HEALTH AND SOCIAL CARE ACT 2012

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

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

Part 1 – The Health Service in England

The health service: overview

Section 1 - Secretary of State's duty to promote comprehensive health service¹

- 65. This section 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 mental and physical illness.
- 66. Section 1 of the NHS Act now has four subsections. The Act introduces a new *subsection (3)* and makes changes to *subsections (1)* and (2). The Act also makes a technical drafting change to subsection (4) which does not affect its meaning.
- 67. Subsection (1) retains the duty on the Secretary of State to promote a comprehensive health service. This is the core duty, dating back to the founding NHS Act of 1946, which makes the Secretary of State accountable for the health service. The Secretary of State must bear the duty in mind whenever he exercises any of his functions.
- 68. The Act inserts the words "physical and mental" in front of "illness" in section 1(1)(b). This change serves to emphasise that a comprehensive health service is one which addresses mental as well as physical illness.
- 69. This section replaces *subsection* (2) of the existing section 1 of the NHS Act (which imposes a duty on the Secretary of State, for the purposes of promoting a comprehensive health service (as set out at subsection (1)), to "provide or secure the provision of services in accordance with this Act", with a duty to "exercise the functions conferred by this Act so as to secure that services are provided in accordance with this Act". This reflects the fact that the functions of commissioning services and the provision of services will no longer be delegated by the Secretary of State, but will be directly conferred on the organisations responsible for performing them. The Secretary of State's role is to ensure that these functions are being carried out effectively; he or she retains ultimate responsibility for securing the provision of services through the exercise of his functions, such as his powers to set objectives for the NHS Commissioning Board (through the mandate to the NHS Commissioning Board under new section 13A), to oversee the effective operation of the health service and to intervene in the event of significant failure (see new section 13Z2).

¹ Further information about the interpretation of these sections can be found on the Department of Health website at: http:// www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_129415.

- 70. Prior to the amendments made by this Act, the Secretary of State's duty to provide services under section 3 of the NHS Act was for the most part not fulfilled by the direct provision of services by the Secretary of State or by bodies to which he delegated that function. This duty was instead almost entirely discharged by using the power (in section 12 of the NHS Act) to enter into arrangements with other persons or bodies to provide services in other words by commissioning a service and not by direct provision of a service. The majority of service provision is carried out by NHS trusts and foundation trusts, which have their own statutory functions of providing services under existing legislation, or by independent providers under contract. The only services that were directly provided under the Secretary of State's duty were those that PCTs provided prior to their abolition, where the Secretary of State's function of providing services was delegated to the PCT.
- 71. The change made by the Act to subsection (2) of section 1 of the NHS Act largely reflects changes in the delivery of health services which have been implemented by successive governments over a period of approximately 20 years. In the past, the Secretary of State, or the health authorities to which he delegated his functions, have provided hospital or other services directly (the Secretary of State and SHAs are not providers of NHS services). However, in recent years there has been a move towards securing a commissioner/provider split in NHS services. This separation is almost complete. Once PCTs stop providing services, the Secretary of State's section 1(2) duty to provide services (which he delegates to SHAs and PCTs) would no longer be necessary. Under the new arrangements, which seek to complete the implementation of the commissioner/provider split, the Secretary of State, the NHS Commissioning Board and CCGs would not have the function of providing services. The NHS Commissioning and not for their provision).
- 72. The Secretary of State and local authorities will have powers to both commission and provide public health services, under their new functions in relation to the protection of public health and health improvement.
- 73. New subsection (3) of the amended section 1 clarifies that the Secretary of State retains ministerial responsibility to Parliament for the provision of the health service.
- 74. Subsection (4) of the amended section 1 maintains the principle that health services must be free of charge, unless charges are specifically provided for in legislation. Subsection (4) is slightly amended from the NHS Act; this is a drafting change, consequential on subsection (2). The only difference in the wording is to refer to services which are "part of the health service" rather than to the services which the Secretary of State provides or secures. 'Services which are part of the health service' cover all services commissioned by the NHS Commissioning Board, CCGs, and, in relation to public health, local authorities.

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

- 75. This section 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.
- 76. Subsection (1) of new section 1A details the duty on the Secretary of State to exercise the functions conferred on the Secretary of State in relation to the health service in a way that would secure continuous improvements in the quality of services provided as part of the health service. This includes both the Secretary of State's public health functions (the prevention of illness and the protection or improvement in public health) and those functions that the Secretary of State exercises in relation to the NHS along with the NHS Commissioning Board and CCGs (the diagnosis and treatment of illness). Any service that is associated with both public health and the NHS, such as screening, 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 standards.

77. Subsection (2) of new section 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. This duty is also placed on the NHS Commissioning Board and on CCGs by later sections in this Part. In keeping with the policy set out in the White Paper *Equity and Excellence: Liberating the NHS*², the outcomes are to focus particularly on the effectiveness, safety and patient experience aspects of healthcare (subsection (3) of new section 1A).

Section 3 - The Secretary of State's duty as to the NHS Constitution

78. Section 3 inserts new section 1B into the NHS Act, placing a duty on the Secretary of State to have regard to the NHS Constitution when exercising his functions in relation to the health service. Therefore when discharging any of those functions, the Secretary of State must do so with regard to the principles, values, rights and pledges in the NHS Constitution. The NHS Constitution is included in the list of defined expressions in section 276 of the NHS Act, directing readers of the Act to the definition at subsection (2) of new section 1B.

Section 4 The Secretary of State's duty as to reducing inequalities

- 79. This section inserts new section 1C into the NHS Act, which places a further duty on the Secretary of State when exercising his or her functions in relation to the health service. The duty is for the Secretary of State, when exercising his functions in relation to the health service, to have regard to the need to reduce inequalities between the people of England in respect of the benefits that may be obtained by them from the health service. This would include consideration of the need to reduce inequalities in access to health services and the outcomes achieved. This duty encompasses the Secretary of State's functions in relation to both the NHS and public health and relates to all the people of England.
- 80. Equivalent duties to consider the need to reduce inequalities are placed on the NHS Commissioning Board and on CCGs in later sections in this Part. This includes consideration of the need to reduce inequalities in access to health services and the outcomes achieved.
- 81. Later sections in this Part require the Secretary of State, the NHS Commissioning Board and CCGs to include in their annual reports an assessment of how effectively they have discharged their duties as to reducing inequalities.
- 82. In addition, later sections in this Part require the NHS Commissioning Board and CCGs to include in their business plan (NHS Commissioning Board) and commissioning plans (CCGs) an explanation of how each of them proposes to discharge their respective duties, in the exercise of their functions, to have regard to the need to reduce inequalities. The duty imposed by new section 14Z16 of the NHS Act requires the NHS Commissioning Board to include in the annual performance assessment of CCGs an assessment of how well CCGs have discharged their duties as to the need to reduce inequalities.

Section 5 - The Secretary of State's duty as to promoting autonomy

83. This section inserts new section 1D into the NHS Act. It seeks to establish an overarching principle that the Secretary of State should act with a view to promoting autonomy in the health service. Subsection (1) of new section 1D identifies two constituent elements of autonomy: freedom for bodies/persons in the health service (such as CCGs or Monitor) to exercise their functions in a manner that they consider most appropriate (new section 1D(1)(a)), and not imposing unnecessary burdens upon those bodies/persons (new section 1D(1)(b)). The section provides that when exercising

² Copies are available in the Library, and from the Department of Health website at http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm

his functions in relation to the health service, the Secretary of State must have regard to the desirability of securing these aspects of autonomy so far as consistent with the interests of the health service. Subsection (2) of new section 1D makes clear that in the event of a conflict between those aspects of autonomy, on the one hand, and the discharge by the Secretary of State of his duties to promote the comprehensive health service and as to securing the provision of services on the other, it is the latter which take precedence.

- 84. This duty would therefore require the Secretary of State, when considering whether to place requirements on the NHS and local authorities, 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.
- 85. The duty covers the arm's-length body sector and commissioners and providers of NHS services. Although the Secretary of State will not in future have the same direct relationship with providers of NHS services as he has under existing legislation with NHS trusts, he will still have certain functions which impact on providers. For example, he will be able to require certain terms to be included in contracts entered into by the NHS Commissioning Board and CCGs for the provision of NHS services, by virtue of regulations made under new section 6E of the NHS Act.
- 86. Section 23 of the Act inserts new section 13F into the NHS Act, placing a parallel duty on the NHS Commissioning Board to promote autonomy.
- 87. These duties are intended to address the policy outlined in *Liberating the NHS: Legislative Framework and Next Steps*³ 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

Section 6 – The Secretary of State's duty as to research

88. This section places a duty on the Secretary of State to promote research on matters that are relevant to the health service and to promote the use within the health service of evidence obtained from research. Parallel duties to promote research and the use of research evidence are also placed on the NHS Commissioning Board and on CCGs by later sections in this Part.

Section 7 – The Secretary of State's duty as to education and training

- 89. Section 7 inserts a new section 1F into the NHS Act subsection (1) of which places a duty on the Secretary of State to exercise certain functions so as to secure that there is an effective system for the planning and delivery of education and training to people employed, or considering becoming employed, in the health service, or in activities connected to it. The duty would apply to education and training for all healthcare professionals delivering health care including doctors, dentists, nurses, midwives, pharmacists, healthcare scientists and the allied health professions. It would also cover trainee professionals at the start of their career, before they enter employment in the NHS.
- 90. Subsection (2) of new section 1F places a requirement on any person commissioning services as part of the health service to include in the arrangements made for the provision of those services a duty on the provider to co-operate with the Secretary of State in discharging his duty as to education and training. If a Special Health Authority is discharging that duty on behalf of the Secretary of State (such as the planned Special

³ Copies are available in the Library, and is also available from the Department of Health website at: http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm

Health Authority - Health Education England), then the duty will relate to co-operation with that body.

91. Subsection (3) lists the Acts which contain functions which must be exercised by the Secretary of State so as to discharge the duty in subsection (1).

Section 8 – Secretary of State's duty as to reporting on and reviewing treatment of providers

- 92. This section inserts a new section 1G into the NHS Act to impose a duty on the Secretary of State to report on and review the treatment of providers of NHS services.
- 93. Subsection (1) requires the Secretary of State to lay a report before Parliament on any matter, including taxation, which might affect either the ability of NHS health care providers to provide health care services for the purposes of the NHS or the reward available to them for doing so. This report has to be laid before Parliament within 12 months of Royal Assent to this Act.
- 94. Subsection (2) provides that the report must include recommendations as to how any identified differences in the treatment of NHS health care providers could be addressed.
- 95. Subsection (3) requires the Secretary of State to keep under review the treatment of NHS health care providers as respects any matter mentioned in subsection (1).

Section 9 - The NHS Commissioning Board

- 96. This section inserts new section 1H into the NHS Act. This section establishes a new body to be known as the National Health Service Commissioning Board. The NHS Commissioning Board will be an independent body, which will hold CCGs to account for the quality of services they commission, the outcomes they achieve for patients and for their financial performance. The NHS Commissioning Board will have the power to intervene where there is evidence that CCGs are failing or are likely to fail to discharge their functions. The specific functions of the NHS Commissioning Board, such as commissioning specialised services, are conferred by provision made elsewhere in the Act.
- 97. Like the Secretary of State, the NHS Commissioning Board will be subject to the duty to promote the comprehensive health service (as set out in section 1 of the NHS Act). However, in relation to the NHS Commissioning Board this duty would not apply to those services falling within the public health functions of the Secretary of State or local authorities.
- 98. Subsection (3) of new section 1H provides that, in order to fulfil this general duty, the NHS Commissioning Board has two specific functions:
 - a) Firstly, it must commission services in accordance with the NHS Act. The services which the NHS Commissioning Board may, by regulations, be required to commission are described in new section 3B and include services which can be more effectively commissioned at national level, or which it would be inappropriate or impractical for CCGs to commission. Those services could include some dental services, specialised services, prison health services and health services for the armed forces. The NHS Commissioning Board will also be responsible for commissioning primary care services and high secure psychiatric services.
 - b) Secondly, when exercising functions in relation to CCGs (for example, when issuing commissioning guidance under new section 14Z8), the NHS Commissioning Board must do so in such a way as to secure the provision of services.
- 99. Subsection (2) introduces Schedule 1.

Schedule 1 - The National Health Service Commissioning Board

- 100. This Schedule inserts new Schedule A1 into the NHS Act. This new Schedule makes provision for the constitution and establishment of the NHS Commissioning Board. Paragraph 1 provides that the NHS Commissioning Board (a non-Departmental public body) is not to be regarded as a servant or agent of the Crown.
- 101. Paragraph 2 makes provision about the membership of the NHS Commissioning Board.
- 102. Sub-paragraph (3) of paragraph 2 requires that the number of executive members of the NHS Commissioning Board must not exceed the number of non-executive members. This would mean that where there were resignations, suspensions or other departures of non-executive members, it might be necessary to appoint additional members or remove members from the NHS Commissioning Board to ensure that the number of executives was less than the number of non-executives.
- 103. Paragraph 3 provides that the executive members of the NHS Commissioning Board must be appointed by the non-executive members. Sub-paragraph (2) requires that the appointment of the chief executive receives the approval of the Secretary of State. Sub-paragraph (3) provides that the chief executive and the other executive members must be employees of the NHS Commissioning Board. Sub-paragraph (4) requires that the Secretary of State appoints the first chief executive of the NHS Commissioning Board. The other remaining first executive members will therefore be appointed by the non-executive members.
- 104. Paragraph 4 makes provision about the terms of appointment and tenure of office of non-executive members of the NHS Commissioning Board which are equivalent to those for members of Monitor under Schedule 8 to the Act: the terms of their appointment will set out the detail of the basis on which non-executive members will hold and vacate office. In sub-paragraph (2) provision is made to enable a non-executive member to resign at any time by giving notice to the Secretary of State and sub-paragraphs (3) and (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 their duties as a non-executive member.
- 105. Sub-paragraphs (5) and (6) specify that the maximum term of appointment for nonexecutive members of the NHS Commissioning Board is 4 years and that a person who ceases to be a non-executive member is eligible for re-appointment.
- 106. 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 (4)*.
- 107. 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 could choose in practice to appoint a deputy chair (regardless of any suspension of the chair).
- 108. Paragraph 7 requires 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. Sub-paragraph (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 HM Treasury approval.
- 109. Paragraph 8 gives the NHS Commissioning Board powers to appoint employees.
- 110. 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 arm's-length bodies covered by this Act (for example, NICE and the Information Centre), the NHS Commissioning Board will 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.

- 111. 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 not employees of the NHS Commissioning Board.
- 112. 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.
- 113. Paragraph 12 provides that the NHS Commissioning Board is to regulate its own procedure and must make any arrangements that it considers appropriate for the discharge of its functions. The NHS Commissioning Board may, for example, use this power to manage the risk of a conflict of interest by preventing executive members from being involved in determining their own pay.
- 114. Paragraph 13 gives the NHS Commissioning Board the power to arrange for the exercise of any of its functions on its behalf by:
 - a) any non-executive member,
 - b) any employee (including any executive member), or
 - c) one of its committees or sub-committees.
- 115. Paragraph 14 gives the Secretary of State power to require the NHS Commissioning Board to provide the Secretary of State with such information as the Secretary of State requires, 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.
- 116. Paragraph 15 requires that the NHS Commissioning Board 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 HM Treasury). The chief executive of the NHS Commissioning Board is to be its accounting officer.
- 117. The NHS Commissioning Board sits within the Department of Health accounting and budgeting boundaries and the Department requires information to effectively and efficiently manage its 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.
- 118. Paragraph 16 requires the NHS Commissioning Board to prepare consolidated annual accounts in respect of each financial year. Consolidated annual accounts should contain the NHS Commissioning Board's own annual accounts and separately a consolidation of the NHS Commissioning Board's own annual accounts and the annual accounts of each CCG.
- 119. Sub-paragraph (3) of paragraph 16 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 HM Treasury 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 HM Treasury in its annual Financial Reporting Manual (FReM). In turn, the accounts of all bodies that are consolidated into the Department's Resource Account must be prepared in accordance with the same HM Treasury accounting framework. The Secretary of State therefore requires powers to

ensure that the NHS Commissioning Board's accounts, including the consolidation of its accounts with those of CCGs, are prepared in accordance with the requirements set by HM Treasury.

- 120. Sub-paragraph (4) of paragraph 16 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.
- 121. Additional provision is made in paragraph 17 for the Secretary of State, with the approval of HM Treasury, to require in-year 'interim' accounts to be prepared and for the Secretary of State to direct that these are audited.
- 122. Paragraph 18 makes provision in relation to the NHS Commissioning Board's seal.

Section 10 (new section 11) - Clinical commissioning groups

- 123. As set out in *Equity and Excellence: Liberating the NHS*⁴, the Act will create a comprehensive system of CCGs. Their purpose would be to commission most NHS services, supported by and accountable to the NHS Commissioning Board.
- 124. This section inserts new section 1I into the NHS Act. The new section provides that there are to be corporate bodies to be known as clinical commissioning groups (CCGs). Subsection (1) of new section 1I provides that CCGs will be established in accordance with Chapter A2 of Part 2 of the NHS Act and subsection (2) sets out that CCGs will have the function of commissioning services for the purposes of the health service in England in accordance with the NHS Act.

Arrangements for provision of health services

Section 11 - The Secretary of State's duty as to protection of public health

- 125. This section 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.
- 126. 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 Act is an 'all hazards' approach in that the Act 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.
- 127. 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 dangers to health and providing national vaccination and screening programmes. As well as vaccination and screening, the Secretary of State would also be able to provide other services for example, the provision of treatment for tuberculosis for the prevention, treatment or diagnosis of illness, if the Secretary of State considered it an appropriate step to protect public health. Many of the activities falling within this provision are currently carried out by the Health Protection Agency, which is abolished in Part 2.
- 128. Subsections (3) and (4) of new section 2A require the Secretary of State to consult the Health and Safety Executive, 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

⁴ Copies are available in the Library, and from the Department of Health website at http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm

which the Health and Safety Executive also has a function. This ensures consistency of action, for instance in a radiation incident.

Section 12 – Duties as to improvement of public health

- 129. This section 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 the provision of advice and information to help people who want to adopt healthier behaviour.
- 130. The section 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, and gives the Secretary of State the power to take appropriate steps to improve the health of the people of England. 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 also applied elsewhere in the Act.
- 131. 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 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 instance 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).
- 132. Subsection (4) provides that the steps which local authorities may take include 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 particular 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).

Section 13 - Duties of clinical commissioning groups as to commissioning certain health services

- 133. This section amends section 3 of the NHS Act to provide for the duties of CCGs in relation to commissioning certain health services.
- 134. CCGs would be the appropriate commissioners under the NHS Act, unless there is a duty on the NHS Commissioning Board to commission that service. Subsections (1) and (2) amend section 3 of the NHS Act to provide that CCGs 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.
- 135. The persons for whom CCGs will be responsible are set out in new section 3(1A) that is, those persons who are provided with primary medical services by a member of the CCG and those persons who usually reside in the CCG's area and are not provided with primary medical services by another member of any CCG. Under new section 3(1B), persons who have a prescribed connection with the CCG's area or who have previously been provided with a service by a member or former member of a CCG, may also be the responsibility of a CCG, where regulations so provide. This could, for example,

include people who are receiving continuing healthcare for a long term condition. New section 3(1C) makes it clear that the regulation-making power in new section 3(1B) must be exercised so as to provide that CCGs are responsible for providing emergency care to everyone present in their area.

- 136. New section 3(1D) provides that regulations may provide that CCGs do not have responsibility for certain people or cases that would otherwise meet the criteria in new section 3(1A). It is intended that this power will be exercised, for example, in order that people who are resident in Scotland, but registered with a practice that is a member of a CCG are not the responsibility of a CCG for these purposes. Subsection (8) of section 13 of the Act makes these regulations subject to the affirmative procedure in Parliament.
- 137. New section 3(1E) sets out that CCGs are not under a duty to commission a service or facility if the NHS Commissioning Board is under a duty to do so.
- 138. New section 3(1F) requires that CCGs in exercising their functions under this section, and section 3A of the NHS Act 2006 (inserted by section 14 of the Act), must act consistently with the duty on the Secretary of State, and the NHS Commissioning Board, under section 1 of the NHS Act to promote a comprehensive health service, and with the mandate published by the Secretary of State under section 13A of the NHS Act (inserted by section 23 of the Act).

Section 14 - Power of clinical commissioning groups as to commissioning certain health services

- 139. This section inserts a new section 3A into the NHS Act. Subsection (1) of that new section provides a power for a CCG to commission such services or facilities 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.
- 140. Subsection (3) provides that sections 3(1A), 3(1B) and 3(1D) of the NHS Act apply for the purposes of determining the persons for whom a CCG has responsibility. Subsection (2) makes clear that a CCG may not exercise these powers where the NHS Commissioning Board has a duty to commission services under either section 3B (Secretary of State's power to require the NHS Commissioning Board to commission services) or 4 (high security psychiatric services) of the NHS Act.

Section 15 - Power to require Board to commission certain health services

- 141. This section inserts new section 3B into the NHS Act which confers a regulationmaking 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 section, and it allows other services to be specified in the regulations.
- 142. Prior to the amendments made by this Act, most NHS services were commissioned by PCTs. In future it is intended that CCGs 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, CCGs would not be able to commission those services.
- 143. 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 Act.
- 144. The section provides that regulations may require the NHS Commissioning Board to commission certain other services as part of the health service.

- 145. Firstly, regulations under new section 3B 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 section 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 PCTs prior to their abolition commissioned.
- 146. Secondly, regulations under new section 3B may require the NHS Commissioning Board to commission health services for members of the Armed Forces and their families. The Ministry of Defence, through the Defence Medical Services, 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. Regulations under new section 3B would describe the types of services to be provided by the NHS Commissioning Board to members of the Armed Forces or their families.
- 147. Thirdly, this section provides that 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 to prisoners in England will be covered separately by the NHS Commissioning Board's functions in relation to primary care.
- 148. 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. It is intended that the services covered by this regulation making power will, for example, include services commonly described as "specialised services" for rare conditions, which under existing legislation are commissioned nationally by SHAs and regionally by groups of PCTs for each SHA region because of their low volume and high cost.
- 149. Subsection (2) of the new section provides that a service or facility may be prescribed under section 3B(1)(d) only if the Secretary of State considers it appropriate for the NHS Commissioning Board (rather than CCGs) to commission the service, taking into account the factors specified in subsection (3).
- 150. The Secretary of State could take into account the fact that one or more of the factors specified could suggest one course of action, while others could suggest something different- for example, suggesting the NHS Commissioning Board should be the commissioner for some specialised services which may not be expensive but may be low volume. The Secretary of State will take a view on the weight of the factors in order to decide whether the NHS Commissioning Board is the appropriate commissioner. The Secretary of State will be obliged to seek advice appropriate for enabling him to determine which services should be commissioned by the NHS Commissioning Board under this section, including from people or bodies with appropriate expertise and from the NHS Commissioning Board itself.

Section 16 - Secure psychiatric services

- 151. High security 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.
- 152. This section amends section 4 of the NHS Act, which concerns the provision of high security psychiatric services. *Subsection* (2) removes from the Secretary of State the duty to provide high security services and places a duty instead on the NHS

Commissioning Board to arrange for the provision of these services. Subsection (3) stipulates that providers of high security services must be approved for that purpose by the Secretary of State.

- 153. This section also gives the Secretary of State a power to give directions to providers of high security services about their provision of high security services. It is intended that this power will be used in practice in a limited fashion in relation to issues such as safety and security, and children visiting high security hospitals. The existing directions issued in relation to high security services by the Secretary of State are the High Security Psychiatric Services (Arrangements for Safety and Security at Ashworth, Broadmoor and Rampton Hospitals) 2011 and the Visits by Children to Ashworth, Broadmoor and Rampton Directions 1999, which deal with risk assessment and safeguarding.
- 154. Subsection (4) of the section also enables the Secretary of State to give directions to the NHS Commissioning Board about the way it exercises its functions in relation to high security services. It is intended that this power would be used in a limited manner to ensure that the NHS Commissioning Board, in commissioning high security services, would take into account any conditions which might be set by the Secretary of State, including directions to providers and to ensure that there is sufficient capacity to meet the demands of the criminal justice system.

Section 17 - Other services etc. provided as part of the health service

- 155. This section 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 section 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.
- 156. Subsections (3) to (8) 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 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 include school nursing services.
- 157. Subsection (8) amends paragraph 7B(1) of Schedule 1 to the NHS Act to extend the power of the Secretary of State to make regulations relating to the processing of information resulting from any weighing or measuring of children under regulations under paragraph 7A of that Schedule to include any other prescribed information relating to the children concerned. It also extends paragraph 7B(2) to allow the Secretary of State to require any person exercising functions in relation to weighing and measuring to have regard to guidance relating to information prescribed under subparagraph (1).
- 158. Subsection (9) inserts a new paragraph 7C into Schedule 1 and confers on the Secretary of State the duty to make arrangements for the collection, screening and supply of blood (and related services) and for the facilitation of 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 this Act. As now, the functions would be performed by NHS Blood and Transplant, a Special Health Authority, rather than by the Department of Health.
- 159. Subsections (10) and (11) amend paragraphs 9 and 10 of Schedule 1 so as to transfer to CCGs 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 CCGs' other duties than with local authorities' health improvement duties.

- 160. Subsection (12) 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.
- 161. Finally, *subsection (13)* 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, CCGs 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 CCGs 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 PCTs through the normal commissioning process. Local authorities would only be able to use the power in relation to their public health activities.
- 162. While new paragraph 13 enables the Secretary of State, the NHS Commissioning Board, a CCG or a local authority to obtain and analyse data or other information, it does not require the bodies holding the information to supply it and does not set aside any obligation of confidentiality that might apply to those bodies.

Section 18 – Regulations as to the exercise by local authorities of certain public health functions

- 163. This section inserts a new section 6C into the NHS Act, giving 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.
- 164. *Subsection (1)* of the new section 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, that is 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 (such as providing contraceptive services).
- 165. *Subsection* (2) enables the Secretary of State to make regulations specifying the particular public health services, facilities or other steps that local authorities must provide or take under their duty to improve public health (new section 2B) or their duties under Schedule 1 (such as arranging medical treatment of school pupils).
- 166. The Secretary of State could use this power to for example ensure long-term, national availability of a service or respond to a serious local concern about a lacuna in service provision. *Subsection (4)* of the new section clarifies that if the Secretary of State provided in regulations that local authorities had to undertake health protection activity, the Secretary of State will still be able to carry out that protection activity. The Secretary of State will also be able to require or allow local authorities to exercise functions of his that are ancillary to the functions he delegates under new section 6C (e.g. making facilities available to service providers or voluntary organisations under section 12 of the NHS Act).
- 167. *Subsection (5)* provides that when a local authority exercises the Secretary of State's public health functions under regulations under new section 6C, any liabilities incurred will be enforceable against the authority (and no other individual or body). Similarly only the authority will be able to enforce any rights acquired in the exercise of those functions. The effect, in particular, is that the local authority and not the Secretary of

State will be liable for the acts or omissions of the authority when exercising such functions.

Section 19 - Regulations relating to EU obligations

- 168. This section inserts new section 6D into the NHS Act, providing the Secretary of State with powers to confer functions by means of regulations and to direct the NHS Commissioning Board and CCGs 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 SHAs, and to direct them in the exercise of these and other functions to ensure compliance with EU law. This section makes new arrangements for the NHS Commissioning Board and CCGs, in view of the abolition of PCTs and SHAs.
- 169. Subsection (1) of the new section gives the Secretary of State a power to require, by means of regulations, the NHS Commissioning Board or a CCG to exercise a specified EU health function. As *subsection* (2)(a) specifies, 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 CCGs 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 NHS Commissioning Board or a CCG to exercise any functions relating to the making of subordinate legislation (such as regulations) for the purposes of implementing EU obligations.
- 170. Further to the power to delegate some of the Secretary of State's functions relating to EU obligations, *subsection (3)* of the new section provides that the Secretary of State may also direct the NHS Commissioning Board and CCGs about the exercise of any of these delegated functions. This would allow the Secretary of State to indicate to the NHS Commissioning Board and CCGs 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 an individual CCGs in this way if necessary.
- 171. Making regulations under subsection (1) would not prevent the Secretary of State from exercising the delegated EU health functions himself (*subsection* (4)). In addition, this section ensures that the NHS Commissioning Board or CCGs would be liable in the domestic courts for their actions where they are exercising EU functions delegated to them under this section (*subsection* (5)).
- 172. Subsection (6) gives the Secretary of State the power to direct the NHS Commissioning Board or CCGs 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, for example, the actions of an individual CCG, 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.

Section 20 - Regulations as to the exercise of functions by the Board or clinical commissioning groups

- 173. This section 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 CCGs 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 terms used in this section are defined by subsection (10).
- 174. The "standing rules" are intended to allow the Secretary of State to create a rules-based framework for commissioners. They would be generic, and under subsection (8) of the new section it would not be possible for the Secretary of State to develop regulations

only affecting an individual CCG. To a large extent the purpose of the standing rules would be to allow some existing policies to be maintained in the context of the more limited powers of the Secretary of State under this Act. In exercising the regulation-making powers under this section, the Secretary of State would be bound by the duty introduced earlier in the Act to avoid unnecessary burdens on other bodies in the health system.

- 175. *Subsections* (2) to (7) of new section 6E outline the areas where the Secretary of State would have the power to make standing rules.
- 176. 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 set out 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.
- 177. Subsection (4) of new section 6E provides a power for the Secretary of State to require certain matters to be included in the contracts that the NHS Commissioning Board or CCGs use when commissioning services from providers. This includes specifying matters which must appear in commissioning contracts entered into by the NHS Commissioning Board or CCGs, and requiring the NHS Commissioning Board to draft terms and conditions relating to those matters. Subsection (4) also indicates that regulations may require the NHS Commissioning Board or CCGs 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.
- 178. 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 NHS Commissioning Board to draft terms and conditions that it considers appropriate for inclusion in commissioning contracts. The regulations must also allow the NHS Commissioning Board to require CCGs to use such terms and conditions in their commissioning contracts ((5)(b)) and to draft model commissioning contracts ((5)(c)).
- 179. Under *subsection* (6) of new section 6E, the NHS Commissioning Board could be required to consult specified persons on any draft contracts that it produces.
- 180. Subsection (7) of new section 6E lists generic requirements which may be imposed on the NHS Commissioning Board or CCGs 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 NHS Commissioning Board or CCGs 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.
- 181. Subsection (7)(b) of new section 6E allows for regulations that would secure compliance with EU obligations by specifying the manner in which the NHS Commissioning Board and CCGs carry out their functions. This is complementary to the previous section.
- 182. Finally, subsection (7)(c) of new section 6E allows for regulations to require the NHS Commissioning Board or CCGs 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 resolution procedure in Parliament (as outlined in subsection (2) of this section).

183. Subsection (9) of new section 6E specifies that if any regulations under this section come into force on any day other than 1st April each year, 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 NHS Commissioning Board or CCGs would be aligned with the Secretary of State's annual mandate to the NHS Commissioning Board. If this were not possible, and regulations had to be introduced in the intervening period, the Secretary of State would be under a duty to explain why.

Section 21 - Functions of Special Health Authorities

- 184. *Subsection (2)* of this section 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. This function could be a function of the Secretary of State or any other person.
- 185. 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 that 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 CCGs in the new system. Where the Secretary of State is directing a Special Health Authority to undertake the functions of another organisation, he must do so through regulations that are subject to the negative resolution procedure (subsection (6)).
- 186. For existing Special Health Authorities (NHS Blood and Transplant, NHS Business Services Authority and the NHS Litigation Authority), there would be no need to reissue the current directions specifying their functions and they would continue in force as if given under the new power - this is provided for in paragraph 5 of Schedule 6.
- 187. Subsection (1A) of the amended section 7 prevents the Secretary of State from delegating the function of making orders or regulations to Special Health Authorities.
- 188. New subsection (1B) provides that 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.
- 189. New subsection (1C) 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.

Section 22 - Exercise of public health functions of the Secretary of State

190. This section 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 CCGs, or to local authorities which have a duty to improve public health (see new section 2B). "Public health functions" are functions under section 2A (duty to take steps to protect public health), section 2B (power to take steps to improve public health) or certain functions under Schedule 1 (such as providing contraceptive services).

- 191. Subsection (4) of the new section provides that where functions are delegated to the NHS Commissioning Board under such arrangements, the NHS Commissioning Board may in turn delegate those functions to CCGs.
- 192. Subsection (5) provides that when the NHS Commissioning Board, a CCG or local authority exercises the Secretary of State's public health functions under such arrangements, any liabilities incurred will be enforceable against that body (and no other individual or body). Similarly only the body which exercises the function in question will be able to enforce any rights acquired in their exercise.
- 193. Subsection (6) provides that the arrangements may include provision for the Secretary of State to provide funding to the NHS Commissioning Board or CCGs in relation to the delegated functions. The intention is to provide flexibility and efficiency in the way that public health services are delivered. The provision could be used, for example, to delegate responsibility to the NHS Commissioning Board for commissioning a national vaccination or screening programme.

Section 23 - The NHS Commissioning Board: further provision

- 194. This section inserts a new Chapter A1 into Part 2 of the NHS Act.
- 195. *Mandate to the Board.* New section 13A 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 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 NHS Commissioning Board should seek to achieve (section 13A(2)(a)), and any other requirements that the Secretary of State considers necessary to ensure those objectives are met (section 13A(2)(b)). The objectives must relate to the current financial year and such subsequent financial years as the Secretary of State considers appropriate. The requirements set out in the mandate will be given effect by regulations subject to the negative resolution procedure.
- 196. The intention is to require the Secretary of State to provide the NHS Commissioning Board with a single annual set of objectives and requirements in order to provide stability and clarity, allowing the NHS Commissioning Board to develop effective medium and long-term planning assumptions.
- 197. Subsection (3) of section 13A provides the Secretary of State to specify in the mandate the limits on the NHS Commissioning Board's capital and revenue resource use for the financial year, provided for in new section 223D (as inserted by the following section). Subsection (4) allows the Secretary of State also to specify any proposals as to the limits that will apply for subsequent financial years. Such information may help the NHS Commissioning Board in planning how to achieve objectives which extend beyond the current financial year. Subsection (5) enables the Secretary of State to specify in the mandate any matters that are proposed for consideration in assessing the NHS Commissioning Board's performance for that financial year. 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 CCG. This restriction, in subsection (6), mirrors that in relation to the standing rules (established under section 20).
- 198. Before specifying any objectives or requirements in the mandate, the Secretary of State must consult the NHS Commissioning Board, Healthwatch England and such other persons as the Secretary of State considers appropriate to ensure that the mandate would be effective, under subsection (8). Once the mandate is published, the NHS Commissioning Board will be under an obligation to seek to achieve the objectives and comply with the requirements specified, under subsection (7) (provided, in the case of requirements, that they are given effect to by regulations see subsection (9)).

- 199. *The mandate: supplementary provision.* New section 13B of the new Chapter A1 establishes the rules around in-year changes to the mandate. Subsection (1) places a duty on the Secretary of State to keep the NHS Commissioning Board's performance in achieving the objectives and requirements in the mandate under review, which underpins the Secretary of State's responsibility to hold the NHS Commissioning Board to account.
- 200. Should the Secretary of State have to make any change to the limits on the NHS Commissioning Board's total capital and revenue resource use (as provided for in new section 223D, as inserted by the following section), the mandate would have to be revised accordingly to reflect these changes. However, if the Secretary of State were to alter the objectives and requirements in the mandate, then they would not necessarily be required to revise these limits.
- 201. Subsection (3) provides that the Secretary of State may only make other changes to the mandate if the NHS Commissioning Board agrees to the revision or if the Secretary of State feels that there are exceptional circumstances that make the revision necessary. The Secretary of State may also revise the mandate following a parliamentary general election. 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 (5). Any changes to the requirements in the mandate would be given effect through regulations (see subsection (4) which makes provision comparable to section 13A(9)). This would ensure that the Secretary of State remained accountable to Parliament for any changes relating to the mandate.
- 202. *General duties of the Board*. New sections 13C to 13P confer some general duties on the NHS Commissioning Board.
- 203. Duty to promote NHS Constitution. New section 13C places a duty on the NHS Commissioning Board to promote and raise awareness of the NHS Constitution when exercising its functions. This is in addition to the duty on the NHS Commissioning Board under the Health Act 2009 (as amended by paragraph 175 of Schedule 5) to "have regard" to the NHS Constitution. The new duty means that when exercising all of its functions, the NHS Commissioning Board has to act with a view to securing that health services are provided in a way that promotes the NHS Constitution, and is required to promote awareness of the NHS Constitution among patients, staff and members of the public. This means that not only must the NHS Commissioning Board act in accordance with the NHS Constitution but it should also ensure that people are made aware of their rights under it and that they contribute as far as possible to the advancement of its principles, rights, responsibilities and values, through its own actions and through facilitating the actions of stakeholders, partners and providers.
- 204. *Duty as to effectiveness, efficiency etc.* New section 13D is a duty on the NHS Commissioning Board to exercise its functions in a way that is effective, efficient and economical.
- 205. Duty as to improvement in quality of services. New section 13E puts the NHS Commissioning Board under a duty to exercise its functions with a view to improving the quality of services provided as part of the health service. This also reflects the accepted definition of quality outcomes⁵ as comprising effectiveness, safety and patient experience. The NHS Commissioning 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", such as the NHS Outcomes Framework; and b) the Quality Standards that the National Institute for Health and Care Excellence (NICE) produces (see notes on Part 8 of the Act, below). This duty mirrors the Secretary of State's duty in new section 1A to improve quality of services as inserted earlier in this Part.

⁵ For example see the NHS Outcomes Framework published by the Department of Health on 20 December 2010 - http:// www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122944

- 206. Duty as to promoting autonomy. New section 13F requires the NHS Commissioning Board, in exercising its functions, to have regard to the desirability of securing, so far as is consistent with the interests of the health service, that any person exercising functions in relation to the health service, or providing services for its purposes is free to exercise those functions, or provide those services, in the manner that they consider most appropriate, and that they are not subject to unnecessary burdens. This mirrors the duty placed on the Secretary of State earlier in this Part.
- 207. This duty would therefore require the NHS Commissioning Board, when considering how to exercise its functions in relation to CCGs such as publishing commissioning guidelines, or when determining matters to be included in contracts with healthcare providers for example, 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 desirable.
- 208. The duty will 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 providers of NHS services. Although the NHS Commissioning Board will not have the same direct relationship with providers of NHS services as SHAs and PCTs have under existing legislation with NHS trusts, it will still have certain functions which impact on providers. For example, it will be able to require certain terms to be included in contracts entered into either by the NHS Commissioning Board itself or by CCGs for the provision of NHS services by virtue of regulations made under new section 6E.
- 209. This duty is intended to address the policy outlined in *Liberating the NHS: Legislative Framework and Next Steps*, which stated among its aims 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 service⁶

- 210. Subsection (2) of new section 13F makes clear that in the event of a conflict between those aspects of autonomy, on the one hand, and the discharge by the NHS Commissioning Board of its duties to promote the comprehensive health service and to exercise its functions in relation to CCGs so as to secure the provision of services on the other, it is the latter which takes precedence.
- 211. Duty as to reducing inequalities. New section 13G(1)(a) requires the NHS Commissioning Board when exercising its functions to have regard to the need to reduce inequalities between patients with respect to their ability to access health services; the NHS Commissioning Board must 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 NHS Commissioning Board may seek to narrow inequalities in ability to access through providing guidance to CCGs on how information about NHS services are to be communicated to specific groups, on opening hours, on reducing late presentation, or about where particular services should be located in order to be more accessible to specific populations. 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 complies with this duty.
- 212. New section 13G(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 must seek to narrow clinically unjustifiable inequalities in the outcomes of health care. For example, the NHS Commissioning Board may seek to improve the outcomes of care for specific groups through guidance to CCGs on access issues, on appropriate referral practices for

⁶ Copies are available in the House library, and from the DH website at http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/index.htm

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 Equality Act 2010 or by area deprivation or socio-economic group, it is expected that this will be increasingly helpful in guiding the NHS Commissioning Board's actions.

- 213. Duty to promote involvement of each patient. New section 13H requires the NHS Commissioning Board, in exercising its functions, to promote the involvement of individual patients and their carers and other representatives in decisions about their own care (shared decision-making). This duty is intended to address the commitment outlined in the White Paper *Equity and Excellence: Liberating the NHS* to the policy of "no decision about me without me".
- 214. The duty would apply to any decisions at all stages of that individual's health care, from preventative measures, diagnosis of an illness, and any subsequent care and treatment they receive. Effective involvement of patients in these decisions might include such things as opportunities for patients to participate in treatment decisions in partnership with health professionals, to be supported to make informed decisions about the management of their care and treatment and to discuss opportunities for patients to manage their own condition.
- 215. In addition to the commissioning of those services for which the NHS Commissioning Board will be directly responsible, it could exercise this duty through promoting the importance of involving patients in its dialogues with CCGs. The NHS Commissioning Board will also be required to publish guidance on how CCGs could discharge their equivalent duty to which CCGs must have regard.
- 216. Duty as to patient choice. New section 13I requires the NHS Commissioning Board to act with a view to enabling 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 CCGs, local authorities, voluntary sector groups, patient-led support groups and Healthwatch, for example. The intention is that the NHS Commissioning Board will also develop and agree with the Secretary of State the guarantees for patients about the choices they can make. In addition, the NHS Commissioning 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.
- 217. Duty to obtain appropriate advice. New section 13J provides that the NHS Commissioning Board must obtain appropriate advice from other professionals, so it can effectively discharge its functions. This would include, for example, obtaining advice when making commissioning decisions and when designing NHS pricing structures. In the Government response to the NHS Future Forum report, published on 20 June 2011, the Government proposed that potential sources of such advice could include clinical networks, which bring together groups of healthcare professionals to form networks that are specific to a particular health condition or profession, and clinical senates, groups of experts covering different areas of the country.
- 218. Duty to promote innovation. New section 13K places a duty on the NHS Commissioning Board, when exercising its functions, to promote innovation in the provision of health services by, for instance, encouraging both innovative commissioning and the commissioning of innovative health services. This could be achieved, for example, through the NHS Commissioning Board developing commissioning guidelines for CCGs as well as hosting some clinical networks where appropriate. New section 13K also provides for the NHS Commissioning Board to make payments as prizes in order to promote innovation in the provision of health services.

- 219. Innovation will originate primarily from the actions of commissioners and providers but it is intended that the NHS Commissioning Board will take a lead role in promoting it. The duty will support delivery of the NHS Commissioning Board's duty to secure continuous improvements in the quality of health care under new section 13E. This duty is similar to the duty that previously applied to SHAs.
- 220. Duty in respect of research. New section 13L confers a duty on the NHS Commissioning Board in the exercise of its functions, 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 will 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 NHS Commissioning Board could 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 NHS Commissioning 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.
- 221. Duty as to promoting education and training. New section 13M places a duty on the NHS Commissioning Board, when exercising their functions, to have regard to the need to promote education and training so as to assist the Secretary of State in the discharge of his related duty in new section 1F. This will also apply to any Special Health Authority supporting the Secretary of State in the discharge of his duty.
- 222. Duty as to promoting integration. New section 13N requires the NHS Commissioning Board to exercise its functions with a view to securing that health services, health and social care services, and other health-related services (for instance services such as housing that may have an effect on the health of individuals, but are not health services or social care services) are provided in an integrated way where it considers that this would either improve the quality of health services and the outcomes they achieve, or reduce inequalities in access to or outcomes from health services. This requirement would cover both integration between service types (such as between health and social care) and integration between different types of health services (such as hospital and community care). This will apply to all the NHS Commissioning Board's functions, not just its commissioning functions, including, for example, when it exercises public health functions under arrangements with Public Health England. The practical effect should be that services are integrated around the needs of the individual.
- 223. Subsection (3) requires the NHS Commissioning Board to encourage CCGs to enter into joint arrangements with local authorities under section 75 of the NHS Act where this would improve the quality of health services or reduce inequalities in outcomes from or access to health services. The intention is that the NHS Commissioning Board should encourage CCGs to work closely together with local authorities in arranging for the provision of integrated services.
- 224. Duty to have regard to impact on services in certain areas. New section 13O requires the NHS Commissioning 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 intended that CCGs, in practice, will also have regard to the impact of their commissioning decisions on border areas.
- 225. Duty as respects variation in provision of health services. New section 13P prohibits the NHS Commissioning Board from exercising its functions for the purpose of increasing or decreasing the market share of any particular type of provider whether public or private sector or according to some other aspect of its status in the provision of NHS services. This means the NHS Commissioning Board may not pursue a policy designed

to encourage the growth of a particular sector of provider. It would not prevent the NHS Commissioning Board from commissioning services from whoever it considered the most suitable provider, including new service providers, or from seeking to develop integrated services.

Public involvement

226. Public involvement and consultation by the Board. New section 13Q requires the NHS Commissioning Board to make arrangements to secure 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 an impact on the range of services provided and / or the manner in which they are provided; and (c) decisions affecting the operation of commissioning decisions. The duty applies to the NHS Commissioning Board only as respects health services which it commissions and its plans, proposals or decisions about such services. This reflects the duty that previously applied to PCTs under section 242 of the NHS Act.

Functions in relation to information

- 227. Information on safety of services provided by the health service. Following abolition of the National Patient Safety Agency under Part 10, new section 13R will give the NHS Commissioning Board responsibility for the functions currently carried out by the 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 CCGs and the contracts they agree with providers.
- 228. *Guidance in relation to processing of information.* New section 13S places a duty on the NHS Commissioning 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 health services. 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. Provisions within Part 10 of this Act insert new section 20A into the Health and Social Care Act 2008, which incorporates the definition of "processing" in the Data Protection Act.

Business plan and report

- 229. *Business plan.* New section 13T 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. The NHS Commissioning Board's business plan must, in particular, set out how it intends to discharge its duties as to improvement of quality under section 13E, as to reducing inequalities under 13G and as to the involvement of the public under 13Q as well its various financial duties under new sections 223C to 223E of the NHS Act. CCGs are required to cover similar matters in their commissioning plans.
- 230. Annual report. New section 13U requires the NHS Commissioning Board to publish an annual report, as soon as practicable after the end of each financial year, on how it has exercised its statutory functions during that year. In particular, the annual report must set out how, in its view, the NHS Commissioning Board has progressed against the proposals it made in its business plan for that year and the objectives and requirements set for it by Secretary of State in the mandate. It must also include an assessment of how effectively it has discharged its duties as to improvement of quality under section 13E,

as to reducing inequalities under 13G and as to the involvement of the public under 13Q. 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 has performed for the previous year against its statutory duties and the objectives and requirements set for it in the mandate. This letter must also be laid before Parliament.

Additional powers

- 231. *Establishment of pooled funds*. New section 13V allows the NHS Commissioning Board and one or more CCGs 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 NHS Commissioning Board and CCGs working together to discharge their functions, allowing them to share financial resources to meet expenditure requirements.
- 232. *Board's power to generate income*. New section 13W 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 will have a duty to remain within the resource limits set by the Secretary of State under new section 223D of the NHS Act and any income it generates could therefore reduce the funding required from public finances.
- 233. *Power to make grants etc.* New section 13X enables the NHS Commissioning Board to make payments by way of loans as well as grants to voluntary organisations that provide, or arrange for the provision of, services similar to those which the NHS Commissioning Board will be responsible for commissioning. This reflects the power that the Secretary of State has under section 64 of the Health Services and Public Health Act 1968, (exercised by SHAs and PCTs prior to their abolition). Equivalent provision is provided in the Act for CCGs under new section 14Z6.
- 234. *Board's incidental powers: further provision.* New section 13Y 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 NHS Commissioning Board).

Exercise of functions of Board

235. *Exercise of functions.* New section 13Z confers a power on the NHS Commissioning Board to exercise any of its functions by or jointly with a Special Health Authority, a CCG or any other body specified in regulations. Regulations may specify which functions of the NHS Commissioning 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 NHS Commissioning Board and the other body under arrangements agreed between them.

Power to confer additional functions

236. *Power to confer additional functions on the Board.* New section 13Z1 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 NHS Commissioning Board if this were beneficial for the effective operation of the health service. A function may only be conferred on the NHS Commissioning Board if it is connected to another function of the NHS Commissioning Board.

Intervention powers

- 237. *Failure by the Board to discharge any of its functions.* New section 13Z2 confers a power on the Secretary of State to intervene in cases of significant failure of the NHS Commissioning Board to carry out any of its functions properly or at all. Failure to discharge a function properly would include failure to discharge that function consistently with what the Secretary of State considers to be in the interests of the health service (subsection (5)). It is in line with similar powers in the case of significant failure of the other arm's-length bodies.
- 238. Similar intervention powers exist in respect of Monitor and the Care Quality Commission, but with the difference that as regards those bodies the Secretary of State would not be able to intervene in a particular case - he would have to demonstrate that the failure was more widespread. This limitation is intended to maintain the independence of the regulators, but is not appropriate with respect to the NHS Commissioning Board. The NHS Commissioning Board has a wide range of functions in relation to the health service. As a result, in the event of significant failure, it might be appropriate for the Secretary of State to intervene in a particular case, for example if the NHS Commissioning Board failed to allocate funds to a particular CCG or if it failed to commission a service as required by the NHS Act.
- 239. The powers conferred by this new section are not intended to be powers that the Secretary of State would use regularly or routinely to intervene in the affairs of the NHS Commissioning Board.

Disclosure of information

- 240. *Permitted disclosures of information.* New section 13Z3 sets out categories of information obtained by the NHS Commissioning Board that it is permitted to disclose. It also deals with the relationship between the powers under the section and the rules of common law on disclosure.
- 241. *Interpretation.* New section 13Z4 sets out interpretation of various terms used throughout Chapter A1, including the definition of health services. Subsections (2) and (3) list those references to functions of the NHS Commissioning Board in Chapter A1, elsewhere in the Act and in other legislation that are to include public health functions that are delegated to the NHS Commissioning Board by the Secretary of State using the powers in new section 7A. Those powers and duties would therefore apply when the NHS Commissioning Board exercises any delegated public health functions.

Section 24 - Financial arrangements for the Board

- 242. This section inserts new sections 223B (funding of the Board), 223C (financial duties of the Board: expenditure), 223D (financial duties of the Board: controls on total resource use), 223E (financial duties of the Board: additional controls on resource use), and 223F (power to establish contingency fund) into the NHS Act. Broadly, this section sets out how the Secretary of State would fund the NHS Commissioning Board. It also sets out the general financial duties of the NHS Commissioning Board, including restrictions on the use of resources. The Secretary of State would specify annually in the mandate to the NHS Commissioning Board limits on the total amounts of capital and revenue resources the NHS Commissioning Board and CCGs could make use of in that financial year. The Secretary of State would then make payments to the NHS Commissioning Board up to an amount allotted for that year, which would be calculated by reference to the NHS Commissioning Board's spending plans against the resource limits specified in the mandate.
- 243. *Funding of the Board*. New section 223B provides that the Secretary of State must pay sums not exceeding the amount allotted to the NHS Commissioning Board for that year to enable it to perform its functions. The NHS Commissioning Board will be notified in writing of the amount it has been allotted for that year (the allotment). Payment of the

allotment would be subject to the NHS Commissioning Board keeping such records, pertaining to the funds, as the Secretary of State requires (new section 223B(5)).

- 244. The Secretary of State would only be able to make a new allotment in any given financial year, either increasing or reducing the previous allotment, under certain circumstances. Either the NHS Commissioning Board must agree to the change, a parliamentary general election must have taken place, 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. The allotment would in practice be calculated by reference to the controls on resource use specified in the mandate to the NHS Commissioning Board.
- 245. *Financial duties of the Board: expenditure.* Under new section 223C, the NHS Commissioning Board will have an obligation to ensure that total expenditure by both the NHS Commissioning Board and CCGs (total health expenditure) does not exceed the aggregate of the amount allotted to the NHS Commissioning Board by the Secretary of State for that year, which includes the money paid to CCGs, and any income derived from other sources. This is in effect an annual "cash limit" on the total amount of cash expenditure which may be incurred by NHS commissioners.
- 246. The income which counts for the purposes of this limit would include, for instance, funds received as a result of the power of the NHS Commissioning Board to generate its own income (see new section 13W) or any money received by NHS Commissioning Board in order to comply with its freedom of information obligations. It would also include sums paid to the NHS Commissioning Board or to CCGs for carrying out the Secretary of State's public health functions under arrangements made between the NHS Commissioning Board and the Secretary of State under new section 7A of the NHS Act, as inserted by the previous section.
- 247. The Secretary of State has the power to determine by directions what will and what will not count when calculating whether total health expenditure has remained within the aggregate of the sums received and the amount allotted to it for that year. New section 223C(4) also 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 Commissioning Board under new section 223B, or by a CCG under new section 223G, but not yet spent must be treated for the purposes of this section as part of total health expenditure, and to which financial year's expenditure they must be attributed.
- 248. *Financial duties of the Board: controls on total resource use.* New section 223D is concerned with the NHS Commissioning Board's annual resource allocation. Under this section, the total use of capital resources and the total use of revenue resources by the NHS Commissioning Board and CCGs in a financial year must not exceed amounts specified by the Secretary of State. The NHS Commissioning Board is placed under a duty to ensure that these total limits are not exceeded. These are known as resource allocations and the amounts would be specified by the Secretary of State in the mandate for that year.
- 249. The resource allocations include not only the NHS Commissioning 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 NHS Commissioning Board (new section 223D(8)). 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 NHS Commissioning Board's resource allocation. 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 2000.

- 250. Subsections (4) to (6) give the Secretary of State a power to give directions that specify what descriptions of resources must be treated as capital or revenue resources, and the uses of resources that must, or must not, be taken into account, when determining whether the NHS Commissioning Board and CCGs have remained within the resource allocations for a financial year. Where the Secretary of State specifies that a particular description of resources must or must not be treated as a capital or revenue resource, or that a particular use of resources must be excluded, that applies to the other financial duties on the NHS Commissioning Board and CCGs in Chapter 3 (section 223E and new sections 223G to 223K of the NHS Act).
- 251. As with the allotment, the Secretary of State may only vary the resource allocations within a financial year if the NHS Commissioning Board agrees that the change is necessary, if there is a parliamentary general election, or if the Secretary of State believes there to be exceptional circumstances which demand a variation of the allocation. This is set out in subsection (7). As both the revenue and capital resource allocations will be set out in the Secretary of State's mandate to the NHS Commissioning Board, any change to them will therefore require the Secretary of State to revise the mandate and lay it before Parliament along with an explanation for the change (see new section 13B).
- 252. Financial duties of the Board: additional controls on resource use. New section 223E(3) enables the Secretary of State to specify additional limits within the total revenue resource limit on both the maximum use of resources attributable to administrative matters by both the NHS Commissioning Board and CCGs (223E(3)(a)), and the maximum use of resources by the NHS Commissioning Board on these matters (223E(3)(b)). It will be for the NHS Commissioning Board to then set an equivalent limit for each CCG under new section 223J. The matters relating to administration which count for the purposes of these limits will be set out in regulations.
- 253. Under new section 223E(1) and (2), the Secretary of State will also be able to set additional limits on total revenue or total capital resource use attributable to particular matters specified in directions. Subsection (5) requires that the Secretary of State may only impose such limits for the purpose of complying with limits imposed by HM Treasury. These limits relate to specific budgetary limits applied across all Government Departments on certain elements of spending. For example within the revenue Departmental Expenditure Limit (RDEL), HM Treasury applies a ring-fence to spending on depreciation. HM Treasury applies controls on Annually Managed Expenditure (AME) under which there are limits on the creation of new provisions (charges for spending that is likely to happen in future years eg clinical negligence or redundancy costs). The Department would also apply a limit on the balance of spending not covered by the specific limits, again to provide consistency with the controls applied by HM Treasury. These types of spending will fall within the total resource limits but need to be separately controlled within them.
- 254. The Secretary of State will be able to specify in directions certain uses of capital or revenue resources which must, or must not, count for the purposes of these limits (subsection (4)). In addition, the Secretary of State directions on what resources are to be treated as capital or revenue resources, and the uses of resources which are not to be taken into account, made under section 223D(4) and (5) apply to the limits under this section.
- 255. *Power to establish contingency fund.* New section 223F 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 NHS Commissioning Board or to CCGs to enable them to discharge their commissioning functions or to enable a CCG to discharge its other functions exercisable by virtue of regulations under section 75 of the NHS Act.

Further provision about clinical commissioning groups

Section 25 – Clinical commissioning groups: establishment etc.

- 256. *Establishment of clinical commissioning groups.* This section inserts Chapter A2 into Part 2 of the NHS Act, which makes further provision about CCGs. New sections 14A to 14O of the NHS Act make provision about the establishment of CCGs.
- 257. *General duties of Board in relation to clinical commissioning groups.* New section 14A sets out the general duties of the NHS Commissioning Board in relation to CCGs. Subsection (1) requires the Board to ensure that, at any time after the date specified by an order of the Secretary of State, all providers of primary medical services (for instance GP practices) in England are members of a CCG.
- 258. Subsection (2) requires the NHS Commissioning Board also to ensure that, from the date so specified by the Secretary of State, the areas specified in each CCG's constitution taken together cover the whole of England and do not coincide or overlap. This will ensure, for instance, that there is no ambiguity as to which CCG is responsible for a person that is not registered with a GP practice or who needs access to emergency healthcare.
- 259. Subsection (3) specifies 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 to provide primary medical services of a type set out in regulations it is intended that these regulations will prescribe essential primary medical services to registered patients in core hours. Together, these subsections have the effect that all GP practices that hold an NHS contract must be members of a CCG. 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 (7)).
- Applications for the establishment of clinical commissioning groups. New section 14B 260. makes provision for applications to be established as a CCG to be made to the NHS Commissioning 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 the proposed CCG. Under subsection (3), applications must include a copy of the CCG's proposed constitution, the name of the person whom the CCG wishes the NHS Commissioning Board to appoint as its accountable officer and such other information that the NHS Commissioning Board may specify. Any specification made by the Board for these purposes must be published in a document. Subsection (4) provides for persons to become applicants or withdraw from being applicants at any time before the application is decided by the NHS Commissioning Board. Subsection (5) provides that, with the agreement of the NHS Commissioning Board, applicants can modify the proposed constitution at any time before the application is determined. Subsection (6) introduces Part 1 of Schedule 1A (inserted by Schedule 2 to the Act), which makes provision about the constitution of a CCG.
- 261. *Determination of applications*. New section 14C provides for the determination of applications by the NHS Commissioning Board. The NHS Commissioning Board must, under subsection (1), grant an application for the establishment of a CCG if it is satisfied of the matters covered in subsection (2). These matters are:
 - that the constitution complies with the requirements set out in Part 1 of Schedule 1A: for example that it sets out the name (which must meet requirements to be set out in regulations), members and area of the constitution, that it specifies

the arrangements the CCG has put in place for the discharge of its functions, and the procedures for decision making, discharging its duties in relation to conflicts of interest and ensuring effective participation by members; and that it is otherwise appropriate;

- that each member of a CCG will be a provider of primary medical services (i.e. that they will be a GP practice) on the date of establishment of the CCG;
- that the area of the CCG is appropriate;
- that the NHS Commissioning Board considers it appropriate to appoint as the CCG's accountable officer the person proposed by the applicants;
- that the applicants have made appropriate arrangements to discharge the CCG's functions; and
- that the applicants have made appropriate arrangements to ensure that the CCG will have a governing body that meets the requirements of the Act.
- 262. Regulations under subsection (2)(g) may set out other matters that the NHS Commissioning 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 make provision about the procedure for the making and determination of applications.
- 263. *Effect of grant of application*. New section 14D provides for the establishment of a CCG upon the grant of an application (under section 14C). The grant of an application for establishment has the effect that the CCG is established as a statutory body and the CCG's proposed constitution then has effect. This section also introduces Part 2 of Schedule 1A, which makes further provision about CCGs.
- 264. *Variation of constitution.* New sections 14E and 14F make provision about the variation of a CCG's constitution. Under section 14E, a CCG may apply to the NHS Commissioning 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 NHS Commissioning Board must or may grant, or must or may refuse, an application; and factors the NHS Commissioning Board must or may take into account when deciding whether to grant or refuse an application.
- 265. Section 14F gives the NHS Commissioning Board powers to vary a CCG's constitution otherwise than on application by the CCG. The NHS Commissioning Board may change the area specified in a CCG's constitution, and may add any provider of primary medical services to, or remove any provider from, a CCG's list of members. Before exercising these powers, the NHS Commissioning Board must consult the CCG and any other CCGs that, in the Board's view, might be affected by the proposed variation. The powers can only be exercised if the CCG whose constitution is to be varied agrees to the change, or if the NHS Commissioning Board considers that it is necessary to make the variation to discharge its duties under section 14A (that is, to ensure that every provider of primary medical services is a member of a CCG or to ensure that the areas specified in the constitutions of CCGs together cover the whole of England and do not coincide or overlap). Regulations may be made setting out further circumstances in which the NHS Commissioning Board may vary the constitution of a CCG, the circumstances in which those powers can be exercised and the procedure to be followed.
- 266. *Mergers, dissolution etc.* New sections 14G and 14H make provision about the merger and dissolution of CCGs. Section 14G allows CCGs to apply to the NHS Commissioning Board to merge, that is for those CCGs to be dissolved and for a new CCG to be established in their place. Any application under section 14G must include a copy of the proposed constitution of the new merged CCG, the name of the person whom the CCG wishes the NHS Commissioning Board to appoint as its accountable officer, and such other information that the NHS Commissioning Board may specify.

Sections 14C and 14D, which make provision about the determination of applications and effect of grant of applications, also apply here.

- 267. Section 14H provides for a CCG to apply to the NHS Commissioning Board to be dissolved. Regulations under subsection (2) may make provision about the circumstances in which the NHS Commissioning Board must or may grant, or must or may refuse, applications under this section; the factors that the NHS Commissioning Board must or may take into account in determining whether to grant those applications; and the procedure for making and determining applications.
- 268. *Transfers in connection with variation, merger, dissolution etc.* Under section 14I, when variations, mergers or dissolutions take place, the NHS Commissioning Board may make a scheme providing for the transfer of property or staff, or any associated rights and liabilities, of the CCG to the NHS Commissioning Board or to another CCG. Section 14I also introduces Part 3 of Schedule 1A which makes further provision about transfer schemes.
- 269. *Publication of constitution of clinical commissioning groups*. Section 14J requires a CCG to publish its constitution. It also, under subsection (2), requires a CCG to publish a constitution if it is varied under 14E or 14F as it has been varied.
- 270. *Guidance about the establishment of clinical commissioning groups etc.* Under section 14K, the NHS Commissioning Board may publish guidance about how applications for establishment as a CCG should be made, including guidance as to the form, content and publication of the proposed constitutions and guidance on applications to vary, merge or dissolve a CCG). This would enable the NHS Commissioning Board, for instance, to issue guidance on how good governance principles might be reflected in a CCG's constitution.
- 271. *Governing bodies of clinical commissioning groups.* Section 14L specifies that each CCG must have a governing body. The governing body will have the role of assuring that the CCG has made the appropriate arrangements to ensure that it complies with its duty to act with effectiveness, efficiency and economy (new section 14Q). It must also ensure that the CCG has appropriate arrangements in place to comply with generally accepted principles of good governance as are relevant to it. These are described in subsection (2) as the 'main functions' of the governing body.
- 272. Governing bodies also have the function, under subsection (3)(a), of determining the remuneration, fees and allowances payable to CCG employees and others providing services to it (such as self-employed IT consultants) and of determining the allowances payable under a pension scheme established by the CCG under paragraph 11(4) of Schedule 1A (under subsection (3)(b)). Regulations under subsection (6) may require governing bodies to publish specified information in relation to such determinations In addition, the NHS Commissioning Board may publish guidance (under subsection (7)) for governing bodies on the exercise of their functions in relation to pay and remuneration.
- 273. Subsection 3(c) allows the CCG constitution and regulations to confer further functions upon the governing body, provided that these are connected with the main functions of the governing body.
- 274. Subsection (4) specifies that only the following can be members of the governing body:
 - A CCG member who is an individual;
 - An individual, appointed by virtue of regulations made under 14N(2);
 - An individual, of a description set out in the CCG's constitution.
- 275. Subsection (5) allows regulations to prescribe circumstances in which a CCG must obtain the approval of its governing body before the CCG exercises specified functions.

- 276. *Audit and remuneration committees of governing bodies.* Section 14M requires CCG governing bodies to have both an audit committee and a remuneration committee. The audit committee has such functions in relation to the financial duties of the CCG as the governing body considers appropriate. Its role is to assist the governing body in ensuring the CCG carries out its prescribed functions appropriately.
- 277. The remuneration committee has the function of making recommendations to the governing body about the determination of remuneration, fees and allowances payable to CCG employees and others providing services to it and determining the allowances payable under a pension scheme established by the CCG under paragraph 11(4) of Schedule 1A. Regulations and the CCG constitution can confer additional, functions on the audit and remuneration committees, provided that they are connected with the governing body's main functions.
- 278. *Regulations as to governing bodies of clinical commissioning groups*. Section 14N provides a number of regulation-making powers. It is intended that regulations made under these powers will, without being overly prescriptive, set out some of the detail needed for the set-up of CCGs' governing bodies and their statutory committees.
- 279. Regulations may:
 - specify the minimum number of members of governing bodies;
 - specify certain requirements as to membership of governing bodies and their statutory committees- for example that the governing body must include the CCG's accountable officer and requirements as to membership of healthcare professionals of a prescribed description and lay persons;
 - make provision as to the qualification, appointment and tenure of members of governing bodies and their statutory committees;
 - make provision as to the qualification, appointment and tenure of chairs;
 - specify information to be included in constitutions (in relation to paragraph 7 of Schedule 1A (as set out in Schedule 2 to the Act) which concerns the decision making process; and
 - make such other provision about the procedure of governing bodies or their statutory committees as the Secretary of State deems appropriate, including as regards frequency of meetings.
- 280. *Registers of interests and management of conflicts of interest.* New section 140 subsection (1) requires a CCG to maintain one or more registers of the interests of members of the group, the members of the governing body, employees of the group, and members of committees and sub-committees of the group, and committees and sub-committees of the governing body. Sub-section (2) requires that the registers are published by the CCG or arrangements made by the CCG to ensure that they are available to the public on request.
- 281. Under subsection (3), each CCG must make arrangements to ensure that members of the group, the members of the governing body, employees of the group, and members of committees and sub-committees of the group and committees and sub-committees of the governing body declare any conflict of interest, or potential interest they may have in relation to a decision to be made by the group in the exercise of its commissioning functions,. The declaration must be made as soon as possible after the individual becomes aware of the potential conflict, and in any event within 28 days. The arrangements made by the CCG must ensure that the declaration so made is included in the appropriate register of interests.
- 282. Under subsection (4), the CCG must make arrangements for managing conflicts and potential conflicts of interest, so they do not influence the group's decision making, or appear to do so.

- 283. Under subsection (5), the NHS Commissioning Board must issue guidance for CCGs on the discharge of their functions under this section.
- 284. Subsection (6) requires that CCGs have regard to this guidance.
- 285. This section also inserts new Schedule 1A (set out in Schedule 2 to the Act) into the NHS Act.

Schedule 2 – Clinical commissioning groups

New Schedule 1A, Part 1

- 286. *Constitution of clinical commissioning groups.* Part 1 of new Schedule 1A makes provision for the constitution of CCGs. Paragraph 1 provides that a CCG must have a constitution.
- 287. Paragraph 2 provides that the constitution must specify the name and members of the CCG and the geographical area of the CCG. This geographical area is relevant (among other matters) to the CCG's commissioning responsibilities under subsection (1B) of amended section 3 of the NHS Act (for example in relation to people who are not registered with any GP practice). The geographical area is also relevant to the health and wellbeing board(s) of which it must be a member. Under paragraph 2(2), each CCG's name must comply with any requirements as may be set out in regulations.
- 288. Paragraph 3 provides that the constitution must specify the arrangements for the discharge of the CCG's functions, including functions in relation to determining the 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 CCG and its employees, such as members of the public. The arrangements may also include provision for any of the functions of the CCG to be exercised on its behalf by any of its members or employees, its governing body or a committee or subcommittee of the group.
- 289. Paragraph 4 provides that the constitution must specify the procedures that the CCG will follow in making decisions and the arrangements made to secure that decisions are made transparently.
- 290. Paragraph 5 provides that the constitution must specify the arrangements made by the group for the discharge of its duties under section 14O.
- 291. Paragraph 6 sets out that the provision made by virtue of paragraphs 3 and 4 must ensure that there is effective participation by each member of the CCG in the exercise of the CCG's functions
- 292. Paragraphs 7 and 8 provide that CCG's constitutions must specify a number of matters as regards governing bodies.
- 293. Paragraph 7 provides that the constitution must specify the arrangements made by the CCG for the discharge of the governing body's functions. Those arrangements must include provision for the appointment of the audit and remuneration committees and may include arrangements for the appointment of any other committees and subcommittees of the governing body. The arrangements for the audit committee may allow for people who are not members of the governing body to sit on the audit committee. Only members of the governing body can sit on the remuneration committee. As regards other committees that may be established, the committee members may include persons who are not members of the governing body, but are members of the CCG, or individuals of a description as specified in the constitution. Arrangements specified may also include arrangements for governing body functions to be delegated to committees, individual governing body members, individual CCG members, or individuals of a description as specified in the constitution. These arrangements may

include arrangements in respect of functions delegated to the governing body by the CCG under paragraph 3(3) of the Schedule.

- 294. Paragraph 8 sets out that the constitution must specify: the procedure to be followed by the governing body in its decision-making, and the arrangements made to ensure transparency of decision making. In particular these last arrangements must include provision for making meetings of the governing body open to the public, except where it would not be in the public interest in relation to all or part of a meeting.
- 295. Paragraph 9 provides that CCGs 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 Act

New Schedule 1A, Part 2

- 296. New Schedule 1A Part 2 makes further provision about CCGs. Each CCG is to be a body corporate (paragraph 10) which may appoint employees on such terms and conditions as it determines, with such remuneration and other allowances in accordance with determinations made by its governing body (paragraph 11).
- 297. CCGs are to be granted the status of 'Employing Authorities' by amending the NHS Pension Scheme Regulations (after the passage of the Act). This means that (like other NHS bodies such as foundation trusts) CCGs 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, CCGs would have the power under paragraph 11(3) to (5) to offer alternative pension arrangements or schemes should they wish. Foundation trusts already have this power.
- 298. Paragraph 12 provides that each CCG must have an accountable officer, who may be either a member of the CCG or an employee. The accountable officer is appointed by the NHS Commissioning Board. They may be the accountable officer for more than one CCG. If the accountable officer is not an employee of a CCG, the CCG may remunerate and pay other allowances to the accountable officer in accordance with determinations made by its governing body.
- 299. The CCG may make arrangements to provide pensions, allowances and gratuities to its accountable officer, including by way of compensation in respect of loss of office or loss or reduction of total remuneration access to any pension scheme the CCG establishes (under paragraph 11(4) of Schedule 1A) note that this would be an alternative to the NHS Pension Scheme.
- 300. The accountable officer is responsible for ensuring the CCG complies with its financial obligations (under new sections 223H to 223J of the NHS Act), its requirements for keeping proper accounts (under paragraph 17 of this schedule), its requirements for providing financial information to the NHS Commissioning Board (under paragraph 18) and its duty to provide information required by the Secretary of State (under paragraph 19). The accountable officer is also responsible for ensuring that the CCG fulfils its duties to exercise its functions effectively, efficiently and economically under new section 14Q, and its duties under new section 14R in relation to improvement in the quality of services. Furthermore, the accountable officer must ensure that the CCG exercises its functions in a way which provides good value for money. Other obligations under the NHS Act may be specified in a document published by the NHS Commissioning Board for these purposes.
- 301. Paragraph 13 allows for payment to be made to members of the governing body of remuneration, travelling or other allowances and gratuities, as well as for provision of pensions. These arrangements may include the establishment and administration of pension schemes, or access to any pension scheme the CCG establishes (under paragraph 11(4) of Schedule 1A) and arrangements for the provision of pensions, allowances or gratuities by way of compensation for loss or reduction of total

remuneration. However, the arrangements for providing pensions, allowances or gratuities do not apply to members of the governing body who are members or employees of the CCG, or members or employees of a practice which is a member of the CCG.

- 302. Paragraph 14 permits a CCG to pay such travel and other allowances as it considers appropriate to members of the group who are individuals (as opposed to practices), individuals authorised to act on behalf of a member of the group in its dealings with the group, and any members of committees or sub-committees of the group or its governing body. This is intended to ensure that, where persons who are not employees undertake work on behalf of the group, they can receive expenses.
- 303. CCGs may hold property on trust and paragraph 15 confers a power on the Secretary of State to make an order appointing trustees to oversee the management of any property held on trust. The order may make provision for naming the trustees, the number of trustees, their term of office and any conditions of appointment. Where an order has been made, the Secretary of State may transfer property from the CCG to the trustees.
- 304. Paragraph 15 enables a CCG 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 CCG'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.
- 305. Under paragraph 17 a CCG must keep proper accounts and records, and prepare annual accounts for each financial year. The NHS Commissioning Board may direct a CCG, with the approval of the Secretary of State, to prepare a set of accounts in respect of a "particular" period or periods of time. Powers are conferred on the NHS Commissioning Board to direct CCGs, 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 extant legislation. The Comptroller and Auditor General may examine a CCG's annual accounts and any related records, and any report on those accounts produced by an auditor or auditors. Section 306(7)(a) will ensure that the Secretary of State may, in a commencement order under section 306(4), provide that the duties to keep proper accounts and records, and to prepare annual accounts for each financial year, do not apply in relation to the whole or part of the "initial period" (the period between the coming into force of the provisions for the establishment of CCGs and the date specified by the Secretary of State by which every provider of primary medical services in England is to be a member of a CCG, proposed to be 1 April 2013). The power may be exercised in relation to all CCGs or only groups meeting certain conditions (e.g. those groups which were receiving income or incurring expenditure).
- 306. Paragraph 18 enables the NHS Commissioning Board to direct a CCG 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 CCG income, expenditure or use of resources.
- 307. Paragraph 19 requires disclosure by all CCGs to the NHS Commissioning 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 is necessary for the purposes of the Secretary of State's functions in relation to the health service.
- 308. The NHS Commissioning Board can also be required to provide, to the Secretary of State, any information obtained from CCGs.
- 309. Just as with the NHS Commissioning Board, CCGs sit within the Department of Health accounting and budgeting boundaries. The Department require information

to effectively and efficiently manage its 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 CCG or a "particular" group of CCGs. The Secretary of State must exercise the power in the same way in relation to all CCGs, for example by making the same request for information to all CCGs.

- 310. Paragraph 20 clarifies that CCGs under section 2 of the NHS Act have the power 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.
- 311. Paragraph 21 gives CCGs the ability to execute a deed, for example, where passing a legal title, interest or right in relation to a transfer of land, under seal. It allows a CCG to authorise an individual or individuals, whose signature would authenticate use of a seal, so it would be taken as evidence that this was on behalf of the CCG. As an alternative, the CCG may authorise an individual to execute a document by signature, and this too must be taken as evidence that this was on behalf of the CCG.

New Schedule 1A, Part 3

- 312. Part 3 (paragraphs 22 to 26) of new Schedule 1A sets out further details in respect of property and staff transfer schemes that may be made under new section 14I. 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 22).
- 313. A property or staff transfer scheme may also make supplementary, incidental, transitional and consequential provision (paragraph 23). 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).
- 314. A property scheme may make provision for the shared ownership or use of property (paragraph 24). A staff transfer scheme may make provision that is the same or similar to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) (paragraph 25). Both a property and staff transfer scheme can 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 26).

Section 26 – Clinical commissioning groups: general duties etc.

- 315. This section inserts new sections 14P to 14Z24 into the NHS Act, which contain CCGs' duties, and powers, and provision for the NHS Commissioning Board to intervene in the event of failure.
- 316. Duty to promote the NHS Constitution. New section 14P imposes a duty upon CCGs both to act in the exercise of its functions (for example through their commissioning functions) with a view to securing that health services are provided in a way that promotes the NHS Constitution and to promote awareness of it among staff, patients and the public. This means that not only must CCGs act in accordance with the NHS Constitution, but they should ensure that people are made aware of their rights under it. They may also do this by contributing, as far as possible, to the advancement of the

Constitutions principles, rights, responsibilities and values, through their own actions and through facilitating the actions of stakeholders, partners and providers.

- 317. *Duty as to effectiveness, efficiency etc.* Under new section 14O, each CCG must exercise its functions effectively, efficiently and economically.
- 318. Duty as to improvement in quality of services. New section 14R places CCGs under a duty to exercise their functions with a view to securing continuous improvements in the quality of services provided to individuals, as part of the health service. This also reflects the accepted definition of quality⁷ as comprising effectiveness, safety and patient experience. Subsection (4) requires CCGs, in discharging this duty, to have regard to any guidance issued by the NHS Commissioning Board under new section 14Z8 (on how CCGs should discharge their commissioning functions).
- 319. Duty in relation to quality of primary medical services. New section 14S provides that each CCG must assist and support the NHS Commissioning Board in discharging its duty under 13E as to improvement in the quality of services insofar as that relates to securing continuous improvement in the quality of primary medical services. In this way, each CCG would support the continuous improvement in the quality of primary medical services provided by CCG members.
- 320. *Duties as to reducing inequalities.* New section 14T sets out that CCGs 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.
- 321. Duty to promote involvement of each patient. Section 14U requires CCGs in exercising their functions, to promote the involvement of patients and their carers and representatives in decisions about their own care (shared decision-making). This duty is intended to address the commitment outlined in the White Paper Equity and Excellence: Liberating the NHS to the policy of "no decision about me without me".
- 322. The duty would apply to any decisions at all stages of that individual's health care, from preventative measures, diagnosis of an illness, and any subsequent care and treatment they receive. Effective involvement of patients in these decisions might include such things as opportunities for patients to participate in treatment decisions in partnership with health professionals, to be supported to make informed decisions about the management of their care and treatment and to discuss opportunities for patients to manage their own condition. The NHS Commissioning Board must publish guidance on how to discharge this duty, to which CCGs must have regard.
- 323. *Duty as to patient choice.* Section 14V imposes a duty on CCGs, in the exercise of their functions, to act with a view to enabling patient choice (for example, by commissioning so as to allow patients a choice of treatments, or a choice of providers, for a particular treatment).
- 324. Duty to obtain appropriate advice. New section 14W requires CCGs to obtain appropriate advice from people who taken together have a broad range of professional expertise in relation to the prevention, diagnosis or treatment of illness, and the protection or improvement of public health to enable them to discharge their functions effectively. This could involve, for example, a CCG employing or otherwise retaining healthcare professionals to advise the CCG on commissioning decisions for certain services, or appointing professionals to any committee that the CCG may set up to support commissioning decisions. It could also involve consulting clinical networks and senates. The NHS Commissioning Board may publish guidance on the exercise of this duty to which CCGs must have regard.
- 325. *Duty to promote innovation*. New section 14X imposes a duty on CCGs, in the exercise of their functions, to promote innovation in the provision of health services and in

⁷ See, for example, the NHS Outcomes Framework published by the Department of Health on 20 December 2010, available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122944

making arrangements for the provision of health services. This means that not only will CCGs have to encourage new ways of thinking through commissioning, but they will also have to promote different commissioning methodologies.

- 326. *Duty in respect of research.* New section 14Y puts a duty on CCGs in respect of research. Each CCG must, in the exercise of its functions, promote health research and the use of evidence obtained from such research. A CCG could, for example, use evidence obtained from health research to inform its commissioning plan.
- 327. Duty as to promoting education and training. New section 14Z places a duty on each CCG in the exercise of their functions to have regard to the need to promote education and training to persons who are employed, or who are considering becoming employed, in an activity which involves or is connected with the provision of services as part of the health service in England, to assist the Secretary of State under his duty under new section 1E to secure an effective system for the planning and delivery of education and training in England for these people.
- 328. Duty as to promoting integration. New section 14Z1 gives CCGs a duty in relation to promoting integration, where it would benefit patients. They must exercise their functions with a view to securing that services are provided in an integrated way where this would improve the quality of the services, reduce inequalities of access or reduce inequalities in outcomes. In this manner, integration is not the aim itself, but a tool to encourage service improvement. This integration can be integration of health services with other health services or health services with health-related services (such as housing services where these have an effect on the health of individuals), or health services with social care services.
- 329. Public involvement and consultation by clinical commissioning groups. New section 14Z2 sets out requirements for involving the public (whether by consultation or otherwise). CCGs 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 an impact on how services are provided or the range of health services available; and in decisions that would likewise have a significant impact.
- 330. Each CCG must set out in its constitution a description of the arrangements made by it to fulfil this duty and a statement of the principles it will follow in implementing those arrangements. The NHS Commissioning Board may publish guidance for CCGs on how to discharge their duties under this section and CCGs must have regard to any such guidance.
- 331. The NHS Commissioning Board could, for instance, give guidance on effective ways 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 NHS Commissioning Board could also give guidance to help CCGs decide in what circumstances the duty to involve might most appropriately be met by providing information and in what circumstances a CCG should actively seek people's views through consultation.
- 332. *Arrangements with others*. New sections 14Z3 and 14Z4 enable CCGs to collaborate with each other and, in particular circumstances, with Local Health Boards.
- 333. Arrangements by clinical commissioning groups in respect of the exercise of functions. New section 14Z3 enables CCGs to collaborate in respect of the exercise of their commissioning functions. CCGs may make arrangements under subsection (2)(a) for one CCG to take a role as lead commissioner and exercise commissioning functions on behalf of other CCGs. CCGs may, under subsection (2)(b), exercise their functions jointly. In exercising these powers, a CCG may make payments to other CCGs, may make the services of its employees or other resources available to other CCGs, and

may establish pooled funds. Subsection (6) makes clear that these arrangements do not change the responsibility of any CCG to ensure its functions are discharged properly or any liabilities arising from the exercise of those functions.

- 334. Joint exercise of functions with Local Health Boards. Regulations may be made under new section 14Z4 to allow any prescribed functions of a CCG 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 also make provision for any such functions to be exercised by a joint committee of the CCG and the Local Health Board. Subsection (3) makes it clear that these arrangements do not change the responsibility of any CCG to ensure its functions are discharged properly or any liabilities arising from the exercise of those functions.
- 335. A CCG may also provide advice or assistance to any public authority in the Isle of Man or Channel Islands, on such terms, including as to payment, as the CCG considers appropriate (section 298).
- 336. *Additional powers of clinical commissioning groups*. Additional powers for CCGs are set out in new sections 14Z5 and 14Z6.
- 337. *Raising additional income*. New section 14Z5 enables CCGs to undertake certain activities to raise additional income for improving the health service, provided that this does not significantly interfere with the CCG's ability to perform its functions. These activities are to acquire, produce, manufacture and supply goods; to acquire land by agreement and manage and deal with land; to provide instruction for any person; to develop and exploit ideas and exploit intellectual property; to do anything whatsoever which appears to the CCG to be calculated to facilitate, or to be conducive or incidental to, the exercise of any power conferred by this subsection and to make such charge as the CCG considers appropriate.
- 338. *Power to make grants.* New section 14Z6 enables CCGs to make grants or loans, subject to such conditions as the CCG deems appropriate, to voluntary organisations that provide or arrange for the provision of services similar to the services in respect of which the CCG has functions.
- 339. *Board's functions in relation to clinical commissioning groups*. New sections 14Z7, 14Z8, 14Z9 and 14Z10 make provision for the NHS Commissioning Board to have functions in relation to assisting CCGs.
- 340. Responsibility for payments to providers. New section 14Z7 gives the NHS Commissioning Board the power to publish a document specifying the circumstances in which a CCG is liable to make payments to a provider to pay for services provided under arrangements commissioned by another CCG. This provision would, for instance, enable the NHS Commissioning Board to specify that, where a person uses an urgent care service commissioned by a CCG other than the CCG that is ordinarily responsible for that person's healthcare, the cost of that service is charged to the latter CCG. It could, for instance, decide that CCGs should be left to agree mutual arrangements for sharing costs where patients from a number of different CCGs use the same urgent care service. However, where the NHS Commissioning Board publishes such a specification, a CCG will be required to make payments in accordance with that document (subsections (2) and (3)). In those circumstances, no other CCG 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 NHS Commissioning Board makes a specification, it may publish guidance for the purpose of assisting CCGs understand, and apply, it (subsection (6)).
- 341. *Guidance on commissioning by the Board*. Section 14Z8 provides that the NHS Commissioning Board must publish guidance for CCGs on the discharge of their commissioning functions (subsection (1)). CCGs must have regard to this guidance (subsection (2)). The Healthwatch England committee of the Care Quality Commission must be consulted before the NHS Commissioning Board publishes any guidance or

any revised guidance containing changes that are in the NHS Commissioning Board's opinion significant (subsection (3)).

- 342. *Exercise of functions by the Board.* New section 14Z9 provides that the NHS Commissioning Board may act on behalf of a CCG and arrange for the provision of services and exercise related functions, if requested to do so by the CCG (or in other words, by mutual agreement between the NHS Commissioning Board and the CCG). Regulations may provide that the power does not apply to services or facilities of a prescribed description. Subsection (3) makes provision for terms, including payment terms, to be agreed between the NHS Commissioning Board and CCGs. Subsection (4) makes clear that these arrangements do not change the responsibility of any CCG to ensure its functions are discharged properly or any liabilities arising from the exercise of those functions.
- 343. *Power of Board to provide assistance or support.* New section 14Z10 provides that the NHS Commissioning Board has the power to provide assistance or support to CCGs (including financial assistance and making employees or other resources of the NHS Commissioning Board available to CCGs). This assistance may be provided on such terms as the NHS Commissioning Board considers appropriate, including payment terms. The NHS Commissioning Board can impose restrictions on the use of any such assistance.
- 344. *Commissioning plans.* New section 14Z11 makes provision with regard to commissioning plans. Section 14Z11(1) stipulates that each CCG must prepare a plan before the start of each relevant period to set out how it will exercise its functions. The plan must, in particular, explain how the CCG proposes to discharge its duties to seek continuous improvement in the quality of services (under new section 14R) and in relation to reducing inequalities (14T) and its financial duties (under sections 223H to 223J) and also its duty in relation to public involvement under 14Z2. This plan must be published and sent to the NHS Commissioning Board before a date specified by the Board. A copy must also be sent to the relevant health and wellbeing board. In a CCG's first financial year the 'relevant period' will begin on a date specified by the NHS Commissioning Board and end at the end of that financial year, it will then be each subsequent financial year. The NHS Commissioning Board may publish guidance on consultation on, and revision of, commissioning plans, to which CCGs must have regard.
- 345. *Revision of commissioning plans.* Under new section 14Z12, the commissioning plan may be revised. Should the proposed revision be deemed 'significant' by the CCG, it must give a copy to the NHS Commissioning Board by a date specified by the Board and must provide the relevant health and wellbeing board with a copy having carried out consultation under new section 14Z11 (below). Where the CCG revises the plan and the changes are not significant, it must still publish the revised plan. A copy must also be provided to each relevant health and wellbeing board and the NHS Commissioning Board.
- 346. *Consultation about commissioning plans.* Under new section 14Z12, when preparing a commissioning plan, or making a change it deems significant, the CCG must:
 - consult individuals for whom it has responsibility for the purposes of section 3 of the NHS Act, for example the people to whom its members provide primary care services and those included within the CCG's geographic area responsibilities; and
 - involve the relevant health and wellbeing board.
- 347. It must, in particular, provide the relevant health and wellbeing board with a copy of the draft plan or revised plan (as the case may be) and consult it on whether it adequately takes the latest joint health and wellbeing strategy into account. This means that CCGs would need to discuss their plans in advance with health and wellbeing boards to help ensure that they reflected joint health and wellbeing strategies.

- 348. The health and wellbeing board would have to give the CCG its opinion on this. It could also give its opinion to the NHS Commissioning Board. If it did so, the CCG must be given a copy of the opinion. If the CCG went on to make further changes, this process would have to be repeated. The revised plan would have to be published and a copy given the relevant health and wellbeing board and the NHS Commissioning Board.
- 349. When CCGs send their commissioning plans to the NHS Commissioning Board, they would be under an obligation to include:
 - a summary of the views of individuals consulted;
 - an explanation of how those views were taken into account; and
 - a statement as to whether the relevant health and wellbeing board(s) agreed that the plans has due regard to the joint health and well-being strategy or strategies.
- 350. *Opinion of health and wellbeing boards on commissioning plans.* 14Z14 enables each health and wellbeing board to provide the NHS Commissioning Board with its opinion on whether a CCG's commissioning plan has taken proper account of the relevant joint health and wellbeing strategy. If it does so, it must provide a copy of this opinion to the CCG in question.
- 351. *Reports by clinical commissioning groups.* Under section 14Z15, in each financial year, save the first year of operation, each CCG must prepare and provide to the NHS Commissioning Board an annual report on how it has discharged its functions in the previous financial year. The report must, in particular, explain how it has fulfilled its duties to seek continuous improvement in the quality of services (section 14R), in relation to reducing inequalities (14T), and to involve patients and the public in commissioning decisions (section 14Z2). The CCG must publish the report and present it at a public meeting. The NHS Commissioning 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 14Z2.
- 352. Performance assessment of clinical commissioning groups. New section 14Z16 specifies that the NHS Commissioning Board must conduct an assessment of how well each CCG has discharged its functions during each financial year. In particular, it must assess how well the CCG has discharged its duty to seek continuous improvement in the quality of services (under new section 14R), its duty in relation to reducing inequalities (14T), its duty to obtain appropriate advice (14W), its duty to involve and consult the public (14Z2), its financial duties (under new sections 223H to 223J) and its duty to have regard to any relevant joint health and wellbeing strategy. In assessing performance, the NHS Commissioning Board must consult each relevant health and wellbeing board on whether the CCG has taken proper account of the relevant joint health and wellbeing strategy. It must also have regard to any relevant document published by the Secretary of State, which includes the NHS Outcomes Framework, and to any commissioning guidance published by the NHS Commissioning Board. Each financial year, the NHS Commissioning Board must publish a report containing a summary of the results of the performance assessments.
- 353. *Power to require documents and information etc.* New sections 14Z17 to 14Z20 are concerned with the NHS Commissioning Board's powers to require and use information. The NHS Commissioning Board can use the powers in section 14Z18 and 14Z19 to require documents, information and explanations, where it has reason to believe that a CCG might have failed, might be failing or might fail to discharge any of its functions properly, or where it believes the area of a CCG is no longer appropriate (see new section 14Z17(1)). A failure to discharge a function properly for these purposes includes a failure to discharge it consistently with what the NHS Commissioning Board considers to be the interests of the health service.

- 354. New section 14Z18 provides that, where the conditions in section 14Z17 are met, the NHS Commissioning Board may require the provision of any information, documents, records or other items from a CCG or any member or employee of the CCG having possession or control of the item, where the NHS Commissioning Board considers that it is necessary or expedient to have this for the purposes of any of its functions in relation to the CCG. When that information is stored on a computer, it must be provided to the NHS Commissioning Board in a legible form. By virtue of subsection (5) this power does not include the power to require the provision of personal records, as defined by reference to section 12 of the Police and Criminal Evidence Act 1984. This power does not therefore permit the NHS Commissioning Board to require 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.
- 355. *Power to require explanation.* New section 14Z19 sets out the NHS Commissioning Board's power, where the conditions in section 14Z17 are met, to require an explanation, either orally (at such time and place as the NHS Commissioning Board may specify), or in writing, regarding any matter relating to the CCG's exercise of its functions. That explanation can include an explanation of how the CCG is proposing to exercise its functions.
- 356. *Use of information*. Where the NHS Commissioning Board obtains information from a CCG in these ways, new section 14Z20 permits the NHS Commissioning Board to use this information in connection with any of its functions which relate to CCGs.
- 357. *Intervention powers:* New section 14Z21 sets out the NHS Commissioning Board's powers to intervene in the operations of CCGs.
- 358. *Power to give directions, dissolve clinical commissioning groups etc.* Under new section 14Z21, if the NHS Commissioning Board is satisfied that a CCG is failing or has failed to discharge any of its functions (which includes a failure to discharge a function consistently with what the Board considers to be the interests of the health service), or there is a significant risk that it will fail to do so, the NHS Commissioning Board has powers to:
 - direct the CCG to discharge a functions in a particular way and within a specified period;
 - direct the CCG 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 CCG'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 CCG.
- 359. Subsection (8) provides that, where a direction is given for the CCG to cease performing any specified functions, the NHS Commissioning Board may exercise those specified functions. Alternatively, the NHS Commissioning Board may direct that another CCG or the accountable officer of another CCG discharge those functions (providing the NHS Commissioning Board has consulted that CCG). Where the NHS Commissioning Board changes the constitution of a CCG or dissolves a CCG, it may make a scheme transferring any property, liabilities, or staff (as at Part 3 of Schedule 1A) of the affected CCG to the NHS Commissioning Board or another CCG. Subsection (9) sets out that where the NHS Commissioning Board exercises the function of a CCG

under subsection (8), the CCG must co-operate with the NHS Commissioning Board. Subsection (9) also provides that when a CCG's functions are being discharged by another CCG or the accountable officer of another CCG, the CCG whose functions are being discharged must co-operate with the other CCG or the accountable officer in question.

- 360. *Procedural requirements in connection with certain intervention powers.* New section 14Z22 impose procedural requirements which the NHS Commissioning Board must follow before dissolving a CCG under new section 14Z21(7). The NHS Commissioning Board must consult with that CCG, any relevant local authorities (defined in subsection (7)), and any other persons the NHS Commissioning Board considers appropriate; and provide those persons with a statement explaining its proposed actions and the reasons for them. The NHS Commissioning Board must, under subsection (3), publish a report in response to this consultation and, where it decides to exercise its power to dissolve a CCG, explain in the report its reasons for doing so (subsection (4)).
- 361. Subsection (5) of new section 14Z22 provides that regulations may be made as to the procedure that the NHS Commissioning Board must follow before exercising its powers to require information or explanation (under new sections 14Z18 or 14Z19) or before exercising the intervention powers in new section 14Z21. 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.
- 362. Subsection (6) of new section 14Z22 provides that the NHS Commissioning 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.
- 363. *Permitted disclosures of information.* New section 14Z23 makes provision as to the circumstances when a CCG may disclose information obtained in the exercise of its functions. Unless the information has previously been lawfully disclosed to the public, the disclosure would be made under or pursuant to regulations under section 113 or 114 of the Health and Social Care (Community Health and Standards) Act 2003 (complaints about health care or social services), in accordance with any enactment or court order, or for the purpose of criminal proceedings, the CCG may not disclose information under section 14Z23 if to do so would be contrary to any rule of common law..
- 364. *Interpretation*. New section 14Z24 sets out when references to CCGs' functions include public health functions of the Secretary of State that have been delegated to them by virtue of arrangements under section 7A of the NHS Act. This list includes certain provisions of other Acts of Parliament that are amended by this Act. There is also a power for the list of provisions specified to be amended by order of the Secretary of State.

Section 27 - Financial arrangements for clinical commissioning groups

365. This section sets out the financial arrangements for CCGs, inserting new sections 223G to 223K into the NHS Act. The Secretary of State and the Department's Accounting Officer will remain accountable to Parliament for the Parliamentary Estimates of spending and 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 NHS Commissioning Board and the NHS Commissioning Board has statutory duties to ensure that the commissioning sector as a whole lives within its spending and resource limits. The NHS Commissioning Board will in turn allocate resources to CCGs and CCGs will have a duty to live within their own spending and resource limits.

- 366. *Means of meeting expenditure of clinical commissioning groups out of public funds.* New section 223G sets out the NHS Commissioning Board's duties to make annual financial allotments to CCGs and, over the course of the relevant financial year, allows CCGs to draw down funding from this allotment to meet the CCG's expenditure. Subsection (1) sets out the latter duty. The funds that a CCG 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 NHS Commissioning Board, but which are treated as paid by the CCG (see section 51 and Schedule 3 to the Act).
- 367. Subsection (2) provides that, in determining a CCG's annual allotment, the NHS Commissioning Board may take into account the expenditure of the CCG during any previous financial year. This enables the NHS Commissioning Board to reduce a CCG'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 NHS Commissioning Board keeps within its overall expenditure limit. Subsection (2) also enables the NHS Commissioning Board to take into account any amount that it proposes to hold as a contingency fund.
- 368. Subsection (3) provides for the NHS Commissioning Board to notify a CCG in writing of its annual financial allotment.
- 369. Subsection (4) allows the NHS Commissioning Board to make an in-year adjustment to a CCG's allotment, provided that it acts reasonably in line with general administrative law controls and subsection (5) provides that, where the NHS Commissioning Board allots an amount to a CCG or makes a new allotment, it must notify the Secretary of State.
- 370. Subsection (6) provides that the NHS Commissioning Board may direct that sums paid to a CCG as part of an increase in a CCG'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.
- 371. The NHS Commissioning Board may also give directions to a CCG in respect of charges and other sums related to the valuation and disposal of assets, which are payable to the NHS Commissioning Board. This would allow for monies from the sale of assets to be clawed back and therefore prevent CCGs 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 NHS Commissioning Board, but the Board would deduct these amounts from the amount of capital funding provided.
- 372. *Financial duties of clinical commissioning groups: expenditure*. Section 223H sets out the duty for CCGs to break even on their commissioning budget, in other words to ensure that their cash expenditure in a financial year does not exceed the allotment given to them by the NHS Commissioning Board together with any other sums received by the CCG by other means. The NHS Commissioning Board has powers of direction to determine whether specified sums count for these purposes as being received by a CCG (in other words whether or not this income is treated as increasing the amount that a CCG can spend in a financial year) and whether specified expenditure made by a CCG, or sums received by a CCG from its allotment but not yet spent, must be treated for these purposes as counting towards its expenditure.
- 373. New section 223H also specifies that the Secretary of State may make directions requiring CCGs to use banking facilities specified in those directions for the purposes specified in those directions. It is an HM Treasury requirement that all NHS money is held in Government Banking Service (GBS) accounts. However, under this Act, the Secretary of State does not have general powers of direction over CCGs. The Government needs to ensure that firstly, all allocations to CCGs are held by CCGs in a GBS account, and secondly, that this is the account in which CCGs keep their allocation

and that the monies allocated to CCGs 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.

- 374. Financial duties of clinical commissioning groups: use of resources. Section 223I sets out the duty for CCGs to ensure that their use of resources in a financial year does not exceed an amount specified by the NHS Commissioning Board. The NHS Commissioning Board will specify in directions a limit on capital resource use and a limit on revenue resource use. The NHS Commissioning Board can vary those limits inyear, provided that it acts reasonably in line with general administrative law principles. A CCG's use of resources will differ from its cash expenditure during a financial year. For instance, insofar 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 insofar as there is a change in the value of assets belonging to the CCG, such as through depreciation. Any Secretary of State's directions under section 223D as to the descriptions and uses of resources, which must or must not be taken into account, apply for the purposes of these limits. In addition, the NHS Commissioning Board may give directions determining to which CCG a use of resources applies, when examining whether a CCG has lived within its resource limit. Where the NHS Commissioning Board gives directions to CCGs under this section, it must notify the Secretary of State.
- 375. The resource-use limits include not only CCGs' 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 CCG. 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 CCG's resource-use limit. This system of setting not only a cash limit on the CCG expenditure, but also a limit on use of resources reflects the system for controlling government resources under the Government Resources and Accounts Act 2000.
- 376. Financial duties of clinical commissioning groups: additional controls on resource use. Section 223J gives the NHS Commissioning Board a power to direct the maximum amounts of resources a CCG may use in respect of particular matters specified in the direction or prescribed matters relating to administration. Such 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 NHS Commissioning Board can vary any of these specified amounts and can determine by directions. the uses of capital and revenue resources that must or must not be taken into account for the purposes of any of these limits. In addition, any Secretary of State directions under section 223D of the NHS Act (inserted by section 24 of the Act), as to the description of resources which must or must not be treated as capital or revenue resources, apply for the purposes of these limits. Similarly, if the Secretary of State specifies in directions under section 223D(5) that a particular use of resources must not be taken into account, that use must not be taken into account for the purposes of the resource limits of CCGs.
- 377. The NHS Commissioning Board may not give directions to specify limits on the use of capital resources on specified matters, or the use of revenue resources on specified matters, unless the Secretary of State has given directions to the NHS Commissioning Board on those matters under section 223E(1) or 223E(2) of the NHS Act (inserted by section 24 of the Act).. Similarly, it may not give specify a limit the use of revenue resources for matters relating to administration, unless the Secretary of State has given a direction to the NHS Commissioning Board in relation to those matters under section 223E(3)(a) of the NHS Act.
- 378. *Payments in respect of quality*. New section 223K gives the NHS Commissioning Board the power to make a payment to a CCG after the end of the financial year.

- 379. In determining whether to make a payment and, if so, the amount, the NHS Commissioning Board must assess at least one of the following:
 - quality of relevant services provided during the financial year;
 - improvement in quality of relevant services provided during the financial year compared to previous financial years;
 - the outcomes identified during the financial year as having been achieved from the provision at any time of relevant services; and
 - improvements in outcomes, identified during the financial year as having been achieved from the provision at any time of relevant services when compared to outcomes identified in previous financial years.
- 380. In this way, it can both reward the performance delivered by a CCG and any improvements in performance. The NHS Commissioning Board may also take into account any relevant inequalities identified during that year and any reduction in inequalities identified during that year in comparison with relevant inequalities identified over previous financial years. Regulations may specify principles or other matters that the NHS Commissioning Board must or may take into account in assessing these factors. Further regulations may prescribe the circumstances in which the NHS Commissioning Board may decide to reduce a payment or not to make one.
- 381. Regulations may also prescribe how any payment made to a CCG in respect of quality may be spent, including its distribution amongst the CCG's members.
- 382. Each CCG must publish an explanation of how it has spent any payment made under this section.

Section 28 - Requirement for primary medical services provider to belong to clinical commissioning group

383. This section 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 CCG. These matters include a requirement to be a member of a CCG and to nominate an individual to act on behalf of the contract holder in its dealings with the CCG. *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

Section 29 - Other health service functions of local authorities under the 2006 Act

- 384. This section enables the transfer to local authorities of PCTs' existing functions around dental public health, and extends to local authorities a duty to help deliver and sustain good health among the prison population.
- 385. *Subsection* (2) of this section 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). 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.
- 386. *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.

387. In each case, the functions apply to those 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.

Section 30 - Appointment of directors of public health

- 388. This section requires local authorities and the Secretary of State to appoint directors of public health and makes related provision. PCTs are currently required to appoint directors of public health to provide local leadership and co-ordination of public health activity, but the section would in effect transfer that requirement to local authorities. The intention is that the director of public health role will become integral to the new public health responsibilities that this Act confers on local authorities. The provision applies to local authorities which have a duty to improve public health under new section 2B of the NHS Act.
- 389. The section inserts a new section 73A into the NHS Act. Subsection (1) provides that each local authority must, acting jointly with the Secretary of State, appoint a director of public health. It then defines the responsibilities of directors of public health as including:
 - a) the new health improvement duties that this Act would place on local authorities;
 - b) the exercise of any public health functions of the Secretary of State which the Secretary of State requires the local authority to exercise by regulations under section 6C of the NHS Act;
 - c) any public health activity undertaken by the local authority under arrangements with the 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 to 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 making representations about the grant of a license to use premises for the supply of alcohol).
- 390. Directors of public health will be local authority employees. Local authorities will be able to dismiss their directors of public health, but only after consulting the Secretary of State (although the Secretary of State will not have a veto) (subsections (5) and (6)).
- 391. Where the Secretary of State considers a director of public health has failed or might have failed 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. The Secretary of State would not be able to take action in relation to the public health functions conferred directly on the local authority by the NHS Act (e.g. section 2B). The action which the Secretary of State may require consists of reviewing and investigating the director of public health'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).

Section 31 - Exercise of public health functions of local authorities

- 392. This section 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. *Subsections (1)* and (2) require 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; for example this power may be used to require local authorities to have regard to the Department's public health outcomes framework. The public health outcomes framework sets 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.
- 393. *Subsection* (4) provides that any document or guidance issued by the Secretary of State under this may include guidance to local authorities about the staff they employ to discharge their public health functions.
- 394. *Subsections* (5) and (6) require directors of public health to publish annual reports on the health of their local population and local authorities to publish that report. The reports are intended to help directors of public health to account for their activity and to chart progress over time.

Section 32 - Complaints about exercise of public health functions by local authorities

- 395. This section inserts new section 73C into the NHS Act, which gives the Secretary of State powers to make regulations setting up procedures for dealing with complaints about the exercise of public health functions by local authorities in England.
- 396. Subsection (1) of the new section provides for regulations to be made providing for the handling and consideration of complaints. These would apply to the exercise by a local authority of any public health functions under the NHS Act (see in particular section 11); the exercise of the Secretary of State's public health functions by a local authority; the exercise by a local authority of other functions relating to public health which are the responsibility of its director of public health; or the provision of services by another person following arrangements made by a local authority in exercising these functions.
- 397. Under subsection (2), the regulations may provide for who may consider a complaint. This may be the relevant local authority, an independent panel or any other person or body. It is envisaged that regulations will provide that the complaint be made to the local authority that is the subject of the complaint, where an attempt will be made to investigate and resolve the matter.
- 398. Under subsection (3), the regulations may provide for a complaint, or any matter raised by a complaint, to be referred to a Local Commissioner (i.e. the local government ombudsman) for consideration as to whether to investigate the complaint under local Government legislation, or to any other person or body for consideration as to whether to take action otherwise than under the regulations.
- 399. Subsection (4) sets out that where regulations provide for a complaint to be referred to a Local Commissioner, they may provide for the complaint to be treated as complying with the requirements of the Local Government Act 1974 as to who can complain, and the procedure for making a complaint, to a Commissioner.
- 400. Subsection (5) provides that supplementary provisions in section 115 of the Health and Social Care (Community Health and Standards) Act 2003 apply in relation to regulations made under new section 73C. The regulations may therefore provide for matters such as who may make a complaint and to whom a complaint may be made, the complaints which may or may not be made, and the procedure for making, handling and considering a complaint. Provision may also be made in relation to charges in relation

to the consideration of a complaint, making information available to the public about the procedures to be followed, and the disclosure of information or documents. The Department envisages making provision similar to that in the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

401. Subsection (6) provides that 'local authority' has the same definition in new section 73C as in section 2B of the NHS Act; i.e. those local authorities which exercise public health functions under the Act (see section 9).

Abolition of Strategic Health Authorities and Primary Care Trusts

Section 33 - Abolition of Strategic Health Authorities

402. This section abolishes SHAs, and repeals Chapter 1 of Part 2 of the NHS Act, which makes provision for SHAs. It is intended that SHAs will be abolished on 1st April 2013.

Section 34 - Abolition of Primary Care Trusts

- 403. This section abolishes PCTs and repeals Chapter 2 of Part 2 of the NHS Act, which makes provision for PCTs.
- 404. The commissioning functions currently undertaken by PCTs are intended to fall to other health bodies such as CCGs, the NHS Commissioning Board, or local authorities. CCGs will be responsible for commissioning the great majority of health services, while the NHS Commissioning Board will be responsible for commissioning groups, 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 Public Health England.
- 405. Following this transfer of responsibilities, PCTs will no longer have commissioning responsibilities in the NHS. The Government intends for PCTs to retain commissioning responsibility until April 2013, as CCGs become developed and established. Once CCGs are able to take on their commissioning responsibilities, it is intended that PCTs will be abolished this is intended to occur in April 2013.

Functions relating to fluoridation of water

Section 35 - Fluoridation of water supplies

- 406. This section amends Chapter 4 of Part 3 of the Water Industry Act 1991 (fluoridation), as amended by the Water Act 2003. Subsections (2) to (8) amend the Act to provide for the Secretary of State to make arrangements with a water undertaker to fluoridate a water supply. However, he may only do so if a local authority has made a fluoridation proposal, consulted on that proposal, and taken a final decision in accordance with the new sections of the 1991 Act inserted by section 36.
- 407. Subsection (5) inserts new subsections (7A) and (7B) of section 87 of the 1991 Act. Subsection (7A) requires the Secretary of State to consult local authorities on the terms of any fluoridation arrangements entered into with a water undertaker. Subsection (7B) defines local authorities for the purposes of the provisions. The effect is that upper-tier authorities are responsible for fluoridation proposals – i.e. county councils, a district council for an area in England where there is no county council (which includes "unitary boroughs"), London borough councils and the Common Council of the City of London.
- 408. Subsection (6) inserts new subsections (7C) to (7F) of section 87 of the 1991 Act. These subsections require co-ordination between the Secretary of State and Welsh Ministers in relation to schemes adjoining areas either side of the border. Currently there are no cross-border fluoridation schemes between England and Wales, nor are there any proposals for any. The requirements to co-ordinate would only be in put in place once

the legislation was brought into force in relation to both England and Wales. It is for Welsh Ministers to commence the provisions in relation to Wales.

- 409. Subsection (9) inserts new subsection (3A) into section 87A of the 1991 Act (target concentration of fluoridation). Currently the target concentration for fluoridation schemes is 1 milligram per litre 1 part per million. Subsection (9) provides for a situation where, for technical reasons, a water undertaker is unable to provide this level of concentration to an area covered by a fluoridation scheme. For example, this might apply to an area that is distant from the water treatment works at which the fluoride is added to the water. New subsection (3A) ensures that when the Secretary of State receives a notification of such a technical problem, he would have to enter new arrangements or vary existing arrangements, so as to have a lower target concentration, but only having consulted the local authorities affected. The local authorities would in practice need to consider if the benefits to oral health at this lower concentration were still equal to the cost of fluoridating the area.
- 410. Arrangements (contracts) for water fluoridation schemes contain complex legal and technical requirements. It is possible that there will on occasions be disagreements as to the exact terms of these requirements. *Subsection (10)* therefore amends section 87B of the 1991 Act so that in the event that the Secretary of State and the water undertaker are unable to agree the terms of an arrangement, or a variation in those terms, the Secretary of State may determine the terms of the arrangement or he could appoint an independent person to arbitrate if he so wished.
- 411. Subsection (14) amends section 90A (review of fluoridation) of the 1991 Act which relates to monitoring the effect of fluoridation schemes on the health of the population affected. The new subsection (5A) requires the Secretary of State to consult the relevant local authorities when carrying out such monitoring, and in particular before producing the report required by section 90A(1)(b) of the 1991 Act. This ensures that affected local authorities would be fully conversant with any effects identified and that the Secretary of State is provided with relevant information and views.

Section 36 - Procedural requirements in connection with fluoridation of water supplies

412. This section inserts new sections 88A to 88O into the Water Industry Act 1991 (the 1991 Act). These sections provide for a local authority or a group of local authorities, to make a fluoridation proposal to the Secretary of State. They provide for consultation on the proposal and set out the procedures and duties relevant to the taking of decisions. They also cover the variation and termination of fluoridation schemes. Finally, they contain a regulation making power in relation to the maintenance of a fluoridation scheme.

Section 88B of the 1991 Act – requirement for fluoridation proposal: England

413. Section 88B allows for a fluoridation proposal to be made by one or more local authorities in England. A fluoridation proposal is a proposal that the Secretary of State enters into arrangements with one or more water undertakers to increase the fluoride content of the water supplied by the undertaker or undertakers to a specific area. Subsection (4) allows for local authorities to propose fluoridation for their own area, or a larger area which includes some or all of their area.

Section 88C of the 1991 Act – Initial consultation etc. on fluoridation proposal

414. Section 88C applies if a fluoridation proposal is made. The proposer must consult with the Secretary of State and the water undertaker as to whether the proposal would be operable and efficient. The proposer must inform the Secretary of State of the opinion of the water undertaker. Only if the Secretary of State is of the opinion that the proposals are operable and efficient can the proposals proceed.

Section 88D of the 1991 Act – Additional requirements where other local authorities affected

415. Once the Secretary of State has agreed that the proposal is operable and efficient and the proposer wishes to take further steps in relation to the proposal, the proposer must notify all other local authorities affected by the proposal and make arrangements for the authorities to decide how to proceed. Subsection (4) requires the Secretary of State to make regulations on the details of how these decisions should be reached by the local authorities concerned. For example, the regulations might provide for voting and might further provide that votes be weighted by the proportion of population in each local authority that would be affected by the proposal.

Section 88E of the 1991 Act - Decision on fluoridation proposal

416. Section 88E of the 1991 Act provides that where the proposer decides to proceed with the proposal, it must comply with any requirements provided for in regulations as to the steps to be taken for consultation and ascertaining opinion. The proposer must then decide whether to proceed in the light of the views expressed. Subsection (6) empowers the Secretary of State to make regulations specifying the factors which the proposer must consider in deciding whether to proceed and the procedure to be followed in reaching that decision.

Section 88F of the 1991 Act - Decision-making procedure: exercise of functions by committee

417. Section 88F requires that, unless either the proposal affects only a single local authority or it affects more than one authority, but the other authorities do not wish to participate in the decision, the affected local authorities must exercise functions under section 88E of the 1991 Act either through an existing joint committee, a new joint committee or a joint sub-committee of health and wellbeing boards. Subsection (4) of section 88F of the 1991 Act empowers the Secretary of State to make regulations on the composition and procedures of these joint committees or joint sub-committees.

Section 88G of the 1991 Act– Secretary of State's duty in relation to fluoridation proposal

- 418. Section 88G of the 1991 Act places a duty on the Secretary of State to implement a fluoridation proposal by entering into arrangements with a water undertaker.
- 419. The Act ensures that the Secretary of State has initially satisfied himself that a scheme is operable and efficient (see section 88C of the 1991 Act). In addition, subsection (2) of section 88G of the 1991 Act requires that the Secretary of State be satisfied that the requirements imposed by sections 88B to 88F of the 1991 Act have been met. This does not require the Secretary of State to consider the adequacy of any steps taken for the purposes of complying with any requirement to consult or to ascertain opinion.

Section 88H of the 1991 Act – Payments by local authorities towards fluoridation costs

420. Section 88H of the 1991 Act provides a mechanism under which local authorities can be made to bear the full cost of fluoridation. Under section 88H(2) of the 1991 Act, the Secretary of State can require the local authorities affected by arrangements made by the Secretary of State for the fluoridation of water with a water undertaker to meet the Secretary of State's costs incurred under the terms of the arrangement. Subsection (4) of section 88H provides for the Secretary of State to determine what amounts are payable by each authority in the absence of an agreement between the local authorities (or by a joint committee of the local authorities or joint sub-committee of health and wellbeing boards), with a power to appoint an independent person to arbitrate if he wishes. Subsections (5) and (6) provide for requests for variations in the amounts agreed, once a fluoridation scheme is set up, to be treated in the same way.

Sections 88I to 88N of the 1991 Act -Variation and/or termination

- 421. Sections 88J to 88N of the 1991 Act relate to the variation or termination of arrangements for the fluoridation of water. They largely replicate the provisions concerning new fluoridation proposals in sections 88B to 88G of the 1991 Act.
- 422. The Secretary of State is able to vary or terminate arrangements without a proposal from a local authority, in certain limited cases. Section 88I(4) provides for regulations to be made prescribing the cases where the Secretary of State can vary or terminate arrangements without a local authority making a proposal.

Section 88O of the 1991 Act – Variation and termination

423. Subsection 880 of the 1991 Act contains a regulation-making power in relation to consultation or ascertaining opinion on the maintenance of existing fluoridation arrangements. The power also covers the procedures to be followed in relation to a proposal to maintain arrangements. The regulations must make provision requiring the Secretary of State to give notice to the water undertaker under section 87C(7) of the 1991 Act if the local authorities do not want to maintain fluoridation arrangements and the Secretary of State is satisfied that any requirements imposed by regulations have been met.

Section 37 - Fluoridation of water supplies: transitional provision

- 424. *Subsections (1) and (2)* provide for existing fluoridation arrangements between water undertakers and SHAs to be treated as if they were arrangements entered into by the water undertaker with the Secretary of State under section 87(1) of the 1991 Act.
- 425. *Subsection (3)* provides that where arrangements are to be treated as existing arrangements, payments by local authorities towards fluoridation costs are to be determined by agreement between the affected local authorities.

Functions relating to mental health matters

426. These sections make a number of changes to the Mental Health Act 1983 (the 1983 Act) in the light of the abolition of PCTs and SHAs and the other proposals in White Paper *Equity and Excellence: Liberating the NHS*⁸.

Section 38 - Approval functions

- 427. This section amends the 1983 Act to provide new ways in which the Secretary of State's approval functions under that Act may be exercised. Previously, the Secretary of State's approval functions were delegated to SHAs, by means of directions given by the Secretary of State under section 7 of the NHS Act.
- 428. 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.
- 429. 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 1983 Act.

⁸ Copies are available in the Library, and from the DH website at http://www.dh.gov.uk/en/Healthcare/LiberatingtheNHS/ index.htm

- 430. The section inserts three new sections into the 1983 Act.
- 431. 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 may cover the approval function in general, or only to a more limited extent. For example, there may 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.
- 432. An agreement may be for a fixed period, or may specify how decisions about the termination of the agreement will be made. However, it will 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 may 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 may include provision for the Secretary of State to pay the other party compensation if this were to happen.
- 433. The other party has to comply with other instructions given by the Secretary of State. It is for the Secretary of State to decide how these other instructions should be given, but they have to be published. In practice, at least for approved clinicians, these instructions may 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. Previously, these matters were dealt with in directions to SHAs.⁹
- 434. Agreements under the new section 12ZA may include arrangements for Secretary of State to make payments to the other party. The Secretary of State may also make payments to other people in connection with the exercise of approval functions under the agreement. For example, the Secretary of State may 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.
- 435. 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 may require the NHS Commissioning Board or a Special Health Authority to exercise one or both of the approval functions, and (as in section 12ZA) that may apply to the function generally, or to a more limited extent.
- 436. It is also possible for approval functions to be exercised concurrently both by the NHS Commissioning Board or a Special Health Authority under section 12ZB and by another person under section 12ZA.
- 437. Like a party to an agreement under section 12ZA, the NHS Commissioning Board or Special Health Authority will have to comply with instructions given by the Secretary of State. The Secretary of State will have to publish those instructions. The Secretary of State will be able to end (or vary) the requirement on the NHS Commissioning Board or Special Health Authority at any time, which would in turn end (or vary) the Board or authority's power to approve people.
- 438. Where the Secretary of State requires the NHS Commissioning Board or a Special Health Authority to exercise an approval function, that function will be treated as a function under the NHS Act. That means, for example, that the Secretary of State will have to take that function into account when allocating funding to the NHS Commissioning Board or the authority. As in section 12ZA, the Secretary of State may also make payments to a third party in connection with the exercise of the approval function by the NHS Commissioning Board or a Special Health Authority.

⁹ The Approved Clinician (General) Directions 2008, available at www.dh.gov.uk/en/Healthcare/Mentalhealth/ InformationontheMentalHealthAct/DH_106657

- 439. 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 allows 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 may, for example, allow one approving body to pass on to another approving body information it has received from, or about, an applicant, without having to obtain that applicant's consent.
- 440. Although sections 12ZA and 12ZB give the Secretary of State new ways in which to arrange for these approval functions to be exercised, there is nothing to prevent the Secretary of State deciding to exercise them directly through the Department of Health.
- 441. The section 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 did not apply to cases against the Secretary of State, SHAs 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 is true in respect of cases against the NHS Commissioning Board and Special Health Authorities as a result of a separate amendment made by this Act.
- 442. Nothing in this section affects the exercise of approval functions under the 1983 Act in Wales.

Section 39 - Discharge of patients

- 443. This section 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.
- 444. Section 23 previously gave 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 had 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 had 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 was exercisable in relation to Wales by the Welsh Ministers. Section 23 similarly allowed 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 had commissioned the service the patient was receiving from that registered establishment.
- 445. The section removed 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 section also made a number of consequential changes to the 1983 Act and other legislation to reflect the abolition of these discharge powers.

Section 40 - After-care

- 446. This section 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.
- 447. Section 117 is a free-standing duty. Case-law¹⁰ 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-law¹¹ 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.
- 448. The main effect of this section is to transfer the duty on PCTs under section 117 to CCGs. As now, the duty will fall in the first place on the CCG for the area in which the person was resident before being detained. However, the new section 117(2E) inserted into the 1983 Act by this section would allow the Secretary of State to make regulations conferring the duty instead on another CCG or on the NHS Commissioning Board.
- 449. These regulations could, for example, be used to ensure that the CCG responsible for section 117 after-care for a patient was the same CCG 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 NHS Commissioning Board, rather than CCGs, was responsible for commissioning under provisions earlier in this Act. In those cases, the regulations could say that it was the Board, rather than any individual CCG, which was responsible for commissioning such services as part of the person's after-care under section 117.
- 450. The effect of new subsection (2D) is to make clear that the duty on a CCG (or the NHS Commissioning Board) is to commission, rather than provide, after-care.
- 451. The section also includes a number of technical changes to other provisions.

Section 41 - Provision of pocket money for in-patients

- 452. This section 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 was previously delegated to PCTs by means of regulations. 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.
- 453. CCGs 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 in section 20.

¹⁰ R. v Manchester City Council Ex p.Stennett [2002] UKHL 34; [2002] 4 All ER 124

¹¹ *R. v Mental Health Tribunal, Ex p. Hall* [1999] 3 All ER 132

454. The section 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 section 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.

Section 42 - Transfers to and from special hospitals

- 455. This section 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 was 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.
- 456. The section 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 does not affect the validity of the detention of anyone who has previously been transferred under section 123, nor prevent the recapture of anyone who escaped from custody while being transferred under that section.

Section 43 - Independent mental health advocates

- 457. This section 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.
- 458. Previously, section 130A of the 1983 Act placed a duty on the Secretary of State to make arrangements to enable qualifying patients to have access to an IMHA. 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.
- 459. The Secretary of State previously delegated the duty to commission IMHA services to PCTs, by means of directions under section 7 of the NHS Act. This section 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 is responsible for which qualifying patients.
- 460. The section 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 allows the Secretary of State to issue directions and statutory guidance to local social services authorities about the exercise of this function.
- 461. IMHA arrangements in Wales are a devolved matter, and in 2010 the National Assembly for Wales passed legislation amending the provisions in the 1983 Act which deal with IMHA services in Wales. In doing so, the Assembly also made some consequential amendments to the provisions as they apply in England. The changes made by this section 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.

Section 44 - Patients' correspondence

462. This section 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. It amends that section so that it is no longer possible for such a request to be made to the Secretary of State (or, therefore, to the Welsh Ministers). It continues 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.

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

Section 45 - Notification of hospitals having arrangements for special cases

- 464. This section 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.
- 465. This section transfers that duty from PCTs to CCGs.

Emergency powers

466. Sections 46 and 47 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.

Section 46 - Role of the Board and clinical commissioning groups in respect of emergencies

- 467. This section inserts a new section 252A into the NHS Act and sets out the role and responsibilities of the NHS Commissioning Board and CCGs 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.
- 468. Subsection (1) of section 252A confers duties on the NHS Commissioning Board and each CCG 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 NHS Commissioning Board or CCGs to provide NHS services.
- 469. Subsections (2) and (4) of section 252A provide that the NHS Commissioning Board also has duties to take steps to secure that CCGs and providers of NHS services are properly prepared for emergencies.
- 470. Subsections (3) and (5) of section 252A provide that these duties include a responsibility for monitoring compliance by CCGs 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 NHS Commissioning Board or CCGs.
- 471. Subsection (6) of section 252A allows the NHS Commissioning Board to coordinate the responses between CCGs and service providers to emergencies that might affect those bodies. Subsection (7) of section 252A allows the NHS Commissioning Board to arrange for any other person or body to exercise any of its functions under subsections (2) to (6) of that section in relation to securing the preparedness of CCGs and NHS providers.
- 472. Subsection (8) of section 252A ensures that if the NHS Commissioning Board makes arrangements under subsection (7) of that section for another body or person to carry out any of its responsibilities for emergency planning, resilience and response, it may also arrange for that other person or body to exercise any functions that the Board has

by virtue of the NHS Commissioning Board being a Category 1 responder under the Civil Contingency Act 2004.

- 473. Subsection (9) of section 252A 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 NHS Commissioning Board or CCGs and that the NHS Commissioning Board is provided with information that it may require 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".
- 474. Subsection (10) of section 252A is an interpretation provision defining certain terms used in that section. "Relevant emergency" is defined, in relation to the NHS Commissioning Board, a CCG or a service provider respectively, as any emergency which might affect the body in question, whether by increasing the need for services it may arrange or provide, or in any other way. "Relevant service provider" is defined as a body or person providing services in pursuance of service arrangements. "Service arrangements" is defined, in relation to a relevant service provider, as arrangements made by the NHS Commissioning Board or a CCG under or by virtue of section 3, 3A, 3B, 4 or 7A or Schedule 1. 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.

Section 47 - Secretary of State's emergency powers

- 475. 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. The amendments extend the Secretary of State's powers and make them consistent with the new framework for the health service provided for by the Act. This is necessary because, under the new framework, the Secretary of State will not have a general power to give directions to NHS bodies about how they exercise their functions.
- 476. Subsection (2) amends subsection (1) of section 253 to enable the Secretary of State to give a direction under that section where he considers it is appropriate to do so by reason of an emergency. The effect of the amendment is that the power to give directions is not limited to giving directions to ensure that a service is provided. Subsection (3) inserts a new subsection (1A) into section 253 which 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, CCGs, 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.
- 477. *Subsection (4)* substitutes new subsections (2) and (2A) of section 253 which specify 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)* inserts three new subsections into section 253. New subsection (2B) enables the Secretary of State to direct the NHS Commissioning Board to exercise the Secretary of State's functions under section 253. New subsection (2C) enables the Secretary of State to direct the Board about its exercise of any functions that are the subject of a direction under new subsection (2B). New subsection (2C) defines "specified" to mean specified in the direction.

478. Subsection (6) omits subsection (4) of section 253 so as to remove the exclusion of NHS foundation trusts from the Secretary of State's emergency powers. Subsection (7) amends section 273 of the NHS Act (further provision about orders and directions under the Act) so that directions under section 253 can be given either in writing or by regulations, as is the case with many other directions under the NHS Act.

Section 48 – New Special Health Authorities

- 479. This section 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 to Special Health Authorities established following the coming into force of this section of the Act (as outlined in subsection 28A(1)).
- 480. Subsection (2)(a) of new section 28A specifies that any order establishing a new Special Health Authority once the Act 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 Act 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.
- 481. 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)).

Section 49 (new sections 98A, 114A, 125A, 168A) - Primary care services: directions as to exercise of functions

482. This section 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 NHS Commissioning Board that relate to the provision of primary medical services. These would be exercised by the Secretary of State in respect of the NHS Commissioning Board and by the Board in respect of CCGs. 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 CCG.

New section 98A Exercise of functions

- 483. *Subsection (1)* of new section 98A provides that the Secretary of State may direct the NHS Commissioning Board to exercise on his behalf any of his functions relating to the provision of primary medical services.
- 484. *Subsection* (2) of new section 98A clarifies that the functions that may be directed do not include the Secretary of State's regulation and order-making powers.
- 485. *Subsection (3)* of new section 98A provides that the Secretary of State may direct the NHS Commissioning Board as to how it is to exercise any functions that it is directed to exercise under subsection (1). 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 NHS Commissioning 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 NHS Commissioning 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 and the Secretary of State may need to give direction to ensure the NHS Commissioning Board exercises its functions correctly.
- 486. *Subsection (4)* of new section 98A provides that the NHS Commissioning Board may direct a CCG to exercise on its behalf any of the Board's functions relating to the provision of primary medical services.
- 487. *Subsection (5)* of new section 98A provides that the NHS Commissioning Board may direct CCGs as to how to exercise any functions relating to the provision of primary medical services that it is directed to exercise. The details of the functions to be delegated will be a matter for discussion between the NHS Commissioning Board and the CCGs. It is envisaged that CCGs will play some part in monitoring primary medical service contractors and that they may have a role in commissioning some enhanced primary medical services on behalf of the NHS Commissioning Board.
- 488. *Subsection (6)* of new section 98A permits regulations to set out functions that the NHS Commissioning Board cannot direct a CCG 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).
- 489. *Subsection (7)* of new section 98A permits the NHS Commissioning Board to provide information to the CCG where that information is required by the CCG to exercise any function that the Board has directed it to exercise. The supply of information would be limited to that which the NHS Commissioning Board considers necessary to enable the CCG to perform the function effectively.
- 490. Subsections (8), (9) and (10) of new section 98A require the CCG report to the NHS Commissioning 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 medical services functions, such as issues relating to a contractor's performance under its contract.

New section 114A Exercise of functions

491. This section inserts a new section 114A into the NHS Act to provide a power of direction in respect of the exercise by the NHS Commissioning Board of any 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 NHS Commissioning Board.

- 492. Subsection (1) of the new section 114A provides that the Secretary of State may direct the NHS Commissioning Board to exercise on his behalf any of his functions relating to the provision of primary dental services.
- 493. Subsection (2) of new section 114A clarifies that the functions that may be directed do not include the Secretary of State's regulation and order-making powers.
- 494. Subsection (3) of new section 114A provides that the Secretary of State may direct the NHS Commissioning Board as to how it is to exercise any functions relating to the provision of primary dental services (including any functions delegated to it).

New section 125A Exercise of functions

- 495. This section 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 NHS Commissioning Board that relate to the provision of primary ophthalmic services. These will be exercised by the Secretary of State in respect of the NHS Commissioning Board and by the NHS Commissioning Board in respect of a CCG, 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 NHS Commissioning Board, the CCG, the Special Health Authority or any prescribed body.
- 496. Subsection (1) of new section 125A of the Act provides that the Secretary of State may direct the NHS Commissioning Board to exercise on his behalf any of his functions relating to the provision of primary ophthalmic services.
- 497. Subsection (2) of new section 125A clarifies that the functions that may be directed do not include the Secretary of State's regulation and order-making powers.
- 498. Subsection (3) of new section 125A of the Act provides that the Secretary of State may direct the NHS Commissioning Board as to how it exercises any function relating to the provision of primary ophthalmic services (including any functions delegated to it).
- 499. Subsection (4) of new section 125A of the Act provides that the NHS Commissioning Board may direct a CCG, a Special Health Authority or other prescribed body to exercise on its behalf any of the NHS Commissioning Board's functions relating to the provision of primary ophthalmic services.
- 500. Subsection (5) of new section 125A of the Act provides that the NHS Commissioning Board may direct a CCG, 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).
- 501. Subsection (6) of new section 125A of the Act permits regulations to set out functions that the NHS Commissioning Board cannot direct a CCG, a Special Health Authority or such other body as may be prescribed to exercise on the Board's behalf.
- 502. Subsection (7) of new section 125A of the Act permits the NHS Commissioning Board to provide information to the CCG, a Special Health Authority or such other body as may be prescribed where that information is required by the CCG. Special Health Authority or other prescribed body to exercise any function that the NHS Commissioning Board has directed it to exercise. The supply of information would be limited to that which the NHS Commissioning Board considered necessary to allow the function to be performed effectively.
- 503. Subsections (8), (9) and (10) of new section 125A of the Act require the body directed to report to the NHS Commissioning Board on matters that come to its attention as a result of undertaking the NHS Commissioning Board's functions and permit the NHS Commissioning Board to consider those matters when exercising its primary

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

New section 168A Exercise of functions

- 504. This section inserts a new section 168A into the NHS Act to provide a power of direction in respect of the exercise by the NHS Commissioning 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) are to be exercised by the NHS Commissioning Board.
- 505. Subsection (1) of new section 168A of the Act enables the Secretary of State to direct the NHS Commissioning 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.
- 506. Subsection (2) of new section 168A clarifies that the functions that may be directed do not include the Secretary of State's regulation and order-making powers.
- 507. Subsection (3) of new section 168A of the Act enables the Secretary of State to direct the NHS Commissioning 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).

Section 50 - Charges in respect of certain public health functions

- 508. This section 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 sections 11 and 12. The section 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).
- 509. The new section allows 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 public health (section 2A), including charges for any services or facilities provided. However, this power to charge does 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 the existing position for NHS services, which are generally free of charge to patients.
- 510. Subsection (4) of the new section allows the Secretary of State to make regulations specifying the steps to improve public health taken under section 2B that local authorities would be able to charge for. Subsection (4) also allows the Secretary of State to specify the health protection steps taken under section 2A (by virtue of regulations under section 6C(1)) that local authorities would be able to charge for.
- 511. 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.

Section 51 - Pharmaceutical services expenditure

- 512. Sections 164 and 165 of the NHS Act set out the general requirements for determining remuneration for NHS pharmaceutical services.
- 513. This section makes further provision in respect of the arrangement for pharmaceutical services expenditure by inserting a new section 165A and a new Schedule 12A into the NHS Act, which make further provisions to take into account the future NHS architecture.
- 514. Subsections (1) and (2) of new section 165A provide that the NHS Commissioning Board must give the Secretary of State such information as he or she may require in relation to the pharmaceutical remuneration paid by the NHS Commissioning Board to persons providing pharmaceutical services or local pharmaceutical services in such form or at such time or within such period as the Secretary of State may require. For example, in order for the Secretary of State to be able to discharge his duties in section 164 and 165 of the NHS Act, the Secretary of State may require the NHS Commissioning Board to notify the Secretary of State of:
 - both the expenditure for which CCGs are to be liable by virtue of determinations and apportionments under the new Schedule 12A, as inserted by Schedule 3 which makes further provision about pharmaceutical remuneration; and
 - the rest of the expenditure by the NHS Commissioning Board on the commissioning of pharmaceutical services under Part 4 of the NHS Act.
- 515. The word "remuneration" is a specific term about which provision is made by section 165(6) of the NHS Act. It covers the fees and allowances that pharmaceutical contractors (community pharmacies, appliance contractors and dispensing doctors) receive for the services provided. It also covers reimbursement for the costs of the products they supply against prescriptions.
- 516. Under existing legislation, the Secretary of State determines the reimbursement price paid by the NHS for the products dispensed. The Secretary of State also determines the level of fees and allowances for pharmaceutical services. These are published monthly in the Drug Tariff.
- 517. The prescriptions dispensed by contractors are processed by the NHS Business Services Authority which then pays the contractors. The costs – for both the services and products – are then charged to PCTs.
- 518. The NHS Business Services Authority charges these costs to PCTs by deducting the relevant amount from the total sums that PCTs draw down each month based on their annual unified funding allocation.
- 519. In future, it is expected that the Secretary of State will continue to determine the reimbursement price paid by the NHS for the products dispensed. This is because wider interests are affected, such as pharmaceutical manufacturers and wholesalers. However, as the NHS Commissioning Board will in future be commissioning pharmaceutical services, it is expected that the NHS Commissioning Board will become responsible for determining the level of fees and allowances paid for pharmaceutical services once PCTs are abolished.
- 520. This section also introduces Schedule 3.

Schedule 3 – Pharmaceutical remuneration

- 521. This Schedule inserts new Schedule 12A into the NHS Act.
- 522. Paragraph 1 of the new Schedule makes provision in respect of interpretation. It defines "drugs" by reference to the meaning given in section 126 of the NHS Act so that this term includes listed appliances (such as stoma care products) as well as drugs. It

also defines "pharmaceutical remuneration" so that this term includes both contractors who provide NHS pharmaceutical services and contractors who provide NHS local pharmaceutical services (which would be provided under direct contracts with the NHS Commissioning Board).

- 523. Paragraph 2 of the new Schedule sets out the arrangements for how pharmaceutical remuneration is to be apportioned amongst CCGs. This largely mirrors current funding flows for NHS pharmaceutical services expenditure.
- 524. Sub-paragraph (1) of paragraph 2 provides that the NHS Commissioning Board must determine the elements of pharmaceutical remuneration which will be apportioned to CCGs in relation to the relevant financial year in accordance with that sub-paragraph.
- 525. Sub-paragraph (2) of paragraph 2 provides that the elements of pharmaceutical expenditure to be apportioned each financial year, which the NHS Commissioning Board has determined in accordance with sub-paragraph (1), are to be referred to as "designated elements".
- 526. Sub-paragraph (3) of paragraph 2 requires the NHS Commissioning Board to notify each CCG of its determination of the designated elements of pharmaceutical remuneration on which the apportionment to CCGs during the financial year is based.
- 527. Sub-paragraph (4) of paragraph 2 provides that the NHS Commissioning Board must apportion among all CCGs the sums paid by it for each designated element as the Board thinks appropriate. For example, the NHS Commissioning Board could determine that the drug costs for prescriptions written in Scotland but dispensed in England are to be shared across all CCGs 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 CCG).
- 528. Sub-paragraph (5) of paragraph 2 provides that when the NHS Commissioning Board is apportioning the sums paid by it to CCGs under sub-paragraph (4), the NHS Commissioning Board may, in particular, take into account the financial consequences of the prescriptions issued by GP practices in the CCG in the same way that they will be responsible for the financial consequences of referral decisions. It is intended that this will provide incentives for CCGs to work with practices in the CCG to look in the round at how to achieve the best overall health outcomes from the resources available.
- 529. Sub-paragraph (6) of paragraph 2 provides that the NHS Commissioning Board may deduct the amount of pharmaceutical remuneration it has apportioned to a CCG from the sums it would otherwise pay to the CCG under section 223H and where it does so it must notify the CCG.
- 530. Sub-paragraph (7) of paragraph 2 provides that the Secretary of State may direct the NHS Commissioning Board that a particular element (or elements) of pharmaceutical remuneration should not to be included in a determination the NHS Commissioning Board makes under sub-paragraph (1). For example, the Secretary of State might direct the NHS Commissioning Board that the cost of dental prescriptions is not to be included in a determination by the Board under sub-paragraph(1).
- 531. Sub-paragraph (8) of paragraph 2 provides that the NHS Commissioning Board, when determining the overall allocation to a CCG under section 223H of the NHS Act, must take account of the effect of the new Schedule 12A. The NHS Commissioning Board must therefore take account of pharmaceutical needs, alongside other relevant healthcare needs, when determining the overall allocation.
- 532. Sub-paragraph (9) of paragraph 2 provides that, for the purposes of sections 223H, 223I(3), and paragraph (16) of Schedule 1A, any amount of pharmaceutical remuneration apportioned by the NHS Commissioning Board for a given financial year

which is notified to CCGs under sub-paragraph (6) is to be treated as expenditure of the CCG which is attributable to the performance of its functions in the relevant year.

- 533. Paragraph 3 of the new Schedule makes provision for the reimbursement by the NHS Commissioning Board of other pharmaceutical remuneration. Sub-paragraph (1) makes clear that paragraph 3 does not apply to elements of pharmaceutical remuneration which are designated elements under paragraph 2(2) or other remuneration of a prescribed description. Sub-paragraph (2) makes provision for the NHS Commissioning Board to require a person to reimburse it for any pharmaceutical remuneration to which paragraph 3 applies if the drugs or appliances in question were ordered by that person or ordered in the course of the delivery of a service arranged by that person. This paragraph does not relate to the pharmaceutical remuneration attributable to CCGs. Rather, it enables the NHS Commissioning Board to require providers who deliver services that give rise to pharmaceutical expenditure to cover the costs that may arise. The NHS Commissioning Board would, for example, under sub-paragraph (2), be able to require reimbursement from an 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.
- 534. Paragraph 4 provides that the NHS Commissioning Board may, with the express consent of the Secretary of State, delegate any of its functions under Schedule 12A to a Special Health Authority or arrange for its functions to be exercised by any other person. This would, for example, enable existing arrangements to continue if so desired whereby the NHS Business Services Authority makes payments to contractors for the provision of pharmaceutical services on behalf of PCTs.

Section 52 - Secretary of State's duty to keep health service functions under review

- 535. This section inserts new section 247C into the NHS Act. This gives the Secretary of State a duty to keep health service functions under review. The purpose of this is to make clear on the face of legislation that Secretary of State is ultimately accountable for ensuring that the national level arm's length bodies, such as the NHS Commissioning Board, Monitor and the Care Quality Commission (including the Healthwatch England Committee of CQC), are performing their functions effectively. This duty is backed by powers of intervention in the event of significant failure (see new section 13Z2 of the NHS Act and sections 71, 245, 272 and 294 of this Act). This section was added to the Act following the Department's response to the NHS Future Forum, as a way of emphasising the Government's continuing responsibility for the NHS.
- 536. Section 247C also makes it explicit that the Secretary of State may report on how the national level organisations have discharged their functions, as part of his annual report on the performance of the health service (see section 53).

Section 53 - Secretary of State's annual report

- 537. This section inserts new section 247D 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 there has been a specific requirement for an annual report of this kind, and it is intended to ensure that the performance of the comprehensive health service is subject to the appropriate Parliamentary scrutiny.
- 538. This report would cover both those aspects of the health service commissioned by the NHS Commissioning Board and CCGs, as well as those public health services for which the Secretary of State and local authorities are responsible. Subsection (2) requires the Secretary of State to include in the report his assessment of how effectively he has discharged his duties under sections 1A (Duty as to improvement in quality of services) and 1C (Duty as to reducing inequalities). In addition to these requirements,

the report 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.

Section 54 – Certification of death

539. This section makes amendments to the Coroners and Justice Act 2009 placing responsibility for the appointment of medical examiners and related activities on local authorities (in England) instead of PCTs.

Section 55 - Amendments related to Part 1 and transitional provision

540. This section gives effect to Schedules 4, 5 and 6.

Schedule 4 – Amendments of the National Health Service Act 2006

- 541. 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 Part 1 of this Act.
- 542. **Part 1 of Schedule 4 (the health service in England)** makes amendments to Part 1 of the NHS Act primarily as a result of the abolition of SHAs and PCTs, the establishment of the NHS Commissioning Board and CCGs and changes to the Secretary of State's role as provided for in Part 1 of this Act.
- 543. Paragraph 1 substitutes section 2 of the NHS Act. Previously, section 2 of the NHS Act empowered the Secretary of State to provide such services as the Secretary of State considers appropriate for the purpose of discharging his 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) is no longer necessary because the Secretary of State will no longer be under a duty to provide services. CCGs will however have a power to arrange such services as they consider appropriate for the purposes of the health service under new section 3A (section 14). In relation to what was section 2(1)(b), the new section 2 substituted by paragraph 1 of Schedule 4 to this Act confers powers on the Secretary of State, the NHS Commissioning Board and CCGs to do anything which is calculated to facilitate, or is conducive or incidental to, the discharge of their functions.
- 544. 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 CCGs. 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.
- 545. 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 CCGs, or in relation to public health, provided by the Secretary of State and local authorities.
- 546. References to SHAs and PCTs 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 CCGs 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 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.

- 547. 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 the exercise of 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 NHS Commissioning Board and CCGs.
- 548. Paragraph 9 inserts new section 12ZA into the NHS Act, which makes special provision about commissioning arrangements made by the NHS Commissioning Board and CCGs. For example, it allows those bodies to make their facilities and employees available to service providers.
- 549. Paragraphs 10 to 12 amend sections 12A, 12B and 12D of the NHS Act (inserted by the Health Act 2009) to allow the NHS Commissioning Board, CCGs and local authorities 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, CCGs and local authorities instead of PCTs.
- 550. **Part 2 of Schedule 4 (NHS bodies)**, consisting of paragraphs 13 to 23 of Schedule 4 to this Act, makes a series of amendments to Part 2 of the NHS Act (which deals with NHS bodies). Paragraph 13 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 13. The provision is omitted as a new definition of "NHS body", which does not include SHAs and PCTs, but includes the NHS Commissioning Board and CCGs, is inserted into section 275 of the Act by paragraph 138 of Schedule 4.
- 551. Paragraph 14 amends section 29, which relates to the exercise of functions by Special Health Authorities, to remove references to section 14 and 19 which relate to the exercise of SHA and PCT functions
- 552. Paragraph 15 makes provision for the omission of Chapter 5B of Part 2 of the NHS Act, 'trust special administrators: PCTs.' This is consequential on the abolition of PCTs elsewhere in this Act.
- 553. Paragraph 16 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 in Schedule 21 to this Act (relations between health services), so that it applies only to NHS trusts and Special Health Authorities. Section 67 is amended to remove the references to SHAs and PCTs. References to the NHS Commissioning Board and CCGs are not inserted, as they are subject to separate powers provided for in Part 1 of this Act.
- 554. Paragraph 17 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.
- 555. Paragraph 18 amends section 71 (schemes for meeting losses and liabilities in respect of certain health service bodies) so as to remove references to SHAs and PCTs and insert references to the NHS Commissioning Board and CCGs. This enables the Secretary of State to provide in regulations that the NHS Commissioning Board and CCGs are eligible to participate in such schemes or may administer such schemes.
- 556. 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 19 of Schedule 4 to this Act removes sections 14, 15, 19 and 20 from the list in subsection (1), as those sections relate only to SHAs and PCTs.

- 557. Paragraphs 20 and 21 omit Schedules 2 and 3 to the NHS Act, as they deal with the constitution of SHAs and PCTs.
- 558. Paragraph 22 amends Schedule 4 to the NHS Act, which deals with NHS trusts. Subparagraphs (2) and (3) of paragraph 15, omitted by sub-paragraph 7, provide that an NHS trust may provide high security psychiatric services only where approved by the Secretary of State. Those provisions are omitted, as this Act makes new provision requiring any provider of such services to have approval – see section 16 of this Act.
- 559. Schedule 6 to the NHS 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 23 of Schedule 4 removes SHAs from the list of bodies to which those provisions apply.
- 560. **Part 3 of Schedule 4 (local authorities)** amends Part 3 of the NHS Act (local authorities and the NHS).
- 561. Paragraph 24 amends section 74 by removing references to a SHA and a PCT and inserting references to the NHS Commissioning Board and CCGs so that the expression 'public body' in the Local Authorities (Goods and Services) Act 1970 (c.39) includes the Board and CCGs.
- 562. Paragraph 25 amends section 76 by removing references to a SHA and a PCT and inserting references to the NHS Commissioning Board and a CCG 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.
- 563. Paragraph 26 amends section 77 by removing the references to PCTs.
- 564. Paragraph 27 amends section 78(3) to remove the references to PCTs and SHAs. Section 78 provides a power for the Secretary of State to direct certain bodies to enter into partnership arrangements in the event that they fail to exercise their functions adequately. This section will eventually be entirely repealed by this Act, when section 179 (abolition of NHS trusts) is brought into force.
- 565. Paragraphs 28 and 29 amend sections 80 and 81 by removing references to SHAs and PCTs and inserting references to the NHS Commissioning Board and CCGs. The amendment of section 80 gives the NHS Commissioning Board and CCGs 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 NHS Commissioning Board and CCGs 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 NHS Commissioning Board and CCGs.
- 566. **Part 4 of Schedule 4 (medical services)** makes consequential amendments to Part 4 of the NHS Act. In particular, the NHS Commissioning 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 NHS Commissioning Board will be unable to provide primary medical services itself but will make arrangements for the provision of services with general practitioners and other providers.
- 567. Sections 89 and 94 are amended to clarify that any consequential changes made to a General Medical Services contract or a Personal Medical Services agreement as the result of the establishment of CCGs 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 NHS Commissioning Board

to direct a PCT to exercise its functions under section 92 (personal medical services) arrangements during the interim period between the abolition of SHAs and the abolition of PCTs. 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 NHS Commissioning Board to recognise Local Medical Committees for an area.

- 568. **Part 5 of Schedule 4 (dental services)** makes consequential amendments to Part 5 of the NHS Act. In particular, the NHS Commissioning 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 NHS Commissioning Board will be unable to provide primary dental services itself but will make arrangements for the provisions of services with dentists and other providers.
- 569. Section 107 of the Act is amended to enable the NHS Commissioning Board to enter into arrangements for the provision of primary dental services instead of SHAs. 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 NHS Commissioning Board to direct a PCT to exercise its functions under that section (personal dental services) arrangements during the interim period between the abolition of SHAs and the abolition of PCTs. 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 NHS Commissioning Board to recognise Local Dental Committees for an area.
- 570. **Part 6 of Schedule 4 (ophthalmic services)** makes consequential amendments to Part 6 of the NHS Act. In particular, the NHS Commissioning 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 NHS Commissioning Board will be unable to provide primary ophthalmic services itself. Provision is also made for the Board to recognise Local Optical Committees formed for an area.
- 571. Part 7 of Schedule 4 (pharmaceutical services) makes consequential amendments to provisions in Part 7 of the NHS Act in respect of pharmaceutical services. In particular, provision is made for the NHS Commissioning Board to commission pharmaceutical services for England. The NHS Commissioning Board cannot provide pharmaceutical services itself but will make arrangements for the provision of services with other persons and bodies. Further amendments are made to section 129 of the Act regarding the preparation and publication of pharmaceutical lists of NHS contractors. The NHS Commissioning 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 NHS Act, the NHS Commissioning 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 NHS Act is amended to require the NHS Commissioning 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 NHS Act are also amended to enable the NHS Commissioning 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 NHS Commissioning Board to recognise Local Pharmaceutical Services Committees for an area. Transitional provision is

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

- 572. **Part 8 of Schedule 4 (charging)** makes amendments to Part 9 of the NHS Act by removing references to PCTs and SHAs.
- 573. Paragraph 94 amends section 176 by inserting a reference to the NHS Commissioning 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.
- 574. Paragraph 96 amends section 180 by inserting references to the NHS Commissioning Board so that the Secretary of State must provide by regulations for payments to be made by the NHS Commissioning Board to meet or contribute to the costs incurred in respect of optical appliances and sight tests. The amendment also inserts new subsection (6A) into section 180 to enable the NHS Commissioning Board to direct a Special Health Authority, or such other body as may be prescribed, to exercise any of the NHS Commissioning Board's functions under regulations under section 180. Section 180 of the Act is also amended to include new provision for the NHS Commissioning 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 reflect that this section now relates to payments for both the cost of optical appliances and sight tests.
- 575. Paragraph 98 amends section 183 by removing references to PCTs and inserting references to the NHS Commissioning Board and a CCG so that regulations may provide for the payment by those bodies of travelling expenses to prescribed descriptions of persons.
- 576. Paragraphs 99 and 100 amend sections 185 and 186 by removing references to PCTs and inserting references to the NHS Commissioning Board, CCGs and local authorities 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.
- 577. Paragraph 101 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 PCTs 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 CCGs under section 3(1) (as amended by section 13 of this Act), or by local authorities under their new health improvement powers (new section 2B inserted by section 12 of this Act).
- 578. **Part 9 of Schedule 4 (fraud etc.).** Paragraph 103 amends section 195 as a result of changes made to section 2 of the NHS Act. Paragraph 104 amends section 196 by removing references to SHA and PCT and inserting references to the NHS Commissioning Board and CCGs in the definition of 'NHS body' and 'public health service contractor' for the purposes of sections 195(3) and 197(1). Paragraph 106 amends section 201 by enabling the disclosure of certain information if it is in connection with any of the functions of the NHS Commissioning Board, a CCG or a local authority as well as those of the Secretary of State. Paragraphs 105 and 107 amend

sections 197 and 210 by substituting the references to 'NHS contractor' with references to 'public health service contractor'.

- 579. **Part 10 of Schedule 4 (property and finance).** Paragraph 108 amends section 211 by replacing the reference to a 'local social services authority' with a reference to a 'local authority' in order to accurately reflect the definition and functions of a local authority under this Act. Paragraph 109 amends section 213 by removing the reference to a PCT as a 'relevant health service body' and providing that CCGs and the NHS Commissioning Board are 'relevant health service bodies' who the Secretary of State may provide for the transfer of trust property to and from.
- 580. Paragraph 110 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 NHS Commissioning Board and CCGs to be included as bodies to who all trust property can be transferred and removes the references to PCTs.
- 581. Paragraph 111 amends section 215 consequently upon the amendments to section 214. Paragraph 113 amends section 217 by removing references to Schedules 2 and 3 to the NHS Act (which relate to PCTs and SHAs). Paragraph 114 amends section 218 by removing references to PCTs and SHAs.
- 582. Paragraphs 112 and 115 amend sections 216 and 220 of the NHS Act 2006 to add a reference to this Act's provisions on transfer schemes (in sections 300 and 302). The amendments would ensure that existing provisions on property held on trust by the NHS (e.g. charitable property) continue to apply where such property is transferred by transfer schemes under this Act.
- 583. Paragraph 116 amends section 222 which contains a power for the Secretary of State to exclude, by way of directions, specified descriptions of activities from the list of activities that NHS bodies (other than Local Health Boards) may 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 CCGs 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).
- 584. Paragraph 117 amends section 223 by inserting a reference to the NHS Commissioning Board so that the Board also has powers to form and invest in companies. Paragraph 117(2) also inserts new section 223A to apply section 223 to CCGs.
- 585. Paragraph 118 omits section 224 which concerns the funding of SHAs. Paragraphs 119 and 120 amend sections 226 and 227 to remove the references to SHAs so that the sections only apply to Special Health Authorities. Paragraph 121 omits sections 228 to 231 which concern the funding of PCTs.
- 586. Paragraph 122 provides for the omission of subsection 4 of section 234 to reflect the fact that PCTs are being abolished
- 587. Paragraph 123 amends section 236 replacing the reference to the Secretary of State with a reference to the 'prescribed CCG' so that a CCG must pay remuneration and reasonable expenses under section 236 rather than the Secretary of State. The amendment also omits the reference in section 236(2)(b), which sets out when payments may not be made to a medical practitioner, to a PCT and inserts a reference to arrangements made by the NHS Commissioning Board or a CCG which sets out when payments may not be made to a medical practitioner.
- 588. Paragraph 124 omits Schedule 14. Paragraph 125 amends Schedule 15 by removing references to PCTs and SHAs and by removing the requirement for the Secretary of State to prepare summarised accounts.

- 589. **Part 11 of Schedule 4 (public involvement and scrutiny).** Paragraph 126 removes SHAs and PCTs from the list of bodies to whom duties on public involvement and consultation in section 242 apply. Paragraph 126 omits sections 242A and 242B which provide for regulations to require SHAs to involve health service users in prescribed matters.
- 590. **Part 12 of Schedule 4 (miscellaneous).** Paragraph 128 inserts new section 254A into the NHS Act. This enables the Secretary of State to continue to be able to provide support services to persons providing services or exercising functions in relation to the health service (subject to subsection 5) where it makes sense to coordinate activity centrally. This function was previously carried out in reliance of the Secretary of State's general power in section 2 of the NHS Act.
- 591. Support provided under this new section might include providing advice and assistance to NHS trusts and NHS foundation trusts when they procure medicines or other goods to help them get best value for money, and managing central contracts with section 223 companies which provide services to the NHS (e.g. NHS Professionals, which provides recruitment and temporary staff agency services to NHS trusts and NHS foundation trusts).
- 592. The power does not allow the Secretary of State to commission or provide health services. Nor does it allow him or her to give financial assistance to the private sector.
- 593. Paragraph 129(4) amends section 256 by substituting references to PCTs with references to the NHS Commissioning Board or CCGs so that those bodies they have power to make payments towards expenditure on community services.
- 594. Paragraph 129(4) confers additional powers for the Secretary of State to specify minimum sums that the NHS Commissioning Board must pay to local authorities (or certain other bodies exercising functions in relation to housing) towards expenditure on local authority social care or other community services. This would not affect the powers off the NHS Commissioning Board to make payments to local authorities under these powers in addition to those sums, or the powers of CCGs.
- 595. The Secretary of State may specify in directions the bodies to which those payments must be made and the functions in respect of which the payments must be made. The Secretary of State may also specify the minimum amount to be paid to each local authority (or other body) specified in the direction. Although a direction would relate to a particular financial year, the Secretary of State would be able to amend the direction at any time during the year, in order to change the minimum amount payable (either in total or to a particular body).
- 596. The existing powers in section 256 for the Secretary of State to give directions as to the conditions that should apply to such payments continue to apply. These directions could, for example, include a requirement on a local authority to obtain the agreement of their health and wellbeing board as to how the funds are spent.
- 597. Paragraph 130 amends section 257 by substituting the reference to a PCT with reference to the NHS Commissioning Board and a CCG as a result of amendments made to section 256.
- 598. Paragraph 131 amends section 258 to provide that the Secretary of State, the NHS Commissioning Board and CCGs must exercise their functions to secure that such facilities, as they consider to be reasonably required, are made available in connection with clinical teaching and research. The amendment to this section also removes the references to PCTs and SHAs
- 599. Paragraph 132 amends section 259 as a result of amendments made to the provisions relating to primary medical services (Part 4 of the NHS Act). Paragraph 133 omits section 268.

- 600. Paragraph 135 inserts a new section 271A of the NHS Act so as to provide that services commissioned by the NHS Commissioning Board or a CCG, or provided or commissioned by a local authority in the exercise of its public health functions, are to be treated as "services of the Crown" for the purposes of Schedule 1 to the Registered Designs Act 1949 and sections 55 to 59 of the Patents Act 1977.
- 601. Paragraph 136 amends section 272 to remove any references to provisions that concern PCTs and SHAs.
- 602. Paragraph 137 inserts a reference to the NHS Commissioning Board in section 273 to ensure that a direction under the NHS Act by the NHS Commissioning Board must be given by an instrument in writing.
- 603. Paragraph 138 inserts a new definition of "NHS body" into section 275 and makes transitional provision to ensure the definition includes a reference to PCTs until they are abolished.
- 604. Paragraph 139 amends section 276, which lists various expressions defined by other provisions of the Act. The amendment removes the references to 'NHS Body' and 'PCT order' from the index of defined expressions and inserts references to the definitions in the NHS Act of "public health functions of the Secretary of State" and "public health functions of local authorities", and the NHS Constitution.

Schedule 5 – Part 1: amendments of other enactments

605. This Schedule makes a number of consequential amendments to other Acts. Most of the consequential amendments in this Schedule address references to 'PCTs' and 'SHAs', removing references to those bodies and inserting references to CCGs, the NHS Commissioning Board and local authorities as necessary.

Act	Amendment
National Assistance Act 1948 (c.29), section 24.	This amends the definition of "NHS accommodation" in light of amendments to section 117 of the Mental Health Act 1983, removing references to PCTs.
<i>Local Government Act</i> 1974 (c.7), section 26.	This extends the matters subject to investigation by the local government ombudsman to cover services provided, or to be provided, by local authorities pursuant to arrangements under section 7A of the NHS Act to exercise Secretary of State's public health functions.
Mental Health Act 1983 (c.20), sections 39 and 145.	
	The amendment to section 145 makes provision for circumstances in which Secretary of State may manage a hospital in exercise of public health functions.
Disabled Persons (Services, Consultation and Representation) Act 1986 (c.33), section 11.	Secretary of State to lay reports before Parliament on

606. The following amendments make more substantive changes to other Acts:

Act	Amendment
Local Government and Housing Act 1989 (c.42), section 2.	The amendment to section 2 of the Local Government and Housing Act 1989 (politically restricted posts) adds the director of public health to the list of statutory chief officers in section 2(6). As a statutory chief officer, a person appointed as a director of public health would hold a "politically restricted post", prevented by the 1989 Act from being a member of a local authority and subject to other restrictions on political activity. This puts directors of public health in the same position as other statutory chief officers such as directors of adult social services.
<i>Freedom of Information</i> <i>Act 2000 (c.36,)</i> Part 3 of schedule 1.	The amendment inserts references to CCGs and the NHS Commissioning Board as 'public authorities' for the purposes of the Act.
Health and Social Care (Community Health and Standards) Act 2003 (c.43,)section 45.	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.
<i>Licensing Act</i> 2003 (c.17), sections 5, 13, 16, 69 and 172B.	The Police Reform and Social Responsibility Act 2011 amends the Licensing Act 2003 to add PCTs to the list of existing responsible authorities that are entitled to make representations to a licensing authority in relation to the application for the grant, variation or review of a licence to use premises for the supply of alcohol or to undertake certain entertainment activities. The 2011 Act also adds PCTs to the list of bodies which a licensing authority must consult before determining or revising its statement of licensing policy, and makes provision for representations by responsible authorities, including PCTs, in relation to the new "early morning alcohol restriction orders".
	The amendments to sections 5(3), 13 (4), 69(4) and 172B(4) of the Licensing Act 2003 omit references to PCTs in the definitions of "relevant authority" and insert references to "the local authority in England whose public health functions are within the meaning of the NHS Act 2006 and are exercisable in respect of an area any part of which is in the licensing authority's area".
	The effect is that local authorities with responsibility for health improvement under section 2B of the NHS Act (as inserted by section 11 of this Act) would be responsible authorities able to make representations in relation to licence applications and early morning alcohol restriction orders affecting their area.
<i>Civil Contingencies Act</i> 2004 (c.44), Schedule 1.	The amendment removes references to SHAs and PCTs, and provides that the NHS Commissioning Board is a "category one responder" and CCGs are "category two responders" for the purposes of Part 1 of the Act. Category one responses have specific responsibilities to plan and respond to emergencies, while category two responders have responsibilities to co-operate with such arrangements.
<i>Mental Capacity Act</i> 2005 (c.9), sections 35, 64 and Schedule A1.	The amendment to section 35 makes local authorities, instead of the Secretary of State, responsible for making

These notes refer to the Health and Social Care Act 2012 (c.7) which received Royal Assent on 27 March 2012

Act	Amendment
	arrangements to enable independent mental capacity advocates to represent and support specified persons.
	The amendment to Schedule A1 removes references to PCTs and SHAs 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. The amendment also makes provision for circumstances in which Secretary of State may manage a hospital in exercise of public health functions.
Safeguarding Vulnerable Groups Act 2006 (c.47), sections 6, 17, 21 and 59.	The amendment removes references to SHAs and PCTs and inserts references to CCGs and the NHS Commissioning Board in section 17.
	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.
Health and Social Care Act 2008 (c.14), sections 30, 39, 46, 48, 49, 54, 59, 64, 70, 72 and 81.	The amendment removes references to SHAs and PCTs and where appropriate, inserts references to CCGs and the NHS Commissioning Board.
	The amendment to sections 30 and 39 requires the Care Quality Commission to give notice to certain NHS bodies (when required by regulations) if it takes action against a registered provider.
	The amendment to section 46 removes the requirement on the Care Quality Commission to conduct periodic reviews of health care provided or commissioned by NHS bodies. The amendments to sections 48, 49, 70 and 72 also reflect this change.
	The amendment to section 54 inserts a reference to the NHS Commissioning Board and CCGs so that they are not included in the definition of 'English NHS Body' for the purpose of section 54(1) which relates to the Care Quality Commission's power to undertake studies designed to enable it to make recommendations for improving the management of an English NHS body.
	The amendment to section 59 means that the Secretary of State will not have the power to confer additional functions on the Care Quality Commission relating to improving the economy, efficiency and effectiveness and the financial or other management or operations of certain NHS bodies.
	The amendment to section 81 requires that the Care Quality Commission consults the NHS Commissioning Board on their proposals for the topics of their reviews, studies and investigations.

Schedule 6 – Part 1: transitional provision

- 607. This Schedule is concerned with the transitional arrangements for the establishment of CCGs, the exercise of functions by CCGs during the 'initial period' and for arrangements prior to the abolition of SHAs and PCTs. The initial period is defined in paragraph 1(2) as the period beginning with the commencement of section 25 and ending on a day specified by the Secretary of State for the purposes of new section 14A (the date from which the NHS Commissioning Board must ensure every provider of primary medical services is a member of a CCG and that the areas specified in the constitutions of CCGs cover the whole of England and do not coincide or overlap). It is envisaged that this 'initial period' will run from 1 October 2012 (at the latest) to 31 March 2013. Initial applications are applications made during the initial period. It is proposed that SHAs and PCTs will be abolished at the end of the initial period.
- 608. Paragraph 2 of Schedule 6 allows the Secretary of State to consult a Special Health Authority on proposals for the annual mandate for the Board under new section 13A of the NHS Act and on regulations requiring the NHS Commissioning Board to commission services under section 3B of the NHS Act, before the NHS Commissioning Board is established. A Special Health Authority known as the NHS Commissioning Board Authority was established on 31 October 2011 to make preparations for the establishment and operation of the NHS Commissioning Board
- 609. Paragraphs 3 and 4 of Schedule 6 make provision so that the directions given to SHAs and PCTs under section 7 of the NHS Act continue to have effect, and the Secretary of State can issue new directions to those bodies under that section, until those bodies are abolished.
- 610. Paragraph 5 of Schedule 6 allows existing directions from the Secretary of State to Special Health Authorities to continue once section 21 has been commenced. This means that 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.
- 611. Paragraph 7 provides that, during the initial period, the Secretary of State may direct the Board to exercise any of the functions of the Secretary of State that relate to SHAs or PCTs, 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 PCTs to account for their performance during 2012/13.
- 612. Paragraph 8 of the Schedule makes provision for the conditional establishment of CCGs during the initial period in any cases where the Board is not fully satisfied as to the matters, as to which it would have to satisfy itself before granting an application for establishment, set out in new section 14C. Regulations may be made authorising the NHS Commissioning Board in these circumstances to grant initial applications, but allowing the NHS Commissioning Board to impose conditions or to give a direction that the CCG exercise some of its functions in a certain way or not to exercise specified functions. If the regulations authorise the NHS Commissioning Board to give such a direction, they may also authorise or require the NHS Commissioning Board to exercise those functions. Regulations may also make provision requiring the NHS Commissioning Board to keep any conditions or directions under review and make provision about how the NHS Commissioning Board varies or removes any conditions or directions imposed.
- 613. Paragraph 8(6) enables regulations to be made making modifications to the NHS Act as far as it applies to CCGs established on the grant of an initial application. These regulations may provide that the Board's power to dissolve a CCG (in new section 14Z21) applies where a CCG 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 5(12) provides that, where a conditionally established CCG ceases to be subject to any conditions or directions, it is deemed to have been established on an application granted under new section14C.

- 614. Paragraph 9 of the Schedule provides that, where an application for the establishment of a CCG is granted under section 14C during the initial period, the Board may direct it to exercise only some of its functions during this initial period. This power of direction is necessary to avoid CCGs having concurrent statutory responsibility for commissioning functions that remain with PCTs during the initial period. It is intended that PCTs will retain legal responsibility for commissioning until 1st April 2013. This means that, where CCGs commission services for patients during the initial period, they will be doing so on behalf of PCTs (see paragraph 11 of the Schedule) rather than through exercising the CCG's own statutory functions
- 615. Paragraph 10 of the Schedule provides that a CCG 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 CCG has had conditions imposed on it by a direction from the NHS Commissioning Board).
- 616. Paragraph 11 provides that, during the initial period, a PCT can make arrangements with a CCG under which the CCG carries out functions of the PCT on the PCT's behalf. This will allow CCGs to carry out, on behalf of PCTs, commissioning functions very similar to those for which they are proposed to be responsible for in their own right from April 2013 onwards. These arrangements are intended to support a smooth transition from PCT commissioning to CCGs commissioning. However the legal responsibility for the commissioning will remain with the PCT.
- 617. Paragraph 11(2) ensures that references in the listed provisions of the NHS Act to the functions of a CCG include any function of a PCT the group is exercising on the PCT's behalf, under arrangements made under paragraph 11(1) during the initial period.
- 618. Paragraph 12 enables the Secretary of State to make payments to the NHS Commissioning Board towards meeting the expenditure that the NHS Commissioning Board incurs in exercising its functions during the initial period. Such payments may be made at such times and on such terms and conditions that the Secretary of State considers appropriate.
- 619. Paragraph 13 confers powers on PCTs to provide assistance or support to a CCG during the initial period, including financial assistance, or make available the employees or other resources of the PCT, to such a group. The support may be provided on such terms and conditions, including restrictions on the use of financial support, as the PCT considers appropriate

Part 2 – Further provision about public health

Section 56 – Abolition of Health Protection Agency

620. This section abolishes the Health Protection Agency (HPA) and repeals the Health Protection Agency Act 2004. This is part of a process of reforming the systems for protecting and improving public health. New sections 2A and 2B of the NHS Act 2006, inserted by sections 11 and 12 of this Act, confer on the Secretary of State and certain local authorities duties and powers relating to public health and specify examples of steps that may be appropriate under those duties. The section also introduces Schedule 7 to the Act, which makes amendments to other legislation which are consequential on the HPA's abolition. *Subsection (3)* provides that the repeal of the HPA Act 2004 does not include the amendment made by that Act to Schedule 2 to the Immigration Act 1971, which relates to the appointment of medical inspectors.

Schedule 7 – Part 1: amendments of other enactments

621. This Schedule makes a number of amendments to other Acts which are consequential on the HPA's abolition. More detail about certain of these is given below.

Act	Amendment
Health and Safety at Work etc. Act 1974 (c.37)	Section 16 (approval of codes of practice) states that the Health and Safety Executive shall not approve a code of practice under subsection (1) without the consent of the Secretary of State and shall before seeking his consent consult appropriate government departments and the HPA in particular in the case of a code relating to electromagnetic radiations. The amendment deletes the references to the HPA and the specific reference to electromagnetic radiations.
National Immigration and Asylum Act 2002 (c.41)	
Civil Contingencies Act 2004 (c.36)	 The amendment, by substituting Paragraph 9 of Part 1 of Schedule 1 (Category 1 responders), removes references to the HPA and inserts references to the Secretary of State as regards his functions concerning responding to emergencies by virtue of – a) The Secretary of State's functions under section 2A of the National Health Service Act 2006, b) the Secretary of State's functions under section 57 of the Health and Social Care Act 2012 in so far as it applies in relation to Wales or Scotland, or c) arrangements made by the Welsh Ministers or Scottish Ministers under which the Secretary of State exercises on their behalf functions in relation to protecting the public in Wales or Scotland from disease or other dangers to health.

Section 57 - Functions in relation to biological substances

622. This section confers on the Secretary of State new UK-wide functions in relation to biological substances (see *subsection* (8) for the definition of 'biological substances'). These are functions previously carried out by the HPA. Functions relating to biological substances include standardising and controlling biological medicines like vaccines or blood products to ensure their safety and effectiveness.

- 623. 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 alone or both of them acting jointly in relation to biological substances. *Subsection* (7) provides the definition of 'appropriate authority'.
- 624. *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.
- 625. *Subsections (3) to (5)* provide 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.
- 626. *Subsection* (6) empowers the Secretary of State and the DHSSPS to charge for their activities in relation to biological substances, including on a commercial basis.

Section 58 – Radiation protection functions

- 627. This section confers functions on the Secretary of State in relation to protecting the public from radiation. These are functions previously carried out by the HPA.
- 628. This section 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 in new section 2A of the NHS Act 2006 (Secretary of State's duty as to protection of public health), as inserted by section 11.
- 629. 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 authority in relation to Scotland is the Secretary of State where the matter is not devolved and the Scottish Ministers where the matter is; and the appropriate authority in relation to Northern Ireland is the Secretary of State where the matter is not devolved and the DHSSPS in Northern Ireland where it is.
- 630. *Subsection* (2) specifies some of the steps an appropriate authority may take to protect the public against radiation, in compliance with the duty under subsection (1).
- 631. 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 which is incidental or conducive to it.
- 632. *Subsection* (4) enables the appropriate authority to charge for its activities in relation to radiation protection, including on a commercial basis.
- 633. 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 matter concerning radiation in respect of which either Executive also has a function.

Section 59 – Repeal of AIDS (Control) Act 1987

- 634. This section repeals the AIDS (Control) Act 1987. The Act concerns 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.
- 635. The AIDS (Control) (Northern Ireland) Order 1987 is also revoked.

Section 60 - Co-operation with bodies exercising functions in relation to public health

- 636. This section inserts a new section 247B into the NHS Act 2006. New section 247B imposes a duty of co-operation on all individuals or organisations who carry out health protection functions similar to those of the Secretary of State under new section 2A of the NHS Act. They must co-operate with the Secretary of State, and in turn he must co-operate with them.
- 637. 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. The intention is to make sure that the system works in a co-ordinated and coherent way to deal with threats to public health. Subsection (2) of new section 247B provides for co-operation between the devolved administrations in Scotland, Wales and Northern Ireland and the Secretary of State.
- 638. Under subsections (3) and (5) of new section 247B, 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 co-operation is requested.

Part 3 - Regulation of Health and Adult Social Care Services

Chapter 1 – Monitor

- 639. Monitor is currently the Independent Regulator of NHS foundation trusts. It is responsible for determining whether NHS trusts are ready to become NHS foundation trusts, ensuring foundation trusts comply with the conditions of their authorisations, and supporting their development. Monitor would continue to exist under this Act but would become the regulator for all health care services. Monitor's overarching duty will be to protect and promote the interests of people who use those services, by promoting provision of health care services which is economic, efficient and effective and which maintains or improves the quality of services. Monitor will address anti-competitive or potentially anti-competitive behaviour in the provision of health care services, set or regulate prices and support commissioners in ensuring the continuity of services. To enable it to deliver these functions, Monitor will have the power to licence providers of NHS-funded care. Monitor will also have concurrent powers with the Office of Fair Trading, in relation to healthcare services.
- 640. The Act allows for Monitor's functions to be extended so that they are exercisable in relation to the provision of adult social care services in England.
- 641. Schedule 8 provides for the structure and governance of Monitor, which will remain as a non-Departmental public body. The provisions are designed, as far as is practicable, to be consistent with the other non-Departmental public bodies in the health sector.

Section 61 - Monitor

642. Monitor's current title is the 'Independent Regulator of Foundation Trusts'. This section provides that Monitor continues to exist. The organisation's legal title will become 'Monitor' and it will carry out the duties and additional functions specified in later sections. This section also gives effect to the Schedule described below.

Schedule 8 - Monitor

- 643. This Schedule provides for Monitor's governance arrangements. It includes details of the membership of Monitor and the process for appointments, including the appointment of the chief executive.
- 644. Paragraphs 1 and 2 detail the membership and appointment of the chair, chief executive and other members of Monitor. The chair and at least four other members must be appointed by the Secretary of State. The chief executive and other executive members

are appointed by the non-executive members, with the consent of the Secretary of State. The number of non-executive members must to be equal to or exceed the number of executive members and no more than five executive members could be appointed without the consent of the Secretary of State. This is intended to ensure that Monitor's board remains at an appropriate size and to ensure that appointment of any additional members is justified.

- 645. Paragraphs 3 to 5 make provision for arrangements for the office of non-executive members. Under these paragraphs, tenure of office is in accordance with the terms and conditions of appointment but cannot be for more than four years. The Secretary of State may suspend or remove a non-executive member from office, on the grounds of incapacity, misbehaviour, or failure to carry out duties. Where a non-executive member is suspended from office, the Secretary of State must follow the procedures set out in paragraph 4. The Secretary of State must provide the individual with notice of the suspension, and there is a process for review of the suspension. There is also provision for the Secretary of State to appoint an interim chair when a chair is suspended (see paragraph 5).
- 646. The suspension must be for an initial period of not more than six months. It may be reviewed by the Secretary of State at any time and must be reviewed if the person suspended requests it.
- 647. 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.
- 648. Paragraph 7 provides Monitor with powers to employ staff on such pay, terms and conditions as it may determine, following Secretary of State approval of its policy on the remuneration, pensions etc of employees.
- 649. Paragraph 8 makes provision about pension arrangements for the person appointed as chair of Monitor. Where that person is a member of a public sector pension scheme under section 1 of the Superannuation Act 1972, the Minister for the Civil Service can decide whether time as chair of Monitor can count as years of service for that pension scheme. This paragraph also makes provision for employment with Monitor to be included among the kinds of employment to which such a pension schemes may apply.
- 650. Paragraph 9 gives Monitor the power to appoint committees and sub-committees, and to pay remuneration and allowances to committee members if they are not members or employees of Monitor.
- 651. Paragraph 10 allows Monitor to regulate its own procedure and states that any vacancy amongst the members does not affect the validity of its actions.
- 652. 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.
- 653. Paragraph 12 enables Monitor to engage and pay individuals to contribute to particular cases or types of cases. This will enable Monitor to have access to people with specialist skills during its consideration of such cases.
- 654. 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 is not allowed to borrow money.

- 655. 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.
- 656. Paragraph 15 gives Monitor the power to do anything it needs to in order to exercise its functions.
- 657. Paragraph 16 allows the Secretary of State to fund Monitor's activities to the extent that he considers appropriate.
- 658. Paragraph 17 makes provision about NHS foundation trust accounts. Monitor is required to prepare a set of accounts in each financial year which consolidates the annual accounts of all foundation trusts. The Secretary of State may, with HM Treasury approval, direct Monitor to prepare a set of interim accounts which consolidates any interim accounts prepared by NHS foundation trusts. The Secretary of State may, also with HM Treasury approval, give directions which specify the content and form of the accounts and methods and principles by which the accounts should be prepared. This ensures 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.
- 659. Any consolidated accounts (both annual and interim) prepared by Monitor under this paragraph must be audited by the Comptroller and Auditor General where the Secretary of State directs. Monitor is also required to act with a view to securing that NHS foundation trusts comply promptly with requests from it or from the Secretary of State relating to accounts, and to facilitate the preparation of accounts by the Secretary of State.
- 660. Once the responsibility for preparing consolidated accounts for foundation trusts transfers from Monitor to the Secretary of State, this paragraph will no longer apply.
- 661. Paragraphs 18 to 20 make provision about Monitor's accounts. Monitor is required, 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. Monitor must prepare annual accounts which must be sent to the Comptroller and Auditor General who is responsible for laying copies of the audited accounts (and his report on them) before Parliament.
- 662. The Secretary of State may require Monitor to produce interim accounts in addition to its annual accounts. The Secretary of State may direct that these accounts are sent to the Auditor General and Comptroller for audit. If they are, copies must be laid before Parliament along with the report on the accounts.
- 663. Paragraph 21 provides that Monitor must publish an annual report on how it has exercised its functions. In particular, the report must set out how Monitor has promoted economy, efficiency and effectiveness and include statements of what it did to comply with the its duties in sections 63(2) and 64(1)(h) (duties to have regard to Secretary of State guidance). Monitor must lay a copy before Parliament and send a copy to the Secretary of State. Monitor is also required to provide further information about its own functions and any information that it holds about NHS foundation trusts to the Secretary of State as required.
- 664. Paragraph 22 requires Monitor to respond to recommendations made by the Parliamentary Committees about the exercise of its functions.
- 665. Paragraphs 23 and 24 concern the use of Monitor's seal and its non-Crown status. These provisions replicate those currently in the NHS Act.

Section 62 – General duties

- 666. This section provides for Monitor's principal overarching duty and certain other general duties. Monitor's main duty is to exercise its functions so as to protect and promote the interests of people who use health care services, by promoting the provision of health care services that are economic, efficient and effective and which maintain or improve the quality of services. It is intended that in 'protecting' interests Monitor will act to ensure that the interests of people who use health services are not diminished; whilst 'promote' is intended to mean furthering their interests. *Subsection (2)* provides that Monitor, in carrying out this duty, must consider the likely future demand for health services. These general duties will apply to the exercise of all of Monitor's functions, including those functions it will continue to exercise under the NHS Act.
- 667. Subsection (3) provides that Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of NHS health care services, where such behaviour is against the interests of NHS patients. For example, if providers colluded to fix prices or to restrict the range of services available to commissioners (eg. to restrict provision of care in patients' homes rather than in a clinic or hospital setting), against the interests of patients, then such behaviour may be anti-competitive.
- 668. Subsections (4) to (6) concern the integration of NHS healthcare services, and between health and social care services. Subsections (4) and (5) require Monitor to exercise its functions with a view to enabling the integration of health care services or the integration of health care services with other health-related services or social care services, provided it considers certain conditions are met. These are that the integration of services would:
 - improve the outcomes from or other aspects of the quality of services,
 - improve the efficiency with which they are provided,
 - reduce inequalities in access to services,
 - reduce inequalities between patients in the outcomes services achieved.
- 669. An example of a health-related service in this context could be a pharmaceutical service.
- 670. Subsection (6) should ensure that, in enabling the integration of services, Monitor works effectively with, and where appropriate takes its lead from, commissioners. The subsection requires Monitor, when enabling the integration of services, to have regard to the duties on the NHS Commissioning Board and on commissioners to promote the integration of services.
- 671. Subsection (7) requires Monitor to make proper provision for the involvement of patients and the wider public in its work. It would be for Monitor to decide what arrangements for patient and public involvement would be appropriate to particular aspects of its work and how to secure that involvement. The subsection excludes decisions that Monitor makes in individual cases (such as whether or not to award a licence to a particular provider). There is specific provision elsewhere in the Act for Monitor to consult particular organisations and people when exercising certain functions, for example under section 118 (consultation on proposals for the national tariff).
- 672. *Subsection (8)* requires Monitor, as appropriate, to secure professional clinical and public health advice to help it to discharge its functions effectively. It would be for Monitor to decide what clinical and public health advice would be appropriate to particular aspects of its work and how to secure that advice.
- 673. The Secretary of State has a duty under section 1(1) of the NHS Act to promote a comprehensive health service, and *subsection* (9) requires Monitor to exercise its functions in a manner consistent with the Secretary of State's performance of that duty.

674. Subsection (10) is intended to ensure that Monitor does not, exercise its function for the purpose of causing any variation in the proportion of NHS health care services that are delivered by a particular description of provider, where that description is by reference to whether the provider is public or private sector or some other aspect of their status. The Act provides for similar duties on the Secretary of State and the NHS Commissioning Board.

Section 63 – Secretary of State's guidance on duty under section 62(9)

- 675. This section provides the Secretary of State a power to publish guidance for the purposes of assisting Monitor to comply with its duty under section 62(9) to exercise its functions in a manner consistent with the Secretary of State's duty to promote a comprehensive health service in England.
- 676. Subsection (1) provides that the guidance would address
 - a) the objectives specified in the mandate published under section 13A of the NHS Act which the Secretary of State considers to be relevant to Monitor's exercise of its functions, and
 - b) the Secretary of State's reasons for considering those objectives to be relevant to Monitor's exercise of its functions.
- 677. *Subsection (2)* requires that in exercising its functions, Monitor must have regard to any such guidance.
- 678. *Subsection (3)* provides that where the Secretary of State publishes guidance under subsection (1), the Secretary of State must lay a copy of the published guidance before Parliament.

Section 64 - General duties: supplementary

679. This section makes provision that applies to Part 3 including several definitions. In particular, it provides in *subsection* (6) that Monitor's duties relate only to the supply of services, not goods supplied to services providers. However, Monitor's duties would apply where the goods supplied are an integral part of healthcare services provided. This means, for example, that Monitor's duties extend to the supply to the NHS of the entirety of a hip replacement service, including the replacement joint and necessary drugs. However, the duties would not cover the supply of the joints and drugs from the manufacturers to the supplier of the hip replacement service, which would be commercial matters.

Section 65 - Power to give Monitor functions relating to adult social care services

680. This section allows the Secretary of State to make regulations enabling or requiring Monitor to exercise certain specified functions in relation to adult social care in England.

Section 66 - Matters to have regard to in exercise of functions

- 681. This section provides a list of the considerations to which Monitor must have regard when carrying out its functions.
- 682. Subsection (1) provides that the need to maintain the safety of people who use health care services would be paramount amongst the matters that Monitor must have regard to in carrying out its functions.
- 683. Subsection (2)(a) concerns the need for continuous improvement in quality and efficiency in NHS services. The inclusion of continuous improvement in the quality of NHS healthcare services is to ensure that Monitor's actions must not impede the

Secretary of State, NHS Commissioning Board and CCGs in carrying out their duties with a view to improving quality.

- 684. Subsection (2)(b) to (d) concerns the need for commissioners to ensure fair access to services based on clinical need and make best use of resources in doing so. These provisions are intended to ensure that Monitor acts in concert with commissioners and does not impede them in the exercise of their duties.
- 685. Subsection (2)(e) concerns the desirability for providers of NHS health care services to cooperate with one another to improve the quality of such services. It complements the provision in subsections (4) to (6) of section 62 which place a duty on Monitor to act with a view to enabling integration. Subsection (2)(e) will be relevant in situations where services are integrated and, more generally, to ensure quality of care across organisational boundaries, for example, through appropriate sharing of information. For example, providers would need to cooperate to ensure that patients who are discharged from hospital to other care settings, including domiciliary care, experience a smooth transition and that appropriate information is shared across organisational boundaries to enable continuity and quality of care. Subsection (2)(e) is intended to ensure that in exercising its functions, Monitor has regard to the need for such cooperation.
- 686. Subsections (2)(f) and (g) require Monitor to have regard to the need to promote research into matters relevant to the NHS and to the need for high standards of education and training for healthcare professionals, in carrying out its functions.
- 687. Subsection (2)(h) provides that Monitor must have regard to any guidance the Secretary of State publishes on the parts of the document published for the purpose of section 13E of the NHS Act (improvement of quality of services) which the Secretary of State considers to be particularly relevant to the exercise of Monitor's functions. This may include, for example, guidance on national metrics for quality of care and health outcomes,

Section 67 - Conflicts between functions

- 688. This section places requirements on Monitor when it considers that conflicts arise between its general duties under sections 62 and 66. The requirements include resolving any such conflict in the manner Monitor considers best, and publishing statements of conflicts that have arisen that are of particular significance, how they have been resolved and the reasons for resolving them in the manner chosen. The guiding principle for Monitor in resolving any such conflicts would be its overarching duty to 'protect and promote patients' interests by promoting healthcare services which (a) is economic, efficient and effective, and (b) maintains or improves the quality of the services.
- 689. Subsection (2) requires that Monitor must carry out its functions so that there is not, and could not reasonably be regarded as being, any conflict between: (a) its exercise of the functions it has under the NHS Act and paragraph 17 of Schedule 8 to this Act, and its transitional functions under sections 111 and 113 of this Act, and (b) its exercise of any of its other functions.
- 690. Subsection (3) provides that Monitor must ignore any consideration of its transitional functions under sections 111 and 113 when exercising its competition functions, under Chapter 2, or its pricing functions under Chapter 4. For example, Monitor would need to establish "chinese walls" within its organisation so that any information relating to the exercise of its functions under sections 111 and 113 in individual cases could not influence the exercise of its competition and pricing functions .
- 691. Subsections (4) and (5) create additional requirements for Monitor to act transparently by publishing a statement on how it has resolved any conflict between its general duties that may arise in a particular case. Such a statement must set out: the nature of the conflict; the manner in which Monitor decided to resolve it; and, its reasons for deciding to resolve it in that manner. The cases to which these further requirements apply are

ones, which either: involve a major change to Monitor's activities, including a major change to standard licence conditions under section 94; or are likely to have a significant impact upon persons who provide, or persons who use, NHS services, or the upon the general public in England (or a particular part of England); or, which, Monitor considers are otherwise of unusual importance.

692. Every year, Monitor must include in its annual report a statement setting out the arrangements it has made to avoid conflicts arising in the exercise of its functions, under subsection (2), and a summary of how it has resolved any conflicts arising in particular cases under subsection (5).

Section 68 - Duty to review regulatory burdens

- 693. This section 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 only imposes regulation that is necessary and proportionate, and that this is reviewed over time. This means that where developments over time render a particular regulatory burden no longer necessary then Monitor should remove that burden.
- 694. The remainder of this section stipulates that Monitor is required to publish a statement, reporting upon its duty to review regulatory burdens over the previous year and setting out its plans for the following year. Monitor is then required to have regard to its statement when carrying out its functions. Monitor would be able to revise the statement, but must publish revisions as soon as practicable.

Section 69 - Duty to carry out impact assessments

- 695. This section requires Monitor to carry out and publish an impact assessment, or publish reasons for not carrying out such an assessment, before taking certain actions. Where Monitor carries out an impact assessment, it must allow representations on the proposal. The requirements apply in relation to anything Monitor intends to do that is likely to have a significant impact on patients, providers or the public, or involve either a major change in the activities Monitor undertakes or a major changes in the standard conditions for holding a licence. The section does not apply to the exercise by Monitor of its functions under Chapter 2 (competition), including when carrying out individual investigations.
- 696. Subsections (5) and (6) provide for what the impact assessment must contain and the form it should take. An impact assessment must set out how a particular action was intended to fulfil Monitor's general duties, including what the particular action was intended to achieve and explain why. Where relevant an impact assessment would need to explain why Monitor could not secure the desired outcome by exercising its powers under the Competition Act 1998 or the Enterprise Act 2002. Monitor may decide what else the assessment should include, taking account of general guidance on impact assessments as appropriate.
- 697. Subsections (7) and (8) provide for consultation on impact assessments. The impact assessment must specify a consultation period of not less than 28 days. Monitor cannot implement the proposed action until the consultation period has ended. Subsection (9) also makes it clear that the duty to consult under this section is in addition to any other obligations Monitor has to consult about a particular issue although the consultations may take place at the same time.
- 698. *Subsection (10)* stipulates the way in which Monitor would be required to report upon the assessments it had carried out in each financial year.

Section 70 - Information

699. This section stipulates that Monitor may use any of the information it collects from providers to support any of its regulatory functions. It must supply any information to the Secretary of State as requested for the exercise by him of a function under this Part.

Section 71 – Failure to perform functions

- 700. This section gives power to the Secretary of State to direct Monitor as to the performance of its functions, when he considers that Monitor is failing, or has failed, to perform its functions properly, or at all, and that the failure is significant. Failure to perform a function properly will include failure to perform that function consistently with what the Secretary of State considers to be in the interests of the health service (subsection (6)(b)). It is intended that this power would only be used in exceptional circumstances. Similar powers of intervention are included in the Act for other non-Departmental bodies including the Care Quality Commission and the NHS Commissioning Board. The Secretary of State can direct Monitor to perform those functions. When exercising that power, the Secretary of State must publish the reasons for doing so. However, the Secretary of State may not, under subsection (2), intervene with regard to Monitor's performance of its functions in individual cases. Where Monitor fails to comply with such a direction, the Secretary of State may carry out the functions in question, or make arrangements for some other person to perform them on the Secretary of State's behalf.
- 701. This section does not apply to Monitor's functions under sections 72 and 73. This means that the Secretary of State cannot intervene to perform concurrent functions under the Competition Act 1998 or the Enterprise Act 2002, including undertaking investigations or enforcement action in individual cases.

Chapter 2 – Competition

- 702. This Chapter provides Monitor with powers to protect and promote patients' interests, by preventing anti-competitive behaviour, by providers, that would harm patients interests'; and by enforcing requirements imposed on commissioners of NHS health care services under regulations made under section 75. Nothing in this Chapter provides power for Monitor to promote competition as an end in itself.
- 703. To enable Monitor to tackle abuses and restrictions that act against patient interests, these sections give it concurrent powers with the Office of Fair Trading ('the OFT') under the Competition Act 1998 ('the 1998 Act'). This could be used, for example, to allow Monitor to investigate practices by undertakings that might restrict, distort or prevent 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 to refer features of markets for further investigation by the Competition Commission.
- 704. This Chapter also makes provision about mergers involving NHS foundation trusts and co-operation between Monitor and the OFT.

Section 72 - Functions under the Competition Act 1998

- 705. This section provides Monitor with concurrent functions with the OFT under Part 1 of the 1998 Act in relation to the provision of health care services in England.
- 706. 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 may prohibit organisations from reaching agreements to limit patient choice or apportioning healthcare markets, except where an exemption or exclusion applies. However, it permits beneficial co-operation, for example where the benefits to patients outweigh any disadvantages, in the form of

agreements which contribute to improving the production or distribution of goods and services or promoting technical or economic progress, while allowing consumers (i.e. patients) a fair share of the resulting benefit, and which do not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; and (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

- 707. Chapter 2 of Part 1 of the 1998 Act prohibits undertakings from abusing a dominant position in a market. For example, it prohibits organisations with a dominant position from: imposing unfair trading conditions; limiting production, markets or technical development to the prejudice of consumers (i.e. patients); applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or making the conclusion of contracts subject to supplementary obligations unrelated to the contract.
- 708. Since 2004 the UK has been required to apply EU competition law when applying national competition law. The prohibitions under Chapter 1 and Chapter 2 of the 1998 Act 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 prohibit abuse of a dominant position.
- 709. The 1998 Act is generally applied and enforced by the OFT. The OFT is currently responsible for applying and enforcing the Act in relation to health care services.
- 710. Under the Act, Monitor has concurrent powers with the OFT to conduct investigations where it has reasonable grounds for suspecting that the prohibitions under either UK or EU law have been infringed in the provision of health care services in England.
- 711. Using the concurrent powers, Monitor can also provide remedies for breaches of the prohibitions. It can issue directions to undertakings to bring an infringement to an end and issue fines. For example, Monitor might direct an undertaking to change its conduct, such as ceasing an arrangement that restricted the ability of commissioners to redesign components of services and thereby restricted competition to the detriment of patients and taxpayers. Any revenue from fines would be paid into the consolidated fund.
- 712. There are some functions of the OFT under the 1998 Act which Monitor does not share. For example, 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. Monitor cannot exercise these functions, 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. This arrangement is designed to secure consistent application of that Act. However, Monitor is still required to issue advice and information about the application and enforcement of the 1998 Act in relation to health care services.

Section 73 - Functions under Part 4 of the Enterprise Act 2002

- 713. This section 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 enable Monitor to make market investigation references (see below) to the Competition Commission.
- 714. Monitor can make a market investigation reference 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 are barriers to entry which require more detailed investigation.
- 715. After receiving a market investigation reference the Competition Commission must investigate and publish a report within two years. If it decides that there is an adverse effect on competition and resulting detrimental effects on consumers (i.e. patients), it also decides whether any action should be taken to remedy this.

- 716. Subsection (4) contains provision requiring Monitor and the OFT to consult each other before exercising their concurrent functions under the 2002 Act for the first time. Subsection (5) is 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.
- 717. This section also applies section 117 of the 2002 Act so that Monitor is included (insofar as this is relevant to its functions under this section), in the list of persons and bodies 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.
- 718. There are some functions under Part 4 of the 2002 Act which Monitor does not share. Specifically section 166, which requires the OFT to keep a register of undertakings, and section 171, which 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.

Section 74 - Competition functions: supplementary

- 719. This section makes a number of supplementary provisions relating to Monitor's competition functions.
- 720. *Subsection (1)* states that the concurrent nature of Monitor's powers means that there can be no valid objection that its actions under these powers should have been carried out by the OFT.
- 721. 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 duties and matters to which Monitor must have regard in exercising its functions. Subsection (2) provides that those duties and matters do not apply where Monitor is carrying out its concurrent competition functions under Chapter 2, unless they are matters to which the OFT can also have regard. For example, whilst Monitor and the OFT may both have regard to patients' interests in relation to the provision of healthcare services for the purposes of the NHS, the OFT would not always have regard to considerations relating to promoting research into matters relevant to the NHS. This provision is to avoid inconsistency in the application of competition law, depending on which regulator is exercising the function in a particular instance.
- 722. 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, where the director's organisation had committed a breach of competition law. 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.
- 723. The OFT already has the power to apply to a court to disqualify directors in the health care sector and other industries where there has been a breach of the 1998 Act.
- 724. *Subsections (5) to (7)* amend the 1998 Act and the 2002 Act to include Monitor in provisions of those Acts which are relevant to Monitor's concurrent powers.

Section 75 – Requirements as to procurement, patient choice and competition

725. This section enables the Secretary of State to make regulations imposing requirements on the NHS Commissioning Board and CCGs in order to ensure good practice in relation to procurement, to ensure the protection and promotion of patients' rights to make choices regarding their NHS treatment and to prevent anti-competitive behaviour by commissioners with regard to health care services. This may include requirements on the use of competitive tendering by commissioners and on securing services without competition (in which case the requirements which would apply would depend on the

decision by the commissioner as to which approach would be in patients' best interests). The regulations could also include requirements to manage potential conflicts between the interests involved in commissioning services and the interests involved in providing them (*subsection* (3)). 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 only capture contracts that are primarily for services rather than goods.

726. *Subsection* (4) allows for regulations to provide for exemptions in relation to particular arrangements.

Section 76 – Requirements under section 75: investigations, declarations and directions

- 727. This section makes provision for what may be included in regulations made under the previous section about Monitor's powers to investigate and remedy breaches of the regulations. Monitor could be given the power to investigate a breach of any of the requirements in the regulations following a complaint by an interested party and to initiate an investigation where it has reasonable grounds to suspect that there has been a breach of the requirements in the regulations not to engage in anticompetitive behaviour. It could also be given powers to require commissioners to provide information and explanations of that information during an investigation.
- 728. Subsections (3) to (5) make provision for the regulations to confer on Monitor powers to declare, in specified circumstances, that an arrangement for the provision of services is ineffective (that is, to declare a contract void). Subsection (4) provides that those powers are only be exercisable in circumstances where there has been a sufficiently serious breach of the regulations. Where Monitor deems a particular arrangement for service provision to be ineffective, it would be void, but this would not affect any right acquired or liability incurred under the existing arrangements for service provision.
- 729. Subsection (6) provides that regulations may give Monitor a further power to direct the NHS Commissioning Board or a CCG to take action to address a breach of the regulations. This could include requiring the commissioner to take steps to prevent or mitigate failures, to comply with the regulations or to remedy any such breach, to modify a tendering process or vary an arrangement for the provision of services which was made as a result of a tendering process, or not to exercise such functions in such a manner as may be prescribed in the regulations.
- 730. 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.
- 731. There may be circumstances in which it is possible for a person to bring an action under both the regulations made under the previous section 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 section in relation to the same matter.

Section 77 – Requirements under section 75: undertakings

732. This section allows regulations under section 75 to confer on Monitor a power to accept undertakings ('section 77 undertakings') in lieu of issuing a direction or declaring an arrangement ineffective under section 76. This enables commissioners who are in breach of the regulations to offer undertakings that would address the breach. The undertakings could be to take any of the actions described in paragraphs (a) to (e) of subsection (6) of section 76 or any other actions specified in the regulations.

- 733. Where Monitor accepts an undertaking, *subsection (3)* requires it to cease any investigation and any actions it was taking to bring about an end to the breach, unless the commissioner in question failed to comply with the undertaking. Where a commissioner has partly complied with an undertaking Monitor is required to take this into account when determining further action.
- 734. This section also gives effect to Schedule 9.

Schedule 9 – Requirements under section 75: undertakings

- 735. This Schedule provides further detail about the process for entering into section 77 undertakings. Monitor must consult people it considers appropriate on its procedure for entering into section 77 undertakings and must publish this. Monitor must also publish any section 77 undertakings that it accepts, removing any commercial information that would harm business interests and information relating to a person's private affairs which might affect that person's personal interests. An undertaking can be varied by mutual agreement.
- 736. Monitor may determine that an undertaking has been complied with and issue a certificate of compliance accordingly. The person that has given the undertaking can also apply for a certificate of compliance, in such a form and manner as prescribed by Monitor, at any time, and Monitor must respond to such an application within 14 days.
- 737. Monitor may refuse to issue a certificate of compliance. A person whose application has been refused can complain to the First-tier Tribunal on the grounds that the decision is based on an error of fact, that it is wrong in law or that it is unfair or unreasonable. The First-tier Tribunal can confirm Monitor's decision or can direct that it does not have effect.
- 738. Where Monitor thinks that false or misleading information has been supplied, it can treat that as a failure to comply with the undertaking. If it treats it as a failure to comply, it must revoke any compliance certificate given to the person in question.

Section 78 - Guidance

739. This section requires Monitor to issue guidance on compliance with the regulations made under section 75 and on how Monitor intends to enforce those regulations. Monitor must consult the NHS Commissioning Board and others that it deems appropriate before publishing the guidance. It must also obtain the approval of the Secretary of State before publishing the first version of the guidance. When making subsequent revisions of its guidance it must consult with the NHS Commissioning Board and others that Monitor deems appropriate before publication . This and other requirements in the Act to publish guidance do not affect Monitor's ability to publish guidance on any other matter relating to any of its duties or functions.

Section 79 - Mergers involving NHS foundation trusts

740. This section applies Part 3 of the 2002 Act, which sets out the general merger control regime for enterprises in the UK, to NHS foundation trusts where it would otherwise be uncertain as to whether those provisions would apply to them. This section is intended to avoid legal uncertainty as to when the merger control regime in Part 3 of the 2002 Act would apply to mergers involving NHS foundation trusts. This provision allows for a single regime for merger control, which avoids duplication of the roles of Monitor and the OFT and eliminates risk of double-jeopardy. The OFT must notify Monitor of a merger situation involving one or more Foundation Trusts Monitor in turn must advise the OFT on the likely costs and benefits to patients which would arise. The OFT is obliged to consider the advice from Monitor as part of their general public law duties.

Section 80 - Co-operation with the Office of Fair Trading

741. This section requires Monitor and the OFT to co-operate in exercising their concurrent functions under the 1998 Act and the 2002 Act. In particular, they must 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 – Licensing

- 742. This Chapter establishes a licensing regime for providers of health care services for the purposes of the NHS and provide Monitor with the necessary powers to run the regime. The regime gives Monitor the means to perform its main duty and carry out its functions; for example, it will provide a means for Monitor to collect information needed to set prices.
- 743. The Act gives Monitor powers to determine the licence criteria and conditions and gives it enforcement powers that enable it to ensure that providers comply with the requirements of their licences.
- 744. 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.
- 745. Monitor and the Care Quality Commission are required to co-operate and share information and they are required to establish a joint licensing/registration process.

Licensing requirement

Section 81 - Requirement for health service providers to be licensed

- 746. *Subsection (1)* stipulates that providers of health care services for the purposes of the NHS must hold a licence issued by Monitor. This does not include services provided for the purposes of the public health service.
- 747. Subsection (2) covers situations in which two or more legal persons are involved, in different capacities, in providing a service (eg. a prime contractor and subcontractor). It provides that, in this situation, regulations may set out who will be treated as the service provider for the purposes of the licensing regime. It is intended that this will be the person responsible for ensuring the service complies with the licensing requirements laid out in this (and any other relevant) legislation (eg. the prime contractor). This provision 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.

Section 82 - Deemed breach of requirement to be licensed

748. This section provides that a licence holder is deemed to be in breach of the requirement to hold a licence if the organisation is required to register with the Care Quality Commission, but has not done so. The intention is that only providers who have complied with a requirement to register with the Care Quality Commission should be able to hold a licence.

Section 83 - Exemption regulations

- 749. This section provides the power for the Secretary of State to make regulations exempting providers of NHS services from the requirement to hold a licence. The regulations would be subject to the negative resolution procedure in both Houses of Parliament.
- 750. Individuals, groups of providers, or providers of certain types of health care services could be exempted. Exemptions could be time-limited, and/or conditional. Subsection

(3) gives examples of the sorts of conditions that could attach to an exemption. For example, a person granted an exemption may be required to comply with any direction given by Monitor about a matter specified in the exemption.

- 751. The intention is that exemptions will be used to focus licensing on appropriate parts of the health care sector those where regulation of competition and pricing, or action to support continuity of services is most likely to have a strong positive impact. It is, for example, likely that the licensing regime would cover providers of accident and emergency services and secure mental health services. Exemptions might apply to, for example, smaller providers of family health services such as dentists, optometrists or primary medical care practices.
- 752. Subsections (4) to (7) provide for publication of the Secretary of State's intention to make exemption regulations and for representations to be made. The Secretary of State would have to give specific notice to Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England (provided for in Chapter 1 of Part 5), as well as publishing more widely the proposal to make regulations, the effect of the regulations and the reasons for them. There must be a minimum period of 28 days, during which representations could be made, before the Secretary of State can make the regulations.
- 753. *Subsection* (8) provides that persons granted an exemption must be given notice of it. The Secretary of State must also publish exemptions granted.

Section 84 - Exemption regulations: supplementary

- 754. This section provides a mechanism for the Secretary of State to revoke or withdraw licensing exemptions. *Subsection (1)* provides that the exemption regulations themselves could be revoked in relation to an exemption granted to an individual provider, or amended in relation to regulations granting individual exemptions to more than one provider to enable any of the exemptions to be withdrawn. The Secretary of State can revoke or withdraw an exemption at the request of the provider, in accordance with the relevant exemption regulations themselves (for example if they provided for a conditional exemption), or if the Secretary of State considers it inappropriate for the exemption to continue.
- 755. *Subsection (2)* provides that exemption regulations granting an exemption to a group of providers could be revoked. Exemption regulations granting exemptions to more than one group of providers could also be amended to withdraw any of the exemptions. An exemption could be revoked or withdrawn either in accordance with the relevant exemption regulations themselves, or if the Secretary of State considers it inappropriate for the exemption to continue.
- 756. Under *subsection* (3), the Secretary of State may by direction, withdraw an exemption for a particular provider within a group, whilst the exemption remained in place for the rest of that group. This may be done in accordance with the relevant exemption regulations, if the Secretary of State considered it inappropriate for the exemption to continue, or at the request of an individual provider.
- 757. When the exemption revocation or withdrawal is not at an individual provider's request, the Secretary of State must consult Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England about the proposed withdrawal. If the exemption applies to an individual provider or providers within a group or type of providers that would remain exempt, the Secretary of State must also give notice to the provider(s) from whom he proposes to remove the exemption. If the exemption applied to a group or type of provider the notice of the proposal to remove the exemption must be published. The notice must state the Secretary of State's proposal and reasons for it, and specify a minimum 28-day period during which representations can be made.

Licensing procedure

758. These sections provide for the procedure for applying for a licence, and for Monitor granting, refusing or revoking a licence.

Section 85 - Application for licence

759. This section states that providers seeking a licence must apply to Monitor, who may require supporting information from them and specify the form in which applications may be made.

Section 86 - Licensing criteria

760. This section requires Monitor to set and publish the criteria that a provider must meet in order to be granted a licence. *Subsection (2)* provides that Monitor may revise the criteria and must publish any revised version. This is intended to enable Monitor to adapt the licence criteria as the health care market develops. *Subsection (3)* requires that these criteria, and any subsequent revisions, be approved by the Secretary of State by order. Later provisions require that the first such order must be subject to the affirmative procedure. The additional requirement for the Secretary of State's approval of the criteria for granting licences is to provide a check on their appropriateness.

761. Section 87 - Grant or refusal of licence

- 762. This section stipulates the process once an application for a licence has been made to Monitor. Where Monitor is satisfied that the provider has met the published criteria, it must approve the provider's application and, in accordance with *subsection (3)*, issue the licence to the applicant. If Monitor is not satisfied that the applicant meets the criteria, it must refuse the application.
- 763. Subsection (4) provides that licences are subject to both standard licence conditions and any special licence conditions. Further details about these types of conditions are in later sections. Subsection (4) also provides that licences granted to foundation trusts are subject to any licence conditions imposed under section 111 (imposition of licence conditions on NHS foundation trusts during the transitional period).

Section 88 - Application and grant: NHS foundation trusts

764. This section provides that Monitor must treat an NHS foundation trust in existence at commencement of this section, or an NHS trust which becomes a foundation trust at a later date, as having made an application and met the criteria for a licence. As a result of this, the foundation trusts will not have to make a licence application. Foundation trusts will however still be regarded as applicants for the purpose of the power to include special conditions in an applicant's licence under section 95. Organisations have to go through a robust authorisation process in order to gain foundation trust status under Chapter 5 of Part 2 of the NHS Act. The automatic granting of licences to foundation trusts will limit the regulatory burden on them.

Section 89 - Revocation of licence

- 765. This section 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.
- 766. It is intended that Monitor will not automatically revoke the licence of a provider at their request where the continuity of services they are providing is required. In this way, providers of such services will not be able to avoid their obligations to provide such services simply by requesting revocation of their licence.

767. It is also intended that before revoking a licence for failure to comply with a condition of it, Monitor will first consider whether it could address the situation using its licence enforcement powers.

Sections 90, 91, 92 - Representations, notice and appeals

- 768. The first of these sections 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 must also specify the period within which the provider may make written representations to Monitor, allowing them the opportunity to make a case against Monitor's proposal if they wish to. This period must be at least 28 days.
- 769. The next section specifies that once Monitor reaches a decision to either refuse or revoke a licence, it must notify the relevant provider of its decision and explain the right of appeal. The section also stipulates when Monitor's decision to revoke a licence becomes final. This is (a) if an appeal is brought, when the appeal is concluded or abandoned; (b) when the provider declares its intention not to appeal; or (c) the day after the day that the period for bringing an appeal ended.
- 770. The last of these sections provides for 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 main appeals Tribunal in the UK, run by the Tribunals Service and established by Parliament under the Tribunals, Courts and Enforcement Act 2007. It is also used for Care Quality Commission registration appeals and for other appeals relating to care standards and mental health issues. It is also used for appeals against decisions by other regulators, including the Office of Fair Trading and the Environment Agency.
- 771. Subsection (2) specifies the possible grounds for appeal as an error of fact a mistake in law or unreasonableness. The Tribunal may either confirm Monitor's decision, direct that Monitor's decision is not to have effect, or send the case back to Monitor for reconsideration.

Section 93 - Register of licence holders

- 772. This section requires Monitor to keep and publish a register of licence holders. The register must contain such information as Monitor thinks necessary to keep the public informed about licence holders, including details of every licence granted or revoked. The information must 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. *Subsection (5)* therefore provides for regulations setting out what information should not be accessible. *Subsection (6)* provides Monitor with power to charge a fee for providing a copy or extract of the register.
- 773. This section makes very similar provision to that for the register kept by the Care Quality Commission (see section 38 of the Health and Social Care Act 2008).

Licence conditions

774. These sections make provision in relation to the two types of licence conditions that Monitor may set. Standard conditions will apply to all providers, or to all providers of a certain type (based on their nature, the services they provide, or the areas where they provide the services). Special conditions set individual requirements for individual providers. Creating different types of conditions gives potential providers some certainty over what a licence will entail (standard conditions), whilst enabling Monitor to tailor licences as appropriate (special conditions).

Section 94 - Standard conditions

- 775. This section 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 needs to set prices effectively.
- 776. Before determining the first set of standard conditions, Monitor must publish its draft standard conditions and consult the persons listed in *subsection* (8).
- 777. 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 geographical area in which services are provided. Monitor could use this power to set additional licence conditions to apply to certain providers to ensure the continuity of certain services provided by them. For example, Monitor may set particular requirements on foundation trusts to ensure they are well governed, consistent with foundation trusts' duty to exercise their functions effectively, efficiently and economically, as necessary conditions of their continued ability to provide NHS services (see section 164). The intention is to enable Monitor to differentiate standard licence conditions, where necessary, to protect and promote patients' interests and to reflect particular statutory requirements as they may apply to foundation trusts and other types of healthcare provider. In addition, by differentiating standard licence conditions appropriately, Monitor may seek to achieve a fair playing field for providers.
- 778. Subsections (4) to (6) impose constraints on Monitor's ability to set different licence conditions relating to the nature of the provider. Subsection (5) allows for different standard licence conditions to be imposed in relation to governance to take account of differences in the status of different licence holders. Subsection (6) allows for different standard licence conditions to be imposed so as to achieve an equivalent regulatory burden on providers as a result of the licence, for example, where different standard licence conditions are appropriate to take account of differences in the burdens to which different types of provider are subject.
- 779. 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.

Section 95 - Special conditions

- 780. The power to include special licence conditions under *subsection (1)* is designed to address issues specific to particular licence holders, in situations where it would be problematic to define a description of relevant licences and applicable conditions, and hence to use standard licence conditions alone. For example, Monitor could use this provision to set licence conditions for a provider to secure continuity of NHS services in particular circumstances that Monitor considered were not captured within the standard licence conditions. Also by way of example, Monitor may set special licence conditions for a foundation trust (or other provider) which it considered were necessary in response to risks it identified; or to set special conditions prospectively so that those conditions would come into effect when interventions to secure the continuity of those services were required.
- 781. Monitor is able to include a special condition (or modify an existing one) if the applicant or licence holder consents. If that party does not agree and Monitor still wants the special condition or modification to be included in the licence, it may under section 101, make a reference to the Competition Commission, which will then investigate the appropriateness of including the special condition or making the modification.
- 782. Before including a special condition, or modifying one, Monitor must to comply with the notice requirements in *subsections (2) to (5)*.

Section 96 - Limits on Monitor's functions to set or modify licence conditions

- 783. This section specifies the purposes for which Monitor can set or modify licence conditions. Monitor would only be able to set licence conditions for the purposes specified in *subsection (2)*. For example, Monitor may use its licensing powers to support commissioners in securing continuity of services or to enable integration of services and co-operation between providers.
- 784. *Subsection (4)* provides that Monitor must not exercise its powers to set or modify conditions so as to unfairly advantage or disadvantage providers as a result of their having a particular status, including whether they are in the public or private sector.

Section 97 - Conditions: supplementary

- 785. Subsection (1) provides, by way of example, a non-exhaustive list of conditions that Monitor might include in licences. These include a requirement for licence holders to pay Monitor such fees as Monitor may determine in respect of the exercise of its licensing functions; a requirement that providers charge for services in accordance with the national tariff (see Chapter 4); and the conditions for securing the continued provision of NHS services. 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.
- 786. Subsection (3) specifies that Monitor must not use the powers it has under subsection (1)
 (c) to direct a licence holder to give access to its facilities to another provider.
- 787. Subsection (4)(a) provides that Monitor can require NHS foundation trusts and bodies which were former NHS trusts to notify the Office of Fair Trading if they intend to enter into a merger situation, being arrangements or transactions which would result in the trust's, or another business's, activities ceasing to be distinct. This provision is to ensure that the Office of Fair Trading has notice of mergers involving NHS foundation trusts, or former NHS trusts. Subsection (4)(b) specifies that this requirement no longer applies after five years from the date on which the condition was included in the licence.

Section 98 – Conditions relating to the continuation of the provision of services etc.

- 788. This section makes further provision about Monitor's licensing powers to support commissioners in securing continuity of health care services for the purposes of the NHS. *Subsection (1)* provides that Monitor may, in particular (but not by way of limitation), set conditions under section 97(1)(i)(i) requiring a licence holder: to provide information to commissioners and other persons as directed by Monitor; to allow Monitor to enter and inspect its premises; and to co-operate with persons appointed by Monitor to assist in the management of the licence holder's affairs, business and property. *Subsection (2)* requires commissioners to also co-operate with any such persons appointed by Monitor. Monitor may set such other licence conditions for the terms of its licence as Monitor considers appropriate, subject to sections 94-96. This may include, for example, requirements relating to liquidity and, where appropriate, actions to ensure the provision of services is effective, efficient and economic in the long term.
- 789. Monitor could take a number of measures under licence conditions set under section 97(1)(i)(i) to protect the continuity of NHS services in the case of a provider in financial difficulties (in "distress"). For example, Monitor could direct a provider in distress to appoint a "turnaround team", or require a provider to provide information and access to their records and premises to a continuity of service planning team appointed by Monitor. The aim of such measures would be, wherever possible, to return the provider to normal operation as soon as possible and ensure the continuity of services which required protection.

- 790. Subsection (3) requires Monitor to carry out an on-going assessment of the risks to the continued provision of services to which a licence condition under section 97(1)(i), (j) or (k) applies. This enables Monitor to intervene early to assist providers to reduce any unacceptable risk.
- 791. Subsection (4) requires Monitor to publish guidance for licence holders on the requirements placed on them via licence conditions under section 97(1)(i), (j) or (k) for ensuring the continuity of services. Monitor must also publish guidance for commissioners of services subject to such conditions on the exercise of their functions in connection with the licence holders who provide those services. This could include guidance on their role in the turnaround of licence holders in distress, or in taking steps to plan for possible unsustainability of a licence holder. Before publishing such guidance (whether initially or as revised), Monitor must obtain the approval of the NHS Commissioning Board and the Secretary of State. Subsection (5) requires commissioners of services which are subject to continuity of service conditions to have regard to such guidance.

Section 99 – Notification of commissioners where continuity of services is at risk

792. This section provides for action to be taken by Monitor as part of its ongoing assessment of risk to the continuity of NHS health care services. It obliges Monitor to notify the NHS Commissioning Board and CCGs where it identifies significant risks to the provision of services and is satisfied that this is attributable to the way in which services are configured. *Subsection (5)* requires the Board and CCGs to have regard to such notifications when arranging for the continued provision of NHS health care services. It would be for commissioners to decide how best to respond to notifications under this section and section 126.

Section 100 - Modification of standard conditions

- 793. This section makes provision for modification of standard licence conditions in all providers' licences or in licences of a particular description. Before making such a modification, Monitor must comply with the notice requirements set out in *subsections* (2) to (5). These require Monitor to notify its intention to modify standard licence conditions and create the opportunity for those notified about the proposed modification to make representations.
- 794. Under *subsection* (6)(a) Monitor may make the modification if it received no objections from licence holders who would be affected by the change (relevant licence holders).
- 795. Where Monitor does receive representations from relevant licence holders, it may nonetheless make the modification if the proportion of licence holders objecting were below proportions specified by the Secretary of State in regulations made under *subsection (7)*. These regulations are subject to the affirmative Parliamentary procedure. Regulations must specify two proportions for these purposes. The first is the proportion of relevant licence holders who objected, expressed as a percentage of all relevant licence holders affected (the "objection percentage"). The second proportion is the number of relevant licence holders who objected, weighted according to their share of the supply of such services as may be prescribed (the "share of supply percentage"). This process is designed to enable Monitor to change standard licence conditions, but only where providers collectively do not have substantial objections to the proposed change. Where the objection percentage and/or the share of supply percentage exceed those specified in the regulations, Monitor may only make the proposed change in accordance with section 101.
- 796. Other provisions of section 100 deal with situations where Monitor modifies the standard licence conditions. *Subsection* (10) provides that Monitor must publish the modifications. It also gives Monitor the power to make modifications to other conditions in a licence that might be required as a consequence. Thirdly, Monitor is also

required to make the same modifications to future licences, where that is appropriate. The latter two requirements are to ensure consistency across licences.

Section 101 – Modification references to the Competition Commission

- 797. Under *subsection* (2) Monitor may make a reference to the Competition Commission when the applicant or licence holder refused to accept a proposal to include, modify or omit a special licence condition. Under *subsection* (4) a reference may also be made where Monitor is unable to modify the standard licence conditions because the number of licence holders objecting to the change exceeded one or both of the proportions set out in regulations made under section 100(7).
- 798. The Competition Commission is required to investigate and report on the matters contained in the reference from Monitor. Subsections (2) and (4) set the parameters for the Commission's investigations and reports under this section. In all cases, the Commission must consider whether any of the matters specified in the reference and which relate to the provision (or potential provision in the case of special licence conditions) of healthcare services are operating, or could be expected to operate, against the public interest. The Commission could not, therefore, consider references in terms of the impact on competition as an end in itself. Where a reference is made under subsection (2) and hence follows the refusal by an applicant or licence holder to include, modify or omit a special licence condition, the Commission must also investigate and report on whether the inclusion, modification or omission of a special condition in a licence would remedy or prevent the detriment to the public interest. Where a reference is made under subsection (4) and hence following objections from licence holders to proposals for standard licence conditions, the Commission must also investigate and report on whether the inclusion, modification or omission of standard licence conditions (applicable to all or a group of providers) would remedy or prevent the detriment to the public interest. Hence, in considering references from Monitor under this section, the Competition Commission's prime concern is whether the proposed licence condition or modifications would be in the public interest.
- 799. Subsection (5) gives effect to Schedule 10, which makes provision about investigations by the Competition Commission. Paragraph 7(2) of Schedule 10 requires Monitor to make changes to licence conditions in line with reports by the Commission following these investigations.
- 800. Subsection (7) enables Monitor to make incidental or consequential changes to the other conditions in a licence, where one or more conditions in the licence is changed following a reference to the Competition Commission under this section. Monitor must also modify the conditions in licences it issued in future, so that the these conditions, as they would apply to all providers or all providers of a particular description, are the same. This provision avoids the need for Monitor to give notice and consult where it modifies standard licence conditions following a report by the Competition Commission under this section.

Schedule 10 - References by Monitor to the Competition Commission

- 801. Under paragraph 1, where Monitor makes a reference to the Competition Commission Monitor is able to change what is included in that reference by giving notice to the Commission. The Commission is obliged to accept the variation.
- 802. The intention of paragraph 2 is 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. Paragraph 3 requires Monitor to publish any reference, or variation to a reference, and to send notice of a reference or variation to relevant applicants, licence holders and CCGs and to the NHS Commissioning Board (section 101(5)(a) refers).

- 803. Paragraph 4 requires Monitor to provide relevant information and assistance to the Competition Commission and the Commission to take information supplied into account.
- 804. Under paragraph 5, a reference to the Competition Commission must specify a period – not longer than six months from the date of the reference – within which the Commission must report. The Commission's report only has effect if it is made before the expiry of the period stated in the reference or at the end of an extended period. An extended period applies where the Commission sought this from Monitor and where Monitor is content that special reasons for extending the period existed. An extension may be for no more than six months and Monitor may grant only one extension. Monitor must send notice of the extension to the relevant persons, and publish the notice.
- 805. Paragraph 6 requires the Commission, when reporting on a reference, to present definite conclusions, including details of any aspects it concludes might have negative impacts on the public interest. There must also be explanations as to how the inclusion, modification or omission of licence conditions could remedy or prevent those impacts.
- 806. This paragraph also requires that a conclusion in a report must have the agreement of at least two thirds of the group assigned to the investigation by the Competition Commission. If a member of the group disagreed with a conclusion, they may require the inclusion in the report of a statement of their disagreement and the reasons for it.
- 807. The Commission must ensure a copy of its report on a reference is sent to Monitor, who is then required to send a copy to the Secretary of State. Not less than 14 days after the Secretary of State received the copy under paragraph 6(6), Monitor is required to send a copy to applicants or licence holders affected by the conclusions in the report, the NHS Commissioning Board and CCGs likely to be affected by the matters to which the report relates. Monitor is required to publish the report within 24 hours of complying with this requirement.

Changes following report

- 808. Paragraph 7 requires Monitor to act on relevant recommendations made by the Competition Commission. Before doing so, Monitor must send a notice of the proposed changes to licence conditions to the relevant persons, explaining why it is taking such action, and publish the notice. The notice must specify a period of at least 28 days from the date of publication within which comments on the changes may be made. Once Monitor had considered the responses, it must notify the Commission, specifying the changes it proposes to make in response to the Commission's report.
- 809. There would then be a four-week period, during which the Commission may direct Monitor (under paragraph 8) not to make the changes set out in the notice, or not to make some of the changes. Insofar as the Commission does not issue such directions, Monitor is required (under paragraph 7(11)) to make the changes it has proposed in response to the Commission's report.

Competition Commission's power to veto changes

- 810. Under paragraph 8, the Competition Commission may apply to the Secretary of State asking him to direct that the four-week period for it to veto Monitor's proposed changes to licence conditions be extended by 14 days.
- 811. Where the Commission vetoes changes proposed by Monitor, it must give notice of the changes Monitor proposed and its reasons for directing Monitor not to make them. The Commission is required to make any changes to licence conditions that it considers necessary to address any adverse effects to the public interest identified in its report that it considers would not be remedied or prevented by the changes proposed by Monitor. The Commission must give Monitor and other relevant persons (section 101(5)(a)

refers) 28 days' notice of the changes it proposes to make, during which representations could be made. It must also publish the notice.

812. Once the changes had been made, the Commission must publish details of them and state why it had made them.

Disclosure

813. Paragraph 9 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, no sensitive commercial information and no information which might significantly harm an individual's interests is included.

Powers of investigation

814. Paragraph 10 provides that a number of investigative and enforcement powers under specified sections of Part 3 of the Enterprise Act 2002 apply, with specified modifications, for the purposes of references by Monitor to the Competition Commission.

Section 102 - Modification of conditions by order under other enactments

815. This section 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 to ensure that the licensing regime is consistent with measures taken under that Act, or can be modified as part of remedies imposed under that Act. The inclusion of a provision of this type is consistent with other regulatory regimes.

Section 103 – Standard condition as to transparency of certain criteria

The effect of this section is to require that Monitor must include a standard condition 816. in all licences, which requires licence holders to act transparently in the setting and application of criteria for determining patient eligibility for particular services, for accepting or rejecting referrals, or determining the manner in which services are provided to that person. This is intended to ensure that providers act transparently in determining clinically appropriate care for patients and do not discriminate on nonclinical grounds. Nothing in this section will affect a person's entitlement to a particular treatment under the NHS. This transparency requirement will only operate wherever those services are subject to patient choice of provider. This will enable Monitor to minimise the scope for providers to make extra profits by 'cherry picking'- i.e. delivering a service only in less complex cases – by requiring them to be transparent about these matters. Subsection (3) specifies that certain powers conferred on Monitor, the Secretary of State, the Office of Fair Trading, and the Competition Commission by sections 100, 101 and 102 and Schedule 10 to modify licence conditions may not be used to omit such a condition from licences.

Enforcement

817. Sections 104 to 110 provide Monitor with the necessary powers to enforce the licensing regime. Whilst the Monitor and the Care Quality Commission will work jointly in relation to the licensing procedure, the two organisations have separate enforcement responsibilities. However, they are 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.

Section 104 - Power to require documents and information

- 818. 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 (as specified in subsection (4)). This power would apply to commissioners, applicants for licences, licensees, providers of NHS services exempted from holding a licence, or providers operating without a licence when they should have one. Its purpose is to allow Monitor to obtain the information it would need 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.
- 819. Information might be needed from providers who are currently exempted from licensing if, for example, 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.

Section 105 - Discretionary requirements

- 820. 'Discretionary requirements' are obligations which Monitor may place upon a provider of NHS services if it breached a licence condition, or failed to hold a licence when it is required to; or on any person who failed to provide Monitor with information under the previous section. Discretionary requirements are intended to act as an incentive to comply and a means of rectifying any problems.
- 821. *Subsection (2)* outlines the types of discretionary requirements that Monitor may impose. They are:
 - 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 cease the breach in question, or make sure it did not continue or 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 service, the continuity of which was required, or to take action to mitigate financial risk (in breach of a condition relating to financial viability) that would threaten the continuity of such services;
 - 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 service that it had closed in breach of a licence condition.
- 822. The Secretary of State is given power by regulations to prescribe how turnover would be calculated for the purposes of the 10% limit on variable monetary penalties (subsection (4)).
- 823. *Subsection (3)* provides that Monitor must not impose discretionary requirements on a provider on more than one occasion in relation to the same breach, but Monitor may, however, take action to enforce the discretionary requirements it has imposed on a provider to remedy such a breach.
- 824. *Subsection* (5) provides that a penalty imposed under this section that is not paid in full accrues interest, but the total amount of interest charged may not exceed the amount of the penalty itself.

Section 106 - Enforcement undertakings

825. 'Enforcement undertakings' are settlements offered by a person to rectify one or more breaches for which Monitor would otherwise be able to impose a discretionary requirement. Monitor could choose whether to accept the offered settlement, based on whether it was likely to constitute an appropriate remedy. This alternative to discretionary requirements provides an incentive for providers and others to take responsibility for proposing solutions to problems, and thus to be proactive about remedying breaches.

- 826. *Subsection (3)* specifies what types of enforcement undertakings Monitor may accept:
 - action to cease the breach or to prevent the breach continuing or happening again;
 - action to restore the position to what it would have been before a breach occurred, so far as is possible;
 - action to benefit any licence holder or commissioner affected by a breach, which could be payment of money; or
 - other action as may be specified in regulations.
- 827. Once Monitor accepts an enforcement undertaking, it may only impose a discretionary requirement or revoke a licence if the licensee fails to comply with the undertaking, or any part of it (*subsection (4)*). *Subsection (5)* provides that where a provider has partially complied with an undertaking, Monitor must take the partial compliance into account when deciding whether to take further enforcement action.

Section 107 - Further provision about enforcement powers

828. This section gives effect to Schedule 11, which provides further detail about both discretionary requirements and enforcement undertakings.

Schedule 11 - Further provision about enforcement powers

Part 1 - Discretionary requirements

Procedure

- 829. The procedure for discretionary requirements follows that laid down in section 43 of the Regulatory Enforcement and Sanctions Act 2008.
- 830. Paragraph 1 requires Monitor to give notice to a person of its intention to impose a discretionary requirement on them. The notice must provide specified details, including the grounds for the proposal to impose the requirement, and the notice period within which the person could make written representations, which must be at least 28 days, except where Monitor considers a shorter period is necessary to avoid or minimise further breaches of licence conditions. In these circumstances, Monitor may shorten the notice period, but not to less than five days. A shorter period might be necessary to, for example, require a provider of services subject to continuity of service conditions who had stopped providing those services, to restore them, where continuity of those services was required.
- 831. Paragraph 2 provides that where, following expiry of the notice period, Monitor decides to impose a requirement, a second and final notice must be given to the person involved. This must include information about why the requirement is being imposed, the implications of failure to comply with the requirement, details of how any monetary penalty is to be paid and of the rights of appeal.
- 832. If Monitor wishes to impose a variable monetary penalty, it must give notice of this under paragraph 1 within five years of the breach occurring.
- 833. A person on whom Monitor imposes a discretionary requirement is able to appeal to the First-tier Tribunal (paragraph 3). During an appeal, the duty to fulfil the discretionary requirement(s) being appealed is suspended. There are 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.
- 834. Paragraph 3(4) specifies the measures the First-tier Tribunal may take following the appeal. It could confirm or withdraw the requirement in question, or vary it. Alternatively, the Tribunal has the same powers to act in relation to the breach(es) that gave rise to the appeal as Monitor has in relation to them. The third option is for the First –tier tribunal to remit the decision, or any matter relating to it, to Monitor for reconsideration.
- 835. Paragraph 4 gives Monitor specific powers to withdraw or amend discretionary requirements that it has imposed.

Non-compliance penalties

- 836. Paragraph 5 gives 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 must serve a "non-compliance notice" on the person concerned. This must 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 right of appeal.
- 837. The period for payment must not be less than 28 days from the day after the date on which the notice is 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 person does not pay the fine within the specified payment period, Monitor may increase the non-compliance penalty by no more than 50%.
- 838. The grounds on which a person served with a non-compliance penalty could appeal to the First-tier tribunal are set out in paragraph 6(2). Penalties are suspended whilst an appeal was in progress. The Tribunal may 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

839. Both variable monetary penalties and non-compliance penalties are recoverable summarily as a civil debt (paragraph 7). Monitor must pay money it received from penalties into the Consolidated Fund: it would not retain any element of the fines it imposed (paragraph 8).

Part 2 – Enforcement undertakings

Procedure

840. Paragraphs 9 and 10 stipulate that Monitor must consult upon and then publish a procedure for entering into enforcement undertakings. It may revise that procedure but it would have to publish any revision. Monitor must also publish details of each enforcement undertaking it accepted, but with any commercial information or information that Monitor considered would or might harm any person's legitimate business or personal interests redacted (paragraph 10).

Variation of terms

841. A person giving an enforcement undertaking and Monitor may agree to vary the terms of an enforcement undertaking. This is intended to provide the flexibility to alter the agreement if necessary if, for example, a provider had good reasons for taking longer to carry out a remedial measure than was originally planned and agreed.

Compliance certificates

- 842. If it is satisfied that a person had complied with an enforcement undertaking, Monitor must issue a compliance certificate (paragraph 12). Someone who had given an enforcement undertaking may apply for a certificate at any time.
- 843. Paragraph 13 provides that an appeal to the First-tier Tribunal may 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 may confirm Monitor's decision or decide that it did not have effect.

Inaccurate, incomplete or misleading information

844. If Monitor is satisfied that information supplied by a person in relation to an enforcement undertaking is inaccurate, misleading or incomplete, Monitor may treat the person as having failed to comply with the undertaking. If it did this, Monitor would have to revoke any compliance certificate given to that person in connection with the particular undertaking.

Section 108 - Guidance as to use of enforcement powers

- 845. This section 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 must have regard to the published guidance in exercising those powers. Guidance would give licensees and others a better understanding of the enforcement action that Monitor is likely to take in particular circumstances.
- 846. *Subsection* (4) provides that the guidance must include details of when Monitor is likely to impose a discretionary requirement and when it may not impose one, how it will decide the amount of variable monetary penalties, and how decisions may be appealed.

Section 109 - Publication of enforcement action

- 847. Subsection (1) provides that Monitor must include information in its annual report on discretionary requirements it has imposed and enforcement undertakings it has accepted during the financial year that the report covers. Under *subsection* (2) Monitor is not able to include information if it is satisfied that publication of it would or might significantly harm the legitimate business or personal interests of the person to whom the information relates.
- 848. *Subsection (3)* provides that Monitor is not to include in the report information about discretionary requirements that have been overturned on appeal.

Section 110 - Notification of enforcement action

849. This section provides that Monitor must notify the NHS Commissioning Board, affected CCGs and other relevant regulators of discretionary requirements it imposes and enforcement undertakings it accepts. This provision is designed to ensure that information about provider performance, which may be relevant to the duties and functions of commissioners and other regulators, is shared appropriately.

Transitional provision

Section 111 - Imposition of licence conditions on NHS foundation trusts

- 850. This and the following three sections provide Monitor with transitional intervention powers over all NHS foundation trusts.
- 851. Subsections (1) and (2) provide transitional powers for Monitor to impose such requirements on a foundation trust (in the form of additional licence conditions), as Monitor considers appropriate, to address a governance failing. Monitor can impose such requirements where it is satisfied that this is necessary to prevent or remedy a breach of a foundation trust's licence. Subsection (1) allows Monitor to impose licence conditions relating to governance on a foundation trust where it is satisfied that the governance of the trust will cause it to fail to comply with its licence conditions to provide NHS services. Subsection (2) specifies that the circumstances in which these powers may be used include those where the trust's directors, governors, or both, are failing to comply with conditions in the trust's licence, or are failing to reduce the risk of a breach of licence conditions. Monitor's transitional powers are intended to provide an additional safeguard to protect patients' interests by ensuring that foundation trusts are well-governed and exercise their functions consistently with their duty to do so effectively, efficiently and economically, in the early years of the new regulatory regime, when some foundation trust governors may be inexperienced and when some foundation trusts may be newly authorised.
- 852. *Subsection (3)* provides that any additional licence conditions imposed by Monitor under subsection (1) could continue in force until Monitor's transitional powers were repealed by Parliament by virtue of section 112.
- 853. *Subsections (5) and (6)* provide Monitor with further powers to take action where a foundation trust fails to comply with Monitor's requirements under subsection (1). Specifically, Monitor could intervene to require the trust to remove, replace on an interim basis, suspend or disqualify one or more directors or governors of the trust. If the trust failed to do so, Monitor could take such action itself.
- 854. *Subsection* (7) provides that Monitor's exercise of its transitional powers in subsection (5) is without prejudice to its ability to exercise powers to set and enforce requirements on foundation trusts, including requirements relating to governance, or requirements to ensure a foundation trust's continued ability to provide services for the purpose of the NHS. This clarifies that the transitional powers are in addition to Monitor's continuing non-transitional powers to intervene where a licence holder is in breach of licence conditions, for example, a requirement to maintain continuity of NHS services.
- 855. *Subsection (11)* repeals section 52 of the NHS Act (failing NHS foundation trusts) because Monitor will have permanent powers to protect the continuity of services through the modified regime for unsustainable foundation trusts. It also makes related consequential amendments.

Section 112 – Duration of transitional period

856. This section makes all foundation trusts subject to Monitor's transitional powers until the Secretary of State makes an order to release either some or all trusts from the powers. The first such order may not be made before 1 April 2016, or, in the case of a foundation trust authorised after 1 April 2014, before two years after the date of authorisation. The order would be subject to Parliamentary scrutiny under the negative resolution procedure, since those trusts being considered for release would have effective governance and would therefore be at low risk of needing intervention.

857. *Subsection* (5) provides for the section to be repealed when there are no longer any foundation trusts or NHS trusts which might become foundation trusts to which the powers might apply.

Section 113 – Orders under section 112: criteria for deciding applicable trusts

- 858. This section sets out the process to be followed when the Secretary of State decides to make an order to release foundation trusts from Monitor's transitional intervention powers. *Subsection* (1) provides that the Secretary of State must notify Monitor where he proposes to make an order releasing trusts from the powers in this way.
- 859. Subsection (2) provides that, where Monitor receives a notification under subsection (1), it must develop criteria to decide which foundation trusts should be released from its transitional intervention powers. Subsection (3) requires Monitor to consult the Care Quality Commission and other appropriate persons and to obtain the Secretary of State's approval for the criteria before applying them.
- 860. *Subsection (4)* requires that, following approval by the Secretary of State, Monitor must publish the criteria. Monitor must apply the criteria to decide which foundation trusts should be released from the transitional intervention powers. Monitor must notify the Secretary of State about which foundation trusts it has determined should be released from the transitional powers and publish a list of those trusts.
- 861. *Subsection* (5) provides for a situation where the Secretary of State did not approve the criteria developed by Monitor under subsection (2). Monitor would have to propose revised criteria to the Secretary of State and repeat the process in subsections (3) and (4).
- 862. *Subsection* (6) requires the Secretary of State, on receiving notification from Monitor under subsection (4), to review Monitor's determination about the trusts to be released.

Section 114 - Repeal of sections 112 and 113

863. This section repeals the previous two sections when section 111 (Imposition of licence conditions on NHS foundation trusts) on transitional intervention powers is repealed. That section is repealed when it no longer has any effect in relation to any foundation trusts and there are no NHS trusts left in existence.

Chapter 4 – **Pricing**

864. These sections set the framework for setting prices for health care services provided for the purposes of the NHS.

Section 115 - Price payable by commissioners for NHS services

- 865. This section makes provision about how prices are to be determined for the provision of health care services for the purposes of the NHS. *Subsection (1)* makes provision for prices to be set out in a national tariff (national prices) and *subsection (2)* provides that where a service is not included in the national tariff, the price payable is to be determined in accordance with any rules set out in the tariff to cover such circumstances.
- 866. The commissioners with an interest in pricing under this Chapter are those arranging for the provisions of health care services for the NHS which are the NHS Commissioning Board, CCGs, and the Secretary of State where section 13Z2 (failure by the Board to discharge any of its functions) of the NHS Act applies. The Secretary of State's power under section 13Z2 applies where the Commissioning Board is failing or has failed to discharge, or to properly discharge, any of its functions.

Section 116 - The national tariff

- 867. This section requires Monitor to publish "the national tariff", a document that makes provision about pricing of health care services for the purposes of the NHS. *Subsection* (1) provides that the national tariff must:
 - specify the health care services to which it applies. The tariff would include 'currencies' (i.e. the service specification which may include one or more component health care services) that would be used as the basis for pricing and payments;
 - specify the methodology (or methodologies) that had been employed by Monitor for determining the prices payable under the national tariff (which may be different for different descriptions of services). The methodology would include the input data as well as the process of calculation for determining the prices payable under the national tariff;
 - specify the prices payable for those services, subject to any adjustments that may be provided for under this Chapter;
 - specify a methodology to be used by Monitor when considering agreements under section 124 or applications under section 125 for the local modification of prices payable under the national tariff.
- 868. Subsections (2), (4)(b), (4)(c) and (6) make provision for rules which may be included in the national tariff providing for:
 - providers and commissioners to agree to vary the prices payable under the national tariff or the specification of a health care service specified in the national tariff (*subsection*(2)). The intent is to enable flexibility to be provided within the national tariff, for example, to support innovation in service delivery, integration of services, or unbundling of services to enable components of care to be delivered and paid for separately, where this would be in patients' best interests. Where such variations are agreed, the commissioner is required by *subsection*(3) to keep and publish a written statement of all such variations;
 - determining prices payable for services not specified in the national tariff, (local price setting rules) where the prices payable would otherwise, in the absence of such rules, be agreed locally between commissioners and providers (*subsection* (4)(b));
 - the determination of which 'currency' (see paragraph 832 above) applies where a service is specified in more than one way under the national tariff, or under any local price setting rules (*subsection* (6)); and
 - governing the making of payments to the provider (subsection (4)(c)).
- 869. Subsection (5) provides that local price setting rules under subsection (4)(b) may also include the specification of currencies for health care services which are not specified under subsection (1)(a). This provision would allow standard currencies to be specified at a national level, where the prices are to be determined locally. This would support expansion in the range of services covered by the national tariff over time, where this would be in patients' best interests.
- 870. Subsection (4)(a) provides that the national tariff may also specify variations to the national prices for a service based on the circumstances in which that service is provided or any other factors relevant to providing that service, for example, to take account of whether the service is provided in a hospital setting or in a patient's home, or to take account of clinical complexity.
- 871. *Subsection* (7) provides that the national tariff may include guidance on: the application of any rules included in the national tariff (except rules on making payments to providers); the discharge of the duty under subsection (3) to publish variations

agreed between the provider and commissioner under any such rules; and, the application of variations in the national tariff made in accordance with subsection (4) (a). Commissioners must have regard to any guidance provided.

- 872. Subsection (8) provides that the national tariff may specify different prices payable, or variations of the prices payable, for a specified health care service (or services of a specified description) to different types of provider. However, the different prices payable, or variations of the prices payable, could not be based on whether the provider is in the public or private sector or any other aspect of the status of the prices in central London due to the additional costs of land and buildings but the prices payable cannot be based on whether the provider is public or private sector. Prices specified in the national tariff would not be able to include prices for public health services.
- 873. *Subsection (12)* provides that the national tariff has effect for the period specified in the tariff or until a new edition of the tariff takes effect.
- 874. *Subsection (13)* requires Monitor to have regard to the mandate set by the Secretary of State (published under section 13A (mandate to the Board) of the NHS Act) when carrying out its pricing functions under this Chapter.

Section 117 – The national tariff: further provision

- 875. This section provides that the specification of a health care service in the national tariff or as determined by local price setting rules can take any form, including describing a service:
 - by reference to one or more of its individual components;
 - as a "bundle" of services constituting a course of treatment; or
 - as a group of services.
- 876. *Subsection* (2) provides that where the service is specified in the national tariff by reference to its components, the tariff must specify the prices payable for each component. If two or more services are bundled, the tariff must determine the prices payable for the bundle as a whole. Where services are grouped, the tariff would determine the single price for the provision of any service listed in the group (in other words, the same price would apply to each service listed).
- 877. *Subsection (3)* provides that where a service is specified under local price setting rules, the national tariff may include rules to determine the price for each component or bundle, or the price that would apply to each service specified within a defined group of services.
- 878. Subsection (4) provides for Monitor to direct a commissioner to reverse actions taken where the commissioner agrees to pay a price other than the price payable under the national tariff. Under *subsection* (5) Monitor may direct the commissioner to take steps to prevent recurrence of a failure to comply with rules in the national tariff (for varying a service specification or price, for local price setting, as to payments, or for determining which specification should apply where a service is specified in different ways), or to restore the position to what it would have been had the failure not occurred.

Section 118 - Consultation on proposals for the national tariff

879. The national tariff must include certain elements and *subsections* (7), (8) and (9) require that Monitor and the NHS Commissioning Board agree those elements. The proposals for these elements must be included in a notice published and sent to all commissioners, relevant providers and other persons considered appropriate (*subsection* (1)). The elements are:

- the health care services to which the national tariff would apply, including the 'currencies' or units of services for which there are prices specified in the national tariff;
- the methodology (or methodologies) for determining the prices payable for those services, which would include the input data and the processes of calculation for determining the prices payable under the national tariff;
- the prices payable for those services, including any provision for adjustments that Monitor and the NHS Commissioning Board have agreed should be applicable;
- the methodology to be used by Monitor when considering an agreement for a price modification under section 124 or an application for a price modification under section 125.
- 880. The national tariff may also include other elements. If they are included *subsections* (10), (11) and (12) require that Monitor and the NHS Commissioning Board must also agree those elements and that the proposals for them must be included in the notice published under subsection (1)). These could be:
 - variations on the prices payable and any associated guidance;
 - rules under which providers and commissioners could agree to vary the prices payable under the national tariff and any associated guidance;
 - rules for determining prices payable locally for services not specified in the national tariff and any associated; and
 - rules for determining which 'currency' (see paragraph 832 above) applies where a service is specified in more than one way, either for the purposes of determining the prices payable under the national tariff, or under any rules for the purposes of determining the prices payable for services where such prices are to be determined locally, and associated guidance.
- 881. If agreement cannot be reached between Monitor and the NHS Commissioning Board in respect of any of the components of the national tariff to be published under this section, those matters will be determined by independent arbitration .
- 882. Once agreement has been reached, Monitor must notify all commissioners, relevant providers and others it considers appropriate (for example providers not currently providing NHS services) of the proposed national tariff and the proposals for the components as required or otherwise provided for in this section. The proposals must also be published (*subsection (2)*). There must be a 28-day consultation period, during which objections could be made (*subsection (13)*).

Section 119 - Consultation: further provision

- 883. Subsection (1) of this section places a duty on Monitor and the NHS Commissioning Board, in ensuring that the prices set under the previous section represent fair reimbursement for providers of services, to have regard to the differential costs incurred by providers who treat different types of patient and differences between providers with respect to the range of services they provide. The effect of this is to require Monitor and the Board to make provision for adjustments in the prices payable under the national tariff, or within the rules for determining the prices payable locally, to take account of variations in clinical complexity.
- 884. Subsections (2) and (3) of this section state that when developing standard currencies or units of service to be included in the national tariff for determining the prices payable, or in any rules governing local prices, the Board and Monitor must act with a view to securing standardisation of currencies across England.

885. *Subsection (4)* provides that when the Board and Monitor are developing standard currencies or units of service for determining the prices payable, they must consider whether such standardisation will have any significant adverse impact on the provision of health care services for the NHS.

Section 120 - Responses to consultation

- 886. This section sets out the process for commissioners and relevant providers to challenge the methodology (or methodologies) proposed for determining the prices payable under the national tariff. Where an objection is made, Monitor may confirm the national tariff only if either: the conditions in *subsection (2)* of this section are met or, if they are not met, following a reference to the Competition Commission. The Competition Commission would be required to determine if the methodology is appropriate having regard to Monitor's duties under this Act and in accordance with the provisions of this Chapter.
- 887. The conditions in subsection (2) are that the percentage of commissioners or relevant providers who object to the pricing methodology (the objection percentage), or, as may be prescribed in regulations made by the Secretary of State, the percentage of relevant providers weighted by their share of supply (the share of supply percentage) who objected to the pricing methodology, are both less than the prescribed percentages. The regulations may include provision about the method for determining share of supply.
- 888. This section also gives effect to Schedule 12, which makes provision about the procedure for references by Monitor to the Competition Commission, in circumstances where the objection percentage and/or the share of supply percentage, as may be prescribed, were met and about how the Commission should handle any such references.

Schedule 12 - Procedure on references under section 120

- 889. This Schedule provides that, in making a reference to the Competition Commission, Monitor must outline its reasons for the proposed pricing methodology. Monitor also has to include the reasons for considering that there are no grounds for the Commission to determine that the proposed methodology is inappropriate. The grounds on which the Commission could make such a determination are set out in section 121(4). Monitor must send a copy of any reference to the NHS Commissioning Board and to those persons (i.e. relevant providers or CCGs) who had objected to the proposed methodology (paragraph 1(2)). Those persons can make representations to the Competition Commission about Monitor's reference, within 10 days of receiving the copy of the reference. A person who makes a representation must provide Monitor with a copy. Monitor may reply to the representations, within 10 days of receiving its copy; and, if it chooses to do so, must send the person a copy of that reply (paragraph 2).
- 890. On receipt of a reference, the Chairman of the Commission is required to select a group to consider the reference, make a determination and give any directions to Monitor to give effect to the determination (sub-paragraph (1) of paragraph 3). Sub-paragraphs (2) to (6) of paragraph 3 make provision about the constitution of the group, including that it must comprise three members of the Commission. Sub-paragraph (7) provides that a decision of the group will only be effective if all members are present when the decision is made and two of the three members are in favour of the decision.
- 891. The Competition Commission may make rules on the procedure to be followed in making determinations on references (paragraph 11). In particular, this could include time limits for oral evidence. Any rules must be published.
- 892. Paragraph 4 makes provision about the timetable for references. The group must make a determination within 30 working days of the last date on which Monitor is entitled to respond to the objectors.

- 893. The group may extend the deadline by not more than 20 working days and not more than once. The Competition Commission would have to notify the extension to Monitor, the NHS Commissioning Board and those persons who had objected.
- 894. Paragraph 5 provides that the group may disregard:
 - any representations from a person not raised by that person in the original consultation; and/or
 - any matter Monitor raises in a reply to a representation from a person that is not included in the original reference, if it considered this necessary to secure a determination within the permitted timescales.
- 895. 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 9 and 10 make provision relating to evidence, including provision about default. A failure to provide information or the provision of false information is to be regarded as a contempt of court. However, no person could be compelled to provide information that it could not be compelled to under civil proceedings in the High Court.
- 896. Under paragraph 12, the unsuccessful party must pay the costs the Competition Commission incurs in making a determination on a reference. If the Commission determines that the proposed pricing methodology should be changed, Monitor must pay the Commission's costs. If the Commission determines that the proposed methodology may be implemented without changes, those persons who had objected may be named as those required to pay the Commission's costs. This provision is intended to deter persons from objecting unless they have good reason to do so and to help ensure that Monitor makes sensible and appropriate proposals for pricing methodologies.

Section 121 - Determination on reference under section 120

- 897. This section provides that in making a determination on the pricing methodology, the Competition Commission must have regard to the matters to which Monitor must have regard in carrying out those of its functions to which the determination relates.
- 898. In reaching its determination, the Commission must have regard to any representations made to it by relevant providers or commissioners who had objected to the methodology, under the procedure set out in paragraph 2 of Schedule 12. The Commission may also consider matters that Monitor was not able to take into account, provided the nature of them was such that Monitor would have been entitled to take them into account had it had the opportunity. This provision would enable the Commission to take account of new information that was not available to Monitor when it proposed the pricing methodology, but which was relevant.
- 899. If the Commission determines that Monitor has set the pricing methodology appropriately, Monitor can use that method.
- 900. The Commission could determine that Monitor had not set the pricing methodology appropriately only in the circumstances set out in *subsection (4)*. Those circumstances are that Monitor has failed to have regard to matters relating to pricing methodology to which it is required to have regard; or that the decision is based on an error of fact or wrong in law. Where any of these apply, the Commission must refer the methodology back to Monitor for re-consideration, with the reasons for its decision. The Commission would be required to notify its determination to Monitor, the NHS Commissioning Board and those relevant providers or commissioners who made representations to it; and to publish it, excluding any commercial information that could damage an undertaking's interests or information relating to the private affairs of an individual that could harm that person's interests.

Section 122 - Changes following determination on reference under section 120

901. Where the Competition Commission refers a proposed pricing methodology back to Monitor, Monitor must make any changes it considered necessary to address the issues raised in the Competition Commission's determination. Monitor must notify the Competition Commission and the NHS Commissioning Board of the changes it proposes to make and its reasons for them.

Section 123 - Power to veto changes proposed under section 122

- 902. Within 28 days of receiving notification under section 122 of Monitor's proposed changes, the Commission can direct Monitor not to implement some or all of those changes. When issuing such a direction, the Commission must give notice of the terms of the direction and the reasons for it, and make the necessary changes to the pricing methodology itself. This power of veto is to give the Commission the opportunity, where it considered this necessary, to prevent Monitor from making changes that do not deal adequately with the Commission's determination on a reference.
- 903. The Commission could apply to the Secretary of State for an extension of the 28-day period by 14 days.
- 904. Before making the changes to the pricing methodology, the Commission would have to notify Monitor and the NHS Commissioning Board of those changes including the Commission's reasons for the changes it proposes to make (*subsection* (7)). It must provide a period of at least 28 days for representations (*subsection* (8)).
- 905. If the Competition Commission does not issue a direction to Monitor under this section, section 122(3) requires Monitor to make the changes it has proposed.

Section 124 - Local modifications of prices of services: agreements

- 906. This section specifies the process for a provider of a heath care service for the purposes of the NHS and the relevant commissioner to agree a modification of prices payable in accordance with the national tariff (*subsection (1)*). This may be necessary where an efficient provider cannot recover their costs at the prices determined in accordance with the tariff, for example, due to the services required by commissioners being of relatively small scale such as may be the case where a provider is required to sustain provision of Accident and Emergency or maternity services in a relatively less populated area of the country. Monitor may approve any such modification if, applying the methodology agreed with the NHS Commissioning Board and published in the national tariff under subsection 116(1)(d), it is satisfied that it would be uneconomic for the provider to provide the service (*subsection (5)*). Monitor can require evidence in support of an application for a modification (*subsection (4)*).
- 907. Where Monitor approves an application, it must notify the Secretary of State and those CCGs, providers and others whom it considers appropriate, as well as publishing details of the modification and the date on which it takes effect (*subsections* (6) to (8)).
- 908. The Secretary of State may direct that an agreement is to be of no effect, if the Secretary of State thinks that the agreement might breach EU obligations (for instance, state aid rules) (*subsection* (9)).

Section 125 - Local modifications of prices of services: applications

909. This section deals with situations in which agreement to a local modification under section 124 is sought by a provider but not agreed with the commissioner(s). In such circumstances, the provider in question may make an application to Monitor for a modification of the prices payable in accordance with the national tariff, which must be supported by such evidence as Monitor may require (*subsections (1) and (2)*). If Monitor decided it would be uneconomic for the provider to continue to provide the services as required by the commissioner(s) without modification of the prices payable, Monitor

can grant the application and determine the modification to the price that would apply (*subsection* (3)). In considering an application for such a modification, Monitor must apply the methodology agreed with the NHS Commissioning Board and published in the national tariff under subsection 116(1)(d) and can require evidence in support of an application for a modification. Monitor would have to give notice of any such decision in accordance with *subsections* (6) to (8).

910. The Secretary of State may direct that a modification contained in an application under this section is to be of no effect, if the Secretary of State thinks that the modification might breach EU obligations (for instance, state aid rules) (*subsection* (9)).

Section 126 – Applications under section 125: notification of commissioners

- 911. This section provides for action to be taken by Monitor where it has identified significant risk to the continuity of NHS services as part of its consideration of an application for modification of the prices payable under the national tariff (*subsections* (1)). It obliges Monitor to notify the NHS Commissioning Board and certain CCGs where it has identified such risks and is satisfied that this was attributable to the way in which services were configured.
- 912. Subsection (3) requires Monitor to notify the NHS Commissioning Board and such CCGs as Monitor considers appropriate where:
 - a) a provider of NHS health care services applies to Monitor for a modification to the tariff price, under section 126 (where the provider has previously been unable to agree a modification with the commissioner of the health care services in question), and
 - b) Monitor is satisfied that an unsustainable configuration of certain health care services is putting services subject to a licence condition under section 97(1)(i), (j) or (k) (for the purpose of ensuring the continuity of those services) at significant risk.
- 913. *Subsection (4)* requires Monitor to publish an annual list of the notifications it has sent to commissioners regarding unsustainable service configurations and a summary of its reasoning in each case.
- 914. *Subsection (5)* requires the Board and CCGs to have regard to any such notification received when arranging for the continued provision of NHS health care services. It would be for commissioners to decide what action to take to address any unsustainable configuration of services, in consultation with Local Health and Well-being Boards.

Section 127 - Correction of mistakes

915. If a mistake in the national tariff means that it does not reflect what Monitor and the NHS Commissioning Board have agreed (or what has been determined by arbitration), corrections may be made. Monitor must notify all commissioners, licence holders and other persons as it considers 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 5 – Health special administration

916. This Chapter provides for a health special administration regime, based on insolvency legislation, for the purposes of securing the continued provision of NHS services provided by a company that becomes insolvent. The regime is intended to enable commissioners to secure continued access to NHS services to meet the needs of their communities.

- 917. Health special administration provides an alternative to the corporate insolvency procedures set out in the Insolvency Act 1986 that would otherwise apply if a company providing NHS services becomes insolvent.
- 918. The health special administration regime applies only to "relevant providers" which are defined as companies providing NHS services to which licence conditions have been applied by Monitor for the purposes of ensuring continuity of NHS services. Part 4 of the Act makes separate provision for trust special administration for unsustainable foundation trusts, including arrangements for securing continuity of NHS services in line with requirements determined by commissioners.
- 919. Chapter 6 makes provision about financial assistance in cases of health special administration or trust special administration (for NHS foundation trusts under Chapter 5A of Part 2 of the NHS Act).

Section 128 - Health special administration orders

- 920. Health special administration could commence only by an order of the court on an application made by Monitor.
- 921. A health special administration order may only be sought against a company providing NHS services that is subject to specific licence conditions set by Monitor, under section 97(1)(i), (j) or (k), that relate to the continued provision of NHS services. Section 130 makes provision for the health special administration regulations to set out requirements for Monitor to publish and maintain details of relevant providers that are potentially within the scope of the health special administration regime.
- 922. Where the court makes a health special administration order, a health special administrator is appointed (*subsection* (1)). The health special administrator is an officer of the court and in carrying out their functions acts as the company's agent (*subsection* (4)). Only a qualified insolvency practitioner could be appointed as a health special administrator (*subsection* (5)).
- 923. Under *subsection* (6) the health special administrator is obliged to manage the affairs, business and property of the provider to achieve the objective of health special administration as quickly and efficiently as reasonably practicable.
- 924. In doing so, the health special administrator must ensure that the provider continues 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).
- 925. The health special administrator is also required to act in a manner that, insofar as it is consistent with the objectives of a health special administration, protects the interests of the creditors of the provider as a whole, and, subject to those interests, the interests of its members.

Section 129 - Objective of a health special administration

- 926. Subsection (1) provides that the objective of health special administration is to secure the continued provision of certain NHS services provided by relevant providers, so that it becomes unnecessary for the health special administration order to remain in place. These services are those determined by the relevant commissioners in accordance with the criteria set out in the health special administration regulations.
- 927. Subsection (2) provides that the objective of health special administration may be achieved by either rescuing the provider as a going concern, so that it was able to continue in business, and/or the transfer of all or some of the services it provided to one or more alternative providers.

- 928. The section provides for a hierarchy in these two possible outcomes. The health special administrator is required to work towards rescuing the company as a going concern, under *subsection* (5), and may only make transfers to the extent that:
 - a rescue is 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 the company's creditors as a whole; or
 - transfers would produce a better result for members without prejudicing the interest of creditors.

Section 130 - Health special administration regulations

- 929. Subsection (1) requires the Secretary of State to make regulations setting out the detail of the health special administration regime. The regulations will be subject to consultation and the affirmative resolution procedure in Parliament.
- 930. These provisions are designed so that health special administration can reflect existing insolvency law and practice. *Subsection (2)* provides that the regulations may apply, with modifications, the procedure of administration set out in Part 2 of the Insolvency Act 1986 (which includes provision for the powers of administrators and the process of administration) and other relevant legislation.
- 931. The regulations may also include provision for enabling the court to make a health special administration order if the Secretary of State presents a public interest winding-up petition in relation to a relevant provider (*subsection* (3)).
- 932. The regulations may make provision about the application of other corporate insolvency procedures and the enforcement of security over property, in the context of health special administration.
- 933. The regulations may set out requirements for Monitor to publish and maintain details of companies that are potentially within the scope of the health special administration regime (*subsection* (5)).
- 934. Subsection (6) provides that the regulations may also set out further details about health special administration. In particular, such regulations may make provision for Monitor to issue guidance to commissioners about the exercise of their functions in determining the services which are to be subject to health special administration.
- 935. The regulations may require Monitor to publish such guidance, enable Monitor to revise it and require that any such guidance or revised guidance is approved by the Secretary of State and NHS Commissioning Board before it is published. The regulations may also require commissioners to have regard to any such guidance issued by Monitor. Where commissioners exercising those functions fail to reach agreement, the regulations may make provision for the NHS Commissioning Board to facilitate agreement or to exercise the commissioners' functions in order to determine the issue where agreement cannot be reached. The intention is that any such provision will apply where a relevant provider delivers services to more than one commissioner.
- 936. The regulations may also require a health special administrator to carry out consultation, in accordance with the regulations, on the actions they recommend in relation to a particular provider.
- 937. *Subsections (7) and (8)* provide that the regulations could also modify this Chapter, the Insolvency Act 1986 and any other enactment which either makes provision about what is to be done under that Act or is relevant to insolvency or administration. This ensures that the health special administration regime may be tailored to meet the needs of the health care sector.

938. Subsection (9) provides that further secondary legislation ('rules') may be made under section 411 of the Insolvency Act 1986 to give effect to the health special administration regime. This is consistent with other insolvency regimes, where rules provide the details needed to make the procedures workable in practice. The rules would be made in the normal way and the power to make rules in relation to Scotland is exercisable by the Secretary of State (subsection (10)(b)). Rules made under this provision would apply to any Scottish companies providing NHS services in England.

Section 131 - Transfer schemes

- 939. This section allows for health special administration regulations to make provision about the transfer of NHS services to another provider in order to achieve the objective of health special administration.
- 940. In particular, the regulations may include provision for the transfer of property, rights and liabilities, including the transfer of rights that individuals might have through their contracts of employment, to alternative providers. The regulations may also require that Monitor and relevant providers agree transfer schemes in individual cases, allow Monitor to modify a transfer scheme with the consent of the affected parties, and allow for modifications to a transfer scheme to have effect from a time specified by Monitor.

Section 132 - Indemnities

941. This section enables the health special administration regulations to make provision for Monitor to provide appropriate indemnities in respect of liabilities incurred or loss or damage sustained in connection with the exercise of the health special administrator's functions. Any such indemnity would be paid out of the financial mechanisms established under Chapter 6.

Section 133 - Modification of this Chapter under the Enterprise Act 2002

942. 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 to enable future changes to the health special administration regime, to keep it in line with changes in the underlying insolvency legislation.

Chapter 6 – Financial assistance in special administration cases

- 943. These sections require Monitor to set up effective mechanisms for providing financial assistance to providers in health special administration. This means companies in health special administration and NHS foundation trusts in trust special administration. Funding would be issued to the special administrator and could be used to finance the costs of ensuring the continuity of NHS services, both to meet the costs maintain continuity of services during a period of administration and to fund any one-off costs of securing continuity of NHS services upon exit from special administration. The intention is that providers and commissioners of such services will fund this financial assistance through financial contributions, or other financial mechanisms, determined by Monitor, for example, on the basis of risk. The Government expects that one effect of the new arrangements will be to shift the burden of funding unsustainable providers away from high-performing commissioners and providers. Under the current arrangements, the NHS has typically funded the costs of failure through the reallocation of surplus funding, generated by efficient provision, or by clawing-back funding from allocations to commissioners. Monitor will decide the detail of the new financial mechanisms, but the Government expects it will take account of the risks presented by individual providers and the extent to which commissioners are dependent on one or very few providers for the provision of NHS services.
- 944. A special administrator may, during a period of special administration, use financial assistance to cover operating costs associated with maintaining continuity of services.

This might include the continuing costs of operating services, costs of restructuring the provider to ensure a sustainable future organisation or any indemnities for the administrator and other relevant persons for liabilities incurred, or loss or damage sustained in connection with the exercise of the administrator's powers and duties. Restructuring costs could include, but would not be limited to, renegotiation of service contracts, restructuring of debts, or payments made to a new operator to establish viable provision.

945. The financial mechanisms are not intended to provide long-term funding for organisations experiencing temporary liquidity issues, nor are they intended to provide long-term funding for services that are otherwise uneconomic to supply at national tariff because of market factors or special service requirements. The Government envisages that providers will secure capital from other sources (eg the Foundation Trust Financing Facility or other loans) to address temporary liquidity issues. In addition, the national tariff will include a process and methodology for increasing the prices payable to a provider, in individual cases, where necessary to sustain continuity of services required by commissioners that would otherwise be uneconomic to provide.

Establishment of mechanisms

Section 134 - Duty to establish mechanisms for providing financial assistance

- 946. This section places Monitor under a duty to establish effective financial mechanisms to support the operation of the special administration regimes provided for foundation trusts in Chapter 5A of Part 2 of the NHS Act and for companies in Chapter 5 of this Act.
- 947. Monitor has the power to determine the appropriate form of financial mechanisms (for example by levying contributions to a risk pool, establishing contingent liabilities or other approach that would best fit the risks) and whether and how the mechanisms may need to be varied for different providers. As specified by *subsection (2)*, these mechanisms could include, but need not be limited to:
 - providers and commissioners 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.
- 948. *Subsection (3)* provides that the mechanisms may make provision for Monitor to recover the costs of setting up and running those mechanisms.
- 949. The financial mechanisms are exempt from any provisions of the Financial Services and Markets Act 2000 and therefore not subject to Financial Services Authority regulation. The Government considers that Financial Services Authority regulation is not necessary given the statutory duties placed on Monitor and the better regulation safeguards set out elsewhere in this Act.
- 950. Subsection (6) provides that Monitor's duty to establish a mechanism or mechanisms may be commenced before the rest of this Chapter. This is to allow the substantial development work to be undertaken so that the financing arrangements can be delivered in a timely manner.

Section 135 - Power to establish fund

- 951. Subsection (1) enables Monitor to establish and maintain a fund for the purposes of providing financial assistance to providers in special administration and gives Monitor flexibility to determine the appropriate mechanisms (eg a risk-pool operated by Monitor and funded by contributions from providers and, subject to regulations, commissioners).
- 952. Subsections (3) to (8) impose requirements on Monitor about the management of any such fund. Monitor is required to secure the prudential management of any such fund

and to appoint at least two fund managers. These could be individuals or firms but Monitor must be satisfied:

- in the case of an individual, that the individual has the appropriate knowledge and experience for managing the investments and is not disqualified under the Financial Services and Markets Act 2000, and
- in the case of a firm, that arrangements are in place to ensure that any individual who exercises the firm's fund manager functions, at the time of doing so, has the appropriate knowledge and experience for managing the investments.

Applications for Financial Assistance

Section 136 - Applications

- 953. This section provides for the process by which a special administrator can make an application for financial assistance from Monitor.
- 954. *Subsection* (2) enables Monitor to specify the form of the application and the supporting evidence required. Monitor is required to either grant or refuse the application.
- 955. 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 special administrator may not use the assistance for any other purpose and must observe the conditions.
- 956. *Subsection (6)* obliges Monitor to notify an unsuccessful applicant of its reasons for refusing an application. If a special administrator requests a reconsideration of any refusal, Monitor must reconsider it and may request information from the applicant for that purpose. Any reconsideration must be carried out by individuals other than those who made the original decision to refuse the application (*subsection (7)*).
- 957. Subsection (9) provides that following reconsideration of an application, Monitor must notify the applicant of its decision and successful applicants must be notified of the purpose of the assistance and any conditions attached to it. Where the applicant is unsuccessful Monitor must give reasons for the refusal.
- 958. Financial assistance can be provided only during the period during which a provider was in special administration, however, it could be for a shorter time than the entire period (*subsection* (5)).

Section 137 – Grants and loans

- 959. This section prescribes the circumstances in which Monitor is able to give financial assistance in the form of loans or grants in response to an application from a special administrator. *Subsection* (1) provides that Monitor may only grant financial assistance if it is established that it is necessary to enable a provider to continue to provide some or all of the health care services that it provides for the purposes of the NHS or to secure a viable business to secure continued access to NHS services and that there is no other source of funding available.
- 960. Subsection (3) provides that Monitor would be able to grant financial assistance 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.
- 961. Subsections (4) and (5) provide that Monitor is able to recover overpayments in the provision of grants and loans under this section. This includes a power to recover interest on the amount overpaid.

Charges on Commissioners

Section 138 – Power to impose charges on commissioners

- 962. This section gives the Secretary of State the power to make regulations that would allow Monitor to require commissioners to pay charges which relate to Monitor's functions to ensure continuity of NHS services.
- 963. Subsections (2) and (3) specify what must be included in the regulations, which includes provision about how the charge would be calculated, to whom it should be paid and when. The charge may be fixed in the regulations or determined by reference to criteria set in the regulations. Where a charge is set using criteria, the regulations must require Monitor to consult before imposing the charge. Where a charge is not paid when it is due, regulations must provide for interest to be payable on that amount and allow for any unpaid balance, including interest to be recoverable as a civil debt.
- 964. Where the charge is payable to a provider, Monitor may require the provider to pay Monitor that amount in accordance with the regulations.
- 965. *Subsection (5)* requires the Secretary of State to consult Monitor and the NHS Commissioning Board before making the regulations.
- 966. Subsection (6) states that regulations under this section may provide for consultation based on the consultation provisions in sections 141 and 142 and for calculation of amounts payable based on the provisions in section 143 in relation to charges imposed by commissioners.

Levy on providers

Section 139 – Imposition of levy

- 967. Under Section 135, Monitor has the power to impose levies on providers for the purposes of providing financial assistance during special administration (*subsection* (1)).
- 968. *Subsection (2)* requires that before the beginning of each financial year and before determining any levies to be imposed for that financial year, Monitor must estimate
 - The funds needed to cover the potential costs of providing financial assistance during special administration in the forthcoming financial year;
 - The amount to be collected from commissioners in each financial year; and
 - Any surplus funds that would remain at the end of that financial year.
- 969. Where Monitor decides to impose a levy, *subsection* (3) requires Monitor to determine the methodology for establishing the rate of the levy and when the levy would be payable. An explanation of any changes to the methodology for establishing the rate must be included in the consultation required to be carried out under section 141 on any proposed levy. Monitor is able to differentiate the levies for different providers (*subsection* (5)).

Section 140 – Power of Secretary of State to set limit on levy and charges

970. This section enables the Secretary of State, by order and subject to the approval of HM Treasury, to limit the amount that Monitor may raise through any provider levies and charges on commissioners. The intention is that this power will be used only in exceptional circumstances, if the Secretary of State considers that the total amount that Monitor proposed to raise to support the special administration regimes was excessive. An order under this section is subject to the affirmative resolution procedure.

Section 141 - Consultation

- 971. This and subsequent sections set out the consultation requirements in relation to proposed provider levies and the processes by which they are to be calculated. Analogous provision in relation to commissioner charges may be made through regulations made under section 138(6).
- 972. This section requires Monitor to consult on the proposals for provider levies. The section specifies details about the consultation process, such as the people Monitor must notify and the length of the consultation period.

Section 142 – Responses to consultation

- 973. This section details how Monitor is required to handle objections to the proposals raised in response to the consultation. Monitor may not implement the proposals unless certain conditions set out in *subsection* (2) are met or, if the conditions are not met, Monitor has made a reference to the Competition Commission.
- 974. The conditions in subsection (2) are that the percentage of providers objecting to the proposals (the objection percentage) and, where regulations provide for this, the percentage of providers objecting to the proposals, weighted by their share of supply (the share of supply percentage) are both less than percentages prescribed by the Secretary of State in regulations. Those regulations may also provide for the method to be used in determining what is meant by "share of supply" in relation to a provider (*subsection* (8)).
- 975. If the conditions are not met and a reference to the Competition Commission is made, it must be made in terms that require the Commission to investigate and report on certain matters, specified in *subsection (4)*. Those matters are whether Monitor has failed to give sufficient weight to the matters to which it must have regard under section 66 in carrying out its functions and, if so, whether that failure does or might operate against the public interest and if it does, whether that could be remedied or prevented by changes to the proposals
- 976. Schedule 10 applies to references made under this section, subject to the modifications set out in *subsection (5)*. The Schedule sets out the requirements and processes surrounding the reference to the Competition Commission and the Competition Commission's determination of any reference. The Schedule also provides the process for modification of licence conditions following references to the Competition Commission this is covered in these Notes above (after the notes on section 101).

Section 143 – Amount payable

- 977. *Subsection (1)* 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 may be pro-rated where the provider's liability is only for part of the year (*subsection (2)*). It may also be zero (*subsection (3)*).
- 978. Subsections (4) and (5) enable Monitor to adjust the amount payable by a provider at any time, if Monitor judges that the risk of the provider going into special administration has changed since the start of the financial year or since it last adjusted the amount. Monitor may give notice of the proposed adjustment and where it does, it must specify the adjusted amount.
- 979. Subsections (8) and (9) require Monitor to recalculate the amount payable where a provider requests this, because the provider reasonably believes that the amount has been miscalculated. This provision only applies in relation to amounts payable during the current financial year, not past levies.

980. Subsection (10) specifies that Monitor can recover unpaid levies, including accrued interest, as a civil debt.

Supplementary

Section 144 – Investment principles and reviews

- 981. Subsections (1) and (2) relate to any investments Monitor wants to make for the purposes of providing financial assistance in special administration. A reason for Monitor making investments might be to manage the flows of money into and out of any fund it established to provide such assistance. It is likely that the flows out of a fund would be "lumpy": in that instances where a provider was placed in special administration would be rare, but each would probably result in the drawing-down of significant proportions of the monies held in the fund. The Government anticipates that Monitor may want to take steps to smooth the impact of this "lumpiness" upon providers and commissioners.
- 982. Subsection (1) requires Monitor to prepare and publish a statement on the principles governing its decisions about investments for the purposes of providing financial assistance in special administration.
- 983. *Subsection* (2) provides that Monitor must review the statement annually, revising it if necessary. If Monitor revises the statement, it must re-publish it.
- 984. Subsection (3) requires Monitor to undertake and publish an annual review of the procedure for the operation of the trust special administration regime for foundation trusts and health special administration regime for companies and the financial mechanisms supporting them.
- 985. Subsection (4) specifies the purposes of such a review. Where the fund has been in operation in the year concerned, the review must specify the income and expenditure of the fund during the year. The published review must exclude commercially sensitive information and information about an individual's private affairs, where disclosure would or might harm their interests (subsection (6)).

Section 145 - Borrowing

- 986. This section enables Monitor to take out loans in order to exercise its functions to provide financial assistance. This is intended to give Monitor greater flexibility in the ways it manages the flows of money into and out of any funds it holds. The nature of failure is not entirely predictable, therefore the instances of failure could be zero for a considerable time period and then there could, in theory, be several occurring all at a similar time. In an instance like this, the funds may be tied up in investments to make the most of public money. Borrowing may be a suitable alternative to releasing money at short notice from investments (which may involve penalties).
- 987. *Subsection* (2) provides that Monitor would not be able to borrow beyond a borrowing limit specified by the Secretary of State by order.

Section 146 - Shortfall or excess of available funds, etc.

- 988. Subsection (1) enables the Secretary of State to provide financial assistance to Monitor, if the Secretary of State is satisfied that the financial mechanism established by Monitor to provide funds to special administrators is not generating sufficient funds or the mechanism is not operating effectively. This means that the Secretary of State could top up the financial mechanisms to ensure the continuity of NHS services, where necessary.
- 989. Subsections (2) and (3) provide that the Secretary of State can direct Monitor to transfer funds to the Secretary of State if satisfied that the funds generated by a financial mechanism exceed the level necessary or if the financial mechanism is dormant or

has been wound up. This provision is to ensure excess funds do not go unused. The Secretary of State could use the funds for re-investment in the health service.

Chapter 7 – Miscellaneous and general

Section 147 – Secretary of State's duty as respects variation in provision of health services

990. This section inserts new section 12E into the NHS Act. This is intended to ensure that the Secretary of State does not, in exercising the functions specified in subsection (2), deliberately favour any particular sector, such as the public, private or voluntary sector. Specifically, the new section prohibits the Secretary of State from seeking to increase or decrease the proportion of NHS healthcare services that are delivered by a particular description of providers. The Act provides for similar duties on Monitor under section 62(10) and the NHS Commissioning Board under section 23.

Section 148 - Service of documents

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

Section 149 - Electronic communications

992. This section 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 may impose requirements about how notices are to be sent to it or the Competition Commission electronically; and it must publish whatever requirements it imposes.

Section 150 - Interpretation and consequential amendments

993. This section provides definitions for the purposes of this Part, and gives effect to Schedule 13.

Schedule 13 – Part 3: minor and consequential amendments

994. Schedule 13 contains minor and consequential amendments, most of which reflect the change of Monitor's statutory name.

Part 4 – NHS foundation trusts and NHS trusts

Governance and management

Section 151 – Governors

- 995. This section makes changes to the powers of foundation trust governors as specified in Schedule 7 to the NHS Act and makes provision about their collective duties. It is intended to strengthen foundation trusts' internal governance given that the Act reduces specific oversight of foundation trusts by Monitor, with future controls operating through regulatory licensing and clinically-led NHS commissioning of all providers.
- 996. *Subsection (1)* formally renames the board of governors the "council of governors" in order to avoid confusion between it and the board of directors and to reflect practice.
- 997. The Act 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 Act. *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.

- 998. 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 by members and existing powers over non-executive directors. 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. The trust is required to include any such meetings in its annual report (subsection (8)).
- 999. Subsection (7) amends paragraph 23(4)(c) of Schedule 7 to the NHS Act to enable the Secretary of State to decide who is eligible for appointment as auditor by a foundation trust's governors. This section moves a power currently held by Monitor to the Secretary of State. This is in line with the changes to accounting requirements described below in the Accounts sections. This power supplements paragraph 23(4)(a), which stipulates that a person may be appointed as an auditor if he is a member of one of the bodies mentioned in section 3(7)(a) to (e) of the Audit Commission Act 1998.

Section 152 – Directors

- 1000. This section specifies some of the duties on directors of foundation trusts. *Subsection* (1), by amending Schedule 7 to the NHS Act, places a general duty on the directors to promote the success of the trust.
- 1001. 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, 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 their legal powers, a duty only to exercise their 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 Act specifies the ways in which these duties apply to foundation trust directors. This creates certain exceptions to administrative law principles, for example by permitting a conflict of interest if sanctioned in accordance with the trust's constitution.
- 1002. To ensure 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. *Subsection (5)* requires the foundation trust's constitution to provide for meetings of the board of directors to be held in public, so that governors and through them members and the public may better scrutinise the board's decisions. Provision is also made here for the board of directors to have a closed part of the meeting for specific reasons (for example, to discuss confidential and sensitive matters).

Section 153 – Members

1003. This section requires a foundation trust to take steps to ensure that the membership of any public and patient constituencies is representative of those eligible to be members. Under sections elsewhere in the Act, Monitor will 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 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". Having specific patient constituencies for members is optional for foundation trusts.

1004. *Subsection (2)* requires a foundation trust to have regard to the population it serves in deciding on the geographic areas 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 separate patient constituency if it decided against including the whole area in its public constituency.

Section 154 – Accounts: initial arrangements

- 1005. This section, and the following section on variations to initial arrangements for accounts, make changes to the accounting requirements of foundation trusts. These sections amend provisions 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 was specific to foundation trusts and is not therefore appropriate to its role as health sector regulator.
- 1006. This section 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.
- 1007. The section requires Monitor to seek the approval of the Secretary of State, rather than of HM Treasury, on foundation trust accounting matters. This enables the Secretary of State to ensure that the accounting directions issued by Monitor are 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.
- 1008. During the financial year 2011/12 foundation trusts moved within the Department's accounting boundary under the cross-Government "clear line of sight" initiative. The effect of this is that foundation trusts are fully consolidated into the Department's resource account. Therefore, foundation trust accounts will, 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 must be consistent with HM Treasury accounting guidance.

Section 155 – Accounts: variations to initial arrangements

- 1009. This section provides that after a transitional period, the powers and duties relating to the production of foundation trust accounts will transfer from Monitor to the Secretary of State. It will not be appropriate for Monitor as the sector regulator to have an ongoing and specific role in foundation trust accounts when this will not be the case for other providers.
- 1010. This section will, once commenced, bring the interim accounting arrangements to an end, as stated in *subsection* (7).
- 1011. This section amends paragraphs 24 and 25 of Schedule 7 to the NHS Act (as amended by the previous section) to substitute the Secretary of State for Monitor in respect of those powers and duties relating to the form, content, timing and other matters concerning the accounts of foundation trusts. The section requires the Secretary of State to seek the approval of HM Treasury on foundation trust accounting matters.

Section 156 – Annual report and forward plan

- 1012. This section specifies new requirements relating to Monitor's existing power to determine the content of foundation trusts' annual reports and provides for the transfer of powers relating to annual reports and forward plans to the Secretary of State.
- 1013. 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. This is in line with the requirements on other public sector organisations and those already set out in Monitor's current code of governance. Subsection (2) requires Monitor to consult before imposing significant new requirements regarding the contents of annual reports.
- 1014. *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. He 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.
- 1015. Subsection (4) places a duty on foundation trusts to send their forward plans to the Secretary of State, rather than to Monitor as previously. Alongside provisions on accounts, this is to ensure the Department of Health has the information it needs to manage its financial obligations, since the spending of foundation trusts counts towards the Department's spending. The effect of subsection (5) is that foundation trusts' forward plans will no longer be included on the register of foundation trusts. The public retain the 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 under paragraph 22(1) (e) of Schedule 7 to the NHS Act.

Section 157 – Meetings

- 1016. This section requires foundation trusts to hold an annual meeting of the trust's membership. This meeting must be open to members of the public. *Subsection (1)* inserts a new paragraph 27A into Schedule 7, and gives the membership of a foundation trust a role in relation to considering the organisation's annual report and accounts. This is intended to secure the accountability of governors and directors to the members and to promote transparency about the trust's performance.
- 1017. *Subsection (1)* also 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.
- 1018. 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 held by the membership with a general meeting of the council of governors.

Section 158 – Voting

- 1019. This section inserts a new paragraph 30 into Schedule 7 to the NHS Act. This gives the Secretary of State, in light of new decision-making powers for foundation trusts in subsequent sections, a regulation-making power subject to the affirmative procedure to alter the associated voting arrangements for directors, governors and members of foundation trusts provided for in this Act. This is to ensure that new voting arrangements for foundation trusts could, if necessary, be modified in light of how they work in practice.
- 1020. Existing voting provisions unaffected by this Act, such as the majority of governors required to remove a non-executive director, are 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 section is intended to ensure that the new voting provisions can be modified if necessary. Under this section, 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.

1021. *Subsection* (2) provides that any regulations made under this section would be subject to the affirmative resolution procedure.

Foundation trust status

Section 159 – Authorisation

- 1022. This section changes the nature of foundation trust authorisation to a one-off test, ahead of the repeal of the provisions on authorisation under a later section. Prior to this Act, Monitor set terms of authorisation when authorising an NHS Trust to become a foundation trust, and those terms formed the basis of Monitor's foundation trust-specific regulatory regime. Under Part 3 of this Act, Monitor will issue licences to providers with conditions attached, and all providers will be regulated on the basis of such conditions. An NHS trust wanting to become a foundation trust after implementation of Monitor's licensing regime will 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.
- 1023. This section 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) places a new requirement on Monitor to seek confirmation from the Care Quality Commission that an applicant trust is currently complying with the requirements mentioned in section 12(2) of the Health and Social Care Act 2008 in relation to the regulated activity or activities carried out by the applicant trust, before Monitor authorises its foundation trust status. *Subsection* (5) removes Monitor's discretion to give an authorisation on particular terms, and *subsection* (6) removes Monitor's ability to vary those terms of authorisation. *Subsections* (7) and (9) make consequential changes which remove the requirement for a copy of the authorisation to be on the register and available for public inspection.
- 1024. 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. Monitor as provider regulator will be able to use its licensing regime to require a provider to provide a particular service. The powers under which Monitor could use terms of authorisation to ensure the provision of a particular service are therefore no longer required. Monitor's previous foundation trust-specific powers to enter and inspect a foundation trust's premises are also no longer required given its proposed new functions as regulator of all providers of NHS services, so *subsection (8)* repeals section 49 of the NHS Act which enables Monitor to exercise such a power.

Section 160 – Bodies which may apply for foundation trust status

1025. This section 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 unnecessary. Section 34 will be repealed when Monitor's licensing regime is implemented. The section also makes consequential amendments to the NHS Act, for example removing powers for Monitor to authorise foundation trusts. If an organisation

were to submit an application prior to the repeal of section 34, *subsections* (4) *to* (7) enable Monitor to consider the application and authorise the organisation as a foundation trust.

Section 161 – Amendment of constitution

1026. This section gives foundation trusts powers to amend their constitutions without seeking external permission. The Act retains the existing requirement on foundation trusts to have a constitution and continues to require trusts' constitutions to include certain information. This section 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 will continue to act as the registrar of foundation trusts, so will be responsible for maintaining on the foundation trust register the constitutions of such organisations.

Section 162 – Panel for advising governors

1027. This section inserts a new section into the NHS Act giving Monitor the power to establish a panel to consider questions brought by governors about the appropriateness of actions taken by their foundation trust. Such a panel could 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 be referred to the panel only if more than half of the members of the council of governors of the trust voting agree. Decisions of the panel will 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 will 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 will allow the Secretary of State to introduce term limits.

Finance

Section 163 - Financial powers etc.

- 1028. This section amends powers relating to the financial matters of foundation trusts.
- 1029. The key changes are, firstly, that the taxpayer's investment in foundation trusts will be managed more explicitly through terms applied to loans, public dividend capital and guarantees of payments under externally financed development agreements. Secondly, that the financing the Secretary of State provides to foundation trusts will be subject to detailed transparency requirements. Thirdly, it updates powers on protecting property and fees in light of changes in Part 3.
- 1030. The first and second changes support the management of both the taxpayer investment in foundation trusts and the provision of new financing to foundation trusts under a transparent and rules-based regime. This provides an explicit and transparent way of protecting 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. The conditions on finance will be set to trigger only in exceptional circumstances so that they do not affect the operational freedoms of foundation trusts.
- 1031. Subsection (1) amends section 40 of the NHS Act to require the Secretary of State to publish an annual report detailing all loans outstanding, loan transactions during

the year and the terms under which those loans were let. The subsection also requires publication of similar information on other forms of finance (public dividend capital, grants and other payments) issued during the year and on public dividend capital held by foundation trusts at the year-end.

- 1032. Terms on the taxpayer investment in a foundation trust could include limits on borrowing to reduce risk to the taxpayer investment. Monitor can also, in its role as health sector regulator, set conditions on financial risk which restrict borrowing, in order to ensure that a provider is financially stable to fulfil its role in ensuring continuity of NHS services. This means the statutory prudential borrowing code and the borrowing limits that are calculated using that code are no longer be required so *subsections (2) and (8)* remove the relevant powers.
- 1033. Subsection (6) requires the Secretary of State to produce guidance on his powers to issue finance or guarantees and set terms conferred under sections 40 and 42 of the NHS Act as amended by this Act. The guidance will set out criteria to be applied when setting the terms and conditions of financing issued under section 40 and those that will be applied to public dividend capital under section 42(3) of the NHS Act.
- 1034. The guidance will cover terms and conditions for loans, public dividend capital and guarantees of payment that fall into two categories. Firstly, it will 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 will cover those conditions that do not directly apply to the financing, which will be designed to highlight material changes in the risks to the taxpayer investment and will 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.
- 1035. *Subsection (5)* of this section sets out the terms that the Secretary of State may attach to public dividend capital issued to a foundation trust in order to protect the value of the taxpayer's investment. These terms could limit a foundation trust's ability to provide goods or services, borrow or invest money, provide financial assistance, apply for dissolution, and apply to acquire another body.
- 1036. *Subsection (7)* repeals Monitor's existing powers to protect foundation trust property. Currently, a foundation trust may not dispose of any protected property without the approval of Monitor. Monitor may designate property as protected if it considers it is needed to provide services to the NHS. In future, under Part 3, Monitor as health sector regulator, could set licence conditions that will enable it to protect property required for the delivery of NHS services.
- 1037. Subsection (9) amends section 50 of the NHS Act to repeal Monitor's current power to require a foundation trust to pay an annual fee to the regulator. Instead this subsection will give Monitor a more specific and constrained ability to require foundation trusts to pay Monitor fees associated with Monitor's two permanent foundation trust-specific functions. These are: maintaining the foundation trust register and, if it decides to do so,

establishing an advice panel for governors. Monitor's fee charging powers in respect of its functions as health sector regulator are addressed in the explanatory notes on Part 3.

Functions

Section 164 – Goods and services

- 1038. This section amends section 43 of the NHS Act on authorised services to remove references to ongoing terms of authorisation, since terms of authorisation will no longer exist under changes proposed by the earlier section on foundation trust authorisation.
- 1039. Subsection (1) retains the 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. It provides that the effect of the principal purpose is that a foundation trust must raise the majority of its income from the provisions of goods and services for the health service in England. This covers services commissioned by and for the health service in England, as well as the publicly funded public health services commissioned by local authorities.
- 1040. Subsection (3) requires every foundation trust to explain in their annual reports the impact that non-NHS income earned has had on their NHS service provision. It also places a duty on the directors to detail their proposals to earn non-NHS income in the foundation trust's forward plan and the income they expect to receive from those activities. Subsection (3) also requires governors to consider the forward plan and to satisfy themselves that any proposal to increase non-NHS income would not significantly interfere with the fulfilment by the foundation trust of its principal purpose or the performance of its other functions. Any proposal by the directors to increase the proportion of total income earned from non-NHS work by five percentage points or more requires agreement by more than half of the members of the council of governors of the trust voting. For example, the governors will be required to vote where a foundation trust plans to increase its non-NHS income from 2% to 7% or more of the trust's total income.

Section 165 - Private health care

- 1041. This section repeals the restriction on the amount of income a foundation trust can derive from private charges, otherwise known as the "private patient income cap".
- 1042. The cap, which was introduced in 2003, had 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%. The cap on mental health foundation trusts' income derived from private charges was increased to 1.5% by section 33 of the Health Act 2009. This Act does not repeal the provisions of section 44 of the NHS Act which allow foundation trusts to charge 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.

Section 166 - Information

1043. This section 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 needs 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.

1044. This information was previously collected and provided to the Department by Monitor under the terms of authorisation of foundation trusts. Given Monitor's new remit, it is no longer appropriate for it to continue to collect information on behalf of the Department when it does not have a similar role for other healthcare providers. Therefore, this section requires foundation trusts to provide the required information directly to the Department.

Section 167 – Significant transactions

1045. This section inserts a new section 51A into the NHS Act which 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 will be able to decide which transactions they want to designate as significant, 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" needs 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 will need to be stated in the constitution, ensuring the agreement of the governors.

Mergers, acquisitions, separations and dissolution

Section 168 – Mergers

- 1046. This section, and the subsequent sections enabling other types of organisational change, make the regime for foundation trusts more flexible, in line with legislation on other types of organisations. They also give foundation trust governors a role in decisions on these organisational changes.
- 1047. The section removes the specific discretion that Monitor had in relation to mergers involving foundation trusts and some of the information requirements needed alongside an application. Monitor's licensing powers under Part 3 will allow it to protect patient and public interests by setting licence conditions giving it a role in any organisational changes which impacted on the provision of essential services.
- 1048. A foundation trust planning to merge will still have to make an application to Monitor, but *subsection* (5) provides that Monitor's foundation trust-specific role in relation to such mergers will be limited to ensuring the necessary steps in the process have been followed, which now include the approval of the council of governors. If satisfied on this point, Monitor is required to grant the application to effect the change. *Subsection* (3) retains the need for Secretary of State to support the application if one of the parties is an NHS trust, to ensure that the interests of the public are properly taken into account.
- 1049. The section also clarifies that references to NHS trusts in this context relate only to English NHS trusts, which are those established under section 25 of the NHS Act.

Section 169 – Acquisitions

- 1050. This section inserts a new section 56A into the NHS Act which makes explicit provision for a foundation trust to acquire another foundation trust or an NHS trust in England.
- 1051. The general powers under section 47 of the NHS Act enable a foundation trust to acquire property of an NHS trust. However, a foundation trust cannot currently acquire another foundation trust: the general powers under section 47 cannot be used as there are currently no powers to dissolve the foundation trust being acquired unless it is in failure

or being merged, which would also require the dissolution of the acquiring foundation trust.

- 1052. The foundation trust proposing to make the acquisition, and the foundation trust or NHS trust to be acquired, would make a joint application to Monitor. Monitor's role is limited to ensuring that the process prescribed by statute has been followed. Subsection (4) of new section 56A provides that Monitor must grant the application if it is satisfied that the necessary steps have been taken.
- 1053. Subsection (2) of new section 56A requires that an application for an acquisition could be made only with the approval of the majority of the governors of each of the foundation trusts involved. Subsection (3)(a) provides that an NHS trust must obtain the support of the Secretary of State before it can be acquired by a foundation trust, which is in line with requirements already in place for mergers.
- 1054. The provision for a foundation trust to be able to acquire an English NHS trust will be removed when the relevant NHS trust legislation is repealed.

Section 170 – Separations

- 1055. This section inserts a new section 57A into the NHS Act which makes explicit provision for a foundation trust to separate into two or more new foundation trusts. This may be necessary, for example, if following a merger a foundation trust was too large to manage itself effectively. This section would allow it to take action to address this.
- 1056. An application may be made by the foundation trust to Monitor for the separation. Monitor is required to grant the application effecting the change if it is satisfied that the necessary preparatory steps had been taken. Subsection (2) of new section 56B requires that such an application may be made only with the approval of the majority of the governors of the foundation trust.

Section 171 – Dissolution

- 1057. This section inserts a new section 57A into the NHS Act which makes provision for a foundation trust, with no remaining liabilities, to dissolve.
- 1058. An application may be made by the foundation trust to Monitor which is required to grant the application, and make the order to effect the administration of the dissolution, if it is satisfied that the foundation trust has no liabilities and that the necessary preparatory steps have been taken. Subsection (2) of the new section 57A requires that such an application may be made only with the approval of the majority of the governors of the foundation trust involved.

Section 172 – Supplementary

- 1059. This section extends the supplementary provisions in the NHS Act relating to mergers involving foundation trusts, so that they now cover mergers, acquisitions, separations and dissolutions.
- 1060. The section 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 section requires that such orders must specify the properties and liabilities to be transferred, and to whom they are to be transferred.
- 1061. This section provides that sections 52A to 52E of, and Schedule 8A to the NHS Act (which would have been inserted by the Health Act 2009) will not come fully into force. These sections would have provided 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 will 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 section

also removes references to sections 52A to 52E, in force only for certain purposes, and Schedule 8A to the NHS Act from other parts of the NHS Act.

Failure

Section 173 – Repeal of de-authorisation provisions

- 1062. Under existing legislation, it is possible for unsustainable foundation trusts to be 'deauthorised'. De-authorisation would cause a foundation trust to become an NHS trust, an outcome which would not be consistent with the policy that all NHS trusts are to become foundation trusts. This section repeals provision of the NHS Act which provides for the de-authorisation of foundation trusts. The effect of this is that an unsustainable foundation trust could continue to exist, as a foundation trust, during a period of special administration under this Act.
- 1063. This section removes the existing (and non-operational) arrangements regarding unsustainable foundation trusts set out in sections 53 to 55 of the NHS Act and removes references to these sections in other provisions of the Act.
- 1064. The section also removes references to NHS trusts created through de-authorisation of a foundation trust in section 206(1) of the National Health Service (Wales) Act 2006, and section 15 of the Health Act 2009.

Section 174 – Trust special administrators

- 1065. This section, and subsequent sections, amend the trust special administration provisions in Chapter 5A of Part 2 of the NHS Act (as amended by the Health Act 2009), provisions which have yet to be applied in practice. The amendments provide for a new role for Monitor to appoint a trust special administrator to oversee an unsustainable foundation trust, on Monitor's behalf, to secure continuity of NHS services in line with the requirements determined by commissioners . The Act provides specific grounds for the Secretary of State to exercise a right to veto the action recommended for a foundation trust by the trust special administrator in individual cases.
- 1066. This section provides for the trust special administration provisions to apply to NHS trusts separately from foundation trusts. In the case of an NHS trust the process would remain unchanged from the previous legislation.
- 1067. The section amends Section 65D of the NHS Act to:
 - Allow Monitor to appoint a trust special administrator to take control of a foundation trust's affairs, on Monitor's behalf, and to work with commissioners to secure continuity of NHS services without the foundation trust being de-authorised;
 - Changes the statutory test that would trigger trust special administration for a foundation trust to a test based on whether the trust is clinically and/or financially sustainable in its current form; and
 - Provide for 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. This suspension would not affect the employment of the executive directors and their membership of any committee or sub-committee of the trust. Monitor may indemnify the trust special administrator as it considers appropriate. This is to allow the administrator to retain certain essential personnel, such as the Medical Director, to help him or her manage the foundation trust.
- 1068. The effect of this section is that if Monitor is satisfied that a foundation trust has become, or is likely to become, clinically or financially unsustainable such that it would be unable to meet current liabilities, the process is as follows:

- Monitor makes an order appointing a trust special administrator to exercise the functions of the chairman, directors and governors of the trust and publishes a report setting out its reason for doing so. Before making such an order, Monitor must consult the Secretary of State. They must then consult the trust, the NHS Commissioning Board, the Care Quality Commission and commissioners of NHS services provided by the foundation trust as they consider appropriate. The appointment of the trust special administrator takes effect within 5 working days of the date on which the order is made;
- After the order is made, the Care Quality Commission must provide Monitor with a report on the quality and safety of the services provided by the trust;
- The administrator appointed manages the foundation trust's affairs, business and property, and exercises their functions in order to secure the continuity of NHS services, as required by commissioners, until these requirements are met.

Section 175 – Objective of trust special administration

- 1069. This section introduces an objective for trust special administration: to secure the continued provision of NHS services, as determined by commissioners, having regard to the criteria in *subsection (3)*.
- 1070. That criterion is whether, in the absence of alternative arrangements, ceasing to provide a particular service would either have a significant adverse impact on the health of persons in need of health care services, or on health inequalities, or cause a failure to prevent or ameliorate a significant adverse impact on the health of such persons, or on health inequalities.
- 1071. Subsection (4) specifies that when determining whether the criterion is met commissioners must have regard to current and future need for the provision of the service and whether ceasing provision of services would significantly reduce equality of access to health care services, as well as such other matters as may be specified in guidance by Monitor on the application of the criteria.
- 1072. Monitor would be required to develop such guidance. Before publishing the guidance or re-publishing revised guidance, Monitor would have to obtain the approval of the Secretary of State and the NHS Commissioning Board.
- 1073. *Subsections* (7) *and* (8) set out the role of the NHS Commissioning Board, which is to be responsible for facilitating agreement between CCGs in determining requirements for securing continued access to NHS services to meet the needs of their communities. Where agreement cannot be reached, the Board would make the decision.

Section 176 – Procedure etc.

- 1074. This section amends the process of trust special administration in relation to foundation trusts in order to give Monitor the role in overseeing the work of the trust special administrator under 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.
- 1075. *Subsection (2)* amends section 65F of the NHS Act so as to require the trust special administrator to provide Monitor with a draft report stating the action which he or she recommends Monitor (rather than the Secretary of State) should take in relation to the foundation trust.
- 1076. Subsections (2) and (3) amend sections 65F and 65G of the NHS Act so that the trust special administrator must not provide the draft report to Monitor, or make changes to the report following consultation, without securing the agreement of the commissioners, or where the commissioners cannot agree this, the agreement of the Board. Where the

Board does not agree the draft report, or the change to the draft report, it must publish its reasons and notify the trust special administrator and Monitor.

- 1077. Subsections (4), (5), (6), (7) and (9) amend sections 65H and 65J of the NHS Act to establish Monitor's role in relation to unsustainable foundation trusts and the process of trust special administration. The amendments require the trust special administrator to obtain a written consultation response from and to hold a meeting with the NHS Commissioning Board and local commissioners, and allow Monitor to direct the trust special administrator to obtain a written consultation for sponse from or to hold a meeting with any other persons (section 65H), as well as allowing Monitor to extend the deadlines in producing the draft report, the consultation stage or producing the final report (section 65J).
- 1078. *Subsection* (8) amends section 65I of the NHS Act so that Monitor would receive the trust special administrator's final report and recommendations in individual cases.

Section 177 – Action following final report

- 1079. This section sets out Monitor's role after receiving the final report and the process for Secretary of State to exercise rights of veto over the administrator's recommendation, including specific grounds for exercise of such a veto.
- 1080. Subsection (1) amends section 65K of the NHS Act, so that it only relates to the final decision on reports on NHS Trusts. Subsection (2) sets out the process for foundation trusts by inserting new sections 65KA to 65KD.
- 1081. New section 65KA sets out the process Monitor must undertake when it has received a report from the trust special administrator.
- 1082. Subsection (1) of new section 65KA provides that, upon receipt of the report, Monitor must determine whether it is satisfied that the recommendations would achieve the objective of the trust special administration (to secure continued access to services in line with requirements determined by the commissioner) such that the order would no longer need to remain in force, and that the trust special administrator has carried out his duties. Monitor has 20 working days to make this decision.
- 1083. If Monitor is satisfied, it must submit the recommendations and a copy of the Care Quality Commission's report on the safety and quality of existing services to the Secretary of State as soon as practically possible (subsection (3)). If Monitor is not satisfied, it must inform the trust special administrator of this decision (subsection (4)). In this case, the trust special administrator would start work on a new set of recommendations as directed by Monitor (subsection (5)).
- 1084. New section 65KB sets out the Secretary of State's role upon receipt of a report from Monitor under section 65KA(3).
- 1085. Subsection (1) provides that the Secretary of State has 30 working days from receipt of the report to determine whether or not he is satisfied that:
 - a) the commissioners have carried out their duties correctly in accordance with Chapter 5A of Part 2 of the NHS Act;
 - b) the administrator has carried out his or her duties correctly;
 - c) Monitor, in accepting the recommendations, has discharged its duties correctly;
 - d) the administrator's recommendations would achieve the commissioners' objective to secure continued access to NHS services;
 - e) the recommendations would secure services of required quality and safety at the trust; and
 - f) the recommendations represent good value for money.

- 1086. If the Secretary of State is not satisfied on any of these points, he must publish a statement setting out his decision and the reasons for it (that is which of the points have not been met and evidence to show this is the case), and notify this to the administrator and to Monitor. A copy of the statement must also be laid before both Houses of Parliament.
- 1087. New section 65KC sets out the process to be followed by the trust special administrator if the Secretary of State vetoes the final report.
- 1088. On rejection of the trust special administrator's final report by the Secretary of State, the administrator will have 20 working days to make the changes to the recommendations in order to address the failures identified by the Secretary of State.
- 1089. The administrator would send the revised report to Monitor, who would have 10 days to consider it in the same way that it considered the original report. Monitor would not need to ask the Care Quality Commission for a further report on the trust's safety and quality, however, as the report should still be accurate.
- 1090. The Secretary of State may extend the 20 working day limit for the administrator's report by order. Where this power has been used, the administrator must publish the new deadline for the revised final report and when, if relevant, the consultation on this change would be undertaken.
- 1091. New section 65KD sets out the Secretary of State's role in responding to a re-submitted report. Subsection (1) states that within 30 working days of receipt of the revised report, the Secretary of State must decide whether he is satisfied as to the matters set out in section 65KB(1)(a) to (f)
- 1092. Where the Secretary of State is unsatisfied on any of these specific grounds he must, as soon as practically possible, publish a statement setting out his decision and the reasons for it and lay this before both Houses of Parliament.
- 1093. If the reason for rejecting the final report is that the NHS Commissioning Board has failed in its duties, it will be considered a failure of the Board to discharge the function, and section 13Z1 will apply. The Secretary of State may direct the Board to perform those functions. If the Board fails to comply with this direction, the Secretary of State may perform these functions himself or direct another person to do so.
- 1094. If the reason for rejecting the final report is that a clinical commissioning group has failed to discharge a functions, this will be considered a failure of the clinical commissioning group to discharge its functions. The Secretary of State may exercise the functions of the Board outlined in sections 14Z19(2), (3) and (8)(a) to exercise functions of a clinical commissioning group and the NHS Commissioning Board cannot exercise those functions in the particular case.
- 1095. Where the Secretary of State has taken on the NHS Commissioning Board's functions under subsection (5)(b), any references to the Board in subsection (9) would instead be read as references to the Secretary of State. The Secretary of State would be able to direct a CCG to perform or cease to perform any functions and CCGs would have to comply with the Secretary of State directions. If a CCG failed to comply with the directions, the Secretary of State could perform the function himself.
- 1096. If the reason for rejecting the revised report is that the trust special administrator or Monitor has failed in its duties, that failure is to be regarded as a failure by Monitor and section 67 of the Act applies, with the omission of subsection (3). If Monitor has failed to perform its functions, the Secretary of State can direct it to perform the functions.
- 1097. New section 65KD also sets out how the Secretary of State would decide what action should be taken in relation to the trust after rejecting the revised final report from the special administrator.

- 1098. Where the Secretary of State has taken on the function of the NHS Commissioning Board, a clinical commissioning group, the trust special administrator or Monitor, he has 60 working days to decide what action to take.
- 1099. The Secretary of State must publish a notice of the decision and the reasons for it, and lay this before Parliament.
- 1100. Subsections (3) and (4) of this section amend section 65L of the NHS Act to set out a different approach to a foundation trust coming out of administration to allow Monitor, rather than the Secretary of State, to bring a foundation trust out of administration and to reflect the process for Secretary of State's decisions as regards his right of veto.
- 1101. The amendments to section 65L also enable Monitor to appoint or remove any governor or director in order to ensure that the foundation trust coming out of administration was legally constituted as set out in Schedule 7 to the NHS Act.
- 1102. This section also inserts a new section 65LA which sets out the process for dissolving a foundation trust, should the Secretary of State not veto plans to do so under value for money grounds under new section 65KB or 65KD, or should the Secretary of State decide to dissolve the trust when intervening under section 65KD. Monitor would then be able to make an order dissolving the foundation trust and transferring, or providing for the transfer of, staff, property and liabilities to another foundation trust or the Secretary of State.

Section 178 – Sections 174 to 177: supplementary

- 1103. This section amends sections 65M and 65N of the NHS Act 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.
- 1104. The section also amends section 39 of the NHS Act to require 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.
- 1105. The section also includes a number of consequential amendments to references to these provisions in other legislation.

Abolition of NHS trusts

Section 179 – Abolition of NHS trusts in England

- 1106. This section repeals the legal framework that establishes NHS trusts in England. All NHS trusts should become foundation trusts as soon as clinically feasible. *Subsection* (1) therefore abolishes NHS trusts established under section 25 of the NHS Act and *subsection* (2) repeals Chapter 3 of Part 2 of the NHS Act. The section is to be commenced by order made by the Secretary of State.
- 1107. There is one circumstance under which an organisation could remain as an NHS trust after the NHS trust legislation is repealed. Under what is described as a franchise agreement (which is defined under this section), a franchisee assumes many of the risks and rewards of ownership. It will be required to deliver agreed outcomes as part of the franchise contract. Under the proposed terms of the contract, the trust will retain its NHS trust status. *Subsection (5)* provides the legislative basis that will 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. A trust could also retain its NHS trust status for up to three years after the franchise contract had ended in order for it to be authorised as a foundation trust, or for an alternative solution to be found.

1108. Schedule 14 to this Act (abolition of NHS trusts in England: consequential amendments) makes the necessary consequential amendments to the NHS Act, and other relevant Acts.

Section 180 – Repeal of provisions on authorisation for NHS foundation trusts

- 1109. Subsections (1) and (2) of this section repeal sections 33 and 35 of the NHS Act (which enable 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.
- 1110. Subsection (3) repeals relevant provisions of section 36 of the NHS Act about the effect of authorisation, as the provisions will not be needed when all NHS trusts are foundation trusts.
- 1111. It also repeals provisions about the automatic grant of a licence under Part 3 of this Act to a foundation trust, as set out in section 88, once the NHS trust legislation is repealed. The section also amends the title of section 36 from "effect of authorisation" to "Status etc of NHS foundation trusts", recognising that organisations will not be authorised as new foundation trusts following the repeal of section 33. *Subsection (7)* provides the savings provisions necessary to enable NHS trusts in franchise agreements to apply for foundation trust status and to be granted a licence under section 88 after the legislation relating to NHS trusts has been repealed.

Part 5 – Public involvement and local government

Chapter 1 – **Public involvement**

Healthwatch England

Section 181 - Healthwatch England

- 1112. This section amends Schedule 1 to and Part 1 of the Health and Social Care Act 2008 (the 2008 Act) and makes consequential amendments to other enactments in relation to the establishment of Healthwatch England as a statutory committee of the Care Quality Commission (CQC).
- 1113. Subsection (2) inserts new sub-paragraphs into paragraph 6 of Schedule 1 to the 2008 Act. New sub-paragraph (1A) provides for the establishment of the Healthwatch England committee of the CQC in accordance with regulations. New sub-paragraph (1B) sets out Healthwatch England's purpose. 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 (as to which see section 182).
- 1114. New sub-paragraph (5A), inserted by *subsection (3)*, requires the regulations under subparagraph (1A) to require the person with power to appoint members to secure that a majority of the members are not members of the CQC. New sub-paragraph (5B) enables those regulations to specify other results to be secured. New sub-paragraph (5C) enables the regulations, in particular, to make provision about eligibility for appointment as a member, and about procedures for selecting or proposing persons to be appointed as members. New sub-paragraph (5D) enables the regulations, in particular, to make provision as to the removal or suspension of members and the payment of remuneration or allowances.
- 1115. Subsection (4) inserts new sections 45A to 45C into Chapter 3 of Part 1 of the 2008 Act. Subsections (1) to (6) of section 45A make provision as to the functions to be performed by Healthwatch England. Subsection (1) provides that those functions are functions of the CQC which the CQC must arrange for Healthwatch England to exercise on its behalf.

- 1116. The function in *subsection* (2) is a duty to provide Local Healthwatch organisations with advice and assistance of a general nature in relation to the making of arrangements with local authorities under section 221(1) of the Local Government and Public Involvement in Health Act 2007 (the 2007 Act) (local arrangements relating to patient and public involvement in health and social care), the making of arrangements, pursuant to those arrangements, with "Local Healthwatch contractors" and the carrying-on of activities mentioned in section 221(2) of the 2007 Act. Those activities relate to patient and public involvement in health and social care. "Local Healthwatch contractors" are persons (individuals or bodies) who assist a Local Healthwatch organisation to carry on those activities or who carry on some of those activities on its behalf.
- 1117. The function in *subsection (3)* is a power to make recommendations to English local authorities about the making of arrangements with Local Healthwatch organisations under section 221(1) of the 2007 Act. The function in *subsection (4)* is a power to give written notice to an English local authority in circumstances where Healthwatch England is of the view that the activities mentioned in section 221(2) are not being properly carried on in its area.
- 1118. The function in *subsection* (5) read with *subsection* (6) is a duty to advise and provide information to the Secretary of State, the NHS Commissioning Board, Monitor and English local authorities on various matters. Those matters are the views of users of health or social care services and others on their needs for such services and their experiences of such services and the views of Local Healthwatch organisations and other persons on the standard of provision of such services and whether or how this could or should be improved.
- 1119. The function in *subsection* (5) could include informing the NHS Commissioning Board of concerns Healthwatch England has identified from feedback from Local Healthwatch organisations about problems with, for example, the commissioning of maternity services across England. *Subsection* (7) requires the Secretary of State, the NHS Commissioning Board, Monitor and English local authorities to inform Healthwatch England in writing of their response or proposed response, to advice given by Healthwatch England.
- 1120. Subsection (8) enables Healthwatch England to provide the CQC with advice and information on various matters. Those matters are the views of users of health or social care services and others on their needs for such services and their experiences of such services and the views of Local Healthwatch organisations and other persons on the standard of provision of such services and whether or how this could or should be improved. Subsection (8) also requires the CQC to inform Healthwatch England in writing of its response, or proposed response, to advice given by Healthwatch England.
- 1121. The CQC is required by *subsection (9)* of new section 45A to publish details of what arrangements it has made for Healthwatch England to perform its functions and these details must be published in a separate report to that published under section 83 (annual reports of the CQC). Healthwatch England is required by *subsection (10)*, when performing functions, to have regard to particular aspects of government policy where the Secretary of State so directs.
- 1122. New section 45B requires the CQC and Healthwatch England to have regard to any guidance from the Secretary of State on managing conflicts of interest between themselves. It requires the CQC, in making arrangements for Healthwatch England to exercise functions on its behalf under section 45A, and Healthwatch England, in exercising functions on behalf of the CQC, to have regard to any guidance issued by the Secretary of State on managing conflicts between the exercise of functions by the CQC and the exercise of functions on behalf of the CQC by Healthwatch England.
- 1123. New section 45C requires Healthwatch England to report annually to the CQC on the views of users of health or social care services and others on their needs for such services and their experiences of such services and the views of Local Healthwatch organisations

and other persons on the standard of service provision and whether or how this could or should be improved. It also requires Healthwatch England to publish a report each year on how it has discharged functions during the year. *Subsection (2)* requires Healthwatch England to lay before Parliament its report on how it has discharged its functions and to send a copy of this report to the Secretary of State and to each Local Healthwatch organisation. *Subsection (3)* allows Healthwatch England to publish other reports at other times about matters relating to health and social care. *Subsection (4)* places a duty on Healthwatch England to have regard to recommendations from Local Healthwatch organisations to publish reports on particular matters under *subsection (3)*. *Subsection (5)* requires that before publishing reports under section 45C(1)(b) or (3) Healthwatch England must exclude, as far as is practicable, information relating to an individual's private affairs which, if published, would seriously and prejudicially affect that individual's interests or might do so.

- 1124. Subsections (5) to (10) of section 181 amend section 82 of the 2008 Act which concerns a power for the Secretary of State to issue a direction to the CQC if the Secretary of State considers that the CQC is failing to carry out its functions, or to carry them out properly and enables the Secretary of State to carry out the CQC's functions if the CQC fails to comply with the direction. The amendments to section 82 ensure that the Secretary of State may similarly direct Healthwatch England if the Secretary of State considers that it is significantly failing or has significantly failed to carry out, or properly carry out, the functions set out in new section 45A or any other functions it is required to discharge. If Healthwatch England fails to carry out the direction, the amendments to section 82 enable the Secretary of State to carry out the function in question or to arrange for someone else to carry out the function.
- 1125. Subsections (11) and (12) of this section insert new subsections (1A) and (2A) into section 83 of the 2008 Act. New subsection (1A) has the effect that the duty on the CQC to report annually on its exercise of functions does not apply in relation to its functions under section 45A. The CQC is required by section 45A(1) to arrange for Healthwatch England to carry out those functions and the preparation of annual reports on those functions is the duty of Healthwatch England itself under section 45C(1) of the 2008 Act. New subsection (2A) inserted by subsection (12) has the effect that the CQC's annual report on the provision of NHS care and adult social services must separately set out and identify the contents of Healthwatch England's report made to it on the matters mentioned in section 45A(5). Those matters are the views of users of health or social care services and others on their needs for such services and other persons on the standard of service provision and whether or how this could or should be improved.
- 1126. Subsection (13) makes consequential amendments to the Public Records Act 1958, the House of Commons Disqualification Act 1975 and the Northern Ireland Assembly Disqualification Act 1975 to provide that the records of Healthwatch England are public records for the purposes of the Public Records Act 1958 and that its members are disqualified from being members of the House of Commons and of the Northern Ireland Assembly.
- 1127. *Subsection (14)* has the effect that meetings of the Healthwatch England committee will, in general, have to be open to the public as per the Public Bodies (Admission to Meetings) Act 1960.

Local Healthwatch organisations

Section 182 – Activities relating to local care services

1128. This section amends section 221 of the 2007 Act as part of a set of amendments to Part 14 of that Act, which concerns local arrangements for patient and public involvement in health and social care. Section 221 of the 2007 Act imposes a duty on local authorities to make contractual arrangements for the involvement of people in the commissioning,

provision and scrutiny of health and social services. In this context *subsection (2)* of section 182 replaces references in section 221(2)(a), (b) and (c) of the 2007 Act to "people" with references to "local people"; and *subsection (8)* introduces a definition of "local people" in section 221(6).

- 1129. Subsections (3) to (5) further add to the list of Local Healthwatch activities mentioned in section 221(2) of the 2007 Act in relation to which local authorities must make contractual arrangements. Subsection (3) adds an activity of making people's views known and making reports and recommendations for improvements to health and social care services to Healthwatch England. Subsection (4) read with subsection (5) adds activities of reaching views on service standards and improvements, making those views known to the Healthwatch England committee, giving advice and information about access to local health and social care services and about choices in relation to these services, making recommendations to Healthwatch England to advise the CQC to conduct special reviews or investigations or directly making such recommendations to the CQC, making recommendations to Healthwatch England to publish reports about particular matters relating to health or social care and assisting Healthwatch England. In accordance with amendments made by section 183 to section 222 of the 2007 Act the contractual arrangements would have to be made with Local Healthwatch organisations.
- 1130. Subsection (6) inserts new subsection (3A) into section 221 to place a duty on persons to whom the views of people are made known or reports or recommendations for service improvements are made under section 221(2)(d) to have regard to those views, reports or recommendations when exercising functions relating to health or social care services. Under section 221(2)(d) such views, reports or recommendations could be given or made to persons responsible for commissioning, providing, managing or scrutinising health or social care services.
- 1131. *Subsection* (7) requires the local authority to ensure that only one contract under section 221(1) (with a Local Healthwatch organisation) is in force in relation to its area at any one time.
- 1132. Subsection (11) inserts new section 45D into the 2008 Act which provides a power for the CQC to grant a licence for use of a registered trademark, of which the CQC is the proprietor, to Local Healthwatch organisations in relation to the carrying-on of Local Healthwatch activities. It would enable the licence to provide for the grant of a sub-licence authorising use of the trademark by a Local Healthwatch contractor, in relation to the carrying-on of those activities under arrangements made by Local Healthwatch organisations.

Section 183 – Local authority arrangements

- 1133. This section makes provision as to the contractual arrangements that a local authority is required to make under section 221(1) of the 2007 Act.
- 1134. Subsection (2) amends section 222 of the 2007 Act to specify who a local authority must contract with under section 221(1) for the carrying-on of Local Healthwatch activities. It requires the contractual arrangements under section 221(1) to be made with a body corporate which is a social enterprise, and which satisfies any criteria prescribed by regulations. It inserts new *subsection* (2A) into section 222 which provides that the body contracted under section 221(1) is to have the function of carrying on the Local Healthwatch activities in the area concerned and is to be known as the Local Healthwatch organisation for that area. Subsection (2) of section 183 also inserts new *subsection* (2B) into section 222 of the 2007 Act which enables local authorities to authorise Local Healthwatch organisations to make arrangements (Local Healthwatch arrangements) for other persons (Local Healthwatch contractors) (which could be individuals or bodies) to assist them to carry on the activities or to carry on some of the activities on their behalf.
- 1135. Subsections (3) to (5) make consequential amendments to section 222 of the 2007 Act.

- 1136. Subsection (6) inserts new subsections (7A) and (7B) into section 222 of the 2007 Act. New subsection (7A) places a duty on local authorities to seek to ensure that the arrangements they make with Local Healthwatch organisations are operating effectively and are providing value for money. Subsection (7B) requires the local authority to publish a report of its conclusions in seeking to meet these two objectives.
- 1137. Subsection (7) substitutes subsection (8) of section 222 of the 2007 Act and inserts new subsections (9) and (10) into that section. Subsection (8) as substituted sets out when a body is a social enterprise for the purposes of the duty under section 222(2). For these purposes a body is a social enterprise if it could reasonably be considered to act for the benefit of the community in England (the community benefit test) and it satisfies any criteria prescribed in regulations. New subsection (9) provides a regulation-making power to allow provision to be made about the sort of activities that are to be treated as meeting it. New subsection (10) clarifies that "community", for these purposes, includes a section of the community and provides a regulation-making power to allow provision to be made a section of the community.
- 1138. Subsection (9) inserts new section 222A into the 2007 Act to impose a duty on the local authority to have regard to any guidance from the Secretary of State on managing conflicts of interest between the making of arrangements under section 221(1) of the 2007 Act with Local Healthwatch organisations and the carrying-on of Local Healthwatch activities. It also requires the local authority to require the Local Healthwatch organisation to have regard to such guidance.

Section 184 – Local arrangements: power to make further provision

- 1139. This section amends section 223 of the 2007 Act, which concerns a duty to make regulations concerning the contents of local authorities' contractual arrangements with Local Healthwatch organisations under section 221(1) of the 2007 Act.
- 1140. Subsection (2) makes a consequential amendment to section 223(1) of the 2007 Act.
- 1141. Subsection (3) inserts new subsection (1A) into section 223 which provides a power for the Secretary of State to make regulations requiring local authorities, in their contractual arrangements under section 221(1), to require Local Healthwatch organisations to include particular provision in their arrangements with Local Healthwatch contractors.
- 1142. Subsection (4) makes amendments to section 223(2). These include a power for regulations under section 223(1) or (1A) to require local authorities to include prescribed provision in their contractual arrangements with Local Healthwatch organisations and, similarly, to require local authorities to require Local Healthwatch organisations in their arrangements with Local Healthwatch contractors to include prescribed provision. The provision which may be prescribed includes provision relating to the activities which a Local Healthwatch contractor may not carry out on behalf of a Local Healthwatch organisation, the obtaining (by a Local Healthwatch organisation) of a licence from the CQC for use of a trade mark, the grant of a sub-license to a Local Healthwatch contractor, the use or infringement of the trade mark, and the imposition of a requirement for a Local Healthwatch organisation to act with a view to securing that its Local Health contractors are representative of local residents and service users.

Section 185 - Independent advocacy services

1143. This section requires local authorities to make arrangements for the provision of independent advocacy services in relation to their area for complaints relating to the provision of health services and, as set out in *subsection* (2), removes this duty from the Secretary of State.

- 1144. *Subsection (1)* of this section inserts new section 223A into the 2007 Act to require local authorities to make arrangements for the provision of independent advocacy services in relation to their area.
- 1145. Subsection (2) of new section 223A defines "independent advocacy services". These are services providing assistance (whether by way of representation or otherwise) to persons making various types of complaints in relation to the provision of health services, or to persons intending to make such complaints. Subsection (3) enables a local authority to make other arrangements for the provision of services to assist individuals in connection with complaints relating to services provided as part of the health service.
- 1146. Subsection (4) of new section 223A provides that where a local authority makes arrangements for a person to arrange for the provision of independent advocacy services, that person may not commission the services from a Local Healthwatch organisation. This does not prevent local authorities from making arrangements for the provision of independent advocacy services by Local Healthwatch organisations directly, or by other providers.
- 1147. *Subsection* (5) of new section 223A provides that local authorities must have regard to the principle that, as far as practicable, the provision of independent advocacy services or other services under section 223A should be independent of the person being complained about, or involved in investigating the complaint or adjudicating on it.
- 1148. *Subsection* (6) of new section 223A enables the local authority to make payments to providers of independent advocacy services or other services under section 223A and to persons arranging for the provision of such services.
- 1149. *Subsection (7)* of new section 223A enables the Secretary of State to make regulations to require a provider of independent advocacy services to have in place insurance cover against any claims that could be made against the provider for negligence whilst providing those services.
- 1150. *Subsections (8)* and *(9)* of new section 223A enable the Secretary of State to direct local authorities about the exercise of functions under section 223A, and to vary or revoke such directions. This would allow the Secretary of State to direct local authorities to, for example, make arrangements for the provision of independent advocacy services to a particular level or in a particular way.
- 1151. Subsections (3) and (4) of section 185 make consequential amendments to section 134 of the Mental Health Act 1983 and section 59 of the Safeguarding Vulnerable Groups Act 2006 respectively.

Section 186 - Requests, rights of entry and referrals

- 1152. Subsections (1) to (5) amend section 224 of the 2007 Act, the effect of which is to enable the Secretary of State to make regulations to impose a duty on certain persons such as certain providers or commissioners of health or social care services to respond to requests for information, or reports or recommendations made by Local Healthwatch organisations or Local Healthwatch contractors when those organisations or contractors are carrying on Local Healthwatch activities or when Local Healthwatch organisations are discharging the duty under regulations under section 223(2)(i) to act with a view to securing that Local Healthwatch contractors are representative of the local area.
- 1153. Subsections (6) to (11) amend section 225 of the 2007 Act, the effect of which is to require the Secretary of State to make regulations to impose a duty on certain persons such as certain providers of health or social care services to allow representatives of Local Healthwatch organisations to enter and view premises and carry out observations for the purposes of carrying-on of Local Healthwatch activities, under arrangements under section 221(1) or Local Healthwatch arrangements.

1154. Subsections (12) to (16) make consequential amendments to section 226 of the 2007 Act, which imposes duties on local authority overview and scrutiny committees in relation to referrals of social care matters, including a duty to acknowledge receipt of referrals and to keep the referrer informed of the committee's actions. The amendments provide that those duties apply in relation to referrals by Local Healthwatch organisations or Local Healthwatch contractors instead.

Section 187 – Annual reports

- 1155. This section amends section 227 of the 2007 Act. The effect is that Local Healthwatch organisations are to be required to produce an annual report for each financial year. This includes a 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. Arrangements made by local authorities under section 221 must also have a requirement for the report to be made publicly available. Arrangements made publicly available, to have regard to any guidance issued by the Secretary of State. The report must be required to set out the amounts spent by the Local Healthwatch organisation and its Local Healthwatch contractors and what those amounts were spent on.
- 1156. Subsection (5) amends section 227(4) of the 2007 Act to ensure that arrangements made by local authorities under section 221 must require copies of the annual reports to be sent to the NHS Commissioning Board, relevant CCGs and Healthwatch England in addition to the categories of persons to whom such reports were previously required to be sent. Under the amendments made by *subsection (5)*, those categories no longer include the Secretary of State.

Section 188 – Transitional arrangements

- This section is intended to assist local authorities to transfer arrangements 1157. under section 221(1) of the 2007 Act to Local Healthwatch organisations, upon commencement of the provisions amending 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. Subsections (3) to (9) set out further details in respect of property and staff transfer schemes which may be made. A scheme may make provision for transfer of staff and may make provision which is the same or similar to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (S.I. 2006/246) (subsection (3)). The scheme may transfer property, rights and liabilities, including those that could not otherwise be transferred (subsection (4)). New rights can be created, or liabilities imposed, in relation to the property or rights transferred (subsection (5)). Provision may be made in the scheme about the continuing effect of things a 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 done in relation to the transferor in respect of the things transferred (subsection (6)). A scheme can provide for the continuation of legal proceedings (subsection (7)).
- 1158. *Subsection* (8) enables the Secretary of State's scheme to require a local authority to pay compensation to the transferor and to require the local authority to determine the amount of the compensation or to give powers to the Secretary of State to do so. A scheme may also make supplementary, incidental and consequential provision (*subsection* (9)).

Section 189 – Consequential provision

1159. This section makes amendments to various provisions of legislation consequent on the provisions relating to Local Healthwatch organisations.

Chapter 2 – Local Government

Scrutiny functions of local authorities

Section 190 - Scrutiny functions of local authorities

- 1160. This section amends section 244 of the NHS Act which concerns a power to make regulations on review and scrutiny of matters relating to the health service (health scrutiny) by local authority overview and scrutiny committees. Amongst other things, the amendments have the effect that the regulations may make provision relating to health scrutiny by local authorities themselves. The amendments enable those regulations to authorise the local authority to arrange for an overview and scrutiny committee to discharge the health scrutiny functions.
- 1161. Subsection (2) of this section amends subsection (2) of section 244 of the NHS Act so that the regulation-making power it confers applies in relation to health scrutiny by a local authority itself as opposed to an overview and scrutiny committee of a local authority. Local authorities will no longer be required to have overview and scrutiny committees to discharge health scrutiny functions, but will continue to have such functions (under regulations under section 244), which they will, in general, be able to discharge in various ways. For example, local authorities may choose to continue to operate their existing health overview and scrutiny committees, or may choose to put in place other arrangements such as appointing committees involving members of the public. As such, the amendments made by this section will not prevent a local authority having an overview and scrutiny committee to discharge its health scrutiny functions.
- 1162. The regulation-making powers previously enabled provision to be made on the matters on which an NHS body must consult the local authority overview and scrutiny committee and to require officers of NHS bodies to attend before the committee to answer questions and NHS bodies to provide information to it. The amendments to *subsection (2)* of section 244 will instead provide that requirements to consult the local authority, to attend before it and to provide information to it can be applied to or in relation to "relevant NHS bodies" or "relevant health service providers". This will potentially include CCGs, the NHS Commissioning Board and providers of health services commissioned by the NHS Commissioning Board, CCGs and the local authority, including independent sector providers.
- 1163. Subsection (3) inserts new subsections (2ZA), (2ZB), (2ZC), (2ZD) and (2ZE) into section 244 of the NHS Act.
- 1164. 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 relevant NHS bodies or relevant health service providers must consult the local authority. This includes provision as to circumstances in which those matters may be referred to the Secretary of State, Monitor, or the NHS Commissioning Board. It also includes provision conferring 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 CCG.
- 1165. New *subsection (2ZB)* sets out further details of the powers to give directions that may be conferred under new *subsection (2ZA)*. New *subsection (2ZC)* enables regulations under new *subsection (2ZA)* to either disapply any provision of section 101 of the local Government Act 1972 in relation to the local authority's discharge of the function of making referrals, or to provide for such provision to apply with prescribed modifications. For example, this would enable the regulations to prevent the local authority from arranging for a committee to discharge the function of making such referrals under section 101 of the Local Government Act 1972. New *subsection (2ZD)* provides that the local authority's health scrutiny functions are not functions of an executive of the authority under executive arrangements. This means that, under such arrangements, the functions would be functions of the local authority as a whole.

- 1166. New *subsection (2ZE)* 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.
- 1167. *Subsection (4)* inserts a definition of "relevant NHS body" and "relevant health service provider" into section 244. *Subsection (5)* inserts a definition of "member" in relation to various NHS bodies or certain "relevant health service providers".
- 1168. Subsection (9) amends section 21 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 (2ZE) of section 244 of the NHS Act. This would ensure that local authorities are not prevented from arranging for overview and scrutiny committees to discharge health scrutiny functions. Subsection (10) makes similar amendments to section 9F of the Local Government Act 2000 (which will replace section 21 by virtue of the Localism Act 2011).

Section 191 – Amendments consequential on section 190

- 1169. This section makes consequential amendments to existing provisions on scrutiny in the NHS Act. *Subsections (1) to (5)* of this section amend section 245 of the NHS Act which enables regulations to be made enabling local authorities to discharge their scrutiny functions with each other through a joint overview and scrutiny committee, and to make certain other arrangements. The amendments made by *subsections (1), (2) and (3)* ensure that section 245 reflects the amendments made to section 244 whereby the regulation-making powers apply in relation to local authorities directly as opposed to overview and scrutiny committees. This effectively enables regulations to continue to enable local authorities to make joint or other scrutiny arrangements.
- 1170. *Subsection (4)* has the effect that the regulation-making power in section 245 includes a power to provide that where a local authority arranges for a joint overview and scrutiny committee to exercise any of its health scrutiny functions, the local authority may not discharge that function.
- 1171. Subsections (6) to (9) amend section 246 of the NHS Act. Section 246 provides that in relation to business discussed at a meeting of an overview and scrutiny committee, information is exempt information for the purposes of provisions of the Local Government Act 1972 if certain conditions are met. Those provisions enable certain local authorities to exclude the public from meetings whenever it is likely that exempt information would otherwise be disclosed. The changes made by subsections (6) to (9) reflect the changes to section 244 under which scrutiny functions can be conferred directly on local authorities and could be discharged by committees. This ensures that, as with the current situation for health overview and scrutiny functions at meetings for example, commercially confidential material the public can be excluded from meetings.
- 1172. Subsections (10) to (13) amend section 247 of the NHS Act which makes provision in relation to scrutiny by the Common Council for the City of London. The amendments made by subsections (10) to (13) ensure that section 247 reflects the amendments made to section 244 under which scrutiny functions can be conferred directly on local authorities and could be discharged by committees. The Common Council will have flexibility like other local authorities in discharging its health scrutiny functions.

Joint strategic needs assessments and strategies

Section 192 – Joint strategic needs assessments

- 1173. This section amends section 116 of the Local Government and Public Involvement in Health Act 2007 (the 2007 Act), so that a local authority, and CCGs that have a boundary within or overlapping or coinciding with that local authority, have a duty to prepare a joint strategic needs assessment or assessment of relevant needs. A joint strategic needs assessment is essentially a process to identify the current and future health and social care needs of a population in a local authority area.
- 1174. *Subsection* (2) amends *subsection* (4) of section 116 of the 2007 Act so that the duty to prepare the assessment of relevant needs is transferred from each partner PCT to each partner CCG of the local authority.
- 1175. 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 CCGs. They also widen the scope of a "relevant need" so that it covers both the current and future needs of the local population, and not just current needs.
- 1176. *Subsection (4)* amends *subsection (7)* of section 116 of the 2007 Act to replace references to "the partner PCT" with references to "the partner clinical commissioning group or the National Health Service Commissioning Board".
- 1177. *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 CCG of the local authority.
- 1178. *Subsection (5)* also imposes an additional duty on CCGs and local authorities to involve the Local Healthwatch organisation and the people who live or work in the local authority's area when preparing their joint strategic needs assessment. This subsection also replaces the duty to consult each relevant district council when preparing the assessment with a duty to involve each such council.
- 1179. Subsection (6) inserts a new subsection (8A) into section 116 of the 2007 Act to enable the local authority or partner CCG to consult any person it thinks appropriate when preparing the joint strategic needs assessment.
- 1180. *Subsection* (7) substitutes the definition of "partner PCT" with a definition of "partner clinical commissioning group" and makes consequential amendments to the definition of "relevant district council".

Section 193 – Joint health and wellbeing strategies

- 1181. This section inserts new sections 116A and 116B into the 2007 Act. New section 116A imposes a duty on local authorities and CCGs to produce "a joint health and wellbeing strategy" for meeting the needs identified in the joint strategic needs assessment.
- 1182. New section 116B imposes a duty on partner CCGs, 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 functions.
- 1183. Section 116A does not specify the form the joint health and wellbeing strategy should take. It requires a strategy for meeting the needs identified in the joint strategic needs assessment to be prepared, and requires the local authority and partner CCGs to have regard to the Secretary of State's mandate under section 13A of the NHS Act and any guidance issued by the Secretary of State when preparing the strategy. For example, subject to guidance, 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.

- 1184. *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 CCG must prepare a strategy for meeting those needs.
- 1185. *Subsection (3)* requires the local authority and its partner CCGs 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 wellbeing strategy.
- 1186. Subsection (4) requires the local authority and its partner CCGs to have regard to the Secretary of State's mandate to the NHS Commissioning Board when preparing the joint health and wellbeing strategy. It also requires them to have regard to guidance issued by the Secretary of State in preparing the strategy. This duty mirrors the duty of a local authority and partner CCGs to have regard to guidance on the preparation of the joint strategic needs assessments under section 116 of the 2007 Act.
- 1187. *Subsection (5)* imposes an additional duty on CCGs and local authorities to involve the Local Healthwatch organisation and the people who live or work in the local authority's area when preparing the joint health and wellbeing strategy. This is similar to the duty imposed by section 192(5) in relation to the joint strategic needs assessment.
- 1188. *Subsection (6)* requires the local authority to publish the joint health and wellbeing strategy.
- 1189. *Subsection* (7) enables the local authority and partner CCGs 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.
- 1190. Subsection (1) of section 116B places a duty on a local authority, and each partner CCG in exercising functions to have regard to any joint strategic needs assessment and joint health and wellbeing strategy which is relevant to the exercise of those functions. Subsection (2) places a duty on the NHS Commissioning Board to have regard to any joint strategic needs assessment and joint health and wellbeing strategy which is relevant to its local commissioning functions when discharging those functions.

Health and Wellbeing Boards: establishment

Section 194 – Establishment of Health and Wellbeing Boards

- 1191. This section requires each upper tier local authority to establish a Health and Wellbeing Board for its area (*subsection* (1)).
- 1192. The section also sets out their 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 local authority and/or a councillor or councillors nominated by them (*subsections* (3) and (4)). The Local Healthwatch organisation and each relevant CCG must also appoint representatives (*subsections* (5) and (6)). A CCG may, with the consent of the Health and Wellbeing Board, be represented by the representative of another CCG which has a boundary within or coinciding with the local authority area (*subsection* (7)).
- 1193. Subsection (8) enables the Board to appoint additional persons as members. The local authority will also be able to invite other persons or representatives of other persons to become members, for example local voluntary groups or service providers (subsection (2)(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 CCG to co-operate with the Health and Wellbeing Board in the exercise of the Board's functions.

- 1194. *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.
- 1195. 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.

Health and Wellbeing Boards: functions

Section 195 – Duty to encourage integrated working

- 1196. This section imposes a duty on Health and Wellbeing Boards to encourage integrated working between commissioners of NHS, public health and social care services for the advancement of the health and wellbeing of the local population. A Health and Wellbeing Board must provide advice, assistance or other support in order to encourage partnership arrangements such as the developing of agreements to pool budgets or make lead commissioning arrangements under section 75 of the NHS Act.
- 1197. *Subsection (1)* requires a Health and Wellbeing Board, for the purpose of advancing the health and wellbeing of the people in its area, to encourage persons who arrange for the provision of health or social care services in its area to work in an integrated manner.
- 1198. *Subsection* (2) requires the Health and Wellbeing Board, in particular, to provide advice, assistance or other support as it thinks appropriate for the purpose of encouraging arrangements under section 75 of the NHS Act. These are arrangements under which, for example, NHS bodies and local authorities agree to exercise specified functions of each other or pool funds.
- 1199. 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) enables the Board to encourage such persons to work closely with commissioners of health and social care services. Subsection (6) defines expressions such as "health services", "health-related services" and "social care services" for the purposes of this section.

Section 196 – Other functions of Health and Wellbeing Boards

- 1200. This section makes provision about the functions of Health and Wellbeing Boards.
- 1201. *Subsection (1)* requires the functions of CCGs and local authorities of preparing joint strategic needs assessments and joint health and wellbeing strategies to be discharged by a Health and Wellbeing Board.
- 1202. *Subsection* (2) enables the local authority to delegate any functions exercisable by it to the Health and Wellbeing Board it established. This could, where appropriate, potentially extend to functions relating to wider determinants of health, such as housing, that affect the health and wellbeing of the population.
- 1203. *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 wellbeing strategy in discharging functions.
- 1204. *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 Wellbeing Boards: supplementary

Section 197 - Participation of the NHS Commissioning Board

- 1205. This section provides for participation of the NHS Commissioning Board in a Health and Wellbeing Board's activities. The NHS Commissioning Board will be required to appoint 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 appoint a representative for the purpose of considering 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.
- 1206. 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 2007 Act or a joint health and wellbeing 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.
- 1207. Subsections (3) and (4) have the effect that 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 area of the local authority that established the Health and Wellbeing Board, 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.
- 1208. *Subsection (5)* enables the NHS Commissioning Board to appoint as its representative someone other than a member or employee of its, subject to the agreement of the Health and Wellbeing Board.
- 1209. *Subsection* (6) defines "commissioning functions" in relation to the NHS Commissioning Board, and it defines "the health service".

Section 198 - Discharge of functions of Health and Wellbeing Boards

1210. This section 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. It enables the Boards to arrange for a joint sub-committee to advise them.

Section 199 – Supply of information to Health and Wellbeing Boards

1211. This section allows a Health and Wellbeing Board to request the provision of information from certain persons, for example, the Local Healthwatch organisation represented on the Board and the CCGs so represented, for the purpose of enabling or assisting it to perform functions. *Subsection (2)* requires those persons to supply the information. *Subsection (4)* requires that the information requested must relate to a function of the person from whom the information is requested, or a person in respect of whom a function is exercisable by that person. For example, information could be requested 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

Section 200 – Care Trusts

1212. This section amends section 77 of the NHS Act to make it possible for NHS foundation trusts or CCGs, alongside local authorities, to form Care Trusts, if they decided that

this was the best way to meet the needs of their local populations. The section also makes amendments that abolish the direct role of the Secretary of State in the process of forming or removing the designation of a Care Trust.

- 1213. Care Trusts, provision for which is made in section 77 of the NHS Act, provide opportunities for close integrated working across health and social care services..
- 1214. 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 CCGs to be designated as Care Trusts. Current legislation makes no provision for Care Trusts to be formed with any NHS partners other than PCTs and NHS trusts. Provisions in other Parts of this Act for the abolition of PCTs and NHS trusts mean that Care Trusts, in their current form, would cease to exist without these changes. Inclusion of NHS foundation trusts and CCGs in subsection (10) of section 77 ensures that forming the Care Trust will not affect any of their core functions, rights or responsibilities. In addition, new subsection (5D) (inserted by subsection (7)) 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.
- 1215. Subsections (1), (2) and (5) to (7) address subsections (1) and (5) of Section 77 of the NHS Act; subsections (2) and (5) in particular insert new subsections (1A), (5A), (5B), (5C) and (5D). These changes end the direct involvement of the Secretary of State in the process of forming a Care Trust or removing a designation as a Care Trust. This includes removing the Secretary of State from any direct involvement in specifying the area of the Care Trust. The decision to form or remove the designation of 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 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.
- 1216. 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) of section 200 inserts new sections (1A) and (1B) into section 77 which require the body and the local authority to publish and consult on their reasoning and the proposed Care Trust governance arrangements. Regulations may 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 the Care Trust designation was removed) and the names of the bodies involved in the Care Trust.
- 1217. Subsections (2) and (5) (in particular, new subsections (1B) and (5B)) provide that having decided to form a Care Trust or remove a Care Trust designation, the NHS body and the local authority will have to notify interested parties. The prescribed persons to be notified could include the NHS Commissioning Board, Monitor, the 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 Boards.
- 1218. 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.

- 1219. 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 will not apply to Care Trusts that have already gone through the process under the previous legislative requirements. Care Trusts that have already met those requirements will not have to fulfil any additional requirements to enable them to remain as Care Trusts.
- 1220. Subsections (14) and (15) provide that an NHS trust or PCT which became a Care Trust prior to the commencement of the new provisions but then decided to cancel the arrangement after commencement of this Section, will still need to notify the Secretary of State, who will amend the establishment order to remove the words 'Care Trust' from its title. These provisions will remain in force until the point when PCTs and NHS trusts are abolished. This is because the name of a PCT or NHS trust is set out in its establishment order which could only be amended by an order made by the Secretary of State. By repealing subsection (6) of Section 77 the requirement than an NHS body must include the words "Care Trust" in its title or branding is removed.

Chapter 3 – The Health Service Commissioner for England

Section 201 – Disclosure of reports etc. by the Health Service Commissioner

1221. This section amends section 14 of the Health Service Commissioners Act 1993 to enable the Health Service Commissioner for England, more commonly known as the Health Service Ombudsman, to share complaints investigation reports and statements of reasons with such persons as the Ombudsman 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

Section 202 - Medical services: minor amendments

1222. This section 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.

Section 203 - Persons eligible to enter into general dental services contracts

- 1223. This section 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 section 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.
- 1224. Subsections (2), (3) and (4) 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.
- 1225. Subsections (5), (6) and (7) 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.

Section 204 - Arrangements under section 107 of the National Health Service Act 2006

- 1226. This section 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.
- 1227. Subsections (2) to (4) follow the approach used in the amendment to section 102(1). They amend section 108(1) and insert new subsections (1A), (1B) and (1C) into section 108, which allow the Board to make section 107 (PDS) agreements with a dental corporation or, where certain conditions are satisfied, 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.
- 1228. *Subsection* (5) omits current section 108(2) as the section is no longer required as a consequence of the amendment to section 108(1).
- 1229. 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".

Section 205 - Payments in respect of costs of sight tests

- 1230. This section amends section 180 of the NHS Act (payments in respect of costs of optical appliances). Further amendments to this section are made in Schedule 4 to take account of the fact that in future such payments will be made by the NHS Commissioning Board.
- 1231. Subsection (2) amends section 180 by inserting a new paragraph (za) into subsection (3) which clarifies the existing payment powers that underlie current practice.
- 1232. *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.

Section 206 - Pharmaceutical needs assessments

- 1233. This section makes amendments to sections 24, 24A, 128A, 242 and 242A of the NHS Act.
- 1234. Subsection (1) amends section 128A of the NHS Act which makes provision in respect of the arrangements for preparing pharmaceutical needs assessments. Pharmaceutical needs assessments are closely aligned to joint strategic needs assessments which are addressed in section 189. The amendments to section 128A will ensure that the responsibility for developing, updating and publishing local pharmaceutical needs assessments is transferred from PCTs to health and wellbeing boards in local authorities.
- 1235. Subsections (2) to (5) amend sections 24, 24A, 242 and 242A respectively to remove, pending the abolition of PCTs and SHAs, their consultation and service user engagement obligations. In practical terms, these obligations are effectively discharged by PCTs when complying with the requirements in section 128A when they consult in relation to their pharmaceutical needs assessments.

Section 207 - Control of entry on pharmaceutical lists

- 1236. This section makes amendments to paragraphs 129, 130 and 136 of Schedule 12 to the NHS Act.
- 1237. Subsection (2) amends subsection (2)(c) of section 129 of the NHS Act. Section 129 makes provision in respect of the control of entry test which applies in respect of

the right to be included on the pharmaceutical list in order to provide pharmaceutical services. The amendments to subsection (2)(c) provide that the NHS Commissioning 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 as prescribed in regulations.

- 1238. *Subsection (3)* inserts a new subsection (2ZA) into section 129 of the NHS Act which provides that the NHS Commissioning Board may not include the Secretary of State and such other persons as may be prescribed in regulations in a pharmaceutical list.
- 1239. *Subsection (4)* amends subsection (2A) of section 129 of the NHS Act consequential to the establishment of the NHS Commissioning Board and the requirement to have regard to a pharmaceutical needs assessment prepared in respect of a particular area before granting an application.
- 1240. *Subsection (5)* substitutes subsection (2B) of section 129 of the NHS Act so as to define the "relevant area" in relation to a needs statement, for the purposes of subsection (2A), 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 pharmaceutical needs assessment as currently published and updated by PCTs and in future by health and wellbeing boards.
- 1241. Subsections (6) and (7) amend subsections (2C) and (4)(c) of 129 of the NHS Act consequential to the amendments at subsections (4) and (5) of this section.
- 1242. 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).
- 1243. 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 pharmaceutical needs assessments transferring to health and wellbeing boards and as a consequence of pharmaceutical needs assessments being carried out by reference to "relevant areas" as defined in section 129 of the NHS Act.
- 1244. Subsection (10) amends section 130 of the NHS Act so as to ensure that appeals against the NHS Commissioning 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 NHS Commissioning 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.

Section 208 - Lists of performers of pharmaceutical services and assistants etc.

- 1245. This section makes provision for the NHS Commissioning Board to establish lists of Local Pharmaceutical Service performers and those who assist pharmaceutical contractors in the provision of pharmaceutical services.
- 1246. Subsection (1) of this section omits sections 146, 149 and 150 of the NHS Act which make provision for the compilation and publication of lists of Local Pharmaceutical Service performers and those who assist pharmaceutical contractors in the provision of services.

- 1247. *Subsection (2)* of this section 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 Local Pharmaceutical Service performers and those who assist pharmaceutical contractors in the provision of pharmaceutical services.
- 1248. Subsection (1) of new section 147A provides that the Secretary of State may make regulations providing for the NHS Commissioning Board to maintain and publish one or more lists of those persons who assist pharmaceutical contractors or who are Local Pharmaceutical Service performers.
- 1249. Subsection (2) of new section 147A enables the regulations to provide that persons of a prescribed description (such as pharmacist managers and employees or pharmacy technicians) may not assist in the provision of pharmaceutical services which the Board arranges, or perform local pharmaceutical services, unless such persons are included in a list prepared by virtue of regulations made under subsection (1).
- 1250. Subsection (3) of new section 147A makes detailed provision, carried forward from sections 146 and 149 of the NHS Act, 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.
- 1251. Subsection (4) of new section 147A enables the regulations to provide for the approval of a person who is entered on a pharmaceutical list for the purposes of either paragraph (a) or (b) of subsection (1) to be treated as approval for the purposes of the other paragraph. The regulations may therefore provide that approval for the purposes of entry to a Local Pharmaceutical Service performer's list may similarly be treated as approval for the purposes of entry to a pharmaceutical assistants' list and vice versa.
- 1252. Subsections (5) and (6) of new section 147A enable the 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.
- 1253. Subsections (7) to (9) of new section 147A enable further provision to be made 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.
- 1254. Subsection (10) of new section 147A enables provision to be made authorising the disclosure by the NHS Commissioning Board of information about applicants for inclusion on a list, grants or refusals of applications, or suspensions or removals.
- 1255. New section 147B makes further provision about regulations under section 147A.
- 1256. Subsection (1) of new section 147B enables regulations under section 147A to make provision requiring a person who is included in a pharmaceutical list or a list made under section 132(2) of the NHS Act not to employ or engage another person to assist in the provision of pharmaceutical services unless that person is included in a list mentioned in subsection (2).
- 1257. Subsection (2) of new section 147B sets out the lists referred to in subsection (1) in which a person would need to be included in order to be employed by a person who is included in a pharmaceutical list. These include the lists made under section 147A and also medical, dental or ophthalmic lists.
- 1258. Subsection (3) of new section 147B enables regulations to require that persons referred to in subsection (1) of section 147A must both be included in lists prepared by the Board.
- 1259. *Subsection* (7) of this section makes transitional provision which preserves the effect of any regulations made under section 146 or 149 of the NHS Act despite the repeal of those sections so that the provisions of those regulations continue to have effect as if they had been made under section 147A of the NHS Act.

Part 7 – Regulation of Health and Social Care Workers

- 1260. Part 7 contains provisions relating to three distinct changes:
 - a) the abolition of the General Social Care Council and the transfer of some of its functions to the Health Professions Council;
 - b) reforms to the funding, 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 Health Professions Adjudicator.
- 1261. Schedule 15 makes further consequential and saving provisions in these areas.
- 1262. 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 is renamed the Health and Care Professions Council by the Act;
 - 'the Authority' refers to the Professional Standards Authority for Health and Social Care (which is the new name of the Council for Healthcare Regulatory Excellence);
 - 'the 2002 Act' refers to the National Health Service Reform and Health Care Professions Act 2002;
 - 'the 2001 Order' refers to the Health Professions Order 2001, which is renamed the Health and Social Work Professions Order 2001 by the Act;
 - 'the 2000 Act' refers to the Care Standards Act 2000;
 - 'the 1999 Act' refers to the Health Act 1999; and
 - 'the 1983 Act' refers to the Mental Health Act 1983.
- 1263. This Part, in particular, provides for 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 is 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 name 'Health and Care Professions Council' will be supported by a strapline which will specify the professions which the Council regulate, including social workers in England.

Orders under section 60 of the Health Act 1999

Section 209 – Power to regulate social workers etc. in England

- 1264. This section 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. The power enables primary legislation to be amended. This power replaces the Secretary of State's current power under section 124 of the Health and Social Care Act 2008 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.
- 1265. 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.

- 1266. 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.
- 1267. Schedule 15, at paragraph 45, 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.

Section 210 - Training etc. of approved mental health professionals in England

- 1268. This section 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 to be transferred to the Council from the General Social Care Council.
- 1269. 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 2008¹² provide that local social services authorities in England may also approve mental health and learning disability nurses, occupational therapists and practitioner psychologists. Those regulations also provide that 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).
- 1270. 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.
- 1271. This amendment goes with some other changes to the 1999 Act made in other sections. Section 209 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.
- 1272. Similarly, new paragraph 1B to Schedule 3 to the 1999 Act (added by section 211(3)) specifies 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.

Section 211 – Orders regulating social care workers in England: further provision

1273. This section 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 that can be made under section 124 of the Health and Social Care Act 2008 to regulate or modify the regulation of social care workers.

¹² Statutory Instrument: 2008 No. 1206

- 1274. 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.
- 1275. *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.
- 1276. Subsection (8) provides 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

Section 212 – Abolition of the General Social Care Council

- 1277. This section abolishes the General Social Care Council and consequentially amends section 54 of the Care Standards Act 2000, which established the General Social Care Council and the Care Council for Wales.
- 1278. 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

Section 213 – Regulation of social workers in England

- 1279. This section amends the 2001 Order to provide for the Council to regulate social workers in England. The 2001 Order establishes, and provides the legislative framework for, the Council.
- 1280. *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.
- 1281. 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.

Section 214 – The Health and Care Professions Council

1282. This section provides that the Health Professions Council is to remain in existence and renames it the Health and Care Professions Council.

Section 215 – Functions of the Council in relation to social work in England

- 1283. This section amends the 2001 Order to make provision for the Council to regulate social workers in England.
- 1284. *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 Wales, Scotland and Northern Ireland.

- 1285. *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.
- 1286. 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.
- 1287. Subsections (7) and (8) amend article 12 of the 2001 Order to enable the Council to recognise training undertaken in Wales, Scotland 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.
- 1288. *Subsection (9)* inserts a new article 13B into the 2001 Order which places a 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 as a social worker with one of the Care Councils of Wales, Scotland and Northern Ireland and who are practising in England on a temporary basis.
- 1289. *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.
- 1290. 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 Wales, Scotland and Northern Ireland will not commit an offence under article 39(1)(b).

Section 216 – Appeals in cases involving social workers in England

- 1291. This section amends articles 37 and 38 of the 2001 Order which relate to appeals against decisions of the Council (and its committees).
- 1292. 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.
- 1293. *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.

Section 217 - Approval of courses for approved mental health professionals

- 1294. This section concerns the transfer to the Council of the General Social Care Council's power under section 114A of the 1983 Act to approve training courses for people who are, or who wish to become, approved mental health professionals in England.
- 1295. The section 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.
- 1296. 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.
- 1297. The rest of this section amends section 114A of the 1983 Act to remove the General Social Care Council's power to approve approved mental health professional courses. 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.

Section 218 - Exercise of function of approving courses, etc

- 1298. This section amends the 2001 Order to reflect the Council's new role in approving approved mental health professional courses.
- 1299. The section 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.
- 1300. The section 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.
- 1301. The section 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 which provides for the Council's Education and Training Committee, rather than the Council itself, 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.
- 1302. Between them, the new articles 15A and 15B then provide 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.

- 1303. The new article 15B(5), together with other minor amendments made by this section, 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 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.
- 1304. The section 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 section 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.

Section 219 - Arrangements with other health or social care regulators

- 1305. This section 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.
- 1306. 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.
- 1307. This section was 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.

Section 220 - References in enactments to registered health professionals, etc

1308. This section 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

Section 221 – Functions of the Secretary of State in relation to social care workers

- 1309. This section amends section 67 of the 2000 Act to change certain functions of the Secretary of State.
- 1310. 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.
- 1311. 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.

- 1312. This section 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.
- 1313. *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 Act to the abolition of the General Social Care Council and so was commenced at Royal Assent.

The Professional Standards Authority for Health and Social Care

1314. The following sections concern changes to the Council for Healthcare Regulatory Excellence, which will become the Professional Standards Authority for Health and Social Care.

Section 222 - The Professional Standards Authority for Health and Social Care

- 1315. This section 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.
- 1316. 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.
- 1317. 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 is renamed the Health and Care Professions Council by this Act).

Section 223 - Functions of the Authority

- 1318. This section makes amendments to the 2002 Act to make changes to the functions of the Authority.
- 1319. 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.
- 1320. Subsections (1), (2), (6) and (14) 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.
- 1321. 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.

- 1322. 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 (10)* 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.
- 1323. *Subsections (7) and (8)* amend section 27 of the 2002 Act. Under section 27, the Authority has powers to direct regulatory bodies to make rules.
- 1324. The duties on the Secretary of State under this section to:
 - a) lay a draft of an order setting out directions the Authority has given requiring a regulatory body to make rules before both Houses of Parliament, and
 - b) make regulations about the procedure to be followed in relation to the giving of directions by the Authority,

are conferred instead on the Privy Council. As before, orders made under this section are subject to the affirmative resolution procedure, and regulations made under this section are subject to the negative resolution procedure.

Section 224 - Funding of the Authority

- 1325. This section inserts a new section 25A into the 2002 Act, which provides for changes to the way in which the Authority is funded.
- 1326. New section 25A 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).
- 1327. 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 control 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.
- 1328. 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.
- 1329. *Subsection* (4) of this section 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.

Section 225 - Power to advise regulatory bodies, investigate complaints etc.

- 1330. This section 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.
- 1331. 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 new section 25B 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.
- 1332. 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.

Section 226 - Accountability and governance

- 1333. This section 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.
- 1334. Previously:
 - the chair of the Authority was appointed by the Privy Council,
 - three non-executive members were appointed by the Secretary of State, and
 - one non-executive member was appointed by each of the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland.
- 1335. *Subsection* (2) of this section provides that the three Secretary of State appointments are Privy Council appointments. The number of executive members is also reduced from two to one.
- 1336. *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.
- 1337. *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.
- 1338. The Authority is no longer required to send copies of its annual accounts to the Secretary of State.
- 1339. *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 plans before the four UK parliaments and assemblies as soon as possible after the end of the financial year.

Section 227 - Appointments to regulatory bodies

- 1340. This section 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.
- 1341. 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. The Privy Council's appointments functions in relation to members of the regulatory bodies and the chair of the Authority were delegated to the Appointments Commission by means of directions made under powers in the Health Act 2006. Given that the Appointments Commission is abolished by this Act, it will not 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.
- 1342. 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 (including the appointment of chairs of the regulatory bodies and the determination of the terms of office of members and chairs). It empowers the Authority to assist the Privy Council to make appointments 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.
- 1343. 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.

Section 228 – Establishment of voluntary registers

- 1344. This section inserts new sections 25D, 25E and 25F into the 2002 Act.
- 1345. 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.

- Section 25E defines 'voluntary register' for the purposes of section 25D. A voluntary 1346. 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).
- 1347. 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.
- 1348. 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.
- 1349. 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).
- 1350. 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.
- 1351. 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.

Section 229 - Accreditation of voluntary registers

- 1352. This section 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.
- 1353. 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.
- 1354. More specifically, the Authority is given the power to, on an application by a regulatory body or other person who maintains a voluntary register, 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.
- 1355. The Authority must publish its accreditation criteria, and it has the power to publish a list of accredited registers.
- 1356. 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.
- 1357. 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.
- 1358. 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.
- 1359. 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.
- 1360. *Subsections (2) to (5)* of this section 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.
- 1361. 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.

1362. 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.

Section 230 – Consequential provisions and savings, etc.

- 1363. This section provides for the minor and consequential amendments to primary legislation set out in Parts 1 to 3 of Schedule 15 (part 7: consequential amendments and savings) to have effect. The section also enables the Privy Council, by Order, to make transitional, transitory or saving provision in connection with sections in this Part of the Act.
- 1364. Subsections (3) to (5) provide further detail on how an order made under subsection (2) will be made and the provisions it may contain.
- 1365. *Subsection* (6) ensures that section 60 orders will continue to be able to amend the 2001 Order including those parts inserted by this Act.

The Office of the Health Professions Adjudicator

Section 231 - Abolition of the Office of the Health Professions Adjudicator

1366. This section provides for the abolition of OHPA, for the transfer of its property, rights and liabilities to the Secretary of State and repeals the provisions in the Health and Social Care Act 2008, which establish OHPA and confer functions on it. It also brings into effect Part 4 of Schedule 15, which 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 duties

Section 232 – The National Institute for Health and Care Excellence

1367. This section establishes the National Institute for Health and Care Excellence (NICE) as a body corporate. It also gives effect to Schedule 16.

Schedule 16 – The National Institute for Health and Care Excellence

- 1368. 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 8 for Monitor, and Schedule 18 for the Health and Social Care Information Centre.
- 1369. Paragraph 1 sets out the membership of NICE. Paragraphs 2, 3, 4 and 5 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 is to be determined by the Secretary of State).

- 1370. 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.
- 1371. Paragraph 7 provides for NICE to establish committees and sub-committees. Paragraph 8 allows NICE to regulate its own procedures. Sub-paragraph (2) enables the 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. Paragraph 9 allows NICE to arrange for its functions to be exercised by a non-executive member, an employee or a committee or sub-committee.
- 1372. Paragraph 10 confers general powers and requires NICE to obtain the permission of the Secretary of State before undertaking certain commercial ventures. NICE may, for example, provide advice to overseas Governments under regulations made under section 240. Under the paragraph 10 powers NICE would, with the approval of the Secretary of State, be able to form, participate in the forming of, invest in or provide loans and guarantees to a company and thereby be able to determine the most appropriate business model for any such activities.
- 1373. Paragraph 11 enables the Secretary of State to make payments to NICE out of money provided by Parliament with such conditions as the Secretary of State thinks appropriate. Paragraph 11 also allows Secretary of State to lend money to NICE.
- 1374. Paragraph 12 sets out a requirement for NICE to publish an annual report. The Secretary of State may also 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.
- 1375. Paragraphs 13, 14 and 15 relate to NICE's accounts, including duties of the Comptroller and Auditor General in relation to reporting on NICE's annual accounts, and laying copies of them in Parliament.
- 1376. Paragraph 16 relates to NICE's seal. Paragraph 17 confirms NICE's status as a non-Crown body.

Section 233 - General duties

1377. This section describes the matters that NICE must have regard to in developing its products.

Functions: quality standards

Section 234 - Quality standards

- 1378. This section sets out the process for how the NHS Commissioning Board or the Secretary of State may 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.
- 1379. The Secretary of State and the NHS Commissioning Board are required to have regard to the quality standards in discharging their 'improvement duties' in relation to the health service (see new section 1A and new section 13E inserted in to the NHS Act by Part 1 of the Act). The Secretary of State or the NHS Commissioning Board is responsible for framing the remit of each quality standard, but cannot determine the

content. A quality standard has statutory effect once it has been endorsed by the person who commissioned it (the Secretary of State or the Board). NICE has 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 will be able to commission social care quality standards across all age groups.

Section 235 - Supply of quality standards to other persons

1380. This section 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 could charge for this. The Department anticipates that work carried out by NICE on behalf of the devolved administrations would be on a cost-recovery basis only.

Section 236 Advice or guidance to the Secretary of State or the Board

1381. This section enables the provision by NICE of any advice or guidance on quality matters to the Secretary of State or the NHS Commissioning Board should they require it. A quality matter is defined as a matter in respect of which NICE could be asked to prepare a quality standard.

Functions: advice, guidance etc.

Section 237 – Advice, guidance, information and recommendations

- 1382. This section describes how, as well as preparing quality standards, NICE may be able, under regulations, to give advice or guidance, or provide information or make recommendations on matters relating to the provision of NHS services, public health services or social care in England. The guidance provided for in regulations could 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. Regulations 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.
- 1383. The section gives the Secretary of State a regulation-making power to enable him to confer additional functions on NICE. Subsections (2) and (3) enable provision to be made for functions conferred on NICE by regulations to be exercisable only on or subject to directions of the Secretary of State or the NHS Commissioning Board in relation to NHS services, or the Secretary of State in relation to public health services or social care. The direction-giving powers ensure that either the Secretary of State or the Board will have the flexibility to commission work from NICE. However, neither will 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 for the persons or bodies that may commission work from NICE or 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 of advice or guidance, provision of information or making of 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.
- 1384. Subsections (8) and (9) allow regulations to require specified public bodies to have regard to NICE advice or guidance, or to comply with NICE's recommendations.

The provision allows replication of the effect of an existing funding direction requiring commissioners to make funding available within three months for treatments recommended by NICE's technology appraisal guidance, so they are made normally available. *Subsection* (10) states that such regulations may only apply to local authorities in relation to their public health functions.

Section 238 – NICE recommendations: appeals

1385. This section allows the Secretary of State to include in regulations under section 237 arrangements for appeals against NICE recommendations.

Section 239 - Training

1386. This section allows the Secretary of State to make regulations setting out the arrangements under which NICE could provide or facilitate the provision of training, and when it could charge for these services. NICE currently delivers education, training and development on evidence-based therapeutics and medicines management to healthcare professionals, and regulations made under this section would enable this work to continue.

Section 240 - Advisory services

1387. This section allows the Secretary of State to make regulations setting out the arrangements under which NICE could provide advisory services to other persons, such as the devolved administrations and pharmaceutical companies. The Department anticipates that any work carried out by NICE on behalf of the devolved administrations will be on a cost-recovery basis only.

Section 241 - Commissioning guidance

1388. This section provides for the NHS Commissioning Board to be able to direct NICE to prepare commissioning guidance on its behalf or carry out any other of the NHS Commissioning Board's functions in relation to preparation of commissioning guidance. Commissioning guidance will provide CCGs 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 be required by the Board to disseminate the commissioning guidance.

Functions: other

Section 242 – NICE's charter

1389. This section 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 purposes and how it proposes to fulfil them.

Section 243 – Additional functions

1390. This section enables NICE to carry out additional income generating 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 pursuant to these provisions and may do so on what it considers to be the appropriate commercial basis.

Section 244 – Arrangements with other bodies

1391. This section enables NICE to make arrangements with other bodies for their 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.

Section 245 – Failure by NICE to discharge any of its functions

1392. This section enables the Secretary of State, if he considers that NICE is failing to discharge its functions properly (which includes a failure to discharge a function consistently with what the Secretary of State considers to be the interests of the health service in England), and the failure is significant, to direct NICE to discharge the 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. The Secretary of State is required to publish his reasons for exercising the powers under this section.

Section 246 – Protection from personal liability

1393. This section 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

Section 247 – Interpretation of this Part

1394. This section defines terms used in this Part.

Section 248 – Dissolution of predecessor body

1395. This section provides for the abolition of the Special Health Authority known as the National Institute for Health and Clinical Excellence.

Section 249 – Consequential and transitional provision

- 1396. This section gives effect to Schedule 17 (part 8: consequential amendments) which makes consequential amendments to a range of 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 apply to NICE as re-established. It also includes a change to the Health Act 2009, so that NICE will have a duty to have regard to the NHS Constitution.
- 1397. This section also makes provision to ensure that any pre-existing "quality standard", referred to in *subsection (2)* as a "statement of standards" prepared and published by the Special Health Authority, the National Institute for Health and Clinical Excellence, prior to commencement has the same status on and after commencement as a quality standard prepared by NICE as re-established.

Part 9 – Health and adult social care services: information

Chapter 1 – Information standards

Section 250 – Powers to publish information standards

- 1398. This section enables the Secretary of State or the NHS Commissioning Board to set information standards for health services or adult social care in England.
- 1399. Subsection (1) empowers the Secretary of State or the NHS Commissioning Board to prepare and publish an information standard. Other bodies may assist with the

preparation of standards but the decision to publish a standard rests with Secretary of State or the Board.

- 1400. *Subsection (2)* defines an information standard as a document containing standards that relate to the processing of information. These may include technical standards, data standards or information governance standards. Technical standards could relate to the specification of systems and may, for example, include messaging, system interoperability or security requirements. Data standards include defining the structure and type of information to be recorded, for example how to record dates of birth or a clinical condition. Information governance standards could relate to policies, procedures or guidelines on information processing.
- 1401. *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 or adult social care services in England.
- 1402. Subsection (5) clarifies that a published standard must include guidance on, for example, which types of organisation it is relevant to and on how to implement the standard.
- 1403. Subsection (6) identifies which bodies must have regard to published information standards. These are the Secretary of State, the Board, public bodies exercising functions in connection with health services or adult social care and anyone providing publicly funded health services or adult social care commissioned by or on behalf of a public body.
- 1404. *Subsection (7)* defines the terms used in this section. For example, "processing" has the same meaning as in the Data Protection Act 1998. This is a broad definition that captures a range of activity involving information including obtaining, holding, recording, using and sharing.

Section 251 – Information standards: supplementary

- 1405. *Subsection (1)* places a duty on the Secretary of State or the Board to consult those they determine should be consulted before publishing an information standard.
- 1406. *Subsection* (2) enables the Secretary of State or the Board to adopt existing information standards that are appropriate but have been prepared or published by someone else.

Chapter 2 - The Health and Social Care Information Centre

Establishment and general duties

Section 252 - The Health and Social Care Information Centre

1407. This section establishes the Health and Social Care Information Centre. It also gives effect to Schedule 18.

Schedule 18 – The Health and Social Care Information Centre

- 1408. 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 8 for Monitor, and Schedule 16 for NICE.
- 1409. Paragraph 1 sets out the membership requirements for the Information Centre. Paragraphs 2, 3, 4 and 5 set out provisions relating to the appointment of non-executive directors to the Information Centre, including their tenure, ability to be suspended or removed from post by the Secretary of State, and their remuneration (which is to be determined by the Secretary of State).
- 1410. Paragraph 6 relates to the appointment of the Information Centre's employees. The

- 1411. Information Centre requires the approval of the Secretary of State to its policies on the payment of remuneration, allowances, pensions or gratuities before the Centre can make any such payment to an employee.
- 1412. Paragraph 7 enables the Information Centre to establish committees or sub-committees. Paragraph 8 allows the Centre to regulate its own procedure. Paragraph 9 concerns the exercise of functions by the Information Centre.
- 1413. Paragraph 10 confers supplementary powers on the Information Centre. It requires the Centre to obtain the approval of the Secretary of State before it can form, participate in or invest in companies.
- 1414. Paragraph 11 concerns finance arrangements with the Secretary of State.
- 1415. Paragraph 12 sets out a requirement for the Information Centre to publish an annual report, a copy of which must be laid before Parliament and a copy sent to the Secretary of State. The Secretary of State also has the ability to ask the Information Centre to prepare other reports or provide information at other times, for example as required for in-year monitoring of the Centre's performance and use of central funding.
- 1416. Paragraphs 13, 14 and 15 relate to the Information Centre's accounts. Paragraph 14 includes an obligation on the Comptroller and Auditor General to report on the Centre's annual accounts and lay copies of both the annual accounts and the report before Parliament.
- 1417. Paragraph 16 relates to the Information Centre's seal. Paragraph 17 confirms the Centre's status as a non-Crown body.

Section 253 - General duties

1418. This section 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 exercise its functions effectively, efficiently and economically and seek to minimise the burdens it imposes on others, for example, as a result of collecting or analysing information. The Centre must 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

Section 254 - Powers to direct the Information Centre to establish information systems

- 1419. This section provides the Secretary of State or the NHS Commissioning Board with powers to require the Information Centre to put in place systems for collecting or analysing information. The Secretary of State may direct the Centre to collect or analyse information having considered that it is necessary or expedient for the Secretary of State to have the resulting information in connection with the provision of health services or adult social care in England. The Board may direct the Centre to collect or analyse information having considered that it is necessary or expedient for the Board to have the resulting information in relation to its exercise of functions in connection with the provision of NHS services. Before making such directions, the Secretary of State or the Board are required to consult the Centre so that it can advise on options and methodology. For example, the Centre could advise that it already collects or analyses the information.
- 1420. *Subsection* (7) ensures that the Information Centre can charge the Board a reasonable fee for complying with a direction given by the Board to establish a system for the collection or analysis of information.

Section 255 - Powers to request the Information Centre to establish information systems

- 1421. This section provides for someone other than the Secretary of State or the NHS Commissioning Board to request the Information Centre to set up a system for the collection or analysis of information.
- 1422. The request may be mandatory if made by a principal body such as Monitor, the Care Quality Commission or NICE, or another body specified in regulations.
- 1423. Regulations may prescribe when the Centre may exercise discretion not to comply with a mandatory request, for example in respect of an information collection or analysis that is highly technical or specialised or would significantly impact on core functions the Centre was already exercising.
- 1424. The Secretary of State or the NHS Commissioning Board may direct the Centre to comply with a non-mandatory request made by a body outside England or not to comply with a non-mandatory request made by any person. The Centre would have discretion to refuse other requests for information if, for example, the requestor had not had regard to the code of practice on confidentiality (see section 263) or followed the Centre's advice or guidance, or collecting the information would significantly affect other core functions the Centre was exercising. When considering whether to accept a request, the Centre would also need to take into account its general duty to seek to minimise burdens on others.

Section 256 – Requests for collection under section 255: confidential information

1425. This section restricts the circumstances where a person may make a confidential collection request to the Information Centre. The section defines a confidential collection request as a request relating to information which identifies an individual or from which the identity of a person could be discovered (other than an individual who provides health care or adult social care). Such a request can only be made where the requestor is a principal body able to make a mandatory request (such as Monitor, CQC or NICE) or in the other circumstances set out in the section, for example, where the information may be lawfully disclosed to the requestor.

Section 257 – Requests under section 255: supplementary

1426. This section places a duty on the Information Centre to publish procedures for the making of requests for the collection or analysis of information and for reconsidering any requests that are refused. *Subsection (3)* allows the 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 the Centre before making that request, so that it can advise on options and methodology. The Centre must publish details of all requests (including mandatory requests) for information the Centre is required or decides to collect. This will help to inform any person considering making a request about existing collections and will help to avoid duplicate requests.

Section 258 – Information systems: supplementary

1427. This section places a duty on the Information Centre to consult prior to establishing a new system for collecting or analysing information. This includes consulting the person who required or requested the collection or analysis, bodies from whom the Centre would require or request information and likely end users of the collected or analysed information. The section also provides for the Centre to be able to destroy information that it has collected or derived from a collection (for example through analysing it) when there is no longer a need to retain it.

Section 259 - Powers to require and request provision of information

- 1428. This section provides the Information Centre with powers to require or request those set out in *subsection* (2) to provide the Centre with any information it considers it necessary or expedient for the Centre to have for any function it exercises by virtue of Chapter 2.
- 1429. Subsection (2) specifies that such bodies may be health or social care bodies or organisations providing health services or adult social care in England under arrangements with a public body. When information is needed from bodies other than those described in *subsection* (2), the Centre may request the desired information and may make a payment in respect of the cost of complying with the request (*subsection* (6)).
- 1430. Subsection (3) limits the ability of the Centre to require confidential person- identifiable information from bodies providing publicly funded health or adult social care services. The Centre may only require provision to it of confidential person- identifiable information where it has been requested to do so by a principal body such as NICE, CQC or Monitor or where the person requesting the information could have required the disclosure of the information in any case. Subsection (4) makes clear that the Centre may request such information from a health or social care body or publicly funded provider of health or adult social care services, but there is no obligation to provide it.
- 1431. Subsection (5) obliges the bodies defined in subsection (2) to provide information required pursuant to subsection (1)(a) in a form specified by the Centre within a specified period.
- 1432. Subsection (8) requires the Centre to publish a procedure for notifying health or social care bodies and other persons about information collections and *subsection* (9) requires the Centre to co-operate with other bodies authorised to collect information. The intention is to minimise the burden on the providers of information.
- 1433. Subsection (10) specifies that those providing information to the Centre are not in breach of confidentiality but are subject to any express restrictions on disclosure of information in other legislation.

Section 260 - Publication of information

- 1434. This section requires the Information Centre to generally publish the information it collects or may derive from a collection (for example information that is generated following analysis of collected information). Information which identifies or enables identification of a person must not be published unless that person is a "relevant person". "Relevant person" is defined in *subsection* (7) as a provider of health care or adult social care or a body corporate. In relation to information which identifies (or enables the identification of) a relevant person, *subsection* (2)(a) sets out that the Centre must take into account the public interest as well as the interests of the relevant person in deciding whether it is appropriate for the information to be published. As set out in *subsection* (2)(c), if the Centre considers that information it collects fails to meet information standards and publication would not be in the public interest, the Centre must not publish it. Directions from the Secretary of State or the Board may also prohibit publication of a relevant person, directions may require the Centre to publish it.
- 1435. Subsection (6) provides for the Centre to consider the need to publish information in easily accessible formats, taking into account who will use the information and the uses to which the information is likely to be put. Where the form, manner and timing of publication is specified in a direction or mandatory request, the Centre must comply with the specifications and may comply with such specifications in other requests. Where there is no such specification or in addition to complying with a specification, the Centre has discretion under subsection (5) regarding the manner, form and timing of publication.

Section 261 – Other dissemination of information

- 1436. This section gives the Information Centre power to disseminate information it collects if the information is of a type described in *subsection (2)*. This enables information to be disseminated (shared with a specific person or body rather than published in the public domain) to particular persons or groups of persons if it is already required to be published. Information that fails to meet information standards may also be disseminated if the Centre considers dissemination to be in the public interest. In addition, the Centre may disseminate information which is in a form which would identify, or enable the identification of a relevant person if the Centre considers it appropriate after considering the public interest and the interests of the body identified. "Relevant person" is previously defined as a provider of health care or adult social care or a body corporate. A direction by the Secretary of State or the NHS Commissioning Board which prohibits publication of certain information (as set out in section 262(2) (d)) could enable or require dissemination of that same information.
- 1437. *Subsection (4)* provides that the Centre may also disseminate information which it collects pursuant to a direction or request to establish an information system to any person to whom the information could have been disclosed by the person from whom the Centre collected the information.
- 1438. *Subsections* (5) and (6) set out circumstances where the Centre may disclose information. The question whether the Centre may disclose information sometimes requires consideration of the position at common law. Common law needs to be considered where a disclosure is intended to protect the welfare of an individual, is made to a body exercising public functions for the purposes of those functions, or where disclosure relates to the investigation of a crime. A disclosure may not be made for these purposes if common law would prohibit it. This is consistent with requirements for the disclosure of information by the NHS Commissioning Board and CCGs. But *subsection* (7) makes it clear that nothing in this section is intended to prevent the Centre from relying on any other power or authority that it may have under other legislation to disseminate information, for example, an approval under the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1434).
- 1439. *Subsection* (8) makes clear that any "passing back" of information to a person who initiated a collection or analysis of information is to be treated as dissemination and is therefore subject to the limits on what may be disseminated and to whom imposed by this chapter.

Section 262 – Other dissemination: directions and requests under sections 254 and 255

- 1440. This section makes provision for the Secretary of State or the NHS Commissioning Board to be able to require through directions under section 254 that the Information Centre disseminates certain information it has obtained as a result of complying with the direction. The Secretary of State or the Board can require this where the information obtained by the Centre must be published under section 260, the information identifies or could lead to the identification of an individual (such as a patient) or a health or social care body or body corporate (such as a hospital trust) and the individual or body has consented to the dissemination, or the information falls within section 260(2)(c). In the case of information from which a health or social care body or body corporate could be identified, the Secretary of State or the Board also has power to direct the Centre to disseminate the information provided the direction giver has taken into account the public interest, as well as the interests of the body in considering whether it is appropriate to give the direction.
- 1441. *Subsection (4)* enables anyone to request that the Centre use its powers to disseminate information that it obtains as a result of complying with that person's request to collect or analyse information under section 255. Subsection (5) enables anyone to request that

the Centre does not use its powers to disseminate information obtained by complying with a direction or request by that person.

1442. *Subsection* (7) enables the Secretary of State, Board or a person who has made a request for the collection or analysis of information to include in the direction or request details of to whom they wish the information to be disseminated, as well as the form, manner and timing of dissemination.

Section 263 – Code of practice on confidential information

1443. This section requires the Information Centre to publish a code of practice for health or social care bodies (or those providing publicly funded health or social care) on how to handle person-identifiable or other confidential information. It requires the Centre to consult with (and obtain the approval of) the Secretary of State and the NHS Commissioning Board before publishing the Code. Provision is also made in the section for the Centre to consult anyone else about the Code whom the Centre considers appropriate.

Section 264 - Information Register

1444. This section requires the Information Centre to publish a register containing details of the information the Centre collects or may derive from a collection, for example, following analysis of the information. The register would also need to contain details from other information collections or analyses undertaken by other bodies that have been authorised by the Secretary of State or the NHS Commissioning Board. The record of information collected or analysed will be complementary to the record of all mandatory and other requests with which the Centre is obliged or decides to comply. Together these will provide a reference source for bodies seeking to obtain information on what information is collected and may already be available.

Section 265 - Advice or guidance

- 1445. This section gives the Information Centre discretion to advise bodies described in *subsection (2)* on issues relating to the collection, analysis, publication or other dissemination of information. The section also requires the Centre to provide advice or guidance to any person or body it is requested to advise by the Secretary of State or the NHS Commissioning Board.
- 1446. This is intended to help minimise duplication and burdens relating to information collection. In particular, the Secretary of State is required to request advice on ways of minimising the burden of information collections on health or social care bodies and other persons at least once every 3 years.
- 1447. Subsections (5) and (6) require any health or social care body or other provider of health services or adult social care to whom advice or guidance is given to have regard to the advice or guidance when exercising functions or providing services in connection with the provision of health or adult social care.

Functions: quality of health and adult social care information

Section 266 - Assessment of quality of information

1448. This section requires the Information Centre to publish periodic reports on the extent to which the information it collects meets published information standards.

Section 267 - Power to establish an accreditation scheme

1449. This section enables the Secretary of State, through regulations, to make provision for a scheme to accredit (kite-mark) organisations that act as information intermediaries.

Such accreditation schemes may be run by the Information Centre or by any other body specified by the Secretary of State in regulations.

- 1450. 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 charge those applying for accreditation reasonable fees.
- 1451. 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.
- 1452. *Subsection* (5) defines the types of bodies that may apply for accreditation under a scheme.

Functions: other

Section 268 - Database of quality indicators

1453. This section 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.

Section 269 – Power to confer functions in relation to identification of GPs

1454. Regulations made under this section would enable the Information Centre to carry out functions in relation to issuing GPs with doctor index numbers. Doctor index numbers enable GPs to prescribe drugs to patients and are also used in connection with the management and monitoring of prescribing in primary care.

Section 270 - Additional functions

1455. This section enables the Information Centre to carry out or supply additional income generation functions or services. An additional function can only be undertaken by the Centre if it involves or is connected with the collection, analysis, publication or other dissemination of information. The additional function must not significantly interfere with a function the Centre exercises as a result of this or any other Act. The Centre may charge, and may do so on an appropriate commercial basis, for any services it provides pursuant to the functions conferred by *subsection (1)*.

Section 271 - Arrangements with other bodies

1456. This section enables the Information Centre to make arrangements with other bodies to carry out services on its behalf.

Section 272 - Failure by Information Centre to discharge any of its functions

1457. This section enables the Secretary of State to take action if he considers that the Information Centre is failing to discharge any of its functions properly (including doing so by failing to discharge them consistently with what the Secretary of State considers to be in the interests of the health service in England or (as the case may be) with what otherwise appears to the Secretary of State to be the purpose for which the functions are conferred). The failure must be significant. The Secretary of State is given the power to direct the Centre to discharge the functions within specified timescales and in the way that the Secretary of State may discharge the functions himself or may make arrangements for another body to do so. Where the Secretary of State takes action under this section, he must publish reasons for doing so.

Section 273 - Protection from personal liability

1458. This section 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 Centre.

General and supplementary

Section 274 - Powers of the Secretary of State or Board to give directions

- 1459. This section enables the Secretary of State or the NHS Commissioning Board, through regulations, to give certain directions. These directions could require:
 - a) a health or social care body to exercise an information function of the Information Centre (for example the Centre's function of requiring other health or social care bodies to provide information);
 - b) the Centre or another health or social care body to exercise an information function of the Secretary of State or the Board;
 - c) the Centre to exercise an information function of a health or social care body;
 - d) the Centre to carry out systems delivery functions of the Secretary of State or the Board that are exercisable in relation to the development or operation of information or communications systems.
- 1460. This section could be used, for example, to provide in regulations for the Secretary of State or the Board to direct that another body should collect information that the Centre could be mandated to collect (a direction under a) above). An example could be where there is no intention to publish or disseminate the information that is to be collected or analysed more widely, other than for a single, primary use. It might be an inefficient use of the Centre's resources for it to collect or analyse information solely for the purpose of passing the information to another body. Similarly, it may be more efficient for the Centre to collect certain information instead of this being done as an ancillary function by another health or social care body (a direction under (c) above).
- 1461. Subsection (2) ensures that the Secretary of State or the Board is able to direct the Centre about *how* it is to perform functions it is directed to undertake under *subsection* (1).
- 1462. Subsections (6) and (7) make provision for the Centre to be appropriately resourced for exercising Secretary of State or Board functions in relation to information or communications systems. Where a direction giving power relating to a systems delivery function is conferred on the Secretary of State, the regulations must ensure that a direction could include provision for payments to be made to the Centre. Where such a power is conferred on the Board, the regulations must ensure that a direction will enable the Centre to charge the Board a reasonable fee for carrying out the function which is the subject of the direction.

Section 275 - Interpretation of this Chapter

1463. This section defines terms used in Chapter 2.

Section 276 - Dissolution of predecessor body

1464. This section provides for the abolition of the Special Health Authority known as the Health and Social Care Information Centre.

Section 277 - Consequential provision

1465. This section gives effect to Schedule 19 (part 9: consequential amendments) which contains consequential amendments to a range of statutory provisions to ensure that the Information Centre is referenced appropriately. It includes, for example, changes to

the Freedom of Information Act 2000 and Access to Health Records Act 1990 so that relevant provisions in the Acts would continue to apply to the re-established Centre and information it holds. It also includes a change to the Health Act 2009, so that the Centre would have a duty to have regard to the NHS Constitution.

Part 10 – Abolition of certain public bodies etc

Section 278 - The Alcohol Education and Research Council

- 1466. This section provides for the abolition of the Alcohol Education and Research Council (AERC).
- 1467. The AERC was established by section 6 of the Licensing (Alcohol Education and Research) Act 1981. It was responsible for administering the Alcohol Education and Research fund, established by section 7 of the 1981 Act. The AERC used the fund to finance projects within the United Kingdom for education and research on alcohol related issues.
- 1468. Subsection (1) abolishes the AERC. Subsection (2) repeals the Licensing (Alcohol Education and Research) Act 1981, which established the AERC. Before it was abolished, the AERC used its powers to transfer the whole of the Alcohol Education and Research fund to a new separate charitable body. The fund was transferred to the new body, Alcohol Research UK, in March 2011. The new charitable body continues to use the fund to finance projects within the United Kingdom for research on alcohol related issues.
- 1469. *Subsection (3)* gives effect to Part 1 of Schedule 20 (part 10: consequential amendments and savings) which removes references to AERC in other primary legislation and provides for the Secretary of State to be able to carry out any activity undertaken by or duties required of or in relation to the AERC before, during or after its abolition; and for a report to be prepared on the abolition of the Council up to the date of abolition.

Section 279 – The Appointments Commission

- 1470. This section provides for the abolition of the Appointments Commission. Originally established as the NHS Appointments Commission, a Special Health Authority, in 2001, it was established by section 57 of the Health Act 2006 as a body corporate and executive non-departmental public body in October 2006, changing its name to the Appointments Commission to reflect new powers to provide recruitment and selection services to all Government departments and NHS Foundation Trusts. The section also gives effect to Part 2 of Schedule 20, which makes consequential amendments to legislation and provides for the Secretary of State to be able to carry out any activity undertaken by or duties required of or in relation to the Appointments Commission before, during or after its abolition.
- 1471. The main role of the Appointments Commission was to appoint Chairs and Non-Executive Directors to local NHS organisations and the majority of the Department's national bodies, under direction of the Secretary of State for Health. It also provided services to other Governmental organisations.
- 1472. There will be no local Chair and Non-Executive Director appointments to PCTs and SHAs, and eventually none to NHS trusts. This along with fewer national public appointments makes the Appointments Commission no longer viable. Remaining national appointments will be handled by the Department of Health, in line with the practice of other government departments.

Section 280 – The National Information Governance Board for Health and Social Care

- 1473. This section provides for the abolition of the National Information Governance Board for Health and Social Care (NIGB), and confers its functions on the Care Quality Commission.
- 1474. NIGB was established as a statutory body by section 250A of the NHS Act inserted by the Health and Social Care Act 2008. Its overall role is to support improvements to information governance practice in health and social care.
- 1475. *Subsections (1)* and (2) of section 280 abolish the NIGB and remove the sections of the NHS Act that established it.
- 1476. *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.
- 1477. 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.
- 1478. Subsections (4) and (5) make changes to existing duties:
 - The Care Quality Commission's existing duty to consult the NIGB 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 NHS Commissioning Board is charged with developing standards and guidance in this area.
 - The Secretary of State's existing duty to consult the NIGB before making any new regulations under section 251 of the 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 (subsection (5)). 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.
- 1479. *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 conferred on it by this section. This committee is to be in place until 31 March 2015.
- 1480. The section also gives effect to Part 3 of Schedule 20 which makes consequential amendments and provides for the Secretary of State to be able to carry out any activity undertaken by or duties required of or in relation to the NIGB before, during, or after its abolition; and for a report to be prepared up to the date of abolition.

Section 281 - The National Patient Safety Agency

- 1481. This section provides for the abolition of the National Patient Safety Agency (NPSA).
- 1482. 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.
- 1483. Provision is made in Part 1 of the Act for the NHS Commissioning Board to have responsibility for the functions currently carried out by the NPSA in respect of reporting and learning from patient safety incidents.

- 1484. The National Clinical Assessment Service¹³ (NCAS) and the National Research Ethics Service¹⁴ (NRES) are functions of the NPSA being provided for separately and outwith the Act. The Department intends that, over the next few years, NCAS will become a self-funded service and the Department will seek to agree a date with the service for achieving self-sufficiency. The National Institute for Health and Care Excellence (NICE) will act as an interim host for NCAS from its transfer from the NPSA to the end of 2012/13. The future of NRES was considered as part of a wider independent review¹⁵ of health research regulation and governance which recommended creating a new body to rationalise the regulation and governance of all health research. The Plan for Growth¹⁶, published alongside the Budget on 23 March 2011, announced the Government would set up a new body to streamline regulation and improve the cost effectiveness of clinical trials. The Government established the Health Research Authority in December 2011 as a Special Health Authority with NRES at its core.
- 1485. The function of managing the delivery of the Confidential Enquiries (now known as the Clinical Outcomes Review Programmes CORP), with the relevant provider organisations transferred in September 2011 from the NSPA to the Healthcare Quality Improvement Partnership (HQIP), who currently host the contract to manage and develop the National Clinical Audit and Patient Outcomes Programme. CORP are a series of independent programmes that assess the quality of care patients receive from the health service. CORP will cover four themes each delivered by a separate organisation (mental health, medical and surgical, child health, and maternal and new born).

Section 282 - The NHS Institute for Innovation and Improvement

- 1486. This section provides for the abolition of the NHS Institute for Innovation and Improvement, established as a Special Health Authority in 2006.
- 1487. The NHS Institute supports NHS organisations in analysing their current practices against best practice and implementing changes to achieve better results.
- 1488. Provision is made in Part 1 of the Act 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.

Section 283 – Standing advisory committees

1489. This section provides for the repeal of section 250 of, and Schedule 19 to, the NHS Act 2006. 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 continued to be constituted under this section and will continue in existence as a result of the provision made in *subsection (3)* in respect of the National Health Service (Standing Advisory Committees) Order 1981.

Part 11 – Miscellaneous

Information relating to births and deaths etc.

Section 284 - Special Notices of Births and Deaths

1490. Section 269 of the NHS Act previously provided that local registrars of births and deaths must provide particulars of registered births and deaths to PCTs. In relation to births, the section also required a child's father (for a home birth) or person attending the mother

¹³ NCAS supports the resolution of concerns about the performance of individual clinical practitioners to help ensure their practice is safe and valued.

¹⁴ NRES protects the rights, safety, dignity and well-being of research participants that are part of clinical trials and other research within the NHS.

¹⁵ Academy of Medical Sciences (Jan 2011): A new pathway for the regulation and governance of health research

¹⁶ HM Treasury, Department for Business Innovation & Skills (2011): The Plan for Growth, p92

(in other cases) to notify the PCT in whose area the birth takes place. The section also provided for the local registrar to have access to the notification of births provided to the local PCT.

1491. This section replaces references to PCTs in section 269 of the NHS Act with references to "relevant body or bodies" and provides for a new regulation-making power, which allows the Secretary of State to specify in regulations which bodies are to be notified of births and deaths. "Relevant bodies" are defined as the NHS Commissioning Board, CCGs and local authorities. *Subsection* (8) inserts, among others, a new subsection (12) into section 269 so as to ensure that information received by a local authority by virtue of this section may be used by it only for the purposes of functions exercisable by it in relation to the health service.

Section 285 – Provision of Information by Registrar General

- 1492. This section amends section 270 of the NHS Act. Previously, section 270 of the NHS Act allowed the Registrar General to provide information, such as births and deaths data to the Secretary of State in order to assist the Secretary of State in the performance of his functions in relation to the health service.
- 1493. It amends section 270 of the NHS Act so as to extend the list of persons who can receive information from the Registrar General of Births and Deaths.

Section 286 – Provision of Information by Registrar General: Wales

1494. This section amends section 201 of the National Health Service (Wales) Act 2006 to make provision for the Registrar General to provide information to a number of bodies in addition to Welsh Ministers. These bodies are listed in the insertion made by *subsection* (2)(b).

Section 287 – Provision of Statistical Information by Statistics Board

- 1495. This section amends section 42 of the Statistics and Registration Service Act 2007, which contains provision to specify that the Statistics Board (ONS) may disclose information on births & deaths to a number of bodies.
- 1496. In a similar way to the amendment to section 270, section 287(2) replaces the reference to the Secretary of State with a range of persons and bodies connected to the health service. The section also gives the Secretary of State and Welsh Ministers a new direction making power to specify additional organisations which can receive information from the Statistics Board.
- 1497. The Act also clarifies the respective roles and responsibilities of the Registrar General and the Office for National Statistics as there is considerable overlap between the Statistics and Registration Service Act 2007 and the NHS Act.
- 1498. Previously, there was a memorandum of understanding between the two organisations that defined the responsibilities for providing data to the Secretary of State. Broadly speaking, the Registrar General provides administrative data and the Office for National Statistics provides statistical data. These amendments to section 42 formalise the effect of the memorandum of understanding between the two organisations by limiting the powers of the Office for National Statistics, so that it is required to provide statistical information only.
- 1499. *Subsection (2)* sets out the information which may be disclosed by the Statistics Board as follows:
 - a) information consisting of statistics and is disclosed for the purpose of assisting a person performing health-related functions,

- b) information disclosed for the purpose of assisting a person to produce or analyse statistics for the purpose of assisting a person performing health-related functions.
- 1500. *Subsection (4)* provides definitions of local authorities, clinical commissioning groups and Special Health Authorities.

Duties to co-operate

1501. The subsequent sections contain provisions which ensure that Monitor and the CQC work effectively together and with other relevant bodies.

Section 288 – Monitor: duty to co-operate with Care Quality Commission

1502. This section places a duty on Monitor to co-operate with the CQC in the exercise of their respective functions (*subsection* (1)), including operating a joint licensing and registration regime which must provide for a single application form and document for new applicants, and must ensure consistency of licence conditions with any conditions on a person's registration with the CQC (*subsection* (2)). It also places a duty on Monitor to, on request, provide the CQC with any relevant information in relation to Monitor's concurrent competition functions with the Office of Fair Trading relating to market investigations (*subsection* (3)).

Section 289 – Care Quality Commission: duty to co-operate with Monitor

1503. This section amends section 70 of the Health and Social Care Act 2008 (co-operation between the Commission and the Independent Regulator of NHS foundation trusts), to provide that the CQC's duty to co-operate with Monitor in the exercise of their respective functions mirrors the co-operation duties placed on Monitor under section 288 of this Act.

Section 290 – Other duties to co-operate

1504. This section places a duty on Monitor and each of the bodies listed in *subsection (3)* and a duty on the CQC and each of those bodies to co-operate with each other in the exercise of their respective functions, except in respect of their regulatory functions. Where Monitor or the CQC regulates the activities of a relevant body, the duty to co-operate does not apply to the regulator or the relevant body when regulating or carrying out those activities. The Secretary of State may, by order subject to the affirmative procedure (see section 304(5)(k)), amend the list of relevant bodies.

Section 291 – Breaches of duties to co-operate

1505. This section gives the Secretary of State power to address any breaches of the duties of co-operation in sections 288 or 290, section 70 of the Health and Social Care Act 2008, or any other enactment which imposes co-operation duties on the bodies listed in *subsection (3)* of the preceding section. Where the Secretary of State believes that any of those duties has been breached or there is a significant risk that they will be, a written notice of opinion may be issued to the bodies concerned. If the bodies breach or continue to breach the duty following such a notice, the Secretary of State may prohibit each body from exercising certain functions, or exercising them in a certain way, unless the other body in question agrees in writing that they may continue to exercise those functions. In default of such an agreement, the matter may be determined by arbitration. Any prohibition is limited to a period of one year unless the Secretary of State considers the breach is continuing and is having a detrimental effect on the health service; in which case, the period may be extended by one year.

The Care Quality Commission

Section 292 – Requirement for Secretary of State to approve remuneration policy etc.

1506. This section amends Schedule 1 to the Health and Social Care Act 2008, with the effect that the CQC must obtain the approval of the Secretary of State of its pay and remuneration policy before making any determinations about payments to staff it employs. This would make the approach for the CQC consistent with that for other arm's-length bodies established by this Act (see Parts 8 and 9 regarding NICE and the Information Centre).

Section 293– Conduct of reviews etc. by Care Quality Commission

- 1507. This section amends the Health and Social Care Act 2008 so as to require the CQC to gain the approval of the Secretary of State before undertaking a special review or investigation pursuant to section 48, a study as to economy or efficiency under section 54 or a review of data, studies or research under section 57 of the Health and Social Care Act 2008.
- 1508. The new section 48(1A) of the Health and Social Care Act 2008 provides the CQC with an exemption so that the CQC does not need to seek the Secretary of State's approval for an investigation where the CQC considers that there is a risk to the health, safety or welfare of people receiving care.

Section 294 - Failure to discharge functions

- 1509. This section amends the power the Secretary of State has under section 82 of the Health and Social Care Act 2008 to direct the CQC when he considers that it is failing, or has failed, to perform its functions. This is in line with similar powers of intervention introduced for other non-Departmental public bodies including Monitor and the NHS Commissioning Board. The amendment limits the use of the power to direct to circumstances where the failure is significant and includes a requirement for the Secretary of State to publish the reasons for any intervention. For the purposes of the section a failure to exercise functions properly includes the case where the Secretary of State considers that the CQC is failing to:
 - Discharge its functions consistently with what he considers to be the interests of the health service; or
 - Exercise a function consistently with the purpose for which it was conferred.
- 1510. The amendment also prevents the Secretary of State from being able to intervene in a particular case; he will need to demonstrate that there is evidence of more widespread failure. This is in line with the Secretary of State's intervention powers over Monitor and is necessary to ensure the independence of the regulators. For example, the Secretary of State could use this power if the CQC failed to register service providers carrying on a specific regulated activity. However, he could not use it if he simply disagreed with a regulatory decision made by the CQC in the case of a particular trust.

Arrangements with devolved authorities etc.

Section 295 – Arrangements between the NHS Commissioning Board and Northern Ireland Ministers

1511. This section allows the NHS Commissioning Board to make arrangements with a Northern Ireland Minister to commission services for the purposes of the Northern Ireland health service. Examples of health services which Northern Ireland Ministers might ask the NHS Commissioning Board to commission for the Northern Ireland

health service are specialised services for rare conditions and high secure psychiatric services.

Section 296 – Arrangements between the NHS Commissioning Board and Scottish Ministers etc.

1512. This section allows the NHS Commissioning Board to make arrangements with the Scottish Ministers or a Scottish health body to commission services for the purposes of the Scottish health service. Examples of health services which Scottish Ministers might ask the NHS Commissioning Board to commission for the Scottish health service are specialised services for rare conditions and high secure psychiatric services.

Section 297 - Relationships between the health services

1513. This section introduces Schedule 21.

Schedule 21 – Amendments relating to relationships between the health services

- 1514. 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 PCTs and SHAs, and replacing them with references to CCGs or the NHS Commissioning Board.
- 1515. These amendments are:

Act	Amendment
National Health Service (Scotland) Act 1978 (c.29)	The Schedule removes references to SHAs and PCTs, and adds references to CCGs and the NHS Commissioning Board. It makes certain other adjustments in consequence of the changes made by the Act.
	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.
NHS Act 2006 (c.41)	The Schedule adds Special Health Boards, Healthcare Improvement Scotland and the Scottish Ministers to section 9 of the Act so that arrangements by certain health service bodies with any of these persons will be NHS contracts for the purposes of the NHS Act.
	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.
	Paragraphs 8 to 11 of the Schedule are related to changes made by the Act which impact upon certain bodies in Wales.
National Health Service (Wales) Act 2006 (c.42)	The Schedule removes references to SHAs and PCTs, and adds references to CCGs and the NHS Commissioning Board.
	Paragraph 13 of this Schedule adds Special Health Boards, Healthcare Improvement Scotland and the Scottish Ministers to section 7 of the Act so that arrangements by certain health service bodies with any of these persons will be NHS contracts for the purposes of the NHS (Wales) Act 2006.

Act	Amendment
	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 Act, 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.
Social Services	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.
	Certain amendments to this order are consequential to changes made elsewhere in the Act.

Section 298 - Advice or assistance to public authorities in the Isle of Man or Channel Islands

1516. This section allows the NHS Commissioning Board and CCGs to provide advice or 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

Section 299 – Certificate of consent of community patients to treatment

- 1517. This section 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 CQC 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.
- 1518. 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.
- 1519. 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 treatment patients may not (in general) be treated against their will unless they are recalled to hospital by their responsible clinician.
- 1520. 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.)

- 1521. 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 could previously only be given if they had been approved as appropriate by a SOAD. This is known as the "certificate requirement", because approval had to 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.
- 1522. A SOAD's Part 4A certificate was generally required for medication (after the patient has been on supervised community treatment for one month) and for electro-convulsive therapy. In the 1983 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.
- 1523. It is the rules about these certificates which are changed by this section.
- 1524. The section 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 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 is now sufficient to meet the certificate requirement so long as the patient continues to consent and has capacity to do so. But it is still possible to meet the certificate requirement by means of a Part 4A SOAD certificate instead.
- 1525. 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.
- 1526. The section 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 cases, the patient will 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 a SOAD's Part 4A certificate would be required instead.
- 1527. However, new section 64FA(5) provides 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 does 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 is no legal authority to give the treatment even if a SOAD's Part 4A certificate has been obtained.
- 1528. The section makes some further amendments to the 1983 Act to reflect the fact that there are now two different types of Part 4A certificate. It amends section 64H to enable the Secretary of State in England, and the Welsh Ministers in Wales, to set out different forms for the different Part 4A certificates 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 continue (as before) to apply only to a SOAD's Part 4A certificate. It also amends section 61 to provide that the Care Quality Commission and the Welsh Ministers retain the power to withdraw a SOAD's Part 4A SOAD certificate, but are not able to withdraw an approved clinician's certificate.
- 1529. 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).

- 1530. In general, supervised community treatment patients recalled to hospital are subject to the same rules as detained patients, although section 62A provides 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.
- 1531. This section extends the exception in section 62A to approved clinicians' Part 4A certificates. In other words, a new certificate under section 58 or 58A is not required if the treatment in question is already covered by an approved clinician's Part 4A certificate, provided that the patient continues to consent to the treatment (and still has the capacity to do so).
- 1532. Section 62A also provides 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 section 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 will allow an approved clinician to continue giving medication to a patient who has withdrawn consent if they consider that its discontinuance would cause serious suffering to the patient, but it does 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).
- 1533. 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

Section 300 – Transfer schemes

- 1534. This section enables 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 Act. For example, the schemes may transfer property currently held by a PCT (which are being abolished by the Act) to a CCG; or transfer staff currently involved in the provision of public health commissioning from a PCT to a local authority.
- 1535. *Subsection (1)* allows the Secretary of State to establish transfer schemes for property or staff.
- 1536. *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 22 (property transfer schemes) to a body listed in the corresponding entry in column 2 of that table.
- 1537. *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 23 (staff transfer schemes) to a body listed in the corresponding entry in column 2 of that table.
- 1538. *Subsection (4)* allows the Secretary of State to direct the NHS 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 PCTs or

SHAs. A qualifying company is a company defined for these purposes in *subsection* (8) as wholly or partly owned by the Secretary of State or the NHS Commissioning Board and formed under section 223 of the NHS Act, for the purpose of providing facilities or services to the NHS, or a subsidiary of a company formed under that section and wholly owned by the Secretary of State. Such a company could be used, for example, as an intermediate solution to hold PCT property before it is transferred to, for example, local authorities, consenting persons or public authorities providing services as part of the health service in England, or CCGs. Section 223 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).

- 1539. *Subsection* (5) allows the Secretary of State to give directions to the NHS Commissioning Board or to qualifying company about how to do this.
- 1540. *Subsection* (6) makes provision as to how individuals employed by the civil service are to be treated for the purposes of transfer schemes under section 300 and section 301.
- 1541. Subsections (7), (8) and (9) cover definitions, including defining a "qualifying company" and clarifying that a transfer of property includes the grant of a lease.

Section 301 – Transfer schemes: supplemental

- 1542. This section makes additional provision relating to the transfer schemes made under section 300. It sets out in more detail what may be transferred, and how it may be done for example, it enables transfer schemes to make provision about the shared use of property transferred.
- 1543. *Subsection (1)* makes provision about what may be transferred by a staff or property transfer scheme.
- 1544. Subsection (2) sets out the bodies to whom criminal liabilities can be transferred.
- 1545. *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.
- 1546. *Subsection (4)* allows property transfer schemes to make provision for shared ownership or use of property.
- 1547. Subsection (5) allows staff transfer schemes to make the same or similar provisions to the Transfer of Undertakings (Protection of Employment) Regulations. Subsection (8) defines "TUPE regulations".
- 1548. *Subsection* (6) allows transfer schemes to be modified by agreement once they come into operation.
- 1549. *Subsection* (7) requires the Secretary of State to ensure that all property, rights and liabilities of a PCT, SHA or Special Health Authority covered by a transfer scheme are transferred.

Section 302 – Subsequent property transfer schemes

- 1550. This section allows any property, rights or liabilities initially transferred from a PCT, SHA or the Secretary of State to a Special Health Authority or a qualifying company, to be subsequently transferred to one of the organisations listed in Schedule 22 to this Act.
- 1551. Subsection (2) allows the Secretary of State to establish such subsequent transfer schemes. Subsection (3) ensures that the supplemental provisions for transfer schemes apply in the same way as for other property transfer schemes.

Part 12 – Final Provisions

Section 303 – Power to make consequential provision

- 1552. This section enables the Secretary of State to make an order making changes to other legislation as a consequence of the changes made by the Act, in addition to those consequential changes which are made by the Act itself. If these include amendments to other primary legislation, the order will be subject to the affirmative procedure. The amendments can be made to other legislation, including in some cases legislation made by the devolved authorities (*subsection* (6)).
- 1553. An order under this section may include transitional, transitory or saving provision in connection with the commencement of the consequential change (*subsection* (2)(b)), 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 this Act (*subsection* (3)).

Section 304 – Regulations, orders and directions

1554. This section makes general provisions about the powers to make regulations, orders and directions under the Act 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.

Section 306 – Commencement

- 1555. Subsection (4) of this section provides that most of the provisions of the Act 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* (5)). Certain provisions of the Act come into force on Royal Assent, and these are specified in *subsection* (1).
- 1556. *Subsection* (6) enables a commencement order to make modifications of this Act or other legislation which would only apply until the commencement of another provision of the Act or another piece of legislation.
- 1557. *Subsection* (7) enables a commencement order to provide that the duty on CCGs to prepare accounts does not apply during the period between the coming into force of the provisions for the establishment of CCGs and the date specified by the Secretary of State as the date by which every provider of primary medical services in England is to be a member of a CCG.
- 1558. *Subsection (8)* relates to consultation requirements imposed by the Act and allows the consultations begun before the provision imposing the duty to consult is brought into force to be valid for the purposes of that provision.

Section 307 – Commencement: consultation with Scottish Ministers

- 1559. This section imposes on the Secretary of State a duty to consult Scottish Ministers before commencing certain provisions of the Act by order.
- 1560. *Subsection (1)* lists the provisions in relation to which Scottish Ministers must be consulted. These provisions either relate to public health, or are in Part 7 of the Act (regulation of health and social care workers).

Section 308 – Extent

1561. This section sets out the Act's extent, a full description of which is in the 'Territorial extent' section of this document.