of its functions in relation to the regulation of social workers and the education and training of approved mental health professionals in England to the Health Professions Council. The Health Professions Council will be renamed the Health and Care Professions Council to reflect its wider remit in regulating social

workers in England as well as health professionals in the UK. The Council has confirmed to the Government that the name ‘Health and Care Professions Council’ will be supported by a strapline which will clarify the professions which the Council will regulate, including social workers in England.

Orders under section 60 of the Health Act 1999

Clause 193 – Power to regulate social workers etc. in England

1028. This clause amends the existing power under section 60 of the 1999 Act to provide a power for Her Majesty by Order in Council to regulate (and modify the regulation of) social workers, and social care workers, in England through secondary legislation. The power enables primary legislation to be amended by means of that secondary legislation. This power replaces the Secretary of State’s current power under section 124 of the Care Standards Act 2000 to regulate social workers, and social care workers, in England using secondary legislation. The definitions in *subsections (5) and (6)* are based on those in section 55 of the Care Standards Act 2000.
1029. The existing power under section 60 enables Her Majesty by Order in Council, amongst other things, to modify the regulation of certain specified health professions and to regulate any other profession which appears to Her to be concerned with the physical or mental health of individuals.
1030. *Subsections (11), (12) and (13)* amend section 60A of the 1999 Act to provide that proceedings before a regulatory body relating to social, or social care, workers in England should be subject to the civil standard of proof. This represents no change from the standard of proof used by the General Social Care Council.
1031. Schedule 14, paragraph 40 disapplies section 124 of the Health and Social Care Act 2008 in relation to England. Previously, section 124 of the Health and Social Care Act 2008 enabled the Secretary of State, by way of regulations, to regulate or modify the regulation of social workers and social care workers in England.

Clause 194 - Training etc. of approved mental health professionals in England

1032. This clause further amends section 60 of the 1999 Act to enable section 60 orders to modify the new functions of the Council in relation to the education and training of approved mental health professionals. Those functions are transferred to the Council from the General Social Care Council by clause 201.
1033. The extension of the power in section 60 replaces the power of the Secretary of State in section 126 of the Health and Social Care Act 2008 to make regulations modifying the General Social Care Council’s functions in relation to approved mental health professionals’ education and training.
1034. This amendment goes with some other changes to the 1999 Act made in other clauses.

Clause 193 adds a new subsection (2ZE) to section 60 making clear that acting as an approved mental health professional does not fall within the definition of social work for the purposes of section 60 if the approved mental health professional is not a social worker. This is to ensure that healthcare professionals acting as approved mental health professionals are not required to register as social workers as well as members of the profession to which they belong.

1035. Similarly, clause 195 adds a new paragraph 1B to Schedule 3 to the 1999 Act to say that a section 60 Order may deal with the standards of conduct and performance expected of professionals and social care workers when acting as approved mental health professionals. That is particularly intended to avoid any suggestion that the normal standards of professional conduct and performance set by the Council (or another regulatory body) cannot apply to members of the profession concerned when acting as approved mental health professionals.

Clause 195 – Orders regulating social care workers in England: further provision

1036. This clause amends Schedule 3 to the 1999 Act in relation to the making of orders regulating (or modifying the regulation) of social care workers in England. The amendments broadly mirror the further provisions regarding regulations made under section 124 of the Care Standards Act 2000 to regulate or modify the regulation of social care workers.
1037. *Subsection (2)* gives examples of the matters which a section 60 order could deal with when making provision about the regulation of social care workers in England. These provisions are subject to the limitations set out in *subsection (5)*. This prevents section 60 orders from being used to transfer to any other person certain functions in relation to social care workers in England which have been conferred on the Council or another regulatory body by an enactment.
1038. *Subsection (6)* amends paragraph 9 of Schedule 3 so that the Secretary of State's duty to consult before laying a draft section 60 order before Parliament equally applies in relation to section 60 orders dealing with social care workers in England.
1039. *Subsection (8)* sets out that section 60 orders may also make provision in relation to those who are not currently registered as social care workers in England but are seeking to be, or have previously been, so registered; and in relation to those who engage in work which is connected to social care work in England (for example housing support workers).

The General Social Care Council

Clause 196 – Abolition of the General Social Care Council

1040. This clause abolishes the General Social Care Council by means of amending section 54 of the Care Standards Act 2000, which established the General Social Care

Council and the Care Council for Wales.

1041. The Care Council for Wales will continue in existence and will continue to regulate social workers and social care workers in Wales. Its legislative framework will be unchanged except for amendments consequential on the abolition of the General Social Care Council.

The Health and Care Professions Council

Clause 197 – Regulation of social workers in England

1042. This clause amends the 2001 Order to provide for the Health and Care Professions Council to regulate social workers in England. The 2001 Order establishes, and provides the legislative framework for, the Council.
1043. *Subsection (2)* amends Schedule 3 to the 2001 Order to include social workers in England as a ‘relevant profession’. This amendment is the means by which the Council will be required to regulate social workers in England.
1044. The membership of the Council is made up of registrant and lay members. As social workers in England will now be regulated by the Council, social workers should no longer be able to be lay members. *Subsection (5)* amends the definition of a lay member accordingly to exclude persons who are, or have been, registered as social workers with the General Social Care Council or the Care Councils of Wales, Scotland or Northern Ireland.
1045. *Subsection (6)* renames the 2001 Order as the ‘Health and Social Work Professions Order 2001’.

Clause 198 – The Health and Care Professions Council

1046. This clause provides that the Health Professions Council is to remain in existence and renames it the Health and Care Professions Council.

Clause 199 – Functions of the Council in relation to social work in England

1047. This clause amends the 2001 Order to make provision for the Council to regulate social workers in England.
1048. *Subsection (2)* amends article 3(5)(b) of the 2001 Order to extend the Council’s duty to co-operate with certain specified bodies. The bodies to which the duty is extended are public bodies or other persons concerned with the regulation of social work in England and the provision, supervision or management of the services of persons engaged in social work in England. *Subsection (3)* specifies that this duty includes, in particular, the Care Councils of Scotland, Wales and Northern Ireland.

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1049. *Subsection (4)* amends article 3 of the 2001 Order to extend the existing power of the Council to make recommendations to the Secretary of State about healthcare professions which it believes should be regulated to also cover social care workers in England. The Council may also give guidance (to those with an interest) on what criteria should be considered in deciding whether social care workers in England should be regulated.
1050. *Subsections (5), (6), (10) and (13)* extend to social workers the current provisions in the 2001 Order which relate to visiting health professionals from relevant European states.
1051. *Subsections (7) and (8)* amend article 12 of the 2001 Order to enable the Council to recognise training undertaken in Scotland, Wales and Northern Ireland as sufficient for admission to its register as a social worker. Related to this, the Council is also given the power to assess training or professional experience in social work gained outside England but within the UK, and to compare this with the standard of proficiency it requires for admission to its register as a social worker.
1052. *Subsection (9)* inserts a new section 13B into the 2001 Order which places a new duty on persons to register with the Council as a social worker in order to practise as a social worker in England. The duty will not apply to persons who are registered with one of the Care Councils of Scotland, Wales and Northern Ireland and who are practising in England on a temporary basis.
1053. *Subsection (11)* provides that powers of the National Assembly for Wales under article 20 of the Order do not extend to the regulation of social workers in England.
1054. *Subsection (12)* amends article 39 of the 2001 Order. As a result of the changes to social work regulation, the offences under article 39 will apply in relation to social workers in England in the same way as they apply in relation to the other professions regulated by the Council. However, given that the relevant part of the Council's register will be titled "social worker" rather than "social worker in England" a further amendment is necessary to ensure that a person who uses the title "social worker" as a result of being registered as a social worker with one of the Care Councils of Scotland, Wales and Northern Ireland will not commit an offence under article 39(1)(b).

Clause 200 – Appeals in cases involving social workers in England

1055. This clause amends articles 37 and 38 of the 2001 Order which relate to appeals against decisions of the Council (and its committees).
1056. *Subsection (2)* amends the definition of lay member in article 37 to exclude persons who are, or have been, registered as social workers with the General Social Care Council or one of the Care Councils of Wales, Scotland or Northern Ireland from the definition of lay member. This means that such a person may not be a lay member on

a panel of the Council which is considering an appeal from a decision of the Council's Education and Training Committee. *Subsections (3) and (4)* provide that an appeal against a decision of the Education and Training Committee of the Council relating to a social worker in England must be heard in England.

1057. *Subsections (5) to (7)* amend article 38 to provide that all appeals from a decision of the Council to a court relating to a social worker in England are to be heard by either a county court or the High Court of Justice in England and Wales.

Clauses 201 - Approval of courses for approved mental health professionals

1058. This clause concerns the transfer to the Council of the General Social Care Council's power under section 114A of the Mental Health Act 1983 to approve training courses for people who are, or who wish to become, approved mental health professionals in England.

1059. Approved mental health professionals are professionals with particular expertise in mental health who are approved by local social services authorities to carry out certain important functions under the 1983 Act. It is, for example, approved mental health professionals who make the large majority of applications under the 1983 Act for people to be detained in hospital for assessment or treatment of their mental disorder. Most current approved mental health professionals are social workers, but The Mental Health (Approved Mental Health Professionals) (Approval) (England) Regulations 2008¹³ say that local social services authorities in England may also approve mental health and learning disability nurses, occupational therapists and practitioner psychologists. Those regulations also say those authorities may not approve new approved mental health professionals unless they have completed a training course approved by the General Social Care Council (or the Care Council for Wales).

1060. The clause inserts a new section 114ZA into the 1983 Act giving the Council the power to approve courses for people who are, or wish to become, approved mental health professionals in England. The new section also requires the Council to publish details of current and past approved courses

1061. In practice, courses would actually be approved by the Council's Education and Training Committee, which is already responsible for approving training and education for the professions regulated by the Council. The Committee would also be able to arrange for other people to approve courses on the Council's behalf. It can already do this in relation to the Council's existing powers to approve education and training, although, in practice, it has not made any such arrangements.

1062. The rest of this clause amends section 114A of the 1983 Act to remove the General Social Care Council's power to approve approved mental health professional courses.

¹³ Statutory Instrument: 2008 No. 1206

None of these changes affect the power of the Care Council for Wales to approve courses for people who are, or wish to become, approved mental health professionals in Wales. That power remains in section 114A.

Clauses 202 - Exercise of function of approving courses, etc

1063. This clause amends the 2001 Order to reflect the Council's new role in approving approved mental health professional courses.
1064. The clause amends article 3 of the 2001 Order to acknowledge the Council's new function and to say how the general duties set out in paragraph (5) of that article apply in relation to those approved mental health professionals who belong to a profession which is not regulated by the Council. The Council's general duties include having regard to the interests of people using the services of registrants, considering the differing interests of different categories of registrant, and co-operating with employers, training providers and other regulatory bodies. The effect of subsection (3) is that those general duties apply to non-registrant approved mental health professionals as if they were registrants.
1065. The clause also amends the 2001 Order to deal with the process for approving approved mental health professional courses. The process is modelled closely on the existing provisions in articles 15 to 18 of the 2001 Order, which deal with the approval of education and training for the Council's registrants.
1066. The clause inserts a new article 15B into the 2001 Order, requiring the Council to set and publish the criteria to be applied when endorsing approved mental health professional courses. However, it also inserts a new article 15A saying that it is the Council's Education and Training Committee, rather than the Council itself, which is to approve courses in accordance with those criteria. As explained above, the Education and Training Committee would be able, if it wished, to arrange for other people to approve courses on the Council's behalf.
1067. Between them, the new articles 15A and 15B then say that the Education and Training Committee must ensure that universities and other bodies in the UK involved in providing approved mental health professional courses are told of the approval criteria. It must also take steps to satisfy itself that the approved mental health professional courses that universities and other bodies are providing meet the criteria. In doing so, the Education and Training Committee would be able to approve (or arrange for someone else to approve) UK institutions which it believes are properly organised and equipped to run these courses. Courses run by such approved institutions are the only approved mental health professional courses outside the UK which the Education and Training Committee would be able to approve.
1068. The new article 15B(5), together with other minor amendments made by this clause, means that articles 16 to 18 of the 2001 Order apply to approved mental health professional courses in largely the same way as they apply to other education and

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

training approved by the Council. As a result, article 16 would allow visitors appointed by the Council to visit institutions running, or proposing to run, approved mental health professional courses, and to report their findings to the Education and Training Committee. Article 17 would allow the Education and Training Committee or the Council to require information from such institutions. Article 18 would allow the Education and Training Committee to refuse or withdraw approval for an approved mental health professional course.

1069. The clause also amends article 21 of the 2001 Order to make clear that the Council's standards of conduct, performance and ethics for its registrants (and would be registrants) must also cover the standards expected of them when acting as approved mental health professionals. Finally, the clause extends the Secretary of State's powers under article 45 to provide financial assistance to the Council so that it can include grants or loans in connection with the approval of approved mental health professional courses.

Clause 203 - Arrangements with other health or social care regulators

1070. This clause amends the 2001 Order to enable the Council to make arrangements for the provision of administrative and other services to others who maintain a register of health or social work professionals, or health or social care workers.
1071. This would enable the Council to provide assistance to holders of any registers of health or social care workers or professionals either within or outside the UK. The Council would therefore be able to support other persons and bodies in exercising control over the standards and performance of such professionals and workers to assist with the goal of protecting service users and the public.
1072. This clause is to be commenced on Royal Assent to enable the Council to provide assistance, if such assistance is considered necessary and suitable arrangements are entered into, to the General Social Care Council prior to its abolition.

Clause 204 - References in enactments to registered health professionals, etc

1073. This clause makes amendments to various Acts to exclude social workers and social care workers in England from the definition of 'registered health care professional' and similar terms. This avoids the unintended consequence of social workers and social care workers in England falling within such definitions by virtue of them falling to be regulated by the Council and coming within the remit of a section 60 order.

Role of the Secretary of State

Clause 205 – Functions of the Secretary of State in relation to social care workers

1074. This clause amends section 67 of the Care Standards Act 2000 (the 2000 Act) to

change certain functions of the Secretary of State.

1075. Section 67 sets out the functions of the Secretary of State in relation to the training of social workers and social care workers in England. These functions include ascertaining what training is required by those who are, or who wish to become, social workers or social care workers and drawing up occupational standards for them.
1076. Following the transfer of the regulation of social workers in England to the Council, it will become the Council's responsibility to carry out similar functions. As such, *subsection (1)* provides that these Secretary of State functions do not extend to social workers registered by the Council.
1077. This clause amends subsection (2) of section 67 of the 2000 Act to give the Secretary of State the function of encouraging persons to take part in courses approved by the Council for the purposes of being registered as a social worker in England.
1078. *Subsection (3)* provides that the Secretary of State may make arrangements with the Council for the latter to undertake the functions of the General Social Care Council in the period from Royal Assent of the Bill to the abolition of the General Social Care Council.

The Professional Standards Authority for Health and Social Care

1079. The following clauses concern changes to the Council for Healthcare Regulatory Excellence, which will become the Professional Standards Authority for Health and Social Care.

Clause 206 - The Professional Standards Authority for Health and Social Care

1080. This clause changes the name of the Council for Healthcare Regulatory Excellence to the Professional Standards Authority for Health and Social Care, and makes amendments to the National Health Service Reform and Health Care Professions Act 2002 required as a result of the change of name.
1081. The name change reflects its new functions in overseeing the Health and Care Professions Council, and its new power to accredit voluntary registers of unregulated health professionals and unregulated health care workers in the UK, and unregulated social care workers in England.
1082. The Council for Healthcare Regulatory Excellence was established by section 25 of the 2002 Act and its functions are set out in sections 25 to 29 of that Act. It is currently responsible for the scrutiny and quality assurance of the nine health professional regulatory bodies in the UK, namely the General Medical Council, the General Dental Council, the General Optical Council, the General Osteopathic Council, the General Chiropractic Council, the General Pharmaceutical Council, the Pharmaceutical Society of Northern Ireland, the Nursing and Midwifery Council and

the Health Professions Council (which will be renamed the Health and Care Professions Council in this Bill).

Clause 207 - Functions of the Authority

1083. This clause makes amendments to the 2002 Act to make changes to the functions of the Authority.
1084. Given that the Health and Care Professions Council will take on the regulation of social workers in England, the regulatory bodies which the Authority will have functions in relation to will include a regulatory body that regulates social workers in England. This necessitates a number of changes to the Authority's functions in the 2002 Act.
1085. *Subsections (1), (2), (5) and (8)* amend sections 25 and 26B of, and paragraph 16 of Schedule 7 to, the 2002 Act to provide for those functions of the Authority which relate to the interests of patients or the health, safety and well-being of patients to instead relate to the interests, or the health, safety and well-being, of users of health care, users of social care in England and users of social work services in England.
1086. *Subsection (3)* inserts a new subsection into section 26A of the 2002 Act to empower the Secretary of State to request advice from the Authority on matters connected with the social work profession, or social care workers, in England and requires the Authority to comply with the request. Section 26A already empowers the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland to ask the Authority for advice on any matter connected with a health care profession and to require the Authority to investigate and report on any matter in relation to which it has functions. Subsection (4) imposes a new duty on the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland to pay a fee, determined by the Authority, for any advice requested, or investigations or reports commissioned, under section 26A.
1087. Under section 29 of the 2002 Act, the Authority has the power to refer to court final fitness to practise decisions taken in relation to registered professionals by the regulatory bodies, where it considers that a decision is unduly lenient or should not have been made, and where it considers that a referral would be desirable for the protection of the public. As the regulation of social workers in England is being transferred to the Health and Care Professions Council, the Authority's powers under section 29 will extend to decisions taken in relation to social workers in England. Subsection (7) amends section 29 to provide that, when the Authority refers a decision about a social worker in England to a court, it must be referred to the High Court of Justice in England and Wales. This is to prevent decisions about social workers in England being referred to the Court of Session in Scotland or the High Court of Justice in Northern Ireland, which would not be appropriate.

Clause 208 - Funding of the Authority

1088. This clause inserts a new section 25A into the 2002 Act, which provides for changes to the way in which the Authority is funded.
1089. This section places a duty on the Privy Council to make regulations requiring each regulatory body listed in section 25(3) of the 2002 Act to pay periodic fees in respect of such of the functions of the Authority as are specified in the regulations (with the exception of those functions relating to the provision of advice, investigations and reports under section 26A and its functions in relation to voluntary registration under new sections 25G to 25I).
1090. The regulations will be subject to consultation with the Authority, the regulatory bodies and such other persons as the Privy Council considers appropriate. The regulations will be subject to Parliamentary scrutiny under the negative resolution procedure in the Westminster Parliament and, where they contain matters which fall within the legislative competence of the Scottish Parliament, the Scottish Parliament.
1091. The amount of the fees to be paid by the regulatory bodies will be determined by the Privy Council in accordance with these regulations. The section sets out the process and consultation that the Privy Council must undertake in determining the fees which must be paid by the regulatory bodies, and makes further specific provision about the matters that may be dealt with in the regulations.
1092. *Subsection (4)* of this clause gives the Authority a new power to borrow money for the purposes of, or in connection with, its functions from persons other than the Secretary of State, the National Assembly for Wales, the Scottish Ministers or the Department of Health, Social Services and Public Safety in Northern Ireland.

Clause 209 - Power to advise regulatory bodies, investigate complaints etc.

1093. This clause inserts a new section 25B into the 2002 Act. It empowers the Authority to provide advice or auditing services to the regulatory bodies, or to bodies with functions that correspond to those of the regulatory bodies, whether or not these relate to health or social care.
1094. A compulsory fee, determined by the Authority, will be paid by the bodies to which it provides advice. However, the Authority may only provide advice or auditing services under this section if doing so would assist it in the performance of its functions, apart from its function of providing advice, reports or investigations to the Secretary of State or the devolved administrations under section 26A.
1095. *Subsections (2) and (3)* amend the power under section 28 of the 2002 Act which enables the Secretary of State to make regulations about the investigation by the Authority of complaints made to it about the regulatory bodies. The Secretary of State's power to make regulations will be conferred on the Privy Council instead.

These regulations, as now, will be subject to the affirmative resolution procedure.

Clause 210 - Accountability and governance

1096. This clause amends Schedule 7 to the 2002 Act to make changes to the way in which members of the Authority are appointed, to its constitution, and to its accountability and governance provisions.

1097. At present:

- the chair of the Authority is appointed by the Privy Council,
- three non-executive members are appointed by the Secretary of State, and
- one non-executive member is appointed by each of the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland.

1098. *Subsection (2)* of this clause provides that the three Secretary of State appointments will be made Privy Council appointments. The number of executive members will also be reduced from two to one.

1099. *Subsection (4)* amends paragraph 10 of Schedule 7 to the 2002 Act to confer on the Authority the power to determine the remuneration and allowances of its members and committee or sub-committee members, to determine the pensions of the chair and other members of the Authority, and to determine whether any compensation should be payable to an ex-chair of the Authority.

1100. *Subsections (3) and (6)* amend paragraphs 6 and 15 of Schedule 7 to the 2002 Act to provide for the following of the Secretary of State's current powers to be conferred instead on the Privy Council:

- the power to make regulations about appointments to the Authority and the appointment of, constitution of, and exercise of functions by its committees and sub-committees. These regulations will be subject to the negative resolution procedure;
- the power to determine the form of accounts which must be kept by the Authority;
- the power to determine the form of the annual accounts which must be prepared by the Authority; and
- the power to determine the period after the end of the financial year within which the Authority must send a copy of its annual accounts to the Comptroller

and Auditor General.

1101. The Authority will no longer be required to send copies of its annual accounts to the Secretary of State.
1102. *Subsection (7)* places a new duty on the Authority to publish a strategic plan for the coming financial year (and for such subsequent years as it may determine) by a date determined by the Privy Council. The Authority must also lay its strategic reports before the four UK parliaments and assemblies as soon as possible after the end of the financial year.

Clause 211 - Appointments to regulatory bodies

1103. This clause inserts a new section 25C into the 2002 Act which makes provision in relation to Privy Council appointments to the regulatory bodies and Privy Council and other appointments to the Authority. .
1104. The Privy Council is given the power to appoint members of the regulatory bodies (with the exception of the Pharmaceutical Society of Northern Ireland) under their various governing enactments, and to appoint the chair and three non-executive members of the Authority. At present, the Privy Council's appointments functions in relation to members of the regulatory bodies and the chair of the Authority are delegated to the Appointments Commission by means of directions made under powers in the Health Act 2006. Given that the Appointments Commission will be abolished in this Bill, it will no longer be able to carry out such appointments on the Privy Council's behalf, and a new approach to the making of Privy Council appointments to the regulatory bodies and the Authority is needed.
1105. Therefore, new section 25C empowers the Privy Council and a regulatory body to make arrangements for the regulatory body in question (or a third party, such as a recruitment agency) to assist the Privy Council to make appointments to that regulatory body. It empowers the Authority to assist the Privy Council to make appointments to both the Authority and to the regulatory bodies. It also empowers the Privy Council to make arrangements with any other person to assist it to make appointments to the Authority or the regulatory bodies. In each case, however, the function of making the appointment rests with the Privy Council.
1106. The Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland each have the power to appoint one non-executive member of the Authority and, in subsections (4) to (6) of new section 25C the Authority is given the power to make arrangements with the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland for the Authority to assist them in making these appointments.

Clause 212 – Establishment of voluntary registers

1107. This clause inserts new sections 25D, 25E and 25F into the 2002 Act.
1108. Section 25D empowers the regulatory bodies to establish and maintain voluntary registers of persons who are or have been unregulated health professionals and unregulated health care workers in the UK, and unregulated social care workers in England. With the exception of the Health and Care Professions Council, this power is limited to establishing and maintaining voluntary registers of groups whose work supports or relates to the work of the profession which the body regulates. The terms “voluntary register”, “unregulated health professional”, “unregulated health care worker” and “unregulated social care worker in England” are defined in section 25E.
1109. Section 25E defines ‘voluntary register’ for the purposes of section 25D. A voluntary register is a register of persons who are not required by any enactment to be on that register in order to use a title, practise a profession, engage in health care work in the UK or social care work in England or undertake certain studies. It is defined in such a way that, should one or more of the administrations in England, Scotland, Wales or Northern Ireland decide to make it compulsory for persons in that part of the UK to be on a particular register in order to do one or more of these things, that register would still be regarded as a voluntary register in so far as it registers persons in other parts of the UK (in relation to which no requirement to be on that register exists). It is also defined in such a way that if an enactment makes it compulsory for a person to be on a particular register in order to carry out work or practice of a particular kind but only for a specific purpose, that register will remain a voluntary register. An example would be if a statutory instrument required a person to be on a particular register in order to work as a health care support assistant in the NHS in England (but not in order to work as a health care support assistant outside the NHS in England).
1110. Under section 25D, regulatory bodies may also establish and maintain voluntary registers of certain students. This power, for each regulatory body, is limited to establishing and maintaining voluntary registers of persons studying to become a member of a profession regulated by that body or in relation to which that body maintains a voluntary register, or studying to engage in work as an unregulated health care worker or unregulated social care worker in England in relation to which that body maintains a voluntary register.
1111. All of the regulatory bodies have a UK-wide scope, with the exception of the General Pharmaceutical Council, which is the regulator of pharmacists, pharmacy technicians and pharmacy premises in Great Britain, and the Pharmaceutical Society of Northern Ireland, which is the regulator of pharmacists and pharmacy premises in Northern Ireland. The General Pharmaceutical Council may only establish and maintain voluntary registers under section 25D for persons who are, or have been, engaged in work or participating in studies in Great Britain, and the Pharmaceutical Society of Northern Ireland may only establish and maintain voluntary registers for persons who are, or have been, engaged in work or participating in studies in Northern Ireland. The

exception to this is where the General Pharmaceutical Council and Pharmaceutical Society of Northern Ireland jointly establish a voluntary register, which can have UK-wide scope.

1112. Section 25D also provides a power for the regulatory bodies to establish and maintain a voluntary register jointly with another regulatory body. Where voluntary registers are joint, the regulatory bodies maintaining that register will remain subject to the same limits on the types of register which can be maintained, and their geographical scope, as would apply to each regulatory body maintaining a register individually (with the limited exception described above in relation to a joint register maintained by the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland).
1113. Subsection (12) of section 25D provides that persons requesting registration, or the renewal of registration, on a voluntary register maintained by a regulatory body must pay a fee determined by the regulatory body.
1114. Section 25F imposes a duty on each regulatory body to carry out an impact assessment prior to establishing a voluntary register under section 25D. It provides that the regulatory body must have regard to any appropriate guidance in carrying out the assessment; must consider, in particular, the likely impact on potential registrants, employers of potential registrants and users of health care and English social care and social work services; must publish its impact assessment; and must have regard to the impact assessment in deciding whether to establish a voluntary register. The regulatory body must also consult such persons as it considers appropriate before establishing a voluntary register.

Clause 213 - Accreditation of voluntary registers

1115. This clause inserts new sections 25G, 25H and 25I into the 2002 Act, and makes other amendments to the 2002 Act which relate to the Authority's new functions under these new sections.
1116. Section 25G empowers the Authority to accredit voluntary registers. Accreditation refers to formal recognition by the Authority that a voluntary register meets certain specified criteria that it sets relating to the operation and governance of voluntary registers.
1117. More specifically, the Authority is given the power to, on an application by a regulatory body or other person who maintains a voluntary register, to take any steps it considers to be appropriate in order to establish whether the register meets its accreditation criteria. The Authority's accreditation criteria will be set from time to time and subsection (2) of section 25G sets out a number of particular matters which the Authority may include in its accreditation criteria.
1118. The Authority must publish its accreditation criteria, and it has the power to publish a

list of accredited registers.

1119. The Authority may review accredited registers to determine whether they continue to meet the accreditation criteria, and may remove, suspend or impose conditions on the accreditation of a register if it is not satisfied that the criteria continue to be met.
1120. The Authority may determine the fee to be paid by persons or bodies maintaining voluntary registers for accreditation, and may refuse, or remove accreditation if the fee is not paid.
1121. Section 25H imposes a duty on the Authority to carry out an impact assessment prior to accrediting a voluntary register under section 25G. It provides that the Authority must have regard to any appropriate guidance in carrying out the assessment; must consider, in particular, the likely impact on registrants and potential registrants, employers of registrants and potential registrants, and users of health care and English social care and social work services; may request information from the person or body who maintains the voluntary register in order to carry out the assessment (and may refuse to accredit the register in the case of non-compliance with this request); may publish its impact assessment; and must have regard to the impact assessment in deciding whether to accredit a voluntary register. It must also consult such persons as it considers appropriate prior to accrediting a register.
1122. Section 25I confers three new functions on the Authority. These are:
- to promote the interests of users of health care in the UK, users of social care in England, users of social work services in England, and other members of the public in relation to the maintenance or operation of accredited voluntary registers;
 - to promote best practice in the maintenance and operation of accredited voluntary registers; and
 - to develop principles of good governance for voluntary registers and encourage keepers of voluntary registers to follow these.
1123. *Subsections (2) to (5)* of this clause amend section 26 of the 2002 Act to provide that the Authority's powers under section 26(2) (as limited by section 26(3)) extend to any person who maintains an accredited voluntary register, not just to regulatory bodies.
1124. *Subsection (6)* amends section 26A of the 2002 Act to empower the Secretary of State to request advice from the Authority on any matter connected with the accreditation of voluntary registers, and obliges the Authority to comply with this request. The Scottish Ministers, Welsh Ministers and Department of Health, Social Services and Public Safety in Northern Ireland are also empowered to request advice from the Authority (and the Authority must comply with this request) on any matter connected with the accreditation of voluntary registers, apart from voluntary registers concerned

with unregulated social care workers in England or students of social work or social care work in England. As with the other requests for advice etc that are made under section 26A, a fee of such amount as is determined by the Authority must be paid for such advice.

1125. *Subsections (7) to (9)* amend section 26B of the 2002 Act to provide that the Authority's duties to provide or publish information about the Authority's exercise of its functions and to consult the public on matters relevant to the exercise of its functions do not extend to its functions relating to accreditation of voluntary registers. However, new subsection (1B) provides that the Authority has the power to provide or publish information about the exercise of its functions relating to the accreditation of voluntary registers.

Consequential provision etc.

Clause 214 – Consequential provisions and savings, etc.

1126. This clause provides for the minor and consequential amendments to primary legislation and the savings provision (which provides that anything the General Social Care Council does before it is abolished remains valid) set out in Parts 1 – 3 of Schedule 14 to have effect. The clause also enables the Privy Council, by Order, to make transitional, transitory or saving provision in connection with this part of the Bill.
1127. *Subsections (3) to (5)* provide further detail on how an order made under *subsection (2)* will be made and the provisions it may contain.
1128. Subsection (6) ensures that in the future section 60 order may amend or revoke any amendments made to a section 60 order by this part of the Bill. This ensures that in the future section 60 orders will continue to be able to amend the 2001 Order including those parts of the 2001 Order inserted by this Bill.

The Office of the Health Professions Adjudicator

Clause 215 - Abolition of the Office of the Health Professions Adjudicator

1129. This clause provides for the abolition of OHPA, for the transfer of its property, rights and liabilities to the Secretary of State, repeals the provisions in the Health and Social Care Act 2008, which establish OHPA and confer functions on it and brings into effect Part 4 of Schedule 14 that makes consequential amendments and savings provisions. The clause has UK wide extent.

Schedule 14, Part 4: Consequential amendments and savings

1130. This Part of this Schedule makes consequential amendments to a number of Acts and

statutory instruments and makes savings provisions in connection with the abolition of OHPA.

Part 8 – The National Institute for Health and Care Excellence

Establishment and general duty

Clause 216 – The National Institute for Health and Care Excellence

1131. This clause establishes the National Institute for Health and Care Excellence as a body corporate. It also gives effect to Schedule 15.

Schedule 15

1132. This Schedule deals with the constitution of NICE; in many respects it makes similar provision to that made by Schedule 1 for the NHS Commissioning Board, Schedule 7 for Monitor, and Schedule 17 for the Information Centre.
1133. Paragraph 1 sets out the membership of NICE. Paragraphs 2, 3 and 4 set out provisions relating to non-executive directors of NICE, including their tenure, ability to be suspended or removed from post by the Secretary of State, and their remuneration (which would be determined by Secretary of State).
1134. Paragraph 6 relates to the appointment of NICE's employees. NICE requires the approval of the Secretary of State to its policies on the payment of remuneration, allowances, pensions and gratuities before it can make any such payment to an employee.
1135. Paragraph 7 provides for NICE to establish committees and sub-committees. Paragraph 8 allows NICE to regulate its own procedures. Sub-paragraph (2) enables Secretary of State to make provisions in regulations about particular procedures in order to deal with conflicts of interest. This provision is specific to NICE, due to the nature of its duties. For example, this could be used to avoid the situation whereby the chair of one of NICE's technology appraisal committees had a commercial interest in a company doing research into that particular drug.
1136. Paragraph 10 identifies general powers and requires NICE to obtain the permission of the Secretary of State before undertaking certain commercial ventures. Paragraph 12 sets out a requirement for NICE to publish an annual report. The Secretary of State would also be able to ask NICE to prepare other reports or to provide information at other times, for example as required for in-year monitoring of NICE's performance and use of central funding.
1137. Paragraphs 13, 14 and 15 relate to NICE's accounts, including duties of the Comptroller and Auditor General in relation to reporting on its annual accounts, and

laying copies of them in Parliament.

1138. Paragraph 16 relates to NICE's seal. Paragraph 17 confirms NICE's status as a non-Crown body.

Clause 217 - General Duties

1139. This clause describes the matters that NICE must have regard to in developing its products. These are essentially a continuation of the things that the existing Special Health Authority, the National Institute for Health and Clinical Excellence, currently has regard to extended now to cover social care as well as health. Examples of current products of the National Institute for Health and Clinical Excellence include: quality standards; guidance on new and existing medicines, treatments and procedures; guidance on treating and caring for people with specific diseases and conditions; and guidance on preventing ill health.

Functions – Quality standards

Clause 218 - Quality standards

1140. This clause sets out the process for how the NHS Commissioning Board or the Secretary of State would commission NICE to develop quality standards for the provision of NHS, public health or social care services and the status accorded to the finished product.
1141. The Secretary of State and the NHS Commissioning Board are to be required to have regard to the quality standards in discharging their 'improvement duties' in relation to the health service (see new section 1A inserted in to the NHS Act by clause 2 and new section 13D inserted into that Act by clause 19). The Secretary of State and the NHS Commissioning Board would be responsible for framing the remit of each quality standard, but cannot determine the final content. A quality standard would have statutory status once the person who commissioned it (the Secretary of State or the Board) has endorsed its publication. NICE will have a duty to establish a process for the preparation of quality standards through consultation with interested parties. Responsibility for adult social care rests with the Department of Health and responsibility for children's social care rests with Department for Education. The Secretary of State in this context would be able to commission social care quality standards across all age groups.

Clause 219 - Supply of quality standards to other persons

1142. This clause describes how, under regulations made by the Secretary of State, NICE would be able to supply quality standards to the devolved administrations (Scotland, Wales and Northern Ireland), and other bodies. NICE would be able to amend the quality standards to suit the needs of such customers (for example by translating a

quality standard into Welsh) and may charge for this.

Clause 220 - Advice or guidance to the Secretary of State or the Board

1143. This clause makes provision to enable NICE to provide any other advice or guidance on quality matters to the Secretary of State or the NHS Commissioning Board should they require it.

Advice, guidance etc.

Clause 221 – Advice, guidance, information and recommendations

1144. This clause describes how, as well as quality standards, NICE will be able, under regulations, to give advice or guidance, or provide information or make and recommendations on matters relating to the provision of NHS services, public health services or social care in England. This may include guidance on new and existing medicines, treatments and procedures and treating and caring for people with specific diseases and conditions or with particular social care needs. It might also provide for NICE to be able to publish or disseminate advice, guidance, information or recommendations to the NHS, local authorities or other organisations in the public, private, voluntary or community sectors on how to improve people's health and prevent illness and disease.
1145. This clause gives the Secretary of State a regulation-making power to confer additional functions on NICE. *Subsections (2) and (3)* make provision for functions conferred on NICE by regulations to be subject to directions from the Secretary of State or the NHS Commissioning Board. The direction-making powers ensure that either the Secretary of State or the Board would have the flexibility to commission work from NICE. However, neither would be able to direct NICE as to the substance of its advice, guidance or information or recommendations (*subsection (4)*). *Subsection (5)* describes the additional provision that such regulations might make, such as the persons or bodies that may commission work from NICE and matters relating to the publication or other dissemination of NICE products. *Subsections (5)(c) and (6)* enable such regulations to make provision for NICE to impose charges in connection with such giving advice or guidance, provision of information or making recommendations. *Subsection (7)* requires such regulations to make provision for NICE to set up, through consultation, processes for the development of such advice, guidance, information or recommendations.
1146. *Subsections (8) and (9)* allow regulations to require specified public bodies to have regard to NICE advice, guidance, information or recommendations or comply with NICE's recommendations. This provision would allow replication of the effect of the existing funding direction that requires Primary Care Trusts to make funding available within three months for treatments recommended by NICE's technology appraisal guidance.

Clause 222 – NICE recommendations: appeals

1147. This clause allows the Secretary of State to make regulations that set out arrangements for appeals against NICE recommendations.

Clause 223 - Training

1148. This clause allows the Secretary of State to make regulations setting out the arrangements under which NICE can provide training, for example to help staff in health services to implement NICE guidance recommendations, and when it can charge for these services.

Clause 224 - Advisory Services

1149. This clause allows the Secretary of State to make regulations setting out the arrangements under which NICE can provide services to other persons, such as the devolved administrations and advice to pharmaceutical companies.

Clause 225 - Commissioning guidance

1150. This clause provides for the NHS Commissioning Board to be able to direct NICE to prepare on its behalf or carry out any other of the NHS Commissioning Board's functions in relation to commissioning guidance. Commissioning guidance will provide GP commissioning consortia with practical advice on contracting for the provision of health services with a view to improving the quality of such services. If requested, NICE must provide the NHS Commissioning Board with advice or information on matters connected with the Board's functions as regards commissioning guidance. NICE may also on request be made responsible for the Board's function of publishing or disseminating commissioning guidance.

Functions: other

Clause 226 – NICE's charter

1151. This clause allows the Secretary of State to make regulations that require NICE to publish and review a NICE charter, which would set out publicly NICE's purpose and how it proposed to fulfil it.

Clause 227 – Additional functions

1152. This clause enables NICE to carry out additional functions connected with the provision of health care or social care provided that this work does not interfere with NICE's core functions. NICE may charge for its services under these functions and may do so on what it considers to be the appropriate commercial basis.

Clause 228– Arrangements with other bodies

1153. This clause enables NICE to make arrangements with other bodies for assistance in relation to its services. For example to support the development of its guidance products, and to make payments for this purpose as it sees fit.

Clause 229 – Failure by NICE to discharge any of its functions

1154. This clause enables the Secretary of State, if he considers that NICE is failing to discharge its functions properly, to direct NICE to discharge these functions in the way that the Secretary of State specifies and within stated timescales. If NICE fails to comply with such a direction the Secretary of State may discharge the functions concerned himself or may make arrangements for another body to do so.

Clause 230 – Protection from personal liability

1155. This clause applies existing legislation so that the members and staff of NICE are protected from personal liability whilst carrying out work on behalf of NICE.

Supplementary and general provision

Clause 231 – Interpretation of this Part

1156. This clause defines terms used in this Part.

Clause 232 – Dissolution of predecessor body

1157. This clause provides for the abolition of the Special Health Authority known as the National Institute for Health and Clinical Excellence.

Clause 233 – Consequential provision

1158. This clause gives effect to Schedule 16 which sets consequential amendments to a range of existing statutory provisions to ensure that NICE is referenced appropriately. It includes, for example, changes to the Freedom of Information Act 2000, so that the Act would still apply to NICE. It also includes a change to the Health Act 2009, so that NICE would have a duty to have regard to the NHS Constitution.

Part 9 – Health and adult social care services: information

Chapter 1 – Information standards

Clause 234 – Powers to publish information standards

1159. This clause enables the Secretary of State or the NHS Commissioning Board to set

information standards for health services and adult social care.

1160. *Subsection (1)* empowers the Secretary of State or the NHS Commissioning Board to prepare and publish information standards. Other bodies may assist with the preparation of standards but the decision to publish them rests with Secretary of State or the Board.
1161. *Subsection (2)* defines an information standard as a document containing standards that relate to the processing of information. These may be technical standards, data standards or information governance standards. Technical standards relate to the specification of systems and may, for example include messaging, system interoperability or security requirements. Data standards define the structure and type of data to be recorded, for example how to record date of birth or a clinical condition. Information governance standards relate to policies, procedures and guidelines on information processing.
1162. *Subsections (3) and (4)* prescribe the limits of the Secretary of State or the Board's powers to publish standards in relation to the provision of NHS, health and adult social care services.
1163. *Subsection (5)* clarifies that a published standard must include guidance on which types of organisation it is relevant to and on how to implement the standard.
1164. *Subsection (6)* identifies which bodies must have regard to published information standards. These are the Secretary of State, the Board and public bodies exercising functions covered by a specific standard.
1165. *Subsection (7)* defines the terms used in this section. 'Processing' has the same meaning as the term has in the Data Protection Act 1998. This is a broad definition that captures a range of activity involving information – obtaining, holding, recording, using, sharing.

Clause 235 – Information standards: supplementary

1166. This clause places a duty on the Secretary of State or the Board to consult those they feel should be consulted before publishing an information standard.
1167. *Subsection (2)* enables the Secretary of State or the Board to adopt an information standard published by another body.

Chapter 2 - The Health and Social Care Information Centre

Establishment and general duties

Clause 236 - The Health and Social Care Information Centre

1168. This clause establishes the Health and Social Care Information Centre. It also gives effect to Schedule 17.

Schedule 17

1169. This Schedule deals with the constitution of the Information Centre; in many respects it makes similar provision to that made by Schedule 1 for the NHS Commissioning Board, Schedule 7 for Monitor, and Schedule 15 for NICE.
1170. Paragraph 1 sets out the membership of the Information Centre. Paragraphs 2, 3, 4 and 5 contain provisions relating to non-executive directors of the Information Centre, including their tenure, ability to be suspended or removed from post by the Secretary of State, and their remuneration (which would be determined by Secretary of State).
1171. Paragraph 6 relates to the appointment of the Information Centre's employees. The Information Centre requires the approval of the Secretary of State to its policies on the payment of remuneration, allowances, pensions and gratuities before it can make any such payment to an employee.
1172. Paragraph 7 relates to committees. Paragraph 8 allows the Information Centre to regulate its own procedures. Paragraph 9 concerns the exercise of the Information Centre's functions.
1173. Paragraph 10 identifies general powers, in particular the need to obtain the approval of the Secretary of State to form, participate, or invest in companies.
1174. Paragraph 11 concerns finance arrangements with the Secretary of State.
1175. Paragraph 12 sets out a requirement for the Information Centre to publish an annual report. The Secretary of State would also have the ability to ask the Information Centre to prepare other reports or information at other times, for example as required for in-year monitoring of the Information Centre's performance and use of central funding.
1176. Paragraphs 13, 14 and 15 relate to the Information Centre's accounts, including the Comptroller and Auditor General reporting on their annual accounts, and laying copies of them in Parliament.
1177. Paragraph 16 relates to the Information Centre's seal. Paragraph 17 confirms the

Information Centre's status as a non-Crown body.

Clause 237 - General duties

1178. This clause sets out the general duties of the Information Centre. The Information Centre must have regard to information standards published by or guidance issued by the Secretary of State or the NHS Commissioning Board. It must seek to use its resources effectively, efficiently and economically and minimise the burdens it imposes on others through its collection of information. The Information Centre should also have regard to the need to promote the effective, efficient and economic use of resources in the provision of health and adult social care services in England.

Functions: information systems

Clause 238 - Powers to direct the Information Centre to establish information systems

1179. This clause provides the Secretary of State or the NHS Commissioning Board with powers to direct the Information Centre to put in place systems for collecting, analysing and publishing or disseminating specified information. Before doing so they are required to consult the Information Centre so that it can advise on options and methodology.

Clause 239 - Powers to request the Information Centre to establish information systems

1180. This clause provides for bodies other than the Secretary of State and the NHS Commissioning Board to request the Information Centre to set up a system for the collection of specified information. The request may be mandatory if made by Monitor, the Care Quality Commission, the National Institute for Health and Care Excellence or any other body specified in regulations. Regulations may also prescribe when the Information Centre may exercise a discretion to not comply with a mandatory request, for example in respect of an information collection that is highly-technical or specialised.
1181. The Secretary of State or the NHS Commissioning Board may also direct the Information Centre not to comply with a non-mandatory request. The Information Centre would have discretion to refuse other requests for information if, for example, it might assist to discharge the duty to seek to minimise burdens, or if the requestor has not followed the Information Centre's advice and guidance, or collecting the information would interfere with the statutory functions of the Information Centre.

Clause 240 – Requests under section 239: supplementary

1182. This clause places a duty on the Information Centre to publish procedures for the making of requests for an information collection, and for reconsidering any requests

that are refused. *Subsection 3* allows the Information Centre to charge a reasonable fee to cover the cost of establishing a system. *Subsection 4* places a duty on a person considering making a request to consult with the Information Centre before making a request, so that it can advise on options and methodology. The Information Centre must publish details of all mandatory requests made under section 6 and any other request which it is obliged or decides to comply with. This will enable any person considering making a request to know what systems have already been established, and so what information is already collected.

Clause 241 – Information systems: supplementary

1183. This clause places a duty on the Information Centre to consult prior to establishing a new system for collecting information. It also provides a basis for the Information Centre to destroy information that it has collected when there is no longer a need to retain it.

Clause 242 - Powers to require and request provision of information

1184. This clause provides the Information Centre with powers to require health or social care bodies to provide any information it considers necessary or expedient for it to have to discharge its functions. When information is needed from other bodies the Information Centre may request the desired information and may, exceptionally, make a payment in respect of the costs of compliance with the request. *Subsection (2)* obliges health or social care bodies to comply with a request from the Information Centre and to provide the required information in a form specified by the Information Centre within a specified period. *Subsection (4)* requires the Information Centre to publish a procedure for notifying health or social care bodies and other persons about data collections and *subsection (5)* requires the Information Centre to co-operate with other bodies authorised to collect information. The intention is to minimise the burden on the providers of information.

Clause 243 - Publication of information

1185. This clause requires the Information Centre to generally publish the information it collects unless the information is in a form which would identify, or enable the identification of, an individual, or where directed to not publish information by the Secretary of State or the Board. Where the information that is collected identifies a body that provides health or adult social care services, or would enable the identity of such a body to be ascertained, the Information Centre would take into account the public interest in deciding whether it is appropriate for the information to be published. The Information Centre is expected to publish information in easily accessible formats, for wider uses; for example, in the form of official statistical publications.
1186. Where information has been collected under direction from the Secretary of State or the Board, or is a mandatory collection related to the statutory functions of a relevant

body, the manner and form of publication may be specified. Where there is no such specification or in other circumstances the Information Centre has discretion regarding the manner and form of publication, but must have regard to the need for the information to be easily accessible, the requirements of those most likely to use the information and the uses to which the information is likely to be put.

Clause 244 - Information register

1187. This clause requires the Information Centre to publish a register containing details of what it collects and also of other information collections by other bodies that have been authorised by the Secretary of State or the NHS Commissioning Board. The record of information collections directed or authorised by the Secretary of State or the NHS Commissioning Board will be complementary to the record of all mandatory requests made under section 6 and any other request which the Information Centre is obliged or decides to comply with. Together these will provide a reference for bodies seeking to obtain information to know what information is already collected that may be published.

Clause 245 - Advice or guidance

1188. This clause requires the Information Centre to provide advice or guidance to any person or body it is directed to advise by the Secretary of State or the NHS Commissioning Board, and gives it discretion to advise other bodies, on issues relating to the collection, analysis, publication or other dissemination of information. Advice to the Secretary of State or the Board on ways of minimising information collection burdens on health and social care bodies is specifically identified. *Subsection (4)* requires any health or social care body to have regard to advice or guidance given by the Information Centre when exercising functions in connection with the provision of health and adult social care services.

Quality of health and adult social care information

Clause 246 - Assessment of quality of information

1189. This clause requires the Information Centre to publish periodic reports on the extent to which the information it collects meets published information standards.

Clause 247 - Power to establish an accreditation scheme

1190. This clause enables the Secretary of State, through regulations, to make provisions for a scheme to accredit (kite-mark) organisations that act as information intermediaries. Accreditation schemes may be run by the Information Centre or by any other body specified by the Secretary of State in regulations.
1191. Regulations may provide a body operating an accreditation scheme with the power to establish the accreditation procedure, set accreditation criteria, keep the accreditation

scheme under review and to charge those applying for accreditation reasonable fees. Regulations may also specify that a body operating an accreditation scheme must publish details of the accreditation process, including the criteria that must be met for accreditation, provide an appeals process when an application for accreditation is refused, and provide those applying for accreditation with advice.

1192. *Subsection (5)* defines the types of bodies that may apply for accreditation under a scheme.

Functions: other

Clause 248 - Database of quality indicators

1193. This clause enables the Secretary of State, through regulations, to task the Information Centre with establishing, maintaining and publishing a database of quality indicators relating to health and adult social care services in England. Quality indicators are factors by reference to which performance by service providers can be measured.

Clause 249 – Power to confer functions in relation to identification of GPs

1194. This clause enables the Information Centre to be provided with functions, through regulations, in connection with the identity of GPs who are able to issue prescriptions.

Clause 250 - Additional functions

1195. This clause identifies the additional functions or services the Information Centre can provide. The Information Centre may charge, and may do so on an appropriate commercial basis, for any additional services it provides.

Clause 251 - Arrangements with other bodies

1196. This clause enables the Information Centre to make arrangements with other bodies to carry out services on its behalf.

Clause 252 - Failure by Information Centre to discharge any of its functions

1197. This clause enables the Secretary of State, if he considers that the Information Centre is failing to discharge its functions properly, to direct the Information Centre to discharge these functions in the way that the Secretary of State directs and within specified timescales. If the Information Centre fails to comply with such a direction the Secretary of State may discharge the functions concerned himself or may make arrangements for another body to do so.

Clause 253 - Protection from personal liability

1198. This clause applies existing legislation so that the members and staff of the Information Centre are protected from personal liability whilst carrying out functions on behalf of the Information Centre.

General and supplementary provision

Clause 254 - Powers of the Secretary of State and the Board to give directions

1199. This clause enables the Secretary of State and the NHS Commissioning Board, through regulations, to specify that a health or social care body must exercise a function of the Information Centre (for example the Information Centre's function of requiring other health or social care bodies to provide information) to require requiring the Information Centre or another health or social care body to exercise an information function of the Secretary of State or the Board, or to require the Information Centre to exercise a function similar to an information function of another health or social care body, for example, to collect information that body would be obliged to collect.
1200. A direction giving power under the regulations could be used to direct a health or social care body to carry out a potential function of the Information Centre or to direct the Information Centre to carry out a function similar to an information function that another health or social care body has. This clause would be used, for example, to direct that another body should collect information that would normally be required to be collected by the Information Centre. An example would be where the information that is required to be collected is needed for a single purpose by the body making the request, and there is no intention to publish it. It would be an inefficient use of the Information Centre's resources for it to collect information solely for the purpose of passing the information on to another body. Similarly, it may be more efficient for the Information Centre to collect certain information instead of this being done as an ancillary function by a different health or social care body.

Clause 255 - Interpretation of this Chapter

1201. This clause defines terms used in this chapter.

Clause 256 - Dissolution of predecessor body

1202. This clause provides for the abolition of the Special Health Authority known as the Health and Social Care Information Centre.

Clause 257 - Consequential provision

1203. This clause gives effect to Schedule 18 which sets consequential amendments to a range of existing statutory provisions to ensure that the Information Centre is

referenced appropriately. It includes, for example, changes to the Freedom of Information Act 2000, so that the Act would still apply to the re-established Information Centre. It also includes a change to the Health Act 2009, so that the Information Centre would have a duty to have regard to the NHS Constitution.

Part 10 – Abolition of certain public bodies

1204. Part 10 contains provisions that abolish the Alcohol Education and Research Council, the Appointments Commission, the National Information Governance Board for Health and Social Care, the National Patient Safety Agency and the NHS Institute for Innovation and Improvement. Section 250 of the NHS Act will be repealed, with a saving provision for the continuation of the Joint Committee on Vaccination and Immunisation as a statutory body.

Clause 258 - The Alcohol Education and Research Council

1205. This clause provides for the abolition of the Alcohol Education and Research Council (AERC).
1206. The AERC was established by section 6 of the Licensing (Alcohol Education and Research) Act 1981. It is responsible for administering the alcohol and education research fund, established by section 7 of the 1981 Act. The AERC uses the fund to finance projects within the United Kingdom for education and research on alcohol related issues.
1207. *Subsection (1)* abolishes the AERC. *Subsection (2)* repeals the Licensing (Alcohol Education and Research) Act 1981, which established the AERC. Before it is abolished the AERC will use the power contained in the 1981 Act to transfer the whole of the Alcohol Education and Research Fund to a separate charitable body. The new charitable body will continue to use the Fund to finance projects within the United Kingdom for research on alcohol related issues.
1208. *Subsection (3)* gives effect to Part 1 of Schedule 19 which removes references to AERC in other primary legislation and provides for the Secretary of State to carry out any duties required of the AERC before, during and after its abolition if required; and for a report to be prepared on the abolition of the Council up to the date of abolition.

Clause 259 – The Appointments Commission

1209. This clause provides for the abolition of the Appointments Commission, originally established as a Special Health Authority in 2001. The clause also gives effect to Part 2 of Schedule 19 which provides for the Secretary of State to carry out any duties required of the Appointments Commission before, during and after its abolition if required.
1210. The role of the Appointments Commission, an executive non-departmental public

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body, is to appoint Chairs and Non-Executive Directors to all local NHS and the majority of the Department's national bodies, under direction from the Secretary of State for Health.

1211. Following the Government's plans to reform the NHS and public bodies, there will be no local Chair and Non-Executive Director appointments to primary care trusts, strategic health authorities and NHS trusts and fewer national public appointments, making the Appointments Commission no longer viable. Until its abolition, the Appointments Commission will continue to assist with the management of public appointments. Remaining national appointments will be handled by the Department of Health, in-line with other government departments.

Clause 260 – The National Information Governance Board for Health and Social Care

1212. This clause provides for the abolition of the National Information Governance Board for Health and Social Care, and the subsequent transfer of its functions.
1213. NIGB was established as a statutory body by the NHS Act. Its overall role is to support improvements to information governance practice in health and social care.
1214. *Subsections (1) and (2)* abolish the National Information Governance Board and remove the sections of the NHS Act that established it.
1215. *Subsection (3)* inserts a new section 20A into the Health and Social Care Act 2008 to provide the Care Quality Commission with functions to monitor the practice followed by registered providers in relation to the processing of information relating to patient and adult social care service users, and to keep the NHS Commissioning Board and Monitor informed about such practice.
1216. The new section 20A also places a duty on the Care Quality Commission, in exercising these functions, to seek to improve the practice followed by registered providers in relation to such processing. It defines the information relevant to these functions, the type of activity, and to whom the function applies.
1217. *Subsections (4) and (5)* make changes to existing duties:
- The Care Quality Commission's existing duty to consult the National Information Governance Board on its internal code of practice for managing confidential personal information before publication is changed to a duty to consult the NHS Commissioning Board (subsection (4)). Under provisions in Part 1, the Commissioning Board is charged with developing standards and guidance in this area.
 - The Secretary of State's existing duty to consult the National Information Governance Board before making any new regulations under section 251 of the

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NHS Act (permitting confidential patient information to be processed for certain purposes without consent) is changed to a duty to consult the Care Quality Commission. As the Care Quality Commission has other functions only in relation to England it will not consider Welsh interests when consulted, therefore section 271 of the NHS Act (setting out the territorial limit of the Act) is also amended.

1218. *Subsections (6) and (7)* require the Care Quality Commission to appoint a National Information Governance Committee to advise and assist the Commission in discharging the functions transferred to it by this clause. This committee is to be in place until 31 March 2015.
1219. The clause also gives effect to Part 4 of Schedule 20 which provides for the Secretary of State to carry out any duties required of the National Information Governance Board before, during, and after its abolition if required; and for a report to be prepared up to the date of abolition.

Clause 261 - The National Patient Safety Agency

1220. This clause provides for the abolition of the National Patient Safety Agency (NPSA).
1221. The NPSA was established as a Special Health Authority in 2001. Its core function is to improve the safety of NHS care by promoting a culture of reporting and learning from adverse events.
1222. Provision is made in Part 1 of the Bill for the NHS Commissioning Board to have responsibility for the functions currently carried out by the National Patient Safety Agency in respect of reporting and learning from patient safety incidents.
1223. The National Clinical Assessment Service and the National Research Ethics Service, are functions of the NPSA not being dealt with in the Bill. The Department intends that, over the next few years, the National Clinical Assessment Service will become a self-funded service and the Department will seek to agree a date with the service for achieving self-sufficiency. The future of the National Research Ethics Service is being considered as part of the wider Academy of Medical Science's review of research regulation with a view to moving this function into a single research regulatory body.

Clause 262 - The NHS Institute for Innovation and Improvement

1224. This clause provides for the abolition of the NHS Institute for Innovation and Improvement, established as a Special Health Authority in 2006.
1225. The NHS Institute was established as a Special Health Authority under the NHS Act and is an arm's-length body sponsored by the Department of Health. It supports NHS organisations in analysing their current practices against best practice and

implementing changes to achieve better results.

1226. Provision is made in Part 1 of the Bill for the NHS Commissioning Board to have a duty to promote innovation and to lead on quality improvement. This represents a partial transfer of the functions of the NHS Institute for Innovation and Improvement.

Clause 263 – Standing advisory committees

1227. This clause provides for the repeal of section 250 of, and Schedule 19 to, the NHS Act. Section 250 provides for the establishment of standing advisory committees. The Joint Committee on Vaccination and Immunisation (JCVI) is the only remaining standing advisory committee. It was established under this section but will continue in existence as a result of the provision made in subsection (3) in respect of the NHS (Standing Advisory Committees) Order 1981. The intention is that the Committee will at a future date be abolished as a statutory committee by revocation of the Order and reconstituted with similar functions as a Departmental Expert Committee to secure continuity of its role.

Part 11 – Miscellaneous

Duties to co-operate

1228. These clauses are intended to ensure that Monitor and the Care Quality Commission work together effectively to operate a joint licensing and registration regime. As well as an overall duty to co-operate, both organisations would be under an equal duty to share information and provide for a joint licensing and registration process. The latter would need to ensure that there was a single application form and document for new applicants. These provisions are designed to create a single integrated process and interface for providers. The organisations would also be required to ensure that the conditions which they respectively imposed upon licence holders and registered providers were not inconsistent or contradictory to each other.
1229. Under *subsection (3)* of **clause 264**, Monitor would have to, on request, provide the Care Quality Commission with any information relevant to the Care Quality Commission in relation to Monitor's concurrent competition functions with the Office of Fair Trading.
1230. **Clause 265** amends the Health and Social Care Act 2008 to apply a mirror duty of cooperation to the Care Quality Commission.
1231. Clauses 266 and 267 and place a number of bodies under a duty to co-operate with one another in the exercise of their respective functions. Where the Secretary of State takes the view that relevant bodies are in breach of their duty to co-operate, and that there is a detrimental effect on the health service, he would be able to make an order prohibiting each body from exercising specified functions without the approval of the

other body.

Clause 266 – Duties to co-operate

1232. This clause sets out which bodies would be subject to the duty to co-operate with one another. The duty would apply to the respective functions of the bodies. For example, the co-operation could, subject to agreement between two or more of the relevant bodies, take the form of the bodies requesting information from provider organisations in a co-ordinated way in order to prevent duplication of effort and to reduce the burden on providers.
1233. The clause (along with clauses 264 and 265) adds to existing duties of co-operation with the result that all of the following bodies would be under a duty to co-operate with one another (with certain exceptions as described below):
- Monitor
 - Care Quality Commission
 - National Health Service Commissioning Board
 - National Institute for Health and Care Excellence
 - Health and Social Care Information Centre
 - Special Health Authorities
1234. The NHS Commissioning Board, Special Health Authorities, the Health and Social Care Information Centre and the National Institute for Health and Care Excellence are under a duty to co-operate with one another as a result of section 72 of the NHS Act (as amended by this Bill). Monitor and the Care Quality Commission's mutual obligations to co-operate are set out in section 70 of the Health and Social Care Act 2008 and clauses 264 and 265 of this Bill. The effect of the clause is to add to existing duties of co-operation so that all of the bodies listed would be under a duty to co-operate with one another.
1235. Where a body listed in the clause carries out functions outside England, the duty to co-operate will not apply to functions carried out beyond England.
1236. The clause allows for the Secretary of State (subject to the affirmative resolution procedure in Parliament) to add to the list of bodies to which the duty applies. Any such bodies must have functions relating to health.
1237. The duty to co-operate would not apply in circumstances where one of the listed bodies was regulating the activity of one of the other bodies. An example of regulatory activity would be CQC exercising its registration or enforcement

functions under the Health and Social Care Act 2008 in relation to a Special Health Authority (e.g. NHS Blood or Transplant) which is providing or undertaking other registrable activity in relation to health care.

Clause 267 – Breaches of the duty to co-operate

1238. This clause sets out the powers conferred on the Secretary of State to take action in response to a breach of the relevant duties to co-operate. The Secretary of State, where he believed there was an actual breach of the duty or a significant risk of a breach, would be able to provide a written notice of his opinion to each body.
1239. Where a body listed in the clause carries out functions outside England, the measures relating to a breach of the duty to co-operate will not apply to functions carried out beyond England.
1240. Following that notice, the Secretary of State would also be able to make an order to prohibit each body from exercising specified functions without the agreement of the other body. The purpose of this power is to enable the Secretary of State to press the specified bodies to resolve significant differences or issues between them without intervening directly or acting as an arbiter or judge.
1241. The power would always apply to two or more bodies. It could only be used if the duty to co-operate had actually been breached (and it could not be used in a case where the Secretary of State thought there was merely a significant risk of a breach). It could only be used if the breach was having a detrimental effect on the health service.
1242. The order (which would be subject to the affirmative procedure) would place the bodies subject to it in a position where they needed to work together to carry out the functions subject to the order. The functions could be different for each body, and the power to impose the prohibition could not be used so as to prevent a body from complying with a legal requirement.
1243. Initially, the order will apply for up to a year only. But it will be possible for the Secretary of State to extend that period by up to one more year at a time, provided he is still satisfied that the breach of the duty of co-operation was continuing and continued to have a detrimental effect on the health service.
1244. It is possible that after such an order is made the bodies may not reach agreement in relation to a function or activity specified in the order. To avoid an impasse, the clause provides that either body can refer the matter for determination by arbitration. The arbitration would be of the kind to which Part 1 of the Arbitration Act of 1996 applies by virtue of section 96 of that Act.

The Care Quality Commission

Clause 268 – Requirement for Secretary of State to approve remuneration policy etc.

1245. This clause introduces a requirement on the Care Quality Commission to obtain the approval of the Secretary of State on their pay and remuneration policy before making any determinations for staff they employ. This would make the approach for the Care Quality Commission consistent with that for other arm's-length bodies in this Bill (see Parts 8 and 9 regarding NICE and the Information Centre)

Arrangements with devolved authorities

Clause 269 – Arrangements between the Board and Northern Ireland Ministers

1246. This clause allows the NHS Commissioning Board to make arrangements with a Northern Ireland Minister to commission services at the request of a Northern Ireland Minister for the purposes of the Northern Ireland health service.

Clause 270 – Arrangements between the Board and Scottish Ministers etc.

1247. This clause allows the NHS Commissioning Board to make arrangements with the Scottish Ministers or a Scottish health body to commission services at the request of the Scottish Ministers or a Scottish health body for the purposes of the Scottish health service. An example of health services which Scottish Ministers might ask the NHS Commissioning Board to commission is specialised services for the Scottish health service.

Clause 271 - Relationships between the health services

1248. This clause introduces Schedule 20.

Schedule 20

1249. This Schedule makes a number of amendments to health legislation by or in relation to Northern Ireland, Scotland and Wales. For example, removing references to Primary Care Trusts and Strategic Health Authorities, and replacing them with references to commissioning consortia or the NHS Commissioning board.

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1250. These amendments are:

Act	Amendment
<i>National Health Service (Scotland) Act 1978 (c.29)</i>	<p>The Schedule removes references to Strategic Health Authorities and Primary Care Trusts, and adds references to commissioning consortia and the NHS Commissioning Board. It makes certain other adjustments in consequence of the changes made by the Bill.</p> <p>The Schedule adds NICE and the Health and Social Care Information Centre, to Section 17A of the Act so that arrangements with these bodies will be NHS Contracts for the purposes of the NHS (Scotland) Act 1978.</p>
<i>NHS Act 2006 (c.41)</i>	<p>The Schedule adds Healthcare Improvement Scotland, to Section 9 of the Act so that arrangements by certain bodies with Healthcare Improvement Scotland will be NHS contracts for the purposes of the NHS Act.</p> <p>The amendment adopts the existing dispute resolution mechanism which applies when an agreement is an NHS contract under the NHS Act and a Health and Social Services contract under the NHS Act and the NHS (Scotland) Act 1978.</p> <p>Paragraphs 8 – 11 of the schedule are related to changes made by the Bill which impact upon certain bodies in Wales.</p>
<i>National Health Service (Wales) Act 2006 (c.42)</i>	<p>The Schedule removes references to Strategic Health Authorities and Primary Care Trusts, and adds references to commissioning consortia and the NHS Commissioning Board.</p> <p>The amendments to the rest of the NHS (Wales) Act 2006 made in this schedule are either consequential on the changes made elsewhere in the Bill, or are designed to ensure that provisions which are parallel in the NHS (Wales) Act 2006 and the NHS Act continue to work in parallel.</p>

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Act	Amendment
<i>Health and Personal Social Services (Northern Ireland) Order 1991</i>	<p>The Schedule adds health bodies, for example, Healthcare Improvement Scotland, NICE and the Health and Social Care Information Centre, to Article 8 of the Order so that arrangements by these bodies will be HSS contracts for the purposes of the Health and Personal Social Service (Northern Ireland) order 1991.</p> <p>Certain amendments to this order are consequential to changes made elsewhere in the Bill.</p>

Clause 272 - Advice or assistance to public authorities in the Isle of Man or Channel Islands

1251. This clause allows the NHS Commissioning Board and commissioning consortia to provide advice and assistance to public authorities in the Isle of Man or the Channel Islands, for example, assisting them when they enter into arrangements with bodies for the provision of ‘specialised’ services.

Supervised community treatment

Clause 273 – Certificate of consent of community patients to treatment

1252. This clause amends the rules in the Mental Health Act 1983 (the 1983 Act) about the treatment of patients on supervised community treatment. In particular, it changes the circumstances in which their treatment has to be approved by a second opinion appointed doctor (SOAD), appointed (in England) by the Care Quality Commission or (in Wales) by the Healthcare Inspectorate Wales on behalf of the Welsh Ministers. The effect of the changes is that approval by a SOAD will not generally be necessary if the patient is consenting to the treatment in question.
1253. Supervised community treatment was introduced into the 1983 Act by the Mental Health Act 2007. Patients who have been detained in hospital for treatment for their mental disorder may be discharged by their responsible clinician from detention on to supervised community treatment by means of a community treatment order, provided the relevant criteria are met (see section 17A of the 1983 Act). While on a community treatment order, supervised community treatment patients (referred to in the Act as “community patients”) remain liable to recall to hospital for further treatment, if necessary.
1254. One of the criteria for putting patients on to supervised community treatment is that it is necessary for their own health or safety, or for the protection of others, that they receive medical treatment for their mental disorder. However, supervised community

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treatment patients may not (in general) be treated against their will unless they are recalled to hospital by their responsible clinician.

1255. The rules on treating supervised community treatment patients for mental disorder (unless recalled to hospital) are set out in Part 4A of the 1983 Act. They differ depending on whether the patient has the capacity, or (in the case of a child under 16) the competence, to consent to the treatment. (For the purposes of these explanatory notes, “capacity” will be used to include competence.)
1256. In brief, patients who have the capacity to consent to treatment may not be treated unless they do, in fact, consent. In addition, whether or not the patient has the capacity to consent, certain treatments may only be given if they have been approved as appropriate by a SOAD. This is known as the “certificate requirement”, because approval must be given by the SOAD on a “Part 4A certificate” in a form set out in regulations by the Secretary of State in England, or by the Welsh Ministers in Wales.
1257. A SOAD’s Part 4A certificate is generally required for medication (after the patient has been on supervised community treatment for one month) and for electro-convulsive therapy. In the Act, these are known respectively as “section 58 type treatment” and “section 58A type treatment”, after the sections of the Act which set out the rules on when the treatments in question may be given to detained patients. In emergencies, certificates are not required where the treatment is immediately necessary.
1258. It is the rules about these certificates which are changed by this clause.
1259. The clause amends sections 64C and 64E of the 1983 Act so that, if the patient consents to the treatment in question, the approved clinician in charge of the treatment will be able to satisfy the certificate requirement by issuing their own Part 4A certificate stating that the patient consents to the treatment and has the capacity to do so. This new approved clinician’s Part 4A certificate will be sufficient to meet the certificate requirement so long as the patient continues to consent and has capacity to do so. But it will still be possible to meet the certificate requirement by means of a Part 4A SOAD certificate instead.
1260. This new rule does not apply to electro-convulsive therapy for patients under 18 (nor to any other treatments for such patients which are in future added to section 58A by order of the Secretary of State in England, or the Welsh Ministers in Wales). That is because, unless it is an emergency, treatments covered by section 58A may not be given to any patient under 18 (whether or not they are otherwise subject to the 1983 Act) without the approval of a SOAD.
1261. The clause also inserts a new section 64FA into the 1983 Act to make clear that a supervised community treatment patient who has consented to treatment may at any time withdraw that consent. The new section also sets out what happens if a patient who has consented to treatment subsequently loses the capacity to do so. In both

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cases, the patient would be treated as having withdrawn consent to the treatment in question. This, in turn, means that any approved clinician's Part 4A certificate relating to the treatment would no longer be valid, and (if permitted) a SOAD's Part 4A certificate would be required instead.

1262. However, new section 64FA(5) says that treatment may continue whilst a new certificate is being sought, if the approved clinician thinks that stopping the treatment would cause serious suffering to the patient. This might allow treatment to continue in the case of a patient who has lost capacity to consent, but it would not allow treatment to continue against the wishes of a patient who still has capacity to consent, unless the patient were recalled to hospital. That is because there would be no legal authority to give the treatment even if a SOAD's Part 4A certificate were obtained.
1263. The clause makes some further amendments to the 1983 Act to reflect the fact that in future there will be two different types of Part 4A certificate. It amends section 64H to require the Secretary of State in England, and the Welsh Ministers in Wales, to set out the form of the new approved clinician's Part 4A certificate in regulations. It amends section 17B so that the power in section 17E, to recall a supervised community treatment patient to hospital for examination with a view to a Part 4A certificate, will (as now) apply only to a SOAD's Part 4A certificate. It also amends section 61 to make clear that the Care Quality Commission and the Welsh Ministers retain the power to withdraw a SOAD's Part 4A SOAD certificate, but would not be able to withdraw an approved clinician's certificate.
1264. The rules on treating detained patients are in Part 4 of the 1983 Act. For the most part, detained patients may be given treatment for mental disorder without their consent, even if they have capacity to refuse it (although this does not apply to electro-convulsive therapy unless it is an emergency). However, sections 58 and 58A set out circumstances in which detained patients may not be given medication or electro-convulsive therapy unless it has been approved by a SOAD on a certificate, or an approved clinician has issued a certificate saying that the patient consents to the treatment (and has the capacity to do so).
1265. In general, supervised community treatment patients recalled to hospital are subject to the same rules as detained patients, although section 62A says that a new certificate under section 58 or 58A is not required if the treatment has already been expressly approved by a SOAD on a Part 4A certificate.
1266. This clause extends the exception in section 62A to approved clinicians' Part 4A certificates. In other words, a new certificate under section 58 or 58A would not be required if the treatment in question were already covered by an approved clinician's Part 4A certificate, provided that the patient continued to consent to the treatment (and still had the capacity to do so).
1267. Section 62A also says that, even if the treatment has not been expressly approved by a SOAD's Part 4A certificate, it may be continued while a new SOAD certificate is

sought, if the approved clinician in charge thinks stopping the treatment would cause the patient serious suffering. This clause adds a new section 62A(6A) which extends that to include cases where (either before or during recall) the patient withdraws consent to treatment to which an approved clinician's Part 4A certificate applies, or loses capacity to consent to it. As amended, section 62A might allow an approved clinician to continue giving medication to a patient who had withdrawn consent, but would not allow electro-convulsive therapy to be given against such a patient's will (because it is not possible to obtain a SOAD certificate authorising electro-convulsive therapy for a detained patient who has capacity to consent, but is refusing to do so).

1268. None of these changes affects the ability to give medication or electro-convulsive therapy without a certificate in emergencies, where it is immediately necessary.

Transfer schemes

Clause 274 – Transfer schemes

1269. This clause allows the Secretary of State to establish schemes to transfer staff or property, rights and liabilities from one body to another, in connection with the establishment, modification or abolition of a body by the Bill. For example, the schemes may transfer property currently held by a Primary Care Trust (which are being abolished by the Bill) to a commissioning consortia; or transfer of staff currently involved in the provision of public health commissioning from a PCT to a Local Authority.
1270. *Subsection (1)* allows the Secretary of State to establish transfer schemes for property or staff.
1271. *Subsection (2)* defines a property transfer scheme and sets out the organisations or bodies that may transfer or receive property under these schemes. Property transfers can be made from the bodies listed in column 1 of the table in Schedule 21 to a body listed in the corresponding entry in column 2 of that table.
1272. *Subsection (3)* defines a staff transfer scheme and sets out the organisations or bodies that staff may be transferred from or to under these schemes. Staff transfers can be made from the bodies listed in column 1 of the table in Schedule 22 to a body listed in the corresponding entry in column 2 of that table.
1273. *Subsection (4)* allows the Secretary of State to direct the National Health Service Commissioning Board or a “qualifying company” to exercise the Secretary of State's functions and make staff or property transfer schemes in connection with the abolition of one or more Primary Care Trusts or Strategic Health Authorities. A qualifying company is a company defined for these purposes in section 8 as wholly or partly owned by the Secretary of State and formed under section 223 of the NHS Act, for the purpose of providing facilities or services to the NHS. Such a company could be used, for example, as an intermediate solution to hold Primary Care Trust property before it

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is transferred to either local authorities, providers or consortia. Section 223 is an existing provision and has been used by Secretary of State in the past to set up a number of companies to offer services to the NHS, such as NHS Professionals Limited, Bio Products Laboratory Limited and Community Health Partnerships Limited (the LIFT delivery company).

1274. *Subsection (5)* allows the Secretary of State to give directions to the Board or qualifying company about how to do this.
1275. *Subsection (6)* makes provision as to how individuals employed by the civil service are to be treated for the purposes of transfer schemes under clause 274 and clause 275.
1276. *Subsections (7), (8) and (9)* cover definitions, including defining a “qualifying company” and what is meant by transfer of property.

Clause 275 – Transfer schemes: supplemental

1277. This clause makes additional provisions relating to the transfer schemes made under clause 274. These define in more detail what may be transferred, and how it may be done- for example, it enables transfer schemes to make provision about the use of property transferred.
1278. *Subsection (1)* sets out what may be transferred by a staff or property transfer scheme.
1279. *Subsection (2)* sets out the bodies to whom criminal liabilities can be transferred.
1280. *Subsection (3)* allows property or staff transfer schemes to make supplementary, incidental, transitional or consequential provisions associated with the transfer of staff or property. For example, a covenant could be placed on property transferred under a transfer scheme to require it to be used for healthcare purposes.
1281. *Subsection (4)* allows property transfer schemes to make provision for shared ownership or use of property.
1282. *Subsection (5)* allows staff transfer schemes to make the same or similar provisions to the “Transfer of Undertakings (protection of employment) regulations” (TUPE regulations). Section 8 defines “TUPE regulations”.
1283. *Subsection (6)* allows transfer schemes to be modified by agreement once they come into operation.
1284. *Subsection (7)* requires the Secretary of State to ensure all property, rights and liabilities of a body covered by a transfer scheme are transferred.

Part 12 – Final Provisions

Clause 276 – Power to make consequential provision

1285. This clause allows the Secretary of State to make an order making changes to other legislation as a consequence of the changes made by the Bill, in addition to those consequential changes which are made by the Bill itself. If these include amendments to other primary legislation, the order will be subject to the affirmative procedure (see clause 277(5)(m)). The amendments can be made to other legislation, including in some cases legislation made by the devolved authorities (*subsection (3)*).
1286. Consequential orders may include transitional, transitory or saving provision in connection with the commencement of the consequential change (*subsection (2)(c)*), and this can include modifying the effect of the change, pending the coming into force of other consequential changes or other legislation, including a provision of the Bill.

Clause 277 – Regulations, orders and directions

1287. This clause makes general provisions about orders and regulations in the Bill and for the Parliamentary procedures that apply in relation to such instruments. *Subsection (5)* lists the secondary legislation which is subject to the affirmative resolution procedure.

Clause 279 – Commencement

1288. *Subsection (3)* of this clause provides that most of the provisions of the Bill come into force on the day specified by the Secretary of State in an order, and different days may be specified for different purposes, including different geographical areas (*subsection (4)*). Certain provisions of the Bill come into force on Royal Assent, and these are specified in *subsection (1)*. The provisions dealing with the abolition of NHS Trusts have their own commencement provisions in clause 164.
1289. *Subsection (5)* allows a commencement order to make modifications of the Bill or other legislation which would only apply until the commencement of another provision of the Bill or another piece of legislation.
1290. *Subsection (6)* relates to consultation requirements imposed by the Bill and allows the consultations to begin before the provision imposing the duty to consult is brought into force.

Clause 280 – Extent

1291. This clause sets out the Bill's extent, a full description of which is in the 'Territorial extent' section of this document.

PUBLIC SECTOR FINANCIAL COST AND MANPOWER IMPLICATIONS

Public Sector Financial Cost

1292. The changes proposed within the Health and Social Care Bill carry with them both costs and cash-releasing savings. As outlined within the Impact Assessments, there is an upfront cost associated with the transition from the current system architecture to that proposed by the Bill, and the cost-saving comes from the reduction in administrative spending within the system. The information below gives a summary of the cost and cost-saving implications: more information is available within the Impact Assessments.
1293. The staff transition cost, which is predominantly funding for redundancies, is estimated at approximately £1bn. It is estimated that reducing workforce within non-frontline services within PCTs, Strategic Health Authorities, public bodies and the Department of Health will cost approximately £770m. In addition to this, the proposed abolition of PCTs and SHAs and the conferring of commissioning powers upon commissioning consortia and the NHS Commissioning Board are assumed to incur further costs around redundancies. This is estimated at approximately £250m, giving the total redundancy figure of approximately £1bn. There are also non-redundancy costs associated with the transition from the current to the proposed system architecture, which are assumed to be approximately £380m. This gives a total cost of approximately £1.4bn, which is assumed to be incurred in 2011/12 and 2012/13.
1294. There will also be a reduction in administrative spending as a result of the proposed changes within the Bill. This amounts to a one-third reduction in funding in real terms, or £1.7bn per annum. This is not realised immediately, taking until 2014/15 to be fully achieved. This leads to a cost-saving over the 10-year period 2010/11 to 2019/20 of £13.6bn.
1295. The above figures are based on assumptions outlined in the Impact Assessment and the Department's best estimates at this stage. They are subject to review as local areas introduce the changes set out within the Bill, and make their own decisions.
1296. The changes proposed within the Health and Social Care Bill, most notably around commissioning and provision, are aimed at improving both the quality of care provided and the productivity of organisations. This means patients receiving the best possible care, at the appropriate time, that is delivered efficiently by providers. The Impact Assessments provide more detail on the potential value of this improvement.

Manpower Implications

1297. The Health and Social Care Bill will have a direct impact upon the workforce who are not involved in the delivery of frontline services. The Department estimates that approximately 25,000 non-frontline staff will be made redundant from PCTs,

Strategic Health Authorities, public bodies and the Department of Health.

SUMMARY OF IMPACT ASSESSMENTS

1298. The Impact Assessment, which incorporates the Equality Impact Assessment, for the Bill is structured as follows:

- (i) Coordinating document, including summary Equality Impact Assessment;
- (ii) Annex A: Commissioning Impact Assessment;
- (iii) Annex B: Provision Impact Assessment;
- (iv) Annex C: Local democratic legitimacy Impact Assessment;
- (v) Annex D: Healthwatch Impact Assessment;
- (vi) Annex E: Review of public bodies Impact Assessment; and
- (vii) Annex F: Public health Impact Assessment.

1299. The proposed structural changes and the costs associated with this are covered within the coordinating document, and a subset of them are discussed with the Commissioning Impact Assessment.

- (i) Coordinating document, including summary Equality Impact Assessment

1300. This gives a summary of the proposed changes to the NHS as outlined within the White Paper *Equity and Excellence: Liberating the NHS*¹⁴ and the response to the consultation *Liberating the NHS: Legislative Framework and next steps*¹⁵. It goes through the justification for the various policy interventions, and explains how the proposed changes fit together. This includes the proposed changes that do not require legislation at this stage. The document then describes the costs of the proposed structural changes, as well as the cost-savings that are associated with them.

¹⁴ This is available at:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf

¹⁵ This is available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122661

(ii) Annex A: Commissioning Impact Assessment

1301. This document covers the transfer of commissioning functions from PCTs and Strategic Health Authorities to commissioning consortia and the NHS Commissioning Board. This includes the expected benefits of making these proposed changes, both in terms of improved outcomes for patients and through lower costs to the system from the reduction in administrative spending. The improved outcomes result from improved clinical engagement, more responsive and coordinated care and the alignment of clinical and financial incentives. The cost-savings are quantified, though the improvement in health outcomes is not. The document also covers the upfront costs, both staff and non-staff, that result from the proposed restructuring – these costs are a subset of those outlined within the coordinating document.

(iii) Annex B: Provision Impact Assessment

1302. This document covers the removal of some of the statutory restrictions on NHS providers, and the implementation of a revised regulatory framework. The main benefits come from the promotion of competition between providers to deliver the efficiency and quality benefits of competition and the removal of potential political interference in the system. These benefits are not quantified, though a potential benefits figure is included. The document also covers the costs of the proposed changes, which result from the revisions to Monitor to become the economic regulator and increased running costs of this new organisation.

(iv) Annex C: Local democratic legitimacy Impact Assessment

1303. This document covers the increase of local democratic legitimacy through the introduction of local health and wellbeing boards, whose membership will include democratically elected local councillors. The aim of this policy is to encourage the NHS to be more responsive to the preferences of the population it serves, and to promote integration between organisations involved in delivering health and social care. The health and wellbeing board will have responsibility for producing the Joint Strategic Needs Assessment and the joint health and wellbeing strategy. The assumed costs of this policy change are minimal.

(v) Annex D: Healthwatch Impact Assessment

1304. This document covers the creation of Healthwatch. The purpose of Healthwatch is to strengthen existing functions for patient voice (Local Involvement Networks) and complaints advocacy (Independent Complaints Advocacy Service). The potential benefits of the proposed policy change are around ensuring that local services represent the needs and preferences of the local population, to ensure people are supported to make choices, to ensure that people are supported to make complaints when they wish to do so and to reduce the likelihood of significant adverse effects. The principal monetised benefits included within the document are derived from examples of case studies of some of the Local Involvement Networks. The main

additional costs identified are around the staff in Healthwatch England to support local areas and local Healthwatch capacity to deliver new roles.

(vi) Annex E: Review of public bodies Impact Assessment

1305. This document covers the changes to arm's-length bodies that were proposed in *Liberating the NHS: Report of the arm's-length bodies review*¹⁶ that require legislation at this time. Not all of the proposed changes from the review are therefore covered within this document, and the document makes clear which changes are covered and which are not at this stage. The costs and benefits of no longer proceeding with the implementation of the Office of the Health Professions Adjudicator (OHPA) are also included within this document. A fuller description of not proceeding with the implementation of OHPA is published separately¹⁷.
1306. The main benefits identified in this document are from the reduction in Grant in Aid that will be paid to organisations that either merge or are abolished. The costs covered are predominantly transition costs resulting from the merger or abolition of some of the organisations or changes in the funding mechanisms of the individual functions.

(vii) Annex F: Public health Impact Assessment

1307. This document covers the elements of the Public Health White Paper *Healthy lives, healthy people: our strategy for public health in England*¹⁸ that require legislation at this stage. This includes the creation of a public health service and the transfer of responsibilities for health improvement from PCTs to local authorities. The aim of this, and the potential benefits, are to produce a more efficient service which will have a positive impact upon health and improve health outcomes. The main costs are around the transfer of staff from the Health Protection Agency into the Department of Health.

¹⁶ This is available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117691

¹⁷ This is available at:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122297.pdf

¹⁸ This is available at:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_122347.pdf

COMPATIBILITY WITH THE EUROPEAN CONVENTION OF HUMAN RIGHTS

Section 19 of the Human Rights Act 1998

1308. Section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House to make a statement about the compatibility of the Bill with the Convention Rights (as defined in section 1 of that Act). Andrew Lansley, the Secretary of State for Health, has made the following statement –

“In my view, the provisions of the Health and Social Care Bill are compatible with the Convention Rights.”

Consideration of the European Convention on Human Rights

1309. Although of the view that the Bill is compatible with the rights in the European Convention on Human Rights, the Department has considered the arguments which might be made in relation to the potential engagement of the Convention rights by the provisions in the Bill. The main arguments identified by the Department are considered below.

General application of the Human Rights Act 1998 to the NHS

1310. Section 6 of the Human Rights Act 1998 provides that it is unlawful for a public authority to act in a way which is incompatible with a Convention right. “Public authority” clearly covers existing NHS bodies established under the NHS Act and other statutory health bodies. In addition, however, “public authority” includes any person certain of whose functions are functions of a public nature – section 6(3)(b). The provisions have been the subject of various court decisions¹⁹.
1311. *YL* held that a private company providing residential accommodation under arrangements with a local authority acting under section 21 of the National Assistance Act 1948 was not carrying out a function of a public nature and was not a public authority for the purposes of the Human Rights Act 1998. The Department’s position in relation to services provided as part of the NHS, however, has been that *YL* can be distinguished and that private bodies providing NHS services under arrangements with NHS bodies are carrying out a function of a public nature.
1312. The Bill does not affect the question of whether a particular body is a public authority or not for the purposes of the Human Rights Act 1998, but the Department has considered whether the policy underlying the Bill, in particular the promotion of competition amongst a variety of healthcare providers, means that this view still holds

¹⁹ See in particular the House of Lords in *YL v Birmingham City Council and others* [2008] 1 AC 95 and the Court of Appeal in *London and Quadrant Housing Trust v R. (on the application of Weaver)* [2009] EWCA Civ 587

good. It has concluded that it does. NHS and public health services will continue to be arranged by statutory bodies subject to the NHS Act framework. Services under those arrangements will be funded by the Secretary of State, NHS body or local authority in question, and there will be no contract between the patient and provider (other than for services provided under the direct payments provisions of the NHS Act, which are not materially affected by the Bill). The relevant provisions of the NHS Act will continue to make no distinction between private and NHS provider. The NHS Act, as amended by the Bill, will continue to impose duties on the Secretary of State, NHS bodies and local authorities to arrange the provision of services - the nature of the service provided and the basis on which it is provided will be determined by those bodies in exercise of their statutory functions, and not by the status of the provider.

1313. The Department's view is therefore that, as now, private providers of services under arrangements made with the relevant statutory bodies under the NHS Act, as amended by the Bill, will continue to be carrying out a function of a public nature and will be public authorities, subject to the duty in section 6(1) of the Human Rights Act 1998 in so far as they are providing NHS services.

Commissioning consortia

1314. In the Department's view, two main ECHR issues arise in respect of the establishment of commissioning consortia. Firstly, the fact that existing providers of primary medical services will be required, by the imposition of contract terms in accordance with the Bill, to be members of a commissioning consortium. The contract terms will also stipulate what is required as regards that membership. This may engage the right to the protection of property under Article 1 of Protocol 1, the property in this case being the right to provide primary medical services under a contract (as distinct from the right of a GP to practise as a doctor which is regulated by the General Medical Council). The question is whether there is an interference with, deprivation or control of that possession.
1315. In the view of the Department there will not be a deprivation in that contracts are to be amended, rather than removed. Similarly it can be argued that there is no interference as the current legislation provides for contracts to be amended without contractors' agreement where this is necessary to comply with regulations. If there has been an interference, this can be justified if it is prescribed by law (it will be provided for in the Bill), pursues a legitimate aim and strikes a fair balance between the right of the owner of the possession and the public interest; the interference must be necessary and proportionate to that aim.
1316. The policy pursues a number of legitimate aims; these include the protection of health (by giving responsibility for commissioning secondary care services to groups of GPs to ensure that high quality health care services are commissioned) and the effective use of public funds. In the view of the Department these new terms have a reasonable foundation and are reasonably necessary in the public interest to ensure

commissioning of health care services is devolved down to those (i.e. GP practices) who are best placed to know their patients' needs, and best trusted to commission care on their patients' behalf. Doctors have consistently been considered the most trusted professionals²⁰. The Royal College of General Practitioners said, in their response to *Liberating the NHS: Commissioning for Patients*, "the College is confident that GPs, already having the greatest knowledge and understanding of the healthcare needs of their patients, are supremely well placed to shape the future development of NHS services".

1317. GP contractors also have significant impact on use of NHS resources through the referral and prescribing decisions they make and the quality of the primary care services they provide. Requiring membership and participation in a consortium, which will be responsible for commissioning healthcare, in the Department's view aligns responsibility for referral and prescribing decisions with the responsibility for the financial consequences of those decisions.

1318. As regards a fair balance and proportionality, the test for what is proportionate in these circumstances differs in relation to Article 1 of Protocol 1 claims as compared to other Convention articles. The courts have stated that the: "*starting point is an extant judgment by the state signatory as to what is necessary in the public interest.*"²¹ Assuming that is provided, the State need only exhibit "*a reasonable relationship of proportionality between the means employed and the aim sought to be realised*"²². The Secretary of State has discretion as to how to strike the balance between the public and the private interest. Parliament is to be accorded the broad margin of appreciation that is due to the assessment of the democratically elected legislature in matters of social and economic policy. Legislation in the organisation and delivery of national health services is an area of judgement where the Department would argue that the judiciary should, on democratic grounds, defer to the decision of Parliament as the elected body.

1319. The new obligations imposed upon contract holders will require membership and participation in a consortium but will not compel a particular role; it will be up to the consortium as a whole to decide how to commission and what commissioning role members take on, and how far they employ staff or buy in support (subject to the legislative framework; for example, to have regard to commissioning guidance issued by the NHS Commissioning Board under new section 14V of the NHS Act inserted by clause 22). Contractors will also have some flexibility as regards which consortium they choose to join. Also there will be procedural safeguards available; termination of a primary medical services contract for breach of the new terms (i.e. for refusal to join

²⁰ Based on the Ipsos MORI 'Trust in professionals' survey 2009; doctors have consistently remained the most trusted professionals.

²¹ *R (Hamilton) v UK Central Council for Nursing* (2004) 79 BMLR 30.

²² *James v United Kingdom* [1986] 8 EHRR 123.

and participate in a consortia) would be the ultimate sanction and prior to termination the contractual dispute resolution procedure would have to be followed.

1320. Secondly, Article 6 (right to a fair trial) issues may be raised in relation to determination by the NHS Commissioning Board of applications for establishment as a commissioning consortium. Clause 21 inserts section 14C of the NHS Act which provides for the NHS Commissioning Board to determine applications to be established as a consortium. There is no right of appeal against a refusal of an application. The Department considers that there would be no determination of civil rights in that such a decision by the NHS Commissioning Board is a decision in the administrative sphere rather than one concerning rights and obligations in private law. In these circumstances the “right” in issue is that of the applicants to have their application considered. However, if it were the case that civil rights of providers were engaged, in the Department’s view judicial review of the NHS Commissioning Board’s decision would be sufficient to secure article 6 compatibility, despite the fact that the ability of the Court to review the facts in judicial review proceedings is more limited than in civil law cases.

1321. In the case of *Alconbury*²³ it was stated: “full jurisdiction” does not mean full decision making power. It means full jurisdiction to deal with the case as the nature of decision making requires.” *Alconbury* was expanded upon in *Runa Begum*²⁴. The House of Lords found the High Court had full jurisdiction despite the case involving a mix of law and fact. The Court emphasised the width of judicial review;

“[The Court] may not only quash the authority's decision ... if it is held to be vitiated by legal misdirection or procedural impropriety or unfairness or bias or irrationality or bad faith but also if there is no evidence to support factual findings made or they are plainly untenable or if the decision maker is shown to have misunderstood or been ignorant of an established and relevant fact ... It is plain that the ... judge may not make fresh findings of fact and must accept apparently tenable conclusions on credibility made on behalf of the authority.” and went on to find that although a number of factual issues had to be determined, these decisions were “only staging posts on the way to the much broader judgments”²⁵.

1322. The Department would rely upon *Alconbury* and *Runa Begum* for these purposes and considers that the subsequent case of *Tsfayo v UK*²⁶ can be distinguished and should be restricted to its particular facts. Judicial consideration of the composite approach in relation to compliance with Article 6 subsequent to the case of *Tsfayo* supports the

²³ *R. v. Secretary of State for the Environment, ex parte Holding and Barnes, Alconbury Developments Ltd and Legal and General Assurance Society Ltd*, [2001] UKHL 23

²⁴ *Runa Begum (FC) v. London Borough of Tower Hamlets* [2003] UKHL 5

²⁵ *Ibid* 9(2)

²⁶ [2007] ECHR 656

conclusion that there is a sufficiency of review in the legislative framework as respects the establishment of commissioning consortia²⁷.

1323. Applying the authorities here, the Department takes the view that whilst any applications to the Courts to review decisions in relation to establishment of consortia are likely to involve some factual considerations (but unlikely to involve critical factual disputes or cross examination), such as the actual geographic area of the consortium, or content of the proposed constitution, these would be subsumed into questions of interpretation and analysis of the legislation or for example of the rationality of the conclusion reached by the NHS Commissioning Board such that a Court is likely to consider that it would have sufficient jurisdiction to review the NHS Commissioning Board's decision. The same analysis applies to the applications to, and determinations by, the NHS Commissioning Board under section 14E (applications for variation of constitution), section 14F (variation of constitution otherwise than on application), 14G (mergers) and 14H (dissolution), all inserted into the NHS Act by clause 21.
1324. If the NHS Commissioning Board's decision to refuse an application led to the NHS Commissioning Board deciding to take action under the member's provider contract it could be argued that the NHS Commissioning Board's action was directly decisive of an individual's civil rights and obligations. However in the Department's view the procedure for the determination of those rights under the contract are compatible with Article 6.

Emergency powers

1325. *Clause 39* amends the NHS Act to provide for the Secretary of State to give such directions as he considers necessary or appropriate by reason of an emergency which might affect an NHS body or a provider of NHS services. In relation to providers, the power may be exercised to direct a provider about how it provides services under its contracts with commissioning bodies (the NHS Commissioning Board and commissioning consortia), to direct it to cease to provide such services or to direct it to provide other services for the purposes of the health service for a specified period. In so far as the power may be exercised in relation to a private body or individual, if exercised so as to interfere with contractual rights and obligations there may be a potential infringement of Article 1 of Protocol 1 (right to peaceful enjoyment of possessions). The Department's view is that the provision is compatible for the following reasons. The directions would be given by the Secretary of State who, as a public authority for the purposes of the Human Rights Act 1998, must act compatibly with Convention rights. Also, the Department is to ensure that all providers will have provisions in their contracts with commissioning bodies, to the effect that they should

²⁷ See eg. *R (Gilboy) v Liverpool City Council and Secretary of State for Communities and Local Government* [2008] EWCA Civ 751, *R (M and A) v Lambeth and Croydon*, 2009 UKSC 8, *Ali v Birmingham City Council* UKSC [2010] 2, *R (Primary Health Investment) v Secretary of State* [2009] EWHC 519 and *Shah v NHSLA* [2010 EWHC 2575].

comply with the directions and that the terms of the contract are subject to such directions; if necessary the Secretary of State can require this using his regulation-making powers in new section 6E(4) and (5) of the NHS Act, as inserted by clause 16. To the extent that there was any interference with contractual rights and obligations, the interference would be provided for by law and would be for a legitimate aim – i.e. to ensure an effective response to an emergency affecting the health service for the people of England. The Secretary of State would have to ensure that the exercise of the power, if it involved a potential interference, was proportionate and ensured a fair balance between the general interests of the community (in having the emergency dealt with effectively) and the need to protect the individual rights of the provider or other third party.

1326. In so far as the power includes a power to direct a body to provide additional services, there is a potential issue in relation to article 4(2) of the ECHR, which provides that no one shall be required to perform forced or compulsory labour, in so far as the power applies to private providers. The Department considers that the provision is compatible. The requirement would be for a limited period in response to an emergency. The provider's contract with commissioning bodies would make specific provision for compliance with such directions and the provider would be remunerated for such services.

Economic regulation of health and adult social care services

1327. Part 3 of the Bill raises various ECHR issues. A person who holds a licence from Monitor has an interest in its business of providing health care services which would amount to a possession for the purposes of Article 1 of Protocol 1 and therefore a revocation of a licence could give rise to an interference with such possessions. In so far as Article 1 of Protocol 1 is engaged by the requirement for a licence, the use of conditions or the refusal or revocation of a licence, the Department is of the view that the requirements are compatible with Convention rights since, in controlling the use of property in accordance with the general interest, the requirements strike a fair balance between the private interests affected and the public interest in ensuring the continuity of designated NHS services, the efficient and effective provision of such services, that providers of such services are properly regulated and that there is competition in the provision of such services. The licence would ensure that providers met certain minimum financial and governance requirements, which the Department considers to be essential to ensure the continuity of provision of NHS services in the proposed new market for such services.
1328. Article 1 of Protocol 1 could also be engaged if, under a licence condition set for the purpose of promoting competition, Monitor were to direct a licence holder (A) to provide another licence holder (B) with access to a facility which A uses in providing services for the purposes of the NHS. Any such requirement would amount to a control on A's use of such facility, but would be subject to B paying reasonable access fees to A. Also, before deciding to give such a direction to A, a balancing exercise would have to be carried out by Monitor between the public interest (in

promoting efficiency and competition and conferring the best possible benefits on patients) in imposing such a requirement on A and the rights and interests of A. In doing so, Monitor would be required to have regard to certain factors.

1329. The Department therefore considers that any such direction would be compatible with Article 1 of Protocol 1 because Monitor would be required to strike a fair balance between the private interests affected and the public interest in promoting competition in the supply of NHS services. A would also receive payment from B for the costs of making the facility available to B and therefore the necessary fair balance would be struck without any requirement for further compensation. Additionally, a decision of Monitor to impose such a direction would be subject to an application for judicial review by A.
1330. Under the proposals in relation to licensing, certain services will be designated under clause 69 as designated services and made subject to additional regulation. Such services are those the loss of which would be considered, in the absence of appropriate alternative arrangements for the provision of that service, to materially impact patient outcomes. Providers of those services will therefore be subject to restrictions in relation to such services, including licence conditions requiring them to give Monitor a long period of notice if they want to stop providing a designated service and not to stop providing such a service without Monitor's prior consent.
1331. Article 4(2) ECHR provides that "no one shall be required to perform forced or compulsory labour". Providers of designated services could be required to continue to provide a designated service for longer than they would want to, to enable commissioners of NHS services to find an alternative provider of that service or to make alternative arrangements. Article 4 ECHR could therefore be argued to be engaged, but the Department would disagree because providers will only have services designated that they already provide, with the ECHR only potentially being engaged if they decide to stop providing a designated service; the requirement to continue to provide a designated service would only be for such time as commissioners need to find an alternative provider of that service or to make alternative arrangements; and providers of those services will be paid for doing so, with the possibility of an increase in prices to ensure a provider is not required to provide a designated service at a loss (see clause 110).
1332. Providers of designated services would also be subject to conditions potentially restricting the use and disposal of assets required for the provision of designated services. Such restrictions could amount to a control on the use of such assets. However, the Department considers that such restrictions are necessary and proportionate for fulfilling the legitimate aim of ensuring the continuity of important health care services, in order to prevent harm to patients. Monitor should only impose any such restrictions as it considers to be requisite and expedient to meet that aim. Providers of such services would be adequately paid for the provision of such services and so the Department considers that the necessary fair balance would be struck

without any requirement for any other form of compensation.

1333. A number of proposed provisions will involve decisions by Monitor which can be expected to give rise to Article 6 rights. These include: the grant and revocation, etc. of licences; the amount of any levy charged to providers of designated services towards the funding of financial mechanisms (which in the first instance are planned to be a 'risk pool') to support failing providers, and decisions on whether to make payments under any such risk pool to support any such provider; competition law enforcement (including the imposition of fines); the disqualification of directors for breaches of competition law; declarations of ineffectiveness of contracts awarded in breach of procurement rules; and the imposition of civil sanctions for breaches of licence conditions. In relation to all of these, extensive provision is proposed in respect of the making of representations prior to decisions being made and for appeals, or references to independent bodies (the First-tier Tribunal, the Competition Appeal Tribunal, or the Competition Commission). Otherwise, there would be the possibility of an application for judicial review.
1334. Certain decisions of Monitor under the Bill would be subject to an application for judicial review. The Department considers that the availability of judicial review in these circumstances would be compatible with Article 6 (right to a fair trial), curing any perceived lack on independence of Monitor as economic regulator. This is because Monitor, as a specialist regulator, would be exercising an administrative discretion pursuant to wider policy aims, i.e. promoting competition in the supply of NHS services and the efficiency and economy of such services, rather than largely determining questions of fact, and would have no direct interest in the outcome of its decision. Any necessary findings of fact would be "staging posts on the way to much broader judgments" (see the discussion above of the case law in relation to the adequacy of judicial review for the purposes of Article 6 in connection with commissioning consortia).
1335. In respect of competition law enforcement, the proposal is to give Monitor concurrent powers with the OFT to enforce the existing rules on anti-competitive behaviour under the Chapter 1 and Chapter 2 prohibitions of the Competition Act 1998. The relevant legislation has already been the subject of assessment of compatibility with Article 6 by the Competition Appeal Tribunal and has been found to be compatible²⁸. As to civil sanctions for breaches of licence conditions (clauses 95 and 100 and Schedule 9), the Department proposes to adopt the model laid down in Part 3 of the Regulatory Enforcement and Sanctions Act 2008, which was designed to be compatible with the ECHR. In the case of proposed provisions relating to disqualification under the Company Directors Disqualification Act 1986, only the court has power to make a disqualification order specifying a person subject to disqualification as a director, etc. under that Act.

²⁸ 1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v. Director General of Fair Trading* [2001] CAT 1

1336. The Competition Commission will have powers to require the disclosure of information to it when investigating questions referred to it by Monitor in the context of licence modifications and methodologies for adopting prices and risk pool levies. Schedule 8 applies sections 109 to 116 of the Enterprise Act 2002 (investigation powers of the Competition Commission) for these purposes, including a power to impose penalties for non-compliance. Any penalty imposed by the Competition Commission under these powers would be subject to a full right of appeal to the Competition Appeal Tribunal, an independent and impartial tribunal, under section 114 of the Enterprise Act 2002.
1337. Clauses 120 to 132 and Schedule 10 provide powers for Monitor to establish mechanisms for providing financial assistance to providers of designated services should such providers become subject to a health special administration order. This includes a power to impose a levy on providers of designated services for each financial year (clause 125). The second paragraph of Article 1 of Protocol 1 preserves the power of the State to control the use of property whether in the general interest or “to secure the payment of taxes or other contributions or penalties”. The proposed levy would not amount to a tax, but would be a contribution towards a risk pool designed to help protect the continuity of designated services should a provider of such services become subject to health special administration. The legitimate aim pursued by the financial mechanisms is the provision of any necessary financial assistance towards the continuation of designated services, which ensure the continuity of important health care services, in order to prevent harm to patients.
1338. Clauses 63 and 64 provide the Secretary of State with powers by regulations to impose requirements on the NHS Commissioning Board and commissioning consortia. Such requirements would be for the purposes of securing that the NHS Commissioning Board and consortia adhere to good practice in relation to procurement, protect and promote the right of patients to make choices with respect to treatment or other services provided for the purposes of the NHS, and promote competition in the provision of services for those purposes.
1339. Clause 64 provides that regulations made under clause 63 may confer on Monitor a power to declare that an arrangement for the provision of services is ineffective where there had been a breach of the regulations. This could give rise to loss or damage on the part of a person who had entered into such an arrangement with the NHS Commissioning Board or a consortium. However, clause 64(7) provides that any failure to comply with any regulations made under clause 63 which causes loss or damage is actionable by any person who has suffered such loss or damage. Such a person could therefore bring an action for damages before the courts against the body which had breached the regulations.

Regulation of health and social care workers

1340. It might be argued that the provisions in Part 7 of the Bill relating to the grant, or refusal to grant, a person admission to, or removal of a person from, a voluntary

register of unregulated health professionals, health care workers or social care workers in England, and to the grant, refusal to grant or removal of accreditation of such registers by the Council for Healthcare Regulatory Excellence (CHRE) engage Article 6 (right to a fair trial). It is arguable whether Article 6 is even engaged by such activities, as it is not clear that there is a determination of civil rights and liabilities. However, for the purposes of its consideration, the Department has assumed that civil rights are in issue here.

1341. It is clear that decisions which determine civil rights may be made by administrative authorities, provided there is subsequently access to an independent and impartial tribunal which exercises full jurisdiction. In relation to decisions about individual inclusion in a voluntary register, the court would have supervisory jurisdiction over such decisions, even if there is no distinct private law cause of action²⁹. If the courts found the relationship between those holding voluntary registers and applicants or registrants to be contractual, there would be a civil law claim. There might also be the possibility of judicial review if the registering body were found to be carrying out a public function. In any event, the Department considers that either by means of a private law claim, judicial review or through other supervisory jurisdiction, these decisions will be subject to the scrutiny of the courts. This, together with a robust system for determining applications for registration and a robust process for determining whether a person should be removed from the register on the part of the holder of the voluntary register, will, in the Department's view, be sufficient to ensure compliance with Article 6.
1342. In relation to decisions to accredit voluntary registers, the Department's view is that CHRE is a public authority exercising public functions meaning that the CHRE's decisions would be subject to challenge in the courts. The Department considers that this, together with the systems and processes run by the CHRE in relation to accreditation, will be sufficient to ensure compliance with Article 6.
1343. The Department has also considered the abolition in the Bill of the Office of the Health Professions Adjudicator, a body which was established to undertake adjudication of fitness to practise cases relating to health professionals (although it is not yet carrying out those functions). The Department does not consider that any difficulty with Article 6 (right to a fair trial) compliance will arise as a result of this abolition and the continuation of the current system of adjudication by the regulatory bodies whose decisions are subject to appeal and review by the higher courts. The Courts have consistently held that owing to the availability of subsequent judicial control there is no violation of Article 6 in the adjudication of fitness to practise cases by regulatory bodies.

²⁹ See *Mohdahl v British Athletic Federation* (2002 EWHC Civ 1447)

Provisions in the Bill dealing with disclosure of information

1344. There are several provisions in the Bill which require the disclosure of information, where Article 8 (right to respect for private and family life) is arguably engaged. Article 8 would be engaged to the extent that information which identifies a living individual could be disclosed without that person's consent. Such an interference would be justified if it is prescribed by law, it meets a legitimate aim and is necessary in a democratic society (i.e. it is proportionate). All the interferences would be prescribed by law, as they would be provided for either in the Bill, or in regulations or directions made under it. The Department has considered the legitimate aims and proportionality of the potential disclosures of each provision and these are set out below.
1345. The Secretary of State will have power in the "standing rules" (clause 16, inserting new section 6E into the NHS Act) to use regulations to require the NHS Commissioning Board or commissioning consortia to disclose specified information to specified persons. This information is highly unlikely to consist of information which identifies living individuals. It is likely to be used to require the NHS Commissioning Board or consortia to provide certain information to patients and the public, for example in connection with the exercise of choice. A regulation-making power is considered necessary, rather than specifying the information on the face of the Bill, in order to allow flexibility for unforeseen information needs to be dealt with in future. The Secretary of State, when making the regulations, would have to act compatibly with the Convention. Any information disclosure requirements which did engage Article 8 would need to be justified and proportionate.
1346. Under clause 22 the NHS Commissioning Board has powers to require information, documents, records or other items (section 14Z3) and to require explanations (section 14Z4). The legitimate aims pursued by such requirements include the protection of health (by ensuring that high quality health services are commissioned by consortia) and the protection of public funds (ensuring in particular that consortia are meeting their financial duties in respect of their use of public money and that the NHS Commissioning Board can intervene sufficiently early). The purpose of these powers is to enable the NHS Commissioning Board to assess how consortia are carrying out their functions where the NHS Commissioning Board has reason to believe that the consortium might be failing to discharge its functions. The powers are necessary to ensure that the NHS Commissioning Board has available to it all the proper and necessary information to assess how well these public bodies are performing, and how they are spending public money, when it has concerns about their performance.
1347. In the Department's view these powers are proportionate. Appropriate limitations and restrictions are imposed by the Bill. The powers can only be exercised where the NHS Commissioning Board has reason to believe that the area or number of persons for whom the consortium is responsible is no longer appropriate or where the consortium might have failed, might be failing, or might fail to discharge any of its functions. The power to require documents can only be exercised where the NHS Commissioning

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

Board considers it necessary or expedient. The right to require documents extends only to the consortium or any member or employee of the consortium who has possession or control of the item. There is an additional safeguard in that the power to require documents does not include the power to require the provision of personal records³⁰.

1348. The Board (clause 19, inserting new section 13W) and commissioning consortia (clause 22 inserting new section 14Z8) have power to disclose information obtained in the exercise of their functions if one of the circumstances set out in the clause applies. These circumstances are the same as apply in relation to disclosures made by the CQC under section 79(3) of the Health and Social Care Act 2008. The disclosures could override any common law duty of confidentiality. To the extent that Article 8 would be engaged by any such disclosure, it would pursue the legitimate aim set out in the clause, such as the protection of the welfare of an individual, or it would be necessary or expedient for the exercise of statutory functions by the Board, commissioning consortia or another person, which relate to the protection of health. Any interference represented by the disclosures would be proportionate, in that they could only be made in the circumstances set out in the relevant clauses, and additionally the Board and commissioning consortia, as public authorities, would be bound by the Human Rights Act 1998 to act in a proportionate way.
1349. Monitor will have power to require the disclosure of information, etc. by commissioners and providers of NHS services (clauses 90(1)(c) and 94, or regulations which include the power provided for in clause 64(1)(b)) and powers and duties to share relevant information with other regulatory bodies (e.g. the Care Quality Commission) (clauses 265 and 264). The power to require the disclosure of information is to enable Monitor to carry out its statutory functions and the power to share information is to enable other regulators to perform their statutory functions.
1350. It is not expected that Monitor, as the economic regulator of health care providers (as opposed to, for example, a regulator of quality or safety), would need to process information which identifies living individuals, as anonymised information should be sufficient to enable it to carry out its functions. In relation to any other material, e.g. which relates to a business, it is considered that the law of confidentiality would be a sufficient control on the disclosure of information by Monitor. Furthermore, in exercising its proposed concurrent functions under the Competition Act 1998 (clause 60) and Part 4 of the Enterprise Act 2002 (clause 61), Monitor would be subject to restrictions on the disclosure of information which had come to it in connection with the exercise of those functions laid down in Part 9 (information) of the Enterprise Act 2002. Part 9 of the Enterprise Act would also restrict the ability of the Competition Commission to disclose information it receives in the context of matters referred to it under Part 3 of the Bill.

³⁰ Personal records is defined by reference to the meaning in section 12 of the Police and Criminal Evidence Act 1984.

1351. Certain functions of Local Healthwatch organisations (LHWs) could involve disclosure of information to other organisations such as Healthwatch England (HWE) (clause 168). LHWs will have power to request information from service providers, power to enter and view premises of service providers (clause 171) and a duty to publish annual reports (clause 173). Disclosures of information would be necessary to ensure that the voice of local patients about their experiences and views are heard and fed back to persons involved in the chain of delivery and scrutiny of care, with a view to improving service standards. Powers of entry are necessary in order to back-up the powers to request information, and enable LHWs to influence decision makers and improve services. Whilst such powers engage Article 8, their use would, in the Department's view, be justified for these legitimate aims. Safeguards would be included in the regulations conferring the powers, as there are now in relation to the current local involvement networks.
1352. HWE's functions will include making a report to the Care Quality Commission (CQC) on the views of people on their needs for and experiences of health and social care services and the views of LHWs and others on the standard of service provision (clause 166). HWE will also publish an annual report on the way it has exercised its functions. Disclosure of information, in particular the views of the public and issues affecting service standards, including under-performance, to the CQC pursues the legitimate aim of enabling CQC to identify concerns and ensure action is taken. The CQC's functions include carrying out special reviews and investigations with a view to ensuring quality and safety of services.
1353. Local authority Health and Well-being Boards will have power to request local authorities and certain members of the Boards to provide information, with a corresponding duty on those persons to comply (clause 183). Information will only be able to be requested where this is for the purpose of enabling or assisting the Health and Well-being Board to perform its functions, which are promotion of integrated working in commissioning and preparing Joint Strategic Needs Assessments and Joint Health and Well-being Strategies. Information supplied to the Boards will only be able to be used for this purpose. It is unlikely that the information which would enable or assist the Boards to perform their functions would be such as to engage the Article 8 rights of individuals.
1354. Local authorities will have powers under regulations to request private providers of NHS services to provide information and to attend before them to answer questions (clause 22). The purpose of this power is to enable local authorities to scrutinise the local NHS more effectively and to facilitate improvements.
1355. The Health Service Commissioner for England, more commonly known as the Health Service Ombudsman (HSO) carries out investigations about unfair, improper or poor service by the NHS in England. The HSO cannot currently send investigation reports to anyone other than the complainant, their MP, the NHS body or individual complained about, any commissioning body involved and the Secretary of State. She also cannot send her reasons for declining to investigate (referred to as 'statements of

reasons') to anyone other than the complainant and to any MP or other representative who is assisting them. Clause 185 permits the HSO to share investigation reports and statements of reasons with such persons as the HSO thinks appropriate. This will enable reports and statements of reasons to be shared with regulators, advice and advocacy organisations and other stakeholders. The Department considers this to be a valuable source of feedback on service delivery and has the legitimate aim of the protection of health. Any disclosure which identified a particular individual might engage Article 8 but would be, in the Department's view, justified by having this legitimate aim. The HSO would have to be satisfied that disclosure was appropriate before it could be made.

1356. The Health and Social Care Information Centre (IC) will have certain powers to require information to be provided by health or social care bodies (see clause 242). The Secretary of State and the NHS Commissioning Board will have powers to direct the IC to carry out its functions in relation to information in connection with functions of the Secretary of State or the NHS Commissioning Board. Such information gathering powers pursue the legitimate aim of ensuring the effective operation of the health service by enabling information which would assist in the exercise of functions in connection with the provision of health services or adult social care services to be made available. In addition, where a private person or body requests IC to collect, analyse or release patient identifiable information, IC in considering the request will need to be satisfied that the collection or analysis complies with regulations under section 251 of the NHS Act. The IC will also have to publish procedures for the making and considering of such requests (clause 240(1)).
1357. As a result of clause 30, the Secretary of State and other people exercising functions in connection with the approval of professionals to carry out certain functions under the Mental Health Act 1983 (the 1983 Act) will have an express power to disclose information where they consider it necessary or appropriate in connection with those functions. Where information is being shared between those people (rather than with third parties), disclosure will be allowed despite any rule of the common law to the contrary. So, for example, a body which received an application for approval would be able to share the information in that application with another body to whom the person concerned might also apply, even if a duty of confidence under common law would otherwise prevent that.
1358. Whilst such powers could engage Article 8, their use would, in the Department's view, be justified for the legitimate aim of the protection of health or the protection of the rights of others. Ensuring the proper operation of these approval functions is necessary to promote the effective application, by suitably approved professionals, of the provisions of the 1983 Act relating to the detention and treatment of patients for mental disorder for their own health or safety, or for the protection of others. Any such disclosure of information in connection with the approval functions is likely to be proportionate, particularly in view of the limitations on the exercise of the power in section 12ZC(1) of the 1983 Act, inserted by clause 30, i.e. that the information is such that the body concerned considers necessary or appropriate for or in connection

with the exercise of an approval function (or with the exercise of the Secretary of State's powers of giving approval functions to a person under section 12ZA or 12ZB of the 1983 Act, or with giving an instruction as to the exercise of the approval function).

1359. In the Department's view it is legitimate and proportionate to allow information to be shared between people exercising the above functions, notwithstanding the restrictions of the common law which would otherwise apply, because they will all be concerned with the exercise of the same approval functions under the 1983 Act. Information relevant to the effective exercise of those functions that may be acquired by one person exercising these functions will be of equal importance to another such person in connection with the same functions.

Removal and suspension of statutory office holders and termination of appointments or employment on abolition of statutory bodies

1360. The Department has considered two particular aspects in relation to individuals appointed to statutory office in, or employed by, public bodies affected by the Bill. Firstly, the Bill provides power for the Secretary of State to suspend or remove non-executive members (including the chair) of certain bodies (the NHS Commissioning Board – Schedule 1, NICE – Schedule 15, the Information Centre – Schedule 17 and Monitor – Schedule 7). It is arguable whether such decisions would engage Article 6 (right to a fair trial), as statutory office holders are not employed as civil servants, but hold office in accordance with statutory provisions, meaning that the decision to suspend or remove would not be determinative of civil rights and obligations. However, for the purposes of its deliberation, the Department has considered the position in the event that Article 6 is engaged.
1361. The procedures for suspension and termination would follow a fair procedure. A non-executive member who was suspended (and Article 6 does not, except in exceptional circumstances, apply to interim measures) could request a review of the suspension after three months. In making decisions, the Secretary of State would have to act compatibly with the Convention, and decisions would be subject to judicial review. The Department considers that judicial review would be sufficient for the purposes of Article 6, taking into account the case law referred to above in connection with commissioning consortia.
1362. It might be argued that being suspended or removed from statutory office would engage Article 8 (right to respect for private and family life) or Article 1 of Protocol 1 (right to peaceful enjoyment of possessions). The Department does not consider that such decisions would have consequences which would affect the private life of the person concerned, but even if Article 8 were engaged, the procedures would be fair and any interference would be justified in the interests of the health service to ensure that persons holding statutory office in these bodies are fit to do so. Likewise, the Department does not consider that a statutory office would amount to a possession for the purposes of Article 1 of Protocol 1. Even if it were, its removal would, in the

Department's view, be justified as described above in relation to Article 8.

1363. Secondly, when various statutory bodies (eg Primary Care Trusts, Strategic Health Authorities, the General Social Care Council and others) are abolished by the Bill, statutory office holders' positions and employees' jobs will cease to exist. In relation to statutory offices, whilst it might be argued that Articles 6, 8 and Article 1 of Protocol 1 are engaged by the decision to restructure the NHS and other public bodies, meaning that a statutory office ceases to exist, the Department does not consider that such arguments are tenable.
1364. In relation to employees, decisions which impact on the employment rights of staff would engage Article 6 as being determinative of private rights and obligations. However, in so far as any abolition will involve the transfer of staff to another body the Department does not consider that there will be any determination of employment rights for the purpose of Article 6. Provision is made to enable such transfers as part of the programme of abolition. Staff would be transferred in accordance with TUPE, or government practice ensuring that transfers of staff in a TUPE-like situation are made in line with TUPE principles. Where TUPE or Government policy would not apply, for example because the functions of the transferee body will not be the same as the dissolved body, there is provision to transfer staff but not necessarily on the same contractual terms. In such a case, the transfer would be optional for the employee and would be as an alternative to being made redundant or to being re-employed on new terms.
1365. Whatever transfer provisions are made, these will not remove individuals' statutory rights of transfer under TUPE or their statutory or contractual rights in relation to redundancy. Any staff not transferred, either through choice or due to reductions in numbers, would be subject to the normal employment procedures including redundancy, meaning that statutory and contractual employment rights would not be affected. If there was an argument that there had been an interference with such rights, employees would have access to an employment tribunal, which would fulfil the requirements of Article 6.

Other provisions of the Bill

1366. The Department does not consider that the provisions of the Bill which are not mentioned above can be argued to engage the Convention rights in any meaningful way. In particular it has considered the amendments to the Mental Health Act 1983 and the Mental Capacity Act 2005. In relation to the amendments to the 1983 Act, these are largely consequential on the changes to the organisation of the NHS, but one amendment made by clause 273 (in Part 11 of the Bill) might be argued to engage the Convention.
1367. Clause 273 deals with supervised community treatment. Articles 3 (right to protection from inhuman and degrading treatment) and 8 (right to respect for private life) are potentially engaged to the limited extent that the clause changes the rules as to when a

patient who has been recalled to hospital may be treated without consent. Treatment without consent under the 1983 Act has been held in various cases to be compatible with Articles 3 and 8. This provision changes, at the margins, the circumstances in which a patient recalled to hospital may be given such treatment without the need for a certificate of approval from a second opinion appointed doctor. To that extent, they make a minor change to the specific safeguards in the Act which guard against the inappropriate use of the power to treat without consent. They do not, however, affect the underlying power to treat without consent in section 63 of the Act, and are not considered by the Department to engage Articles 3 or 8.

1368. In relation to the amendments to the Mental Capacity Act 2005, Schedule 5 amends section 35(1) of the Act to make local authorities, instead of the Secretary of State, responsible for making arrangements to enable independent mental capacity advocates (IMCAs) to represent and support specified persons. In circumstances where a local authority proposes to make arrangements to provide a person with residential accommodation, the person lacks capacity to consent to those arrangements, and there is no-one else to consult about the person's best interests, the person would receive support and assistance from an IMCA provided under arrangements made by the local authority. Whilst it could be argued that the IMCA was not independent of the local authority making the decision about the residential accommodation, the Department does not consider that this argument is tenable. Part of the role of an IMCA is to be independent of the person responsible for the decision, but the amendment to section 35 will not affect this independence. All local authorities will make arrangements with a provider or number of providers, which will undertake to make IMCAs available in accordance with a contract. Arrangements for payment to the provider will be made by the local authority in accordance with section 35(5). The provider then makes arrangements with individual IMCAs to provide the service and pay those individuals. The independence of the IMCA would thus not be compromised.

COMMENCEMENT

1369. Clause 279 provides for commencement. The provisions of the Bill will come into force on a day specified in an order made by the Secretary of State, with the exception of the provisions which are to come into force on Royal Assent (these are listed in clause 279) and the provisions in relation to abolition of NHS trusts, which have their own commencement rules (see clause 164).

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

GLOSSARY OF ABBREVIATIONS

Abbreviations used in the Notes

Abbreviation	Meaning
CHRE	Council for Healthcare Regulatory Excellence
CQC	Care Quality Commission
DHSSPS	Department of Health Social Services and Public Safety in Northern Ireland
DPH	Director of public health
ECHR/Convention	European Convention on Human Rights
ECT	Electro-convulsive therapy
FT	Foundation trust
GP	General medical practitioner
IA	Impact Assessment
IMHA	Independent mental health advocate
HIW	Healthcare Inspectorate Wales
HSE	Health and Safety Executive
HWB	Health and Wellbeing Board
IA	Impact Assessment
LA	Local authority
LINKs	Local involvement networks
LHW	Local Healthwatch
LSSA	Local social services authority
Mental Health Act	Mental Health Act 1983

*These notes refer to the Health and Social Care Bill
as introduced in the House of Commons on 19 January 2011*

Abbreviation	Meaning
NHS	National Health Service
NHS Act	National Health Service Act 2006
NICE	Currently the National Institute for Health and Clinical Excellence, changed through this Bill to the National Institute for Health and Care Excellence
OFT	Office of Fair Trading
PCT	Primary Care Trust
SCT	Supervised community treatment
SHA	Strategic Health Authority
SOAD	Second opinion appointed doctor
SpHA	Special Health Authority
UK	United Kingdom

HEALTH AND SOCIAL CARE BILL

EXPLANATORY NOTES

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