

HEALTH ACT 2009

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1 – Quality and Delivery of NHS Services

Chapter 1 - NHS Constitution

Section 1: NHS Constitution

84. *Section 1* identifies the NHS Constitution and the Handbook as the documents published on 21st January 2009, entitled *The NHS Constitution* and *The Handbook to the NHS Constitution*, or as any revised versions of those documents published in accordance with the provisions of Chapter 1.

Section 2: Duty to have regard to NHS Constitution

85. *Section 2* requires specified bodies to have regard to the NHS Constitution when performing their NHS functions. Those functions include the commissioning or provision of NHS services or, in the case of Monitor and the Care Quality Commission, the regulation of those services. The bodies to which the new duty applies are: Strategic Health Authorities, PCTs, NHS trusts, Special Health Authorities, NHS foundation trusts, Monitor and the Care Quality Commission.
86. In addition, those bodies that provide or assist in providing NHS services under arrangements under section 12(1) of the NHS Act or who are providing NHS services under contracts or other arrangements made pursuant to the provisions of the NHS Act listed in *subsection (6)*, must (in doing so) also have regard to the NHS Constitution. This includes bodies providing primary care services, such as pharmaceutical services, dental services and general medical services.
87. *Subsection (7)* defines “NHS services” as being health services provided in England for the purposes of the NHS in England. *Subsection (8)* provides that references to the provision of services include the provision of services carried out jointly with another person.
88. The Constitution is for the NHS in England only. However, on 3 July 2008, England, Scotland, Northern Ireland and Wales committed to a high-level statement declaring the principles of the NHS across the UK. This was to reaffirm that the underlying principles of the NHS across the UK remain the same, even as the way the NHS provides care may vary between the four countries, reflecting their different needs and circumstances.

Section 3: Availability and review of NHS Constitution

89. *Section 3(1)* provides that the Secretary of State must ensure that the NHS Constitution continues to be available to patients, staff and members of the public. The NHS Constitution and the Handbook published on 21 January 2009 were published under the general powers of the Secretary of State in relation to the NHS. The effect of

subsection (1) (and section 5(1)) is to prevent the Secretary of State from using those general powers to withdraw either document.

90. The Secretary of State is obliged to review the whole NHS Constitution at least once every ten years, with the first review to be completed by 5 July 2018 (5 July is the anniversary of the founding of the NHS; this would be the 70th anniversary). The Secretary of State must ensure, when reviewing the Constitution, that the following are consulted: patients and bodies or other persons representing patients; staff and bodies or other persons representing staff (such as unions or professional bodies); members of the public; carers; local authorities; the providers of NHS services and the independent regulators. If any revision is made to the NHS Constitution as a result of a 10 year review, the Secretary of State is obliged to republish it (see subsection (5)).
91. Any revision to the guiding principles in the NHS Constitution must first be set out in regulations made by the Secretary of State. Those regulations will be subject to the negative resolution procedure.
92. [Section 3\(7\)](#) defines “patients” as those to whom NHS services are being provided. It defines the “guiding principles” as the principles described in the NHS Constitution published on 21 January 2009, or any revised version of those principles. It defines “staff” as those persons who are employed by, or working in some other capacity for, the bodies and other persons who, in providing NHS services, are obliged to have regard to the NHS Constitution where those persons are employed or work in (or in connection with) the provision, commissioning or regulation of NHS services. It defines “carers” as persons who, as relatives or friends, care for other persons to whom NHS services are provided, and section 3(8) defines “local authorities” to include unitary, county and district councils. This mirrors the definition of local authorities in section 229 of the Local Government and Public Involvement in Health Act 2007

Section 4: Other revisions of NHS Constitution

93. In addition to any revisions that follow a review, the Secretary of State is able to revise the NHS Constitution from time to time. However, the Secretary of State will be obliged to undertake appropriate consultation – with patients, staff, members of the public and other persons who are affected by the revision – before any such revision.
94. As in section 3, any revision to the guiding principles in the NHS Constitution (though not to the other parts of the Constitution) must first be set out in regulations made by the Secretary of State. Those regulations will be subject to the negative resolution procedure.
95. After any revision, the Secretary of State must republish the NHS Constitution.

Section 5: Availability, review and revision of Handbook

96. [Section 5](#) provides that the Secretary of State must ensure that the Handbook continues to be available to patients, staff and members of the public (see discussion in paragraph 89 above).
97. The Secretary of State is able to revise the Handbook at any time, but is obliged to review it at least once every three years, with the first review completed by 5 July 2012. After any change to the Handbook, the Secretary of State is obliged to republish it. The Government intends this document to be updated periodically, as Department policy or law evolves.

Section 6: Report on effect of NHS Constitution

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

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

Section 7: Regulations under section 3 or 4

100. This section gives the Secretary of State power to make the regulations referred to in sections 3 and 4 by statutory instrument under the negative resolution procedure.

Chapter 2 – Quality Accounts

Section 8: Duty of providers to publish information

101. *Subsection (1)* provides that NHS providers in public ownership (listed in *subsection (2)*) must publish prescribed information in respect of each reporting period, covering the NHS services they provide or procure. The intention is to ensure that providers of NHS services produce regular reports on the quality of the services they provide, and that these reports are publicly available. The definition of “reporting period” in section 9(2) means that NHS providers will have to publish that information for the period 1 April to 31 March each year. Regulations will set out the content of a Quality Account.
102. *Subsection (2)* lists those NHS providers in public ownership. These are PCTs, NHS trusts, Special Health Authorities and NHS foundation trusts
103. The effect of *subsection (3)* is that bodies or other persons not in NHS ownership who provide, or make arrangements for the provision of, NHS services must also publish prescribed information. It defines these persons by referring back to section 2(4) and (5). Those subsections set out different providers of NHS services, including providers of primary medical and other primary healthcare services, by reference to the type of service they provide, and the legislation under which these services are provided.
104. *Subsection (4)* ensures that healthcare providers report on their part of any jointly provided healthcare. The intention is to ensure that each provider should publish their own Quality Account for the services for which they are responsible under any joint arrangement.
105. *Subsection (5)* gives the Secretary of State power to make regulations to exempt providers from the requirement to publish a Quality Account. The intention is to ensure that certain NHS providers, or types of NHS provider, can be exempted if necessary from the requirement to publish a Quality Account. This will be either on a temporary basis to allow certain types of provider, particularly those who are smaller or who are new to providing services for the NHS, to gear themselves up for publication; or on a more permanent basis, in cases where the provider carries out too few NHS services to make it reasonable to require that provider to publish an Account. This subsection also gives the Secretary of State power to make regulations to exempt certain services from appearing in a Quality Account. The intention of this subsection is to exempt certain services if it would not be practicable to include them, for example if the volumes of a particular service are too small to allow users of the Account to draw conclusions about the quality of services offered.
106. *Subsection (6)* defines NHS services by reference back to section 2(7), which defines these services as being those which are provided in England for the purposes of the health service continued by section 1(1) of the NHS Act.

Section 9: Supplementary provision about the duty

107. *Subsection (2)* defines the reporting period for the purposes of section 9. The first reporting period for Quality Accounts will be 1st April 2009 – 31st March 2010, and subsequent reporting periods will run from 1st April – 31st March each year.
108. *Subsection (3)* provides that a provider must republish their Quality Account if they are notified of an error or omission by either the Care Quality Commission or a Strategic Health Authority. Providers must republish the revised Account within 21 days. Guidance will set out how this provision should be applied.
109. *Subsection (4)* requires a provider to send a copy of their Quality Account to the Secretary of State. The Department of Health intends to publish provider Quality Accounts on the NHS Choices website, which is owned by the Department, but not to check or edit the Account.
110. The Act sets out a very basic requirement for the publication of Quality Accounts, and the Government intends to supplement that with subsequent guidelines, which providers will need to have regard to when drawing up their Quality Accounts. Regulations and guidance will have the key objectives of making use of information that providers already collect, of tying that into other NHS reporting cycles, and of keeping burdens on providers down to a minimum.
111. *Subsection (5)* sets out some of the matters about which provision may be made in regulations made under section 8(1) or (3). These matters include the form and content of a Quality Account and the date on which it must be published, duties of the provider to ensure the accuracy of the information contained in the Quality Account, and requirements for the provider to have regard to any guidance issued by the Secretary of State. The intention is to ensure that the content and timetable for publication can be changed easily and speedily in the future to reflect changing national and local healthcare quality priorities, as well as to ensure that providers take responsibility for the reliability of the content of their Quality Account.
112. *Subsection (6)* provides that any person can ask the provider to supply a copy of their Quality Account for the current and the preceding two years. All provider Quality Accounts will be available on the NHS Choices website, but the purpose of this subsection is to ensure that providers are required to supply a hard copy of their Quality Account to anyone who requests one.
113. *Subsection (7)* requires providers to display a notice in their premises informing patients that the latest copy of their Quality Account is available and how a copy can be obtained.
114. *Subsection (8)* sets out that premises that the provider does not own or run (e.g. the patient's own home) or that the provider owns or runs but that patients do not directly access (e.g. a pathology laboratory) are excluded from this requirement.
115. *Subsection (9)* defines "premises" for the purposes of *subsection (8)*.

Section 10: Regulations under section 8

116. **Section 10** makes provision about the procedure for making regulations under section 8. These will be subject to the negative resolution procedure.

Chapter 3 – Direct payments

Overview of provisions

Direct payments for health care

117. **Section 11** inserts new sections 12A to 12D into the NHS Act. New section 12A(1) allows the Secretary of State to make monetary payments directly to a patient, or another person nominated by the patient, to enable them to procure goods and services

in connection with their health care. Such a payment is referred to as a “direct payment” (see new section 12A(5)).

118. Before a direct payment could be made, the patient would have to give their consent, either to receiving a direct payment themselves, or to a direct payment being made to a person nominated by them. For patients who lack capacity to consent, regulations under new section 12B(2)(c) may make provision for a direct payment to be made to a person on the patient’s behalf.
119. The Secretary of State may provide in regulations for PCTs to be able to make direct payments for mental health after-care services that PCTs must provide to patients under section 117 of the Mental Health Act 1983 (the Mental Health Act) (see new section 12A(4)). The patient would be required by the regulations to give consent before a direct payment could be made, as in the case of a payment under new section 12A(1).
120. The Government has set out its intentions for how direct payments might operate in *Personal Health Budgets: First Steps*. A health care direct payment would be analogous to a direct payment for social care. The health care that could be procured using this money is health care for which the Secretary of State is responsible under sections 2(1) or 3(1) of the NHS Act, anything for which the Secretary of State must arrange under paragraph 8 of Schedule 1, or vehicles that the Secretary of State may provide under paragraph 9 of Schedule 1 (see new section 12A(2)). Under section 3(1) of the NHS Act the Secretary of State must provide specified services or facilities to such extent as he or she considers necessary to meet all reasonable requirements. This includes hospital and other accommodation for the purpose of the services provided under the Act, medical, nursing and services or facilities for the care of pregnant women and children and for the prevention of illness, care of persons suffering from illness and the after-care of persons who have suffered from illness and for the diagnosis and treatment of illness.
121. Initially the Secretary of State has power to make direct payments for health care only in pilot schemes under regulations, as required by new section 12A(6). Direct payments for health care could in the future be made more widely available following review and an order made by the Secretary of State under new section 12C(8)(a). The order would be subject to approval by each House of Parliament under the affirmative resolution procedure.

Regulations about direct payments

122. New section 12B(1) gives the Secretary of State power to make regulations covering how direct payments will operate. The factors that regulations could provide for are identified in new section 12B(2) to 12B(4) and are similar to those already provided for in respect of social care direct payments.
123. The regulations could identify the groups of patients who might benefit, such as mental health patients; the health conditions for which direct payments could be made, such as those which are long term and are sufficiently predictable to allow a budget to be set; and the services that could be provided, such as nursing care (see new section 12B(2)(a)).

Direct payments pilot schemes

124. New section 12C(1)(a) provides for the Secretary of State to have power to make pilot schemes under regulations under new section 12B through which the Secretary of State could make direct payments. By directions in writing under sections 7 and 273(4)(c) of the NHS Act, the Secretary of State could delegate the operation of a pilot scheme to a PCT (or a Strategic or Special Health Authority). The Government intends to set up a programme of pilot schemes led by different PCTs to assess the effectiveness of direct payments. In *Personal Health Budgets: First Steps*, the Government invited PCTs to apply to become personal health budget pilots, and it has received a number of applications. The Government intends that there should be a further stage in the application process to select direct payment pilot sites.

125. A pilot scheme must have a specified duration and be subject to review (new section 12C(3) and (4)). The geographical scope may be specified (new section 12C(2)(a)), and a pilot scheme could also be distinguished by characteristics set out in regulations under new section 12B(2) (see section 12C(1)(b)). The Secretary of State is also able to make provision in regulations for changing or discontinuing a pilot scheme or schemes under new section 12C(2)(b).
126. The characteristics of a review of a pilot scheme may be set in regulations. For example, regulations may provide for a review to be undertaken by an independent person or that its findings must be published (new section 12C(5)). New section 12C(6) sets out subjects that a review may, in particular, examine. The Government intends that the review of the pilot schemes should be independent, and the findings should be published. It also intends that the review should cover all the matters mentioned in new section 12C(6), such as the administration of a scheme, the effect of direct payments on cost or quality of care, or the effect of direct payments on patients' behaviour.
127. New section 12C(7) to (10) provides for the Secretary of State to be able by order either to repeal the requirement for direct payments to be made only in accordance with a pilot scheme (see new section 12C(8)(a)), or to repeal new sections 12A, 12B, 12C and 12D (see new section 12C(10)). However new section 12C(7) requires the Secretary of State to have carried out a review of one or more pilot schemes before making any such order. Any such order would be subject to approval by each House of Parliament under the affirmative resolution procedure. If the Secretary of State chose to make an order under section 12C(8)(a), direct payments for health care would no longer need to be made as part of a pilot scheme, and the power to make pilot schemes provided by sections 12C(1) to (4) would be repealed. However, similar time limited schemes could be set up under regulations under section 12B, to continue to test possible extensions or adaptations of a direct payments model.
128. After reviewing a scheme or schemes, an order under new section 12C(8)(b) would enable the Secretary of State to amend, repeal or otherwise modify any other provision of the NHS Act to facilitate the making of direct payments, so long as the changes were necessary or expedient (see section 12C(9)). The power would enable lessons learnt about the legislation from piloting in schemes to be addressed. The order would be subject to approval by each House of Parliament under the affirmative resolution procedure. New section 12C(9) would not allow provision by order to alter unrelated aspects of the NHS Act.
129. New section 12C(10) allows the Secretary of State to repeal sections 12A, 12B, 12C and 12D, for example if, following a review, the Secretary of State does not believe that direct payments are a viable way of delivering services.

Arrangements with other bodies relating to direct payments

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

Jurisdiction of Health Service Commissioner

131. [Section 12](#) amends the Health Service Commissioners Act 1993 (the 1993 Act) to enable the Commissioner to hear complaints about services for which direct payments were made, including those provided by independent organisations. This gives patients receiving direct payments for health care similar rights to those enjoyed by patients accessing services from NHS organisations or from private sector organisations commissioned by PCTs.

Detailed explanation of provisions

Section 11: Direct payments for health care

132. **Section 11** inserts new sections 12A to 12D into the NHS Act.
133. New section 12A(1) allows the Secretary of State to make a direct payment to a patient or their representative, in order to purchase goods or services that might otherwise be provided by the NHS. The goods or services are those identified in new section 12A(2). Section 12A(1) also requires that direct payments be made only with the consent of the patient. However, where a patient lacks capacity, provision could be made in regulations for consent to be given by a representative of the patient under section 12B(2)(c).
134. New section 12A(2) specifies that direct payments may be made in respect of services the Secretary of State may or must provide under sections 3(1) or 2(1) of the NHS Act, must arrange under paragraph 8 of Schedule 1 to the NHS Act or vehicles that that Secretary of State may provide under paragraph 9 of Schedule 1 to the NHS Act.
135. New section 12A(3) causes the Secretary of State's ability to make direct payments to be subject to regulations made under new section 12B.
136. New section 12A(4) provides for regulations to enable a PCT to make a direct payment for after-care services it is obliged to provide by section 117 of the Mental Health Act 1983.
137. New section 12A(5) defines a payment of the kind described in new section 12A(1) or 12A(4) as a direct payment.
138. New section 12A(6) provides that direct payments may only be made as part of a pilot scheme established under regulations under new section 12C and 12B. However, this section may be repealed by order, as laid out in new section 12C(8)(a).
139. New section 12B(1) enables the Secretary of State to make regulations about direct payments. These regulations enable provision to describe in more detail when and how direct payments can be made.
140. New section 12B(2) enables regulations to define the scope of direct payments, which, under new section 12C(1), includes the way pilot schemes will operate. Under new section 12B(2)(a), it will be possible to set out in regulations which services may or may not be suitable, in what circumstances, and which patients may or may not be allowed to receive direct payments in order to purchase services. The regulation-making power is subject to the negative resolution procedure.
141. Direct payments will often be made directly to the patient themselves, but a patient may prefer to nominate someone else to receive and manage direct payments on their behalf. New section 12B(2)(b) allows for circumstances to be prescribed in which direct payments may or must be made to a person nominated by the patient.
142. Where a patient lacks capacity, new section 12B(2)(c) allows for circumstances to be prescribed in which direct payments may or must be paid to someone other than the patient. This will make it possible, where the individual lacks capacity to make the necessary decisions about consenting to and managing a direct payment, to make direct payments to a suitable surrogate on the individual's behalf. The reference to a person who lacks capacity has the same meaning as in the Mental Capacity Act 2005 (see new section 12B(6)(b)). Regulations could also provide for direct payments to be made to a parent or other person in respect of a child where a child is unable to consent to the making of payments.
143. New section 12B(2)(d) allows regulations to set out conditions that must be complied with by the Secretary of State (in effect, by the NHS organisation granting the direct payment on behalf of the Secretary of State) or the PCT (in relation to after-care under section 117 of the Mental Health Act) when making a direct payment. This might

include ensuring that there is an agreed care plan, that there are proper arrangements in place for paying the money into a secure bank account or for carrying out regular reviews of the payments and of the patient's care.

144. New section 12B(2)(e) enables regulations to set out conditions the patient or payee should comply with when a direct payment is granted. These might include: maintaining a separate bank account; agreeing to a care plan that specifies the agreed health outcomes and the types of services to be purchased to help meet those outcomes; or providing records of their spending to demonstrate that it is in line with the care plan.
145. New section 12B(2)(f) enables regulations to make provision about the amount of a direct payment or how it is to be calculated. For example, the regulations are likely to require that the amount be sufficient to cover the whole of the services set out in a care plan for which they are to provide. As methodologies for estimating the required budget emerge these may also be specified in regulations.
146. New section 12B(2)(g) allows regulations to set out when the Secretary of State, or the PCT when making direct payments for after-care under section 117 of the Mental Health Act, may or must stop making direct payments. Relevant circumstances might include when a patient's health is deteriorating such that it cannot be managed within the budget or where there is evidence that the direct payments have been abused.
147. New section 12B(2)(h) allows regulations to describe circumstances in which the Secretary of State, or the PCT when making direct payments for after-care under section 117 of the Mental Health Act may or must require all or part of direct payments to be repaid, for example, when a significant surplus has accumulated.
148. New section 12B(2)(i) allows regulations to include appropriate monitoring arrangements as regards the making of direct payments, their use by the payee, or the services which they are used to secure. For example the PCT, acting on behalf of the Secretary of State, might require the payee or providers contracted using a direct payment on the payee's behalf, to periodically submit copies of receipts. Similar provision could be made in respect of the making of direct payments for after-care under section 117 of the Mental Health Act.
149. New section 12B(2)(j) allows regulations to make provision about the arrangements to be made by the Secretary of State or the PCT to provide information, advice or other support to patients or others. For example, regulations are likely to require PCTs to provide information about the range of services available in their area.
150. New section 12B(2)(k) allows regulations to be made governing how far support for direct payments can be treated as a service for which direct payments can be made. This could allow provision to be made allowing the PCT to give people direct payments to purchase support, for example help with payroll services for employees, or independent advocacy services.
151. New section 12B(3) allows regulations to make provision to govern situations where a patient has fluctuating capacity, for example where, at the time of initially being granted a direct payment, they do not have the ability to consent, but later regain capacity. Regulations might specify circumstances where direct payments should continue to be paid to a surrogate in the period immediately following the regaining of capacity, subject to the consent of the patient.
152. In the event that repayment to the Secretary of State or the PCT is needed and the seeking of repayment under regulations made under new section 12B(2)(h) has been unsuccessful, regulations under new section 12B(4) could allow the sum owed to be recoverable as a civil debt due to the Secretary of State or the PCT. In addition, for serious abuse of the system, criminal sanctions will be available through the Fraud Act 2006 or the Theft Act 1968.

153. New section 12B(5)(a) and (b) allow regulations to define the extent to which, while patients or another person on the patient's behalf may have procured the goods or services directly, those services should be regarded as goods or services provided by the Secretary of State or a PCT. This means that in prescribed circumstances, but only in prescribed circumstances, the Secretary of State could be considered to have fulfilled the duty to provide a service described at new section 12A(2) by making a direct payment. Similarly, a PCT could be considered, in prescribed circumstances, to have fulfilled its obligations under section 117 of the Mental Health Act by making a direct payment.
154. New section 12B(6) contains definitions. New section 12B(6)(a) specifies that a "service" includes anything for which a direct payment may be made, as set out in new section 12A(2) or section 117 of the Mental Health Act. New section 12B(6)(b) defines references to lacking capacity by reference to the meaning in the Mental Capacity Act 2005.
155. New section 12C(1)(a) enables the regulations that may be made under section 12B to provide for the Secretary of State to be able to make pilot schemes in accordance with which direct payments may be made.
156. New section 12C(1)(b) allows the pilot schemes provided for by regulations to include provision for any of the matters covered by new section 12B(2) as long as the pilot schemes comply with the regulations under new section 12B. For example, a pilot scheme might apply to patients with a particular health condition in particular circumstances for which bespoke monitoring arrangements are appropriate.
157. New section 12C(2)(a) allows provision in regulations to provide for or require specification of the geographical area of a pilot scheme. New section 12C(2)(b) allows the regulations to make provision for or require the pilot scheme to provide for the scheme's revocation or amendment.
158. New section 12C(3) requires that regulations must provide that when a pilot scheme is created, its duration is specified, although they may provide for the initial period to be subject to extension by the Secretary of State. This may occur if, for example, the pilot scheme took longer than anticipated to become established and needs to be extended to allow enough patients to use it for robust review.
159. New section 12C(4) requires that regulations must provide for the review of a pilot scheme or require the pilot scheme to include provision for review.
160. New section 12C(5) sets out particular provision that may be made for the form of a review of the pilot scheme. The section allows provision to be made to ensure that an independent person carries out the review, that the findings of the review are published, and that the review considers certain subjects.
161. New section 12C(6) sets out a range of specific matters the review may consider. These include the administration of the scheme, the effect of direct payments on the cost or quality of care, and the effect of direct payments on the behaviour of patients, carers or people providing services.
162. New section 12C(7) allows the Secretary of State, having carried out a review of one or more pilot schemes, to either repeal section 12A(6) and section 12C(1) to (4), using an order described at section 12C(8)(a), or repeal sections 12A to D using an order described at section 12C(10). Repeal pursuant to section 12C(8)(a) would make direct payments generally available subject to any regulations under section 12B. Repeal pursuant to section 12C(10) would prevent the making of direct payments under the new sections in future.
163. New section 12C(8)(b) provides for other provisions of the NHS Act to be amended, modified or repealed, for example where it has become apparent that this is necessary for a general roll out of direct payments. Any orders made under section 12C(7) are

subject to Parliamentary approval by each House of Parliament under the affirmative resolution procedure (see the amendment made by paragraph 10 of Schedule 1 to the Act to section 272(6) of the NHS Act).

164. New section 12C(9) specifies that any amendments, repeals or modifications to the NHS Act carried out by an order described at section 12C(8)(b) must be necessary or expedient for the purpose of facilitating the making of direct payments. This means that changes could be made to the NHS Act to reflect the lessons learnt from the pilot schemes, but prevents the power at section 12C(7) being used to make other changes to the Act.
165. New section 12C(10) provides for the Secretary of State to be able to repeal sections 12A, 12B, 12C and 12D. In the event that the pilot schemes show that direct payments are not a viable way to deliver services, these provisions allow the Secretary of State to remove the powers from the NHS Act through an order subject to approval by each House of Parliament under the affirmative resolution procedure.
166. New section 12D(1) authorises the Secretary of State to make arrangements with other bodies for their assistance in providing or operating or otherwise in connection with direct payments.
167. New section 12D(2) provides that the bodies with whom such arrangements may be made include voluntary organisations.
168. New section 12D(3) provides that the Secretary of State is free to agree terms with such bodies. The Secretary of State may pay a body for its part in the arrangements concerning direct payments.

Section 12: Jurisdiction of Health Service Commissioner

169. **Section 12** amends the jurisdiction of the Health Services Commissioner set out in the 1993 Act.
170. **Subsection (2)** expands the scope of persons subject to investigation to include persons delivering direct payment services who are not health service bodies.
171. **Subsection (3)** expands the definition of independent providers in the 1993 Act to include persons providing direct payment services who are not health service bodies.
172. **Subsection (4)** expands the general remit of the Health Services Commissioner set out in the 1993 Act to allow the Commissioner to investigate a complaint made about a service or other action provided by a person providing direct payment services.
173. **Subsection (5)** amends the 1993 Act to allow the Commissioner to investigate matters arising from commercial and contractual arrangements for the provision of direct payment services.
174. **Subsection (6)** makes a consequential amendment in respect of independent providers who are not persons providing direct payment services.
175. **Subsection (7)** defines direct payment services by reference to section 12A of the NHS Act.

Section 13: Direct payments: minor and consequential amendments

176. **Section 13** introduces Schedule 1, which contains minor and consequential amendments relating to direct payments.

Schedule 1: Direct payments: minor and consequential amendments

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

178. *Paragraph 2* amends the Health Services and Public Health Act 1968 to clarify that pilots in section 63(2)(bb) are pilots set up under section 134(1) of the NHS Act or section 92(1) of the NHS (Wales) Act.
179. *Paragraph 3* has the effect that references to after-care services in the Mental Health Act 1983 include services provided in respect of which a direct payment for social care or a direct payment for health care is made.
180. *Paragraph 4* amends section 2(5) of the Disabled Persons (Services, Consultation and Representation) Act 1986 with the effect that the authorised representative of a disabled person may at any reasonable time visit him or her and interview him or her in private in hospital accommodation that has been procured using a direct payment made under new section 12A(1).
181. *Paragraphs 5(1) and (2)* amend section 45 of the 2003 Act. The amendments have the effect that the obligations of a Welsh NHS body pursuant to Chapter 2 of the 2003 Act apply where the Welsh body provides health care in respect of which an English NHS body has made direct payments, until sections 45 and 46 of the 2003 Act are repealed on the coming into force of paragraphs 37 and 38 of Schedule 5 to the 2008 Act.
182. *Paragraphs 6 to 11* provide for amendments to the NHS Act.
183. *Paragraph 7* has the effect that references to various pilot schemes elsewhere in the NHS Act become references to pilot schemes established under section 134(2) of the NHS Act, which relates to pharmaceutical services, so as to distinguish them from direct payment pilot schemes set up under new section 12C(1)(a) of the Act.
184. *Paragraph 8* confines the definition of a “pilot scheme” set out at section 134(2) so that it applies only to that Part 7 of the NHS Act, rather than the whole Act.
185. *Paragraph 9* amends the order-making power of the Secretary of State at section 246(3) with the effect that an order may vary the descriptions of exempt information at Schedule 17 to the NHS Act to include descriptions in connection with services in respect of which direct payments are made by a body, where an overview and scrutiny committee exercises functions in relation to the body. Under the Local Government Act 1972 the public may be excluded from meetings of an overview and scrutiny committee to prevent disclosure of exempt information during an item of business.
186. *Paragraph 10* amends provision for the procedure that applies to a statutory instrument under the NHS Act in section 272(6) so that an order mentioned in new section 12C(7) under new section 12C(8) or 12C(10) is subject to approval by each House of Parliament under the affirmative resolution procedure.
187. *Paragraph 11* removes the entry for “pilot scheme” from the index of defined expressions at section 276 of the NHS Act, in consequence of the changes made by paragraphs 7 and 8.
188. *Paragraphs 12 to 15* provide for amendments to the Safeguarding Vulnerable Groups Act 2006.
189. The amendments made by *paragraph 13* provide that the Secretary of State (or an NHS body to whom the Secretary of State has delegated a function of making direct payments) or a Primary Care Trust acting under regulations (in the case of section 117 after-care) is not a regulated activity provider by virtue of anything the Secretary of State or it does in connection with the making of direct payments under new sections 12A to 12D.
190. The amendment made by *paragraph 14(2)* has the effect that making a direct payment is controlled activity to the extent that it is not a regulated activity relating to children, and by sub-paragraph (3) that health care, treatment or therapy which is provided to a child out of direct payments is controlled activity.

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

Chapter 4: Innovation

Section 14: Innovation prizes

192. *High Quality Care for All* stated the Department of Health's intention to create prizes for innovations in areas such as the prevention and treatment of lifestyle diseases.
193. Under existing provisions of the NHS Act, the Secretary of State can award grants for research. However, the power is limited to research and does not extend to awarding money retrospectively for work that has already been completed.
194. **Section 14** enables the Secretary of State to make payments as prizes to promote and reward innovation in the provision of health services in England. Prizes may be awarded for work that has already been completed, including research, or for the completion of future challenges.
195. To assist in this matter, the Secretary of State may establish a committee to advise, for example, on the form and allocation of any such prizes. *Subsection (3)* enables the Secretary of State to pay remuneration, allowances or expenses to a member of the committee.

Part 2 – Powers in Relation to Health Bodies

Chapter 1 – Powers in Relation to Failing NHS Bodies in England

Section 15 and Schedule 2: De-authorisation of NHS foundation trusts

196. **Section 15(1)** inserts new sections 52A to 52E into the NHS Act and section 15(2) incorporates Schedule 2 in the Act which inserts new Schedule 8A into the NHS Act. The new sections and Schedule provide for the de-authorisation of NHS foundation trusts. The provisions are in addition to the provisions for de-authorisation of NHS foundation trusts under the trust special administrator provisions of section 16 (see below).
197. New section 52A sets out the NHS foundation trusts to which new sections 52B to 52E apply. They apply to NHS foundation trusts which were authorised after an application by an NHS trust under section 33 of the NHS Act (a “section 33 foundation trust”). The provisions also apply to NHS foundation trusts which have been established under section 56 of the NHS Act (mergers between NHS foundation trusts, or between NHS trusts and foundation trusts), but only where at least one of the trusts which formed part of the merged trust was an NHS trust or a section 33 foundation trust or, where there has been a succession of mergers under section 56, only if any of those mergers involved an NHS trust or a section 33 foundation trust.
198. New section 52B allows Monitor to give the Secretary of State a written notice that an NHS foundation trust should be de-authorised. This notice can be given if Monitor is satisfied that an NHS foundation trust has contravened or failed to comply with any term of its authorisation, or any requirement in legislation, and that the breach (or breaches taken together if more than one) is sufficiently serious to justify de-authorisation. Monitor must consult with the persons or bodies listed in subsection (4) (including the trust and the local Strategic Health Authority) before giving a notice. When it gives a notice, it must also provide a report to the Secretary of State stating the reasons why it is satisfied that the conditions for de-authorisation are met. That report must be published within 7 days of the Secretary of State making an order to de-authorise the trust under new section 52D (new section 52D(8)).

199. New section 52C deals with the grounds for the de-authorisation notice. The section requires Monitor to consider the matters set out in subsection (1) when it is deciding whether a breach is sufficiently serious to justify de-authorisation and whether to give notice to the Secretary of State. In addition, Monitor must publish guidance, following consultation with the bodies and persons set out in subsection (3), on the matters (including the specific matters listed in subsection (1)) which it proposes to take into consideration.
200. New section 52D sets out the procedure for the Secretary of State to make an order de-authorising an NHS foundation trust. On such an order taking effect the trust becomes a National Health Service trust (NHS trust). The Secretary of State must make such an order if Monitor has given notice under new section 52B. The order must specify the name of the NHS trust, the functions of the NHS trust and the number of non-executive and executive directors; if the trust has significant teaching commitments then one of the non-executive directors should be a person from a university with a medical or dental school (subsection (4)). The number of directors of the de-authorised NHS foundation trust may exceed the number permitted under the regulations governing NHS trust membership, or there may be an insufficient number and subsection (5) allows these arrangements to continue for a temporary period, specified in the order. New subsection (7) enables the Secretary of State to appoint or remove directors to meet requirements for NHS trusts.
201. New section 52E enables the Secretary of State to make a written request to Monitor to exercise its power to give a de-authorisation notice, where it appears to the Secretary of State that there are grounds on which Monitor could exercise that power.. The request must specify the NHS foundation trust to which it relates and the grounds for making the request and the request must be laid before Parliament. The request will set a period within which Monitor must either give a de-authorisation notice, or publish its reasons for not doing so (subsection (4)); that period is either 14 days or such longer period as is specified in the request (subsection (5)). If necessary, the Secretary of State may extend that period by order (subsection (6)).
202. *Section 15(2)* and *Schedule 2* insert new Schedule 8A to the NHS Act, which makes provision about de-authorised NHS foundation trusts. In particular the trust's constitution is to cease to have effect on de-authorisation (*paragraph 2*) and, subject to the other provisions of the Schedule, the trust is to be subject to the provisions of the NHS Act in relation to NHS trusts (including the provisions of Schedule 4 relating to the board of directors). Paragraph 4 provides that the number of executive and non-executive directors is to be that of the former NHS foundation trust, but this is subject to any provision made in the de-authorisation order (see section 52D(4) and (5)). In relation to finance, paragraph 7 provides that the public dividend capital (PDC) of the trust continues as public dividend capital of the NHS trust and paragraph 8 makes provision as to the trust's accounts. Paragraphs 9 to 11 provide that the trust may continue to:
- be a party to a contract entered into when the body was an NHS foundation trust,
 - hold property which the trust held as an NHS foundation trust, and
 - be a member of a body corporate (e.g. a company shareholder) of which the trust was a member as an NHS foundation trust,
- and ensure that the rights or liabilities of any third party are not affected by de-authorisation.
203. *Paragraph 12* of the new Schedule 8A clarifies that the provisions for continuity do not affect the power of the Secretary of State to direct the new NHS trust; for example, to direct them to dispose of certain property.

Section 16 and Schedule 2: Trust special administrators: NHS trusts and NHS foundation trusts

204. *Section 16* inserts a new Chapter 5A into the NHS Act (sections 65A to 65O). The new sections provide for the Secretary of State to appoint Trust Special Administrators (TSAs) to NHS trusts and NHS foundation trusts; for the de-authorisation of NHS foundation trusts; and for the functions of the TSA during the period of appointment. In particular, provision is made for consultation by the TSA, the preparation of a draft report making recommendations to the Secretary of State and a final decision by the Secretary of State in relation to the trust. Section 16 and Schedule 2 make further provision for de-authorised NHS foundation trusts.

Application

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

Appointment

206. New section 65B gives the Secretary of State the power to make an order authorising the appointment of a TSA to run an NHS trust, after consulting the trust, any Strategic Health Authority in whose area the trust has hospitals, establishments or facilities, and any other person who commissions services from the trust, for example a Strategic Health Authority or a PCT, where the Secretary of State considers it appropriate. The Secretary of State must be satisfied that the appointment of the TSA to the trust is in the interests of the health service (*subsection (2)*). An example where this might occur is if a key service provided by a small trust has to stop because of new clinical guidance about 24 hour cover and relatively small patient numbers mean that the trust can only provide such cover at a financial loss. Stopping this service may result in the organisation becoming unsustainable. A TSA is only likely to be appointed after previous performance interventions have been unsuccessful. The TSA would be appointed by the Secretary of State (*subsection (6)*) and would hold and vacate office in accordance with the terms of his or her appointment (*subsection (7)*). Under new section 65C, when the TSA’s appointment takes effect the members of the trust’s board of directors, including the chair, executive directors (for example, the Chief Executive) and non-executive directors, would be suspended from performing their duties as members of the board. Although suspended from the board, the executive directors would remain employed in their post with the trust (for example, as Chief Executive, Medical Director or Director of Finance).

De-authorisation of NHS foundation trusts

207. New sections 65D and 65E make specific provision for NHS foundation trusts. New section 65D enables Monitor to give a notice to the Secretary of State which has the effect that the Secretary of State must make an order under new section 65E providing for the trust to cease to be a foundation trust and instead become an NHS trust (described as “de-authorisation”) and an order under new section 65B appointing a TSA for the trust. Monitor would be able to give such a notice only where it was satisfied that the trust had failed to comply with a notice under section 52 and that a further notice would be unlikely to secure the provision of services which the trust is required by its authorisation to provide (new section 65D(1)). This is similar to the existing statutory

test for the dissolution of an NHS foundation trust under section 54 of the NHS Act. A notice under section 52 of the NHS Act requires a specified trust, the directors or board governors of the trust to do, or not to do, specified things within a specified period.

208. The provisions of new Schedule 8A to the NHS Act (inserted by Schedule 2 to the Act) apply in relation to trusts de-authorised by an order under new section 65E(1) as well as to trusts de-authorised under new section 52D(1) – see paragraphs 202 and 203 above for an explanation of the provisions of Schedule 8A, and see the commentary on section 15 above in relation to section 52D. The only difference is that paragraph 5 of Schedule 8A, which does not apply to trusts de-authorised under section 52D, applies to trusts de-authorised under the trust special administrator provisions (section 65E). Paragraph 5 provides that the trust retains its name except for the substitution of the words “NHS trust” for “NHS foundation trust”, and that its functions are the provision of goods or services for the purposes of the NHS in England.

Consultation and report

209. New section 65F requires that, within 45 working days of appointment, the TSA must produce for the Secretary of State and publish a draft report, outlining the action which he or she recommends that the Secretary of State should take in relation to the trust. The Secretary of State must lay this report before Parliament. The TSA must set out, in a published statement, how he or she plans to consult on the draft report (new section 65G(1)). The consultation period will last for 30 working days (new section 65G(2)).
- “210 New section 65H specifies the duties which apply during the consultation period. In particular, it specifies that the TSA must publish a notice stating that the TSA is seeking responses to the draft report and describing how people can give their responses (*subsection (2)*). *Subsections (4) and (5)* provide that the TSA must hold meetings with the public and the staff of the trust and staff representatives. Staff for these purposes includes staff employed by contractors and volunteers working for the trust (*subsection (11)*). Section 65H also requires the TSA to seek written responses from and meet with any Strategic Health Authority in whose area the trust has hospitals, establishments or facilities, and any person to which the trust provides goods and services which the Secretary of State directs the TSA to consult, (in practice likely to be persons who commission goods and services from the trust) (*subsections (7)(a) and (b) and (9)*). The TSA is also required to request a written response from such of the persons named in *subsection (8)* as the Secretary of State directs. In addition, the Secretary of State may, through directions, impose additional requirements to hold meetings or seek written responses; this may include, for example the local university medical school, if the organisation has a training role (*subsection (10)*).
211. New section 65I provides that within 15 working days of the consultation closing, the TSA must provide the Secretary of State with a report containing final recommendations for the trust. The TSA must attach to the report a summary of all oral and written responses to the consultation received during the consultation process. The Secretary of State must publish this report and lay it before Parliament (*subsection (3)*).
212. New section 65J enables the Secretary of State to make an order extending any of the time periods for preparing the draft report, conducting the consultation or providing the final report. The power will be exercisable only where it would not be reasonable to expect the administrator to complete the relevant activity in the specified period and it is envisaged that the power will only be used in exceptional circumstances; for example, where the TSA was seriously ill or if the organisation had to deal with a significant unplanned event, for example a SARS (severe acute respiratory syndrome) outbreak. Where the time is extended, the TSA must publish a notice stating the date when the revised period expires (*subsections (3) and (4)*).

Action by the Secretary of State

213. New section 65K requires the Secretary of State to decide what action to take in relation to the trust within 20 working days of receiving the final report. The decision and the reasons for it must be laid before Parliament as well as published.
214. If the Secretary of State decides to take any action in relation to the trust (for example, to dissolve the trust and merge it with another trust, or to direct it to close or transfer particular establishments or services), the Secretary of State will exercise existing powers under the NHS Act to take that action. If the Secretary of State decides not to dissolve the trust, however, new section 65L provides for the Secretary of State to make an order specifying when the appointment of the TSA and the suspension of the chairman and directors of the trust will come to an end (*subsection (2)*). If the trust is a de-authorised NHS foundation trust, an order must be made specifying the name of the NHS trust, the functions of the NHS trust and the number of non-executive and executive directors. If the trust has significant teaching commitments then one of the non-executive directors should be a person from a university with a medical or dental school (*subsection (4)*). In the case of a de-authorised NHS foundation trust, the number of suspended directors may exceed the number permitted under the regulations governing NHS trust membership, or there may be an insufficient number. New *subsection (5)* therefore enables the Secretary of State to remove directors or appoint new directors to meet requirements for NHS trusts.

Supplementary

215. New section 65M provides that if the TSA ceases to hold office either before the Secretary of State has dissolved the trust or before the Secretary of State has reinstated the chairman and directors to the trust, the Secretary of State must appoint another TSA and publish his or her name. At this point the new TSA takes over at the same stage in the process, unless the Secretary of State directs that the new TSA should start from a different point (for example to start at the beginning of the process) (*subsection (2)*).
216. New section 65N requires the Secretary of State to publish guidance for TSAs, which must include guidance in relation to the publication of notices relating to consultation and extensions of time and also the preparation of the draft report.

Section 17: Trust Special Administrators: Primary Care Trusts

217. *Section 17* inserts a new Chapter 5B into the NHS Act (new sections 65P to 65Z3). The new sections provide the Secretary of State with powers to direct a PCT to appoint a TSA to exercise specified “provider” functions of the PCT. The new sections also set out the functions of the TSA during the period of appointment which will apply if the direction-making power is exercised. In particular, provision is made for consultation by the TSA, the preparation of a draft report making recommendations to the Secretary of State and a final decision by the Secretary of State.

Appointment

218. New section 65P gives the Secretary of State the power to give directions requiring a PCT to appoint a TSA to exercise certain “provider” functions of the PCT on its behalf (*subsection (1)*). A “provider” function is any function which (i) involves the provision of goods and services, but only where that function is exercised by the PCT by means of direct provision (for example not by the making of commissioning arrangements with other persons) and (ii) is not a function of providing goods and services but which may be exercised for that purpose (e.g. employing staff) (*subsection (10)*). Precisely which functions are to be exercised by the TSA will be specified in the directions; that may differ in each case. The Secretary of State may only exercise the direction-making power if the Secretary of State considers it appropriate in the interests of the health service to do so (*subsection (2)*) and only after consulting the PCT, any Strategic Health Authority whose area includes any part of the PCT’s area, and any other person

which commissions services from the PCT, where the Secretary of State considers it appropriate (*subsection (4)*). The TSA holds and vacates office in accordance with the terms of his or her appointment (*subsection (7)*) and the Secretary of State can require in the directions that the terms of appointment contain specified terms, for example provision could be included to ensure that the Board of the PCT cannot interfere in the exercise of the TSA's functions (*subsection (8)*). New section 65Q provides that when the TSA's appointment takes effect, the relevant functions (meaning those exercisable by the TSA) will no longer be exercisable by any committee, subcommittee or officer of the PCT, but that provision will not affect the employment of any PCT employee (*subsection (2)*).

Consultation and report

219. New section 65R requires that, within 45 working days of appointment, the TSA must produce and publish a draft report, recommending the action that the Secretary of State should take in relation to the performance of the relevant functions. The Secretary of State must lay this report before Parliament (*subsection (3)*). The TSA must set out, in a published statement, how he or she plans to consult on the draft report (new section 65S(1)). The consultation period will last for 30 working days (new section 65S(2)).
220. New section 65T specifies the duties which apply during the consultation period. In particular, it specifies that the TSA must publish a notice stating that the TSA is seeking responses to the draft report and describing how people can give their response (*subsection (2)*). It provides that the TSA must hold meetings with the public and staff of the PCT and staff representatives (*subsections (4) and (5)*). Staff for these purposes only includes staff who are employed in connection with the relevant functions (i.e. the provider functions which are being exercised by the TSA) and it includes staff employed by contractors and volunteers working for the PCT (*subsection (10)*). The TSA is required to seek written responses from and meet any Strategic Health Authority in whose area any part of the PCT's area falls, and any person to which the trust provides goods and services which the Secretary of State directs the TSA to consult (in practice likely to be persons who commission goods and services from the trust) (*subsections (7)(a) and (b) and (8)*). The TSA is also required to request a written response from such persons within section 65H(8) as the Secretary of State may direct (*subsection (7)(c)*). The Secretary of State may also direct the TSA to seek written responses from or hold meetings with additional persons specified in the directions (*subsection (9)*).
221. New section 65U provides that within 15 working days of the end of the consultation period, the TSA must give the Secretary of State a report containing his or her recommendations. The TSA must attach to the report a summary of all oral and written responses to the consultation received during the consultation process. The Secretary of State must publish the TSA's report and lay it before Parliament (*subsection (3)*).
222. New section 65V enables the Secretary of State to make an order extending any of the time periods for preparing the draft report, conducting the consultation or providing the final report. The power will be exercisable only where it would not be reasonable to expect the administrator to complete the relevant activity in the specified period and the Government envisages that the power will only be used in exceptional circumstances; for example, where the TSA was seriously ill or if the organisation had to deal with a significant unplanned event, for example a SARS (severe acute respiratory syndrome) outbreak. Where the time is extended, the TSA must publish a notice stating the date when the revised period expires (*subsections (2) and (3)*).

Action by the Secretary of State

223. New section 65W requires the Secretary of State to decide what action to take in relation to the performance of the relevant provider functions within 20 working days

of receiving the final report. The decision and the reasons for it must be laid before Parliament as well as published.

- 224. If the Secretary of State decides to take any action in relation to the relevant provider function (for example, the Secretary of State may decide that the PCT should stop providing services itself and commission them from elsewhere) he or she will exercise existing powers under the NHS Act to take that action.
- 225. New section 65X allows the Secretary of State to give directions to the PCT and the TSA, requiring that the TSA is removed with effect from a specified day.

Supplementary

- 226. New section 65Y provides that if the TSA ceases to hold office before the Secretary of State has published his or her decision, the Secretary of State must appoint a new TSA and publish his or her name. The new TSA takes over at the same stage in the process, unless the Secretary of State directs that the new TSA should start from a different point (for example to start at the beginning of the process) (*subsection (3)*).
- 227. New section 65Z allows the Secretary of State to give further directions to the TSA about the exercise of the TSA's functions.
- 228. New section 65Z1 requires the Secretary of State to publish guidance for TSAs, which must include guidance in relation to the publication of notices relating to consultation and extensions of time and also the preparation of the draft report.
- 229. New section 65Z2 requires the following directions to be laid before Parliament: the initial directions requiring the appointment of a TSA and specifying which functions are to be exercised by the TSA on the PCT's behalf; additional directions about the TSA's exercise of functions; directions bringing the appointment of the TSA to an end.

Section 18 Trust special administrators: consequential amendments

- 230. *Section 18* makes amendments to the NHS Act consequential on the amendments made by section 15 (de-authorisation of NHS foundation trusts) and sections 16 and 17 (trust special administrators). In particular, subsections (2) to (6) amend sections 53 and 54 of the NHS Act so that the existing provisions for voluntary arrangements and the dissolution of NHS foundation trusts apply only to NHS foundation trusts to which the new regime does not apply (meaning those authorised on an application by a body other than an NHS trust under section 34 of the Act, or those established under section 56 which are not within section 65A(2)).
- 231. *Subsection (5)* amends section 53(4) of the NHS Act, to ensure that the existing provisions for voluntary arrangements and the dissolution of NHS foundation trusts apply only to NHS foundation trusts to which the new de-authorisation provisions in new sections 52A to 52E and the trust special administrators regime (Chapter 5A inserted by section 16) do not apply.
- 232. *Subsection (7)* amends section 242 of the NHS Act (public involvement and consultation), so that PCTs, NHS trusts and NHS foundation trusts will not be obliged to consult, or make other arrangements for involvement, in relation to matters to which the draft report or final report relates as relevant consultation will be undertaken by the TSA under the new sections.
- 233. *Subsection (8)* amends section 272 of the NHS Act (orders, regulations, rules and directions) to make provision about the procedure which is to apply to the orders made under new sections 52A to 52E (de-authorisation of NHS foundation trusts) and 65A to 65Z (trust special administrators).
- 234. *Subsections (9) and (12)* provide for the definition of 'NHS trust' in section 275(1) of the NHS Act 2006 and section 206(1) of the NHS (Wales) Act 2006 to include a

body that becomes a NHS trust by virtue of an order for de-authorisation of an NHS foundation trust made under new section 52D(1) or 65E(1).

Chapter 2 – Suspension

Section 19: NHS and other health appointments: suspension

235. **Section 19** gives effect to Schedule 3.

Schedule 3: NHS and other health appointments: suspension

236. **Part 1** of Schedule 3 amends enactments to allow for suspension from office of chairs and members of NHS and other health bodies and to make provision required in consequence of the new powers of suspension. The powers to suspend will allow a flexible approach to enable investigation of allegations or circumstances while considering decisions about whether to remove chairs or members from office. The amendments provide (or enable provision to be made in regulations) for an initial period of suspension, procedures for reviewing, revoking or extending suspension, a right for a person suspended to have the suspension reviewed, the appointment of an interim chair or, in a case where there is a vice or deputy chair appointed by the body in question for the appointment by the Secretary of State of a new vice or deputy chair. The amendments also provide for the membership of a suspended person not to count where legislation provides for a maximum number of members. What is required by way of amendments to primary legislation to achieve the policy varies from case to case.
237. **Part 2** of Schedule 3 makes supplementary provision.
238. **Paragraph 1 of Schedule 3** amends Schedule 1A to the Medicines Act 1968 (provisions relating to Commission on Human Medicine and Committees) as follows—
239. New paragraph 6(2) of Schedule 1A enables the Secretary of State to make certain ancillary provisions in regulations as seem fitting relating to the terms on which members of the Commission on Human Medicine, committees established under section 4 of the 1968 Act or Expert Advisory Groups hold and vacate office. Such provision may be required to give full effect to the suspension regime.
240. **Paragraph 2** amends Schedule 1 to the Licensing (Alcohol Education and Research) Act 1981 (the Alcohol Education and Research Council) as follows.
241. New paragraph 3A of Schedule 1 enables the Secretary of State to suspend a member of the Council from office if it appears to the Secretary of State that one of the grounds for termination of the member's appointment may apply.
242. New paragraph 3B of Schedule 1 sets out details as to how the suspension process will operate including details about notification of suspension, the initial period of suspension, procedures for reviewing, revoking or extending a suspension and providing that a suspended member is not to be counted for the purposes of determining whether the membership of the Council exceeds 15 (the maximum permitted by the 1981 Act).
243. New sub-paragraph (4) of paragraph 4 of Schedule 1 has the effect that when the chairman is suspended from office as a member of the Council, he or she will also be suspended from office as chairman of the Council.
244. New paragraph 4A of Schedule 1 enables the Secretary of State to appoint an interim chairman where the chairman has been suspended, and sets out procedural details including for holding and vacating office, the term of office, resignation or termination of the appointment.

245. **Paragraph 3** amends Schedule 1 to the Human Fertilisation and Embryology Act 1990 (the Human Fertilisation and Embryology Authority: supplementary provisions) as follows—
246. New paragraph 5A of Schedule 1 enables the Secretary of State to suspend a member from office as the chairman, deputy chairman or other member of the Human Fertilisation and Embryology Authority if it appears there may be grounds for the Secretary of State to declare the office vacant.
247. New paragraph 5B of Schedule 1 sets out details as to how the suspension process will operate, including details about notification of suspension, the initial period of suspension and reviewing, revoking or extending a suspension.
248. **Paragraphs 4, 5 and 6** amend Schedule 1 to the Health Protection Agency Act 2004 (the Health Protection Agency) as follows—
249. New sub-paragraph (3A) of paragraph 1 of Schedule 1 to the Health Protection Agency Act 2004 has the effect that where a member of the Agency appointed by the Scottish Ministers, DHSSPSNI or the Welsh Ministers is suspended by that authority pursuant to regulations under the Schedule, another member could be appointed by the authority pursuant to paragraph 1(3). The suspended member would also not be counted toward the total number of members of the Agency prescribed in regulations.
250. New sub-paragraph (5A) of paragraph 1 of Schedule 1 will enable regulations made by the Secretary of State to address what would happen in relation to the deputy chair (who is appointed by the other members of the Agency, not the Secretary of State) if the chairman of the Agency were suspended. Regulations could enable the Secretary of State to direct that the appointment of the deputy chairman would end and provide for the Secretary of State to appoint another non-executive member to be deputy chairman.
251. New sub-paragraph (3) of paragraph 29 of Schedule 1 will enable the Secretary of State to include in regulations under the Schedule certain ancillary provisions that appear to the Secretary of State to be suitable. Such provisions may be required to give full effect to the proposed suspension regime.
252. **Paragraph 7** amends Schedule 2 to the Human Tissue Act 2004 (the Human Tissue Authority) as follows.
253. New paragraph 9A of Schedule 2 to the Human Tissue Act 2004 enables the authority who appointed the chairman or a member (the Secretary of State in the case of the chairman or such other number of members as he or she thinks fit, the Welsh Ministers in the case of one member and DHSSPSNI in respect of one member) to suspend the chairman or member they have appointed as members of the Human Tissue Authority.
254. New paragraph 9B of Schedule 2 sets out procedural details about how the suspension process operates, including details about notification of suspension, the initial period of suspension and reviewing, revoking or extending a suspension. Sub-paragraph (9) of new paragraph 9B ensures that where a member appointed by the Welsh Ministers or DHSSPSNI was suspended by that authority another member can be appointed by the authority pursuant to paragraph 1(1)(c) or (d) of Schedule 2.
255. New paragraph 9C of Schedule 2 enables the Secretary of State to appoint an interim chairman where the chairman has been suspended, and sets out procedural details including for holding and vacating office, the term of office, or resignation or removal from office.
256. **Paragraph 8** amends Schedule 4 to the Health Act 2006 (the Appointments Commission: supplementary) as follows.
257. New paragraph 6(2) of Schedule 4 to the Health Act 2006 enables regulations by the Secretary of State to address what will happen in relation to the vice-chairman (who is appointed by the members of the Commission, not the Secretary of State) if

the chairman of the Appointments Commission is suspended from office. Regulations could enable the Secretary of State to direct that the appointment of the vice-chairman would end and provide for the Secretary of State to appoint another non-executive member to be vice-chairman.

- 258. **Paragraphs 9, 10, 11, 12 and 13** amend Schedules 2 (Strategic Health Authorities), 6 (Special Health Authorities), 8 (Independent Regulator of NHS foundation trusts), and 19 (further provision about standing advisory committees) of the NHS Act as follows.
- 259. Substituted sub-paragraph (d) of paragraph 9 of Schedule 2 to the NHS Act amends the Secretary of State's regulation-making power at paragraph 9 of the Schedule to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Strategic Health Authority.
- 260. Substituted sub-paragraph (d) of paragraph 5 of Schedule 6 amends the Secretary of State's regulation-making power at paragraph 5 of Schedule 6 to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Special Health Authority.
- 261. New sub-paragraph (c) of paragraph 2(2) of Schedule 8 enables the Secretary of State to suspend the chairman or another member of Monitor on suspicion of there being grounds that would enable him or her to remove the member from office.
- 262. New paragraph 2A of Schedule 8 sets out procedural details about how the suspension process will operate, including details about notification of suspension, the initial period of suspension, reviewing, revoking or extending the suspension and that the suspended member will not be counted towards the maximum number of members of Monitor during the suspension.
- 263. New Paragraph 5A of Schedule 19 expands the regulation-making power at paragraph 1 of that Schedule to enable regulations to provide for the Secretary of State to appoint an interim chairman following removal or suspension from office of the chairman of a standing advisory committee. The amendment to paragraph 1(b) of Schedule 19 enables regulations under paragraph 1 to contain provision with respect to removal or suspension from office of members of any standing advisory committee.
- 264. **Paragraphs 14, 15, 16 and 17** amend Schedules 5 (Special Health Authorities established under section 22), 10 (further provision about community health councils), and 13 (further provision about standing advisory committees) of the NHS (Wales) Act as follows.
- 265. Substituted sub-paragraph (d) of paragraph 5 of Schedule 5 to the NHS (Wales) Act amends the Welsh Ministers' regulation-making power at paragraph 5 to enable regulations to provide for suspension of the chairman, vice-chairman or any member of a Special Health Authority.
- 266. New paragraph 2A of Schedule 10 enables regulations about the membership of community health councils to include provision, in cases where the chair elected by the members is removed or suspended from office, for the appointment by Welsh Ministers of a member as interim chair. The omission in paragraph 2(a) of Schedule 10 is consequential on this amendment.
- 267. New paragraph 5A of Schedule 13 enables regulations under paragraph 1(b) of that Schedule to provide for the appointment by Welsh Ministers of an interim chairman following removal or suspension of the elected chairman of a standing advisory committee. The amendment to paragraph 1(b) enables regulations under paragraph 1 to address removal or suspension from office of members of a standing advisory committee.
- 268. **Paragraph 18 of Part 2 of Schedule 3** (supplementary) provides that in the case of a cross-border body, regulation-making powers in relation to such a body conferred on

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

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

Part 3 – Miscellaneous

Tobacco

Section 20: Prohibition of advertising: exclusion for specialist tobacconists

270. **Section 20** amends section 6 of the Tobacco Advertising and Promotion Act 2002 (“the 2002 Act”) (specialist tobacconists) by inserting a new subsection (A1) at the beginning of that section. This new subsection gives the Secretary of State (in relation to England), the Welsh Ministers (in relation to Wales), and DHSSPSNI (in relation to Northern Ireland) power to provide that specialist tobacconists do not commit an offence under section 2 of the 2002 Act (prohibition of tobacco advertising) if a tobacco advertisement on their premises meets certain requirements (including those to be set out in regulations). This power replaces, except in relation to Scotland, an automatic exclusion for specialist tobacconists currently provided by section 6(1) of the 2002 Act. Accordingly, **paragraph 3** of Schedule 4 amends section 6(1) of the 2002 Act to limit its application to Scotland.

Section 21: Prohibition of tobacco displays etc.

271. Section 8 of the 2002 Act (displays) gives the Secretary of State power to impose requirements on the display in England, Wales and Northern Ireland of tobacco products or their prices in a place or on a website where such products are offered for sale. Section 21 inserts new sections 7A to 7D into the 2002 Act, which replace section 8 in so far as it relates to England, Wales and Northern Ireland (it will continue to have effect in its existing form for Scotland).
272. The new section 7A (prohibition of tobacco displays) makes it an offence for a person, in the course of a business, to display tobacco products, or cause tobacco products to be displayed, in a place in England, Wales, or Northern Ireland. It also provides powers for the appropriate Minister to provide by regulations for the meaning of “place” and whether a display, which also amounts to an advertisement, is to be treated as a display, or whether it is to be treated as an advertisement, for the purposes of offences under the 2002 Act. For the purposes of the new sections 7A to 7D, the “appropriate Minister” means the Secretary of State in relation to England, the Welsh Ministers in relation to Wales, and DHSSPSNI in relation to Northern Ireland.
273. The new section 7B (tobacco displays: exclusions and defence) provides for a number of exclusions from the new section 7A prohibition on tobacco displays. The exclusions cover: displays in the course of a business which is part of the tobacco trade which are for the purposes of that trade and are accessible only to persons engaged in, or employed in, the tobacco trade; and, displays made following a particular request by an individual of at least 18 years of age to purchase, or for information about, a tobacco product (a requested display). The appropriate Minister is also given a general power to provide in regulations that no offence is committed under the new section 7A if the display complies with any requirements which are specified in the regulations. New section 7B(5) provides that for the purposes of the offence of making a display to an individual aged under 18 following a request by that individual, it is a defence that the person making the display believed the individual was 18 or over, and either that person

had taken all reasonable steps to establish the individual's age or from the individual's appearance nobody could reasonably have suspected that the individual was aged under 18.. Section 7B(6) provides that a person is treated as having taken all reasonable steps to establish an individual's age only if they had asked the individual for evidence of their age and the evidence produced would have convinced a reasonable person. It is a defence for a person charged with causing a requested display to an individual aged under 18 that they exercised all due diligence to avoid committing the offence (new section 7B(7)).

274. The new section 7C (displays: prices of tobacco products) gives the appropriate Minister power by regulations to impose requirements in relation to the display, in England, Wales, or Northern Ireland (as the case may be) in the course of a business, of prices of tobacco products (subsection (1)). A person who displays or causes to be displayed, prices of tobacco products in breach of any such requirements is guilty of an offence (subsection (2)). New section 7C(3) provides that the regulations may in particular provide for the meaning of "place" and new section 7C(4) that the regulations may make provision for a display which is also an advertisement to be treated for the purposes of offences in England and Wales or Northern Ireland under the Act as an advertisement and not as a display of prices or as a display of prices and not an advertisement.
275. The new section 7D (displays on a website) replaces section 8(1) of the 2002 Act in relation to England and Wales and Northern Ireland, in so far as it applies to websites. It provides power for the Secretary of State by regulations to impose requirements in relation to the display in England and Wales, or Northern Ireland, in the course of a business of tobacco products or their prices on a website where tobacco products are offered for sale.
276. New section 7D makes it an offence to display, or cause to be displayed, tobacco products or their prices in breach of any requirements imposed by regulations (subsection (2)), except where this is in the course of providing information society services by a person established outside the United Kingdom (subsection (4)). A person established in England, Wales, or Northern Ireland who, in the course of providing information society services, does anything in another EEA state which would constitute an offence under new section 7D(2) is also guilty of an offence (new section 7D(3)). For these purposes "EEA state" includes member states of the European Union, as well as Norway, Iceland and Liechtenstein. New section 7D (5) provides that the regulations may provide for a relevant display of tobacco products or their prices which also amounts to an advertisement to be treated for the purposes of offences in England and Wales or Northern Ireland under this Act to be treated as an advertisement and not as a display or as a display and not an advertisement. Under new section 7D(5) a relevant display means a display on a website where tobacco products are offered for sale.

Section 22: Power to prohibit sales from vending machines

277. Subsection (1) of Section 22 inserts a new section 3A (sales from vending machines in England and Wales) into the Children and Young Persons (Protection from Tobacco) Act 1991 ("the 1991 Act"). New section 3A provides power for the appropriate national authority (defined as the Secretary of State in relation to England, and the Welsh Ministers in relation to Wales) by regulations to prohibit the sale of tobacco from vending machines.
278. The regulations must include provision as to the persons who are liable for a breach of a prohibition. Where a prohibition contained in the regulations is breached, any person liable in accordance with the regulations is guilty of an offence punishable with a fine not exceeding level 4 on the standard scale (currently £2,500). Subsection (5) of the new section 3A applies sections 13 (enforcement), 14 (powers of entry, etc) and 15 (offences of obstruction, etc of officers) of the 2002 Act for the purposes of the new

section. Section 13 of the 2002 Act sets out the authorities who will be responsible for enforcing any prohibition; section 14 sets out the powers of entry which enforcement officers may exercise; and section 15 makes obstructing an officer of an enforcement body, or making false statements to an officer, an offence.

279. Subsection (2) of section 22 inserts a new paragraph (c) into section 12D(1) of the Children and Young Persons Act 1933 (restricted premises orders and restricted sales orders: interpretation). This extends the definition of “tobacco offence” for the purposes of sections 12A and 12B of that Act to include an offence committed under the new section 3A of the 1991 Act. The effect of this is to enable a magistrates’ court to impose a restricted premises order or a restricted sales order in response to breaches of the new section 3A, where the conditions for imposing such orders are met. Under sections 12A and 12B if three “tobacco offences” are committed within a period of two years, and if the last of them led to a conviction, then the offender or the relevant premises may be banned from selling tobacco products for up to one year.

Section 23: Power to prohibit sales from vending machines: Northern Ireland

280. Section 23 inserts a new Article 4A into the Children and Young Persons (Protection from Tobacco) (Northern Ireland) Order 1991 (“the 1991 (NI) Order”). New Article 4A makes equivalent provision for Northern Ireland to that made for England and Wales by the new section 3A inserted in the 1991 Act by Section 22.

Section 24 and Schedule 4: Tobacco: minor and consequential amendments

281. [Section 24](#) gives effect to Schedule 4. Schedule 4 makes various minor and consequential amendments. These amendments include—
- limiting the application of sections 6(1) and 8 of the 2002 Act to Scotland;
 - limiting the power of the Secretary of State under section 13(5) of the 2002 Act to take over the conduct of proceedings to proceedings in relation to offences committed in England and giving power to the Welsh Ministers to take over the conduct of proceedings in relation to offences committed in Wales;
 - amending the definition of “appropriate Minister” for the purposes of the 2002 Act, to confer powers on the Welsh Ministers and DHSSPSNI to make regulations in relation to the new provisions about specialist tobacconists and displays and to transfer to them existing powers under section 4(3) of the 2002 Act (power to provide for exclusions from the section 2 prohibition on tobacco advertising); and
 - provision for the procedure to be adopted in relation to regulations made by the Welsh Ministers and DHSSPSNI under the provisions of the 2002 Act as amended by the Act.
282. [Schedule 4](#) also amends section 8 (displays), section 9 (prohibition of free distribution), section 11 (brandsharing) of, and the Schedule (information society providers) to, the 2002 Act to give full effect to Directive [2000/31/EC](#) of the European Parliament and Council of 8th June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce). It also repeals section 16(1A) of the 2002 Act (limitation of penalties for certain offences relating to information society services) to bring the penalties for offences covered by that provision into line with the penalties which apply generally for offences under the 2002 Act.

Pharmaceutical Services in England

283. [Sections 25 to 29](#) introduce changes to the way in which PCTs determine applications by contractors to provide NHS pharmaceutical services [DN: Does this term need to be defined in the Glossary of Terms and Abbreviations?] and also introduce

new provisions enabling PCTs to take action against contractors for breaches of the arrangements for providing those services.

284. In addition, the sections amend current legislation concerning the provision of local pharmaceutical services (LPS) contracts enabling PCTs to provide services under LPS schemes in prescribed circumstances. Under existing legislation, PCTs can only commission such services.
285. These measures follow a Department of Health consultation in the autumn of 2008 on a series of proposals to amend the structure and legislation of NHS pharmaceutical services, following publication of the Government's White Paper *Pharmacy in England: Building on strengths – delivering the future* published in April 2008. A report of the outcome of that consultation, which concerned the measures contained within this Act, was published on 16th January 2009 and is available on the Department of Health website.

Section 25: Pharmaceutical needs assessments

286. **Section 25** inserts section 128A in the NHS Act which creates a new duty for all PCTs in England in respect of their assessments of pharmaceutical needs, commonly known as pharmaceutical needs assessments.
287. Section 128A(1) requires PCTs, in accordance with regulations, to undertake assessments of needs for pharmaceutical services in their respective areas and to publish a statement of their first assessment of those needs and any subsequent revised assessment.
288. Section 128A(2) requires regulations to make provision for certain matters relating to the procedures which PCTs must follow when undertaking their pharmaceutical needs assessments. Regulations must stipulate—
- the minimum information requirements which each pharmaceutical needs statement must contain;
 - the extent to which the pharmaceutical needs assessment is to take account of likely future needs for pharmaceutical services;
 - the date by which each PCT must publish their first assessment; and
 - the circumstances in which a PCT must undertake a new assessment.
289. For example, the regulations might stipulate that a pharmaceutical needs statement must contain information on the demography of the people in its area and any seasonal trends or variations as well as longer-term population projections and age profiles. It might also, for example, stipulate that PCTs must publish their first statement within six months of the regulations coming into force and that they must undertake a new assessment where important new health data, trends in disease or evidence of the effectiveness or ineffectiveness of certain types of service emerge.
290. Section 128A(3) enables regulations to provide for additional matters or make provision relating to pharmaceutical needs assessments. The additional matters may include the kinds of pharmaceutical services which the pharmaceutical needs assessment must relate to, for example, the provision of certain services such as reviews of patient medication, clinical support for patients starting medication to treat a long-term condition, advice and information to patients or other healthcare professionals. The regulations may also impose requirements on PCTs to consult specified persons about specified matters when undertaking their pharmaceutical needs assessment. The PCT may for example, be required by the regulations to consult local authorities, patient and community groups and local professional representative committees. The regulations may also prescribe the manner in which an assessment is to be made. The regulations may require the PCT to show, when publishing its pharmaceutical needs statement, how

it has consulted interested parties. The regulations may also include a range of matters which a PCT must have regard to when making an assessment of pharmaceutical needs. Such matters may include for example—

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

Section 26: New arrangements for entry to pharmaceutical list

291. Section 129 of the NHS Act sets out various requirements under which regulations govern the provision of pharmaceutical services. Section 26 amends section 129 of the NHS Act.
292. **Section 129(2)(c)** sets out the legislative criteria which a PCT must apply when considering applications from pharmaceutical contractors to be included on a PCT's pharmaceutical list for the provision of NHS pharmaceutical services or for changes to a contractor's listing following admittance. These criteria are often referred to as the "control of entry" test. The section inserts new provisions regarding those criteria.
293. **Subsection (2)** of section 26 amends the criteria in section 129(2)(c) to provide for circumstances where an application must be granted by a PCT and circumstances where an application may be granted by a PCT.
294. **Subsection (3)** then sets out the circumstances—
- in which a PCT must grant an application; and
 - in which a PCT may grant an application.
295. Under new subsection (2A), a PCT must grant an application where it is satisfied, having first taken account of what is set out in the statement of its assessment of pharmaceutical needs, and any matters which are prescribed in regulations, that the need for the services or some of the services in the application is established and will be met through grant of the application.
296. Under new subsection (2B), a PCT may grant an application where it is satisfied, having first taken account of what is set out in the statement of its assessment of pharmaceutical needs, and any matters which are prescribed in regulations, that it would secure improvements or better access to pharmaceutical services in its area. The matters prescribed in regulations might include additional criteria such as improvements in access (for example through extended hours), in the choice and diversity of providers or of services in its area (for example, dedicated clinics at evenings or weekends to stop smoking or to review patients' medications), in innovation in the delivery of services or of services which meet the needs of specific groups of people in the PCT's area or local health conditions or diseases.
297. New subsection (2C) makes additional provision in cases where a PCT is satisfied that an application meets the criteria for grant of the application required under subsection (2B). First, new subsection (2C) provides that the regulations may set out the manner in which the PCT is to determine whether to grant the application. For example, a PCT might first seek views from local patient representative bodies and other key interested parties where it is minded to grant an application under new subsection (2B). Second, new subsection (2C) provides that the regulations may stipulate certain matters which a PCT must or must not take into account when deciding

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

- 298. *Subsections (4), (5) and (6)* of Section 26 modify the existing provisions which enable regulations to specify the circumstances in which two or more applications are considered together by the PCT.
- 299. *Subsection (4)* inserts a new subsection (3A) to provide that the regulations may prescribe the circumstances in which two or more such applications may be considered together by a PCT. *Subsection (5)* amends section 129(4) creating a general power to make provision for the case where two or more applications, taken individually, meet the test under new subsection (2A) or (2B), but taken together, do not.
- 300. *Subsection (6)* of section 26 inserts a new subsection (4A) which allows regulations under subsection (4) to include, in particular, the provision mentioned in subsection (5), with or without modification. This new subsection ensures the wording in subsection (5) can be tailored to apply to both parts of the two part test under subsection (2A) and (2B).
- 301. *Subsection (7)* introduces a new provision which enables regulations to specify the circumstances in which, and the manner in which, a PCT can invite applications to be included in its pharmaceutical list. For example, this might be appropriate where a PCT has identified, in its first or subsequent statement of needs, areas where there are gaps in provision or where the PCT wishes to secure improvements in access to, or in the choice or quality of, services provided and wishes to invite applications from pharmaceutical contractors.
- 302. *Subsection (8)* inserts a new provision which requires PCTs to give reasons for decisions made in relation to all applications received under section 129 and provides that references to a “needs statement” in the section are to the most recently published statement, which will be the statement in force at the time the application is decided.

Section 27: Pharmaceutical lists: minor amendment

- 303. *Section 27* corrects an apparent anomaly in section 129(6)(d) of the NHS Act. Section 129(6)(c) refers to a particular kind of application for inclusion in a pharmaceutical list and was not intended to affect the meaning of “such an application” in section 129(6)(d). The amendment makes clear that the provision in section 129(6)(d) for the inclusion of an applicant on a PCT’s list for a fixed period may apply to any application made under section 129.

Section 28: Breach of terms of arrangements: notices and penalties

- 304. Section 28 inserts in Part 7 of the NHS Act a new Chapter 5A, consisting of new section 150A, that concerns the issuing by PCTs of notices to contractors and the withholding of payments to contractors by PCTs.
- 305. New section 150A enables regulations to provide that where a contractor breaches a term of arrangements for providing NHS pharmaceutical services (for example, of a term of service, such as agreed quality standards or of performance in the provision of services) then PCTs will have the power to issue remedial notices, requiring corrective action to be taken or requiring the contractor to refrain from continuing with actions which have led to the breach, within a specified period. The regulations may also enable PCTs to withhold all or part of any payments due to the contractor for a prescribed period in view of such a breach. Powers to withhold payments could be used on their own or in conjunction with the issue of remedial notices.

- 306. Section 150A(2) requires that any regulations under this section must include prescribed rights of appeal for the contractor against decisions made by the PCT under this section.
- 307. Section 150A(3) provides definitions for this section.

Section 29: LPS schemes: powers of Primary Care Trusts and Strategic Health Authorities

- 308. **Section 29** introduces changes to section 144 of, and Schedule 12 to, the NHS Act that remove the restrictions in NHS legislation on PCTs providing LPS or to other PCTs, in certain circumstances, for example, in the event of any emergency such as a flu pandemic or where there was no alternative provider. Where a PCT is a provider of LPS within its own area it is intended that the LPS commissioner would be the Strategic Health Authority.

Pharmaceutical services in Wales

- 309. **Sections 30 to 32** introduce new provisions enabling Local Health Boards (LHBs) to take action against certain NHS contractors for breaches of the arrangements for providing those services. The sections that relate to breaches of arrangements between LHBs and contractors relate to the providers of both pharmaceutical and ophthalmic services in Wales.
- 310. In addition, the sections amend legislation concerning the provision of LPS contracts enabling LHBs to provide LPS in prescribed circumstances. Under existing legislation, LHBs can only commission such services.

Section 30: Pharmaceutical lists - minor amendment

- 311. **Section 30** corrects an apparent anomaly in section 83(6)(d) of the NHS (Wales) Act 2006. Section 83(6)(c) refers to a particular kind of application for inclusion in a pharmaceutical list and was not intended to affect the meaning of “such an application” in section 83(6)(d). The amendment makes clear that the provision in section 83(6)(d) for the inclusion of an applicant on an LHB list for a fixed period of time may apply to any application made under section 83.

Section 31: Breach of terms of arrangements: notices and penalties

- 312. **Section 31** inserts before Chapter 2 of Part 8 of the NHS (Wales) Act a new Chapter 1A, consisting of new section 106A, that concerns the issuing by LHBs of notices to certain NHS contractors and the withholding of payments to such contractors by LHBs.
- 313. Section 106A enables regulations to provide that where a contractor breaches a term of arrangements for providing NHS pharmaceutical services or arrangements for providing general ophthalmic services (for example, of a term of service, such as agreed quality standards or of performance in the provision of services) then LHBs will have the power to issue remedial notices, requiring corrective action to be taken or requiring the contractor to refrain from continuing with actions which have led to the breach, within a specified period. The regulations may also enable LHBs to withhold all or part of any payments due to the contractor for a prescribed period in view of such a breach. Powers to withhold payments could be used on their own or in conjunction with the issue of remedial notices.
- 314. Section 106A(2) requires that any regulations under this section must include prescribed rights of appeal for the contractor against decisions made by the LHB under this section.
- 315. Section 106A(3) provides definitions for this section.

Section 32: LPS schemes: powers of Local Health Boards

316. [Section 32](#) introduces changes to Schedule 7 to the NHS (Wales) Act that will enable LHBs to provide LPS in certain circumstances, for example, in the event of a national emergency. The circumstances in which LHBs are able to provide LPS will be set out in regulations made by the Welsh Ministers.

Private patient income

Section 33: Private patient income of mental health foundation trusts

317. [Section 33](#) amends section 44 of the NHS Act (private health care). Section 44(1) provides for the authorisation of an NHS foundation trust to restrict the provision for purposes other than those of the health service of goods and services by the trust. In the case of a foundation trust that is a former NHS trust, section 44(2) requires the authorisation in particular to restrict the proportion of the trust's total income that may be derived from private charges (defined by section 44(4)). The effect of the amendment made by *subsection (2)* is that an NHS foundation trust designated as a mental health foundation trust may under section 44(2) be permitted to earn up to 1.5% of its total income in each financial year from income derived from private charges. The effect of new subsection (2A) of section 44 inserted by *subsection (3)* is that an authorisation containing a restriction under section 44(2) must designate the NHS foundation trust as a mental health foundation trust for the purposes of section 44 if it appears to Monitor that it provides goods or services relating to mental health as described in new subsection (2A).

Optical appliances

Section 34: Payments in respect of costs of optical appliances

318. [Section 34](#), with section 38 and Schedule 6, repeals paragraph (c) of section 180(2) of the NHS Act.
319. [Section 180\(2\)\(c\)](#) obliged the Secretary of State to make regulations to meet or to contribute to the cost of optical appliances (glasses or contact lenses) for all persons aged 60 or over. Paragraph (c) was introduced by provision in the [Health Act 2006 \(c. 28\)](#) that came into force on 1st August 2008. It was not the Government's intention to extend entitlement to all persons aged 60 or over, regardless of their income, in the Health Act 2006.
320. The existing regulations having effect under section 180 of the NHS Act provide for financial help with the cost of optical appliances by optical vouchers and cover principally children and people on low incomes. Help is also available to those in full time education aged between 16 and 18 and for people who need a complex appliance (meaning an appliance with a high prescription). The repeal does not affect the eligibility for sight tests of persons aged 60 or over under section 115(2)(d) of the NHS Act (to which section 180(2)(c) refers). Nor does it affect eligibility for optical vouchers as prescribed in the National Health Service (Optical Charges and Payments) Regulations 1997. Under these regulations people aged 60 and over who are in receipt of certain benefits, or for whom a prescription is issued for a complex appliance, are entitled to optical vouchers and will continue to be so entitled.
321. The Government never intended that a duty in the form of paragraph (c) of section 180(2) should be imposed. No provision in regulations has been made under that paragraph, and no changes are required to regulations as a result of the coming into force of section 34.

Adult social care

Section 35: Investigation of complaints about privately arranged or funded adult social care

322. **Section 35** introduces Schedule 5. Part 1 of Schedule 5 inserts a new Part 3A into the Local Government Act 1974 Act. Part 3A establishes a new scheme for the investigation by a Local Commissioner of complaints about adult social care which is privately arranged or privately funded. References below to section numbers are to the sections as they will be numbered in the 1974 Act.

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

Section 34A: Interpretation: “adult social care provider” and “adult social care”

323. Section 34A defines the terms “adult social care” and “adult social care provider” for the purposes of delineating the matters subject to investigation under the new scheme (set out in section 34B). The meaning of “adult social care” is defined by reference to Part 1 of the Health and Social Care Act 2008 (the 2008 Act). Section 9 of that Act states that social care “includes all forms of personal care and other practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstance, are in need of such care or other assistance”. Such care falls within the scope of the new scheme if it is provided to persons aged 18 or over.
324. “Adult social care provider” is defined in subsection (3). Only persons providing adult social care which is a regulated activity within the meaning of Part 1 of the 2008 Act will be “adult social care providers” for the purposes of the new scheme. Section 8 of the 2008 Act allows for regulated activities to be prescribed in regulations made under that Act. Only activities that are prescribed will be regulated by the Care Quality Commission. If a service is not regulated by the Care Quality Commission it will not fall within the Local Commissioners’ remit. It is the Government’s intention to prescribe, for example, that provision of care home accommodation and the care provided to residents in a home will be regulated by the Care Quality Commission. Therefore a provider of these types of activity would come within the Local Commissioners’ remit.
325. Subsections (4) and (5) provide that action taken on behalf of a provider will be treated as action by the service provider whether this is action taken by an employee, by a person with whom the provider has contracted to provide the service, or (subsection (5)) where the care is provided by means of a less formal arrangement with another person. The intention of these two subsections is to ensure that complaints about social care provided under any arrangements where the provider has delegated the service remain within the Local Commissioners’ remit.

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

326. Section 34B sets out the matters that a Local Commissioner may investigate and the conditions that need to be satisfied before an investigation can take place. A Local Commissioner may investigate any matter relating to action taken by an adult social care provider in connection with the provision of adult social care. So as explained above, the new scheme is limited to complaints about adult social care which is regulated by the Care Quality Commission.
327. Schedule 5A (inserted by paragraph 3 of Schedule 5) sets out matters which are not subject to investigation under the new scheme. Complaints about social care that already fall within the local authority statutory complaints procedure are excluded since these can be investigated by a Local Commissioner under the existing procedure in Part 3 of the 1974 Act. Complaints about NHS services (which may involve the provision of

social care) are also excluded since these are for investigation by the Health Service Commissioner under the 1993 Act.

328. Section 34B(1)(b) requires one of two conditions to be met before an investigation can take place. Either a complaint has to have been made by someone who can complain (see section 34C) and in accordance with the procedure for making a complaint (set out in section 34D) or the matter has come to the attention of a Local Commissioner and in accordance with section 34E may be treated as though a complaint about the matter had been made directly.
329. Before proceeding to investigate a matter, a Local Commissioner must be satisfied either that the provider has had notice of the matter complained about and an opportunity to investigate and respond, or that it is not reasonable in the circumstances to expect the matter to be brought to the notice of the provider (subsection (6)). A Local Commissioner is able to use discretion to take a flexible approach and proceed with an investigation, if satisfied that it is not reasonable to expect the matter complained about to have first been brought to the attention of the service provider or investigated by the provider. The Government expects that in the majority of cases the complainant would raise the complaint with the provider first, but the scheme allows a person to take the matter up directly with a Local Commissioner. This is because of the vulnerable nature of this group of service users, and allows for the possibility that a person might feel unable, through fear of reprisal or for some other reason, to take up the matter with the provider.

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

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

Section 34E: Matters coming to attention of Local Commissioner

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

Section 34F: Procedure in respect of investigations

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

Section 34G: Investigations: further provisions

333. Section 34G gives a Local Commissioner various powers in order to facilitate their investigations. The Local Commissioner may require the adult social care provider, or any other person who in the Commissioner's opinion is able to provide information or documents relevant to the investigation, to provide such information or documents. For example, a local authority or the Care Quality Commission may have information or documents relevant to an investigation under Part 3A.
334. The Local Commissioner has the same powers as the High Court to compel the attendance and examination of witnesses and the production of documents. This means that anyone not complying with the Local Commissioner's requests may be in contempt of court and subject to the penalties associated with that. Subsection (9) provides that if any person obstructs an investigation, or is guilty of an act or omission in relation to an investigation which would constitute contempt of court in proceedings in the High Court, the Local Commissioner may certify this as an offence to the High Court. The High Court may then deal with the person charged under subsection (9) as though they had committed the same offence in relation to the High Court.

Section 34H: Statements about investigations

335. This section provides for statements to be issued by a Local Commissioner when he or she decides not to investigate or to discontinue an investigation, and when an investigation is completed. If the Commissioner decides not to investigate or to discontinue an investigation, the statement must set out the Commissioner's reasons for that decision.
336. When a Local Commissioner has completed an investigation, the statement must set out the Commissioner's conclusions and any recommendations. The Commissioner may make recommendations for action which, in the Commissioner's opinion, the adult social care provider needs to take to remedy any injustice sustained by the person affected. Recommendations may also be aimed at preventing injustice being caused in the future as a result of similar action of the provider. For example, the Commissioner might recommend an apology to the complainant, compensation to be paid, a refund of charges or changes to be made to the services provided (possibly relating to the service user's facilities, accommodation, equipment) or changes to how staff are managed or trained.
337. The Commissioner must send a copy of the statement to the complainant, the provider and, if someone else took the action complained of, to that person. The statement must identify the provider concerned unless the provider is an individual or doing so would identify an individual. It will then be for the Local Commissioner to decide whether it is appropriate for the individual to be identified. The statement must not identify the complainant or any other person (other than the provider) unless the Commissioner considers it necessary to identify that person.
338. The Local Commissioner may also send copies of the statement to the Care Quality Commission and any local authority. For example it is likely that this would occur in all

cases where the statement draws attention to failings in the safety of services, or where there are implications for many service users, not only the person who has complained.

Section 34I: Adverse findings notices

339. Section 34I requires providers to consider any statement containing recommendations by a Local Commissioner and notify the Commissioner within the “required period” – one month of receiving the statement (or any longer period agreed in writing by the Local Commissioner) – of the action which the provider has taken or proposes to take. If by the end of that period, the Local Commissioner has not received this notification, or is satisfied before the period expires that the provider has decided to take no action, the Local Commissioner may require a provider to publish an adverse findings notice. The Commissioner may also do this in two other circumstances: firstly, if not satisfied with the action which the provider has taken or proposes to take; or secondly, if, after a further month following the end of the “required period” (or any longer period agreed in writing by the Local Commissioner), the Commissioner has not received satisfactory confirmation that the provider has taken the proposed action.
340. Subsection (4) provides that an adverse findings notice, in a form agreed between the provider and a Local Commissioner, should include details of any action recommended in the Local Commissioner’s statement which the provider has not taken, any supporting material required by the Local Commissioner, and an explanation of the provider’s reasons for not having taken the recommended action (if the provider wishes). The adverse findings notice must be published by the provider in a manner directed by the Local Commissioner. The Local Commissioner might for example, require publication in a local newspaper or, if the provider has an internet site, on that site.
341. Under subsection (6), a Local Commissioner must publish an adverse findings notice if the provider fails to do so in accordance with subsections (4) and (5), or cannot agree the form of the notice with the Local Commissioner within one month of the date the notice was received (or longer if agreed in writing by the Local Commissioner). Subsection (7) requires the provider to reimburse the LGO on demand any reasonable expenses incurred by the Local Commissioner in performing the duty under subsection (6).

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

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

Section 34K: Disclosure of information

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

Section 34L: Law of defamation

344. Section 34L confers absolute privilege for the purposes of the law of defamation on certain communications between a Local Commissioner and other parties and certain publications by a Local Commissioner. This means that these communications and publications are not actionable for slander or libel.
345. Communications between a Local Commissioner and an adult social care provider will be privileged. The publication of any matter by a Local Commissioner in communications with a complainant, the Parliamentary Commissioner, the Health Service Commissioner, a local authority or the Care Quality Commission will also be privileged. Privilege will also apply to the publication of statements, adverse finding notices, summaries and reports by a Local Commissioner.

Section 34M: Consultation with other Commissioners

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

Section 34N: Collaborative working with other Commissioners

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

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

348. Sections 34O and 34P allow a Local Commissioner to disclose to the Information Commissioner, or the Care Quality Commission, information that a Local Commissioner receives as result of an investigation that may be relevant to the carrying out of the functions of those organisations. The disclosure of information to the Care Quality Commission enables a direct link to be made between a Local Commissioner's investigation and the regulation of the provider whose services have been the subject of that investigation. Under section 20 of the 2008 Act, the Secretary of State may impose requirements on regulated activities (as carried out by service providers) through regulations. The Care Quality Commission will determine whether the regulatory requirements have been complied with, and information from a Local Commissioner would be an indicator of potential non-compliance on which the Care Quality Commission would be able to act.

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

349. Section 34R provides that a Local Commissioner must review the operation of the provisions of Part 3A of the 1974 Act (the provisions of the new scheme). The review must be carried out in the same financial year as the Commission carries out a review of the provisions of Part 3 (already required under section 23(12) of the 1974 Act) so must happen every three years. A Local Commissioner may convey any recommendations or conclusions from this review to government departments or the Care Quality Commission. A Commissioner may also provide good practice advice or guidance to adult social care providers.
350. Section 34S provides that each Local Commissioner must prepare a report on the discharge of their functions for each financial year. The Commission must then prepare an annual report which must be laid before Parliament and which must be published along with the reports from the individual Commissioners.

Section 34T: Interpretation of Part 3A

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

Part 2 of Schedule 5

352. [Part 2](#) of Schedule 5 makes a number of minor and consequential amendments to Part 3 of the 1974 Act and other Acts.

Disclosure of Information

Section 36: Disclosure of information by Her Majesty's Revenue and Customs

353. [Section 36](#) applies to information held by HMRC in connection with its functions relating to income tax.
354. *Subsection (2)* allows HMRC to disclose certain information relating to GPs and dental practitioners to the persons defined in *subsection (3)*. The information disclosed will be a summary of anonymised information relating to the earnings and expenses of these practitioners and will not extend to other details disclosed to HMRC as part of the tax assessment process such as investment income. Earnings that are identified as unconnected with medical or dental activities will be excluded.
355. *Subsection (3)* defines those persons to whom HMRC may disclose information covered by this section. Those persons are the Secretary of State, Welsh Ministers, Scottish Ministers, the DHSSPSNI or persons providing services to them or exercising functions on their behalf.
356. *Subsection (4)* places restrictions on the format of the information disclosed by HMRC. The information must be summarised or presented as a collection of information. It must not be possible to identify, or link the information to, a particular individual.
357. *Subsection (5)* defines the terms dental practitioner and general medical practitioner for the purpose of this section.

Part 4 – General

Section 37: Power to make transitional and consequential provision etc

358. *Subsection (1)(a)* of section 37 confers on the Secretary of State the power to make transitional or transitory provisions or savings in connection with the coming into force of any provision of the Act. However, *subsection (1)(a)* is limited by the exclusions in *subsection (2)*. *Subsection (3)* provides for appropriate transitional arrangements or savings to be made by the Welsh Ministers. *Subsection (4)* provides for appropriate

transitional arrangements or savings to be made by DHSSPSNI. *Subsection (5)* provides that an order under the section may amend any enactment, and *subsection (12)* defines enactment as an enactment in or in an instrument made under a Measure or Act of the National Assembly for Wales or Northern Ireland legislation as well as an Act of Parliament. *Subsection (6)* provides for modifications by order of a provision brought into force to have effect until another provision comes into force.

359. Transitional arrangements are likely to be necessary in relation to commencement of various provisions of the Act, including the provisions for suspension and in relation to tobacco and pharmaceutical services. Through transitional arrangements it will be possible to modify the application of the Act to existing situations and to ensure transition from the old law and procedures to the new.
360. *Subsection (1)(b)* of section 37 also confers on the Secretary of State power by order to make such supplementary, incidental, or consequential provision as the Secretary of State considers appropriate for the purposes of, in consequence of, or for giving full effect to, any provision of the Act. This would, for example, enable amendments to be made to references in legislation to NHS trusts to take into account the possibility created by provisions of the Act of there being a new kind of NHS trust, a de-authorised NHS foundation trust.
361. By *subsection (5) together with subsection (9)(a)* such orders of the Secretary of State may amend, repeal, revoke or otherwise modify any enactment contained in an Act of Parliament in which case they would be subject to approval by each House of Parliament under the affirmative resolution procedure. By *subsection (5) together with subsection (9)(b)* such orders of the Secretary of State, where they amend other legislation will be subject to the negative resolution procedure. The powers are additional to powers in any other provision of the Act.

Section 38: Repeals and revocations

362. **Section 38** introduces Schedule 6, which contains repeals and revocations.

Section 39: Extent

363. **Section 39** makes provision as to the extent of the provisions of the Act. For further information on extent please refer to the Territorial Extent section of these notes.

Section 40: Commencement

364. **Section 40** provides for the coming into force of the provisions of the Act. *Subsection (1)* provides that the Act, with certain exceptions, will come into force on a day appointed in an order made by the Secretary of State by statutory instrument. By *subsection (4)* different days may be appointed for different purposes or different areas.
365. The first exception is that, on the day on which the Act received Royal Assent, 12th November 2009, various provisions came into force by virtue of *subsection (5)*. The provisions are the repeal of section 16(1A) of the 2002 Act (see paragraph 9(2) and (4) of Schedule 4) together with the associated repeals and revocations made by the Act, and Section 40 itself, together with Sections 37 (power to make transitional and consequential provision etc), 39 (extent) and 41 (short title).
366. Secondly, for the purposes of making regulations, the following regulation-making powers also came into force by virtue of *subsection (6)* on the day on which the Act received Royal Assent: the power at section 8 for the Secretary of State to make regulations to disapply the duty to publish quality accounts, those for regulations providing that no offence is committed in relation to a tobacco advertisement by specialist tobacconists in certain circumstances as inserted into the 2002 Act by Section 20, for making provision in relation to tobacco displays as inserted into the 2002 Act by section 21, for prohibiting or imposing requirements in relation to sales of tobacco

products from vending machines as inserted into the 1991 Act by section 22, or for restricting sales from vending machines in Northern Ireland as inserted into the 1991 (NI) Order by section 23 and the provisions at paragraphs 11 and 12 of Schedule 4.

367. The third exception is in relation to some of the minor and consequential amendments made in relation to the tobacco provisions in Schedule 4 which are identified at *subsection (7)*. These come into force at the end of the period of two months beginning on the day on which the Act received Royal Assent.
368. *Subsection (8)* provides for the section that introduces a provision of a Schedule mentioned in *subsection (5)*, *(6)* or *(7)* to come into force for the purposes of the particular provision only.
369. The Welsh Ministers have power by order made by statutory instrument to bring into force on a day appointed by them provisions of the Act which relate to Wales and are identified at *subsection (2)*. Similarly DHSSPSNI has power by order made by statutory rule for the purposes of the [Statutory Rules \(Northern Ireland\) Order 1979 \(S.I. 1979/1573 \(N.I. 12\)\)](#) to bring into force on a day appointed by DHSSPSNI provisions of the Act which relate to Northern Ireland and are identified at *subsection (3)*. These powers at *subsections (2)* and *(3)* each benefit from the flexibilities provided by *subsection (4)* and respectively constitute further exceptions to the power at *subsection (1)*.
370. Where amendments made by Schedule 3 (introduced by Section 19) relate to bodies operating in Wales, Scotland or Northern Ireland as well as in England, the Secretary of State is obliged to consult the Welsh Ministers, the Scottish Ministers or DHSSPSNI as appropriate before making an order bringing the amendments into force (see *subsections (9)*, *(10)* *(11)* and *(12)*).
371. Insofar as the provisions of Schedule 3 relate to amendments to the NHS (Wales) Act, the Welsh Ministers are obliged to consult the Secretary of State before making an order bringing the amendments into force by virtue of *subsection (13)*.

Section 41: Short title

372. The short title of the Act is the Health Act 2009.