These notes refer to the Health Act 2006 (c.28) which received Royal Assent on 19 July 2006

HEALTH ACT 2006

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

PART 4CHAPTER 1

Pharmaceutical Services

155. Chapter 1 concerns pharmaceutical services provided under section 41 of the National Health Service Act 1977 ("the 1977 Act") and in the case of one section only, corresponding services in Scotland.

156. Pharmaceutical services are provided by pharmacy contractors (who may supply and sell medicines, drugs and appliances) and by appliance contractors (who may only supply or sell appliances such as trusses, wigs and stomacare aids). Collectively, pharmacy contractors and appliance contractors are known as "chemists".

157. In order to provide pharmaceutical services, it is necessary for a chemist to make an application to a Primary Care Trust (PCT) in England to be included in its pharmaceutical list (see section 42(2)(a) of the 1977 Act).

158. In Wales, following the abolition of Health Authorities in April 2003, the applications envisaged by section 42(2)(a) would, by operation of section 27 of the Government of Wales Act 1998, be made to the National Assembly for Wales (the Assembly). However, the Assembly has delegated the functions in respect of pharmaceutical services that were formerly undertaken by Health Authorities, to Local Health Boards (LHBs).

159. An application may only be granted where the PCT or the LHB is satisfied that it is necessary or desirable to grant the application in order to secure in the neighbourhood in which the premises are located the adequate provision of pharmaceutical services. This is known as the "necessary or desirable test" or "control of entry test".

160. This is provided for in section 42(2)(c) of the 1977 Act. For England, the relevant regulation is regulation 12 of the National Health Service (Pharmaceutical Services) Regulations 2005 S.I. 2005/641 ("the Regulations") (as amended). Certain exemptions to that test are set out in regulation 13 of the Regulations.

161. In Wales, the necessary or desirable (or control of entry) test is contained within regulation 4 of the National Health Service (Pharmaceutical Services) Regulations 1992 S.I.1992/662 ("the 1992 Regulations"). There are currently no exemptions to the test contained within the 1992 Regulations.

162. Chapter 1 provides for two changes. First, section 34 provides for charges to be levied in respect of a chemist's application to a pharmaceutical list. Secondly, section 35 provides for regulations to be made authorising a PCT or LHB to take account of any proposals contained in applications relating to the sale or supply of over the counter medicines and other healthcare products and advice in relation thereto.

Section 34: Power to charge

163. Section 34(1) inserts new sections 42A and 42B into the 1977 Act. These sections give the Secretary of State for Health (section 42A in relation to England) and the Assembly (section 42B in relation to Wales) powers to enable charges to be levied in respect of an application to be included in a pharmaceutical list. The fee may be determined either by the Secretary of State (or the Assembly) or by PCTs (or LHBs) where the Secretary of State (or Assembly) so directs.

164. New section 42A(1) enables the Secretary of State to give directions to PCTs requiring them to charge a fee for two types of applications to the pharmaceutical list. First, an application from a person who is not already included in a pharmaceutical list (section 42(2)(c)(i) of the 1977 Act). Secondly, an application from a person who is already included in a pharmaceutical list, but who wants to provide different services or to provide services from different premises (section 42(2)(c)(ii)).

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

166. Section 42A(5) requires a Primary Care Trust, where it determines the fee, to publish the fee. This would most likely be achieved by publishing the amounts of fees on the PCT website or, where the PCT does not have one, on the website of its Strategic Health Authority.

167. Section 42B makes equivalent provision in relation to Wales, save that section 42B(2) additionally enables the Assembly to specify the level of the fee or fees and, as the powers within section 126(4) of the 1977 Act would not be available if the Assembly were to specify the level of the fee or fees payable, it also contains power to enable the Assembly to vary the level of any fee or fees charged and to make different provision for different cases or descriptions of cases.

168. Additionally, section 42B(3) makes provision for the operation of sections 42B(4) and (5) in circumstances where the Assembly delegates its functions of receiving or determining the applications referred to in section 42(2)(c)(i) or (ii) of the 1977 Act. Sections 42B(4) and 42B(5) are in analogous terms to sections 42A(1) and 42B(2).

169. Section 34(2) makes a minor amendment to section 126(4) of the 1977 Act which will in particular allow directions under section 42A or 42B to make different provision for different cases or classes of cases.

Section 35: Applications for provision of pharmaceutical services

170. Section 35 amends the 1977 Act by inserting new subsections (2B) and (2C) into section 42. Subsection (2B) provides for regulations to be made authorising a PCT or, in Wales, the National Assembly for Wales to take account of any proposals contained in the application relating to the sale or supply of over the counter medicines and other healthcare products and advice related to the supply of such products. In practice, in Wales, this function will be delegated to Local Health Boards.

171. *Subsection (2B)* sets out the circumstances in which the sale or supply of over the counter medicines and other health care products and advice related thereto can be taken into account.

172. First, subsection (2B)(a) requires that there must be two or more applications for inclusion in a PCT's (or LHB's) pharmaceutical list. The applications may be from:

- a person not already included in the PCT's (or LHB's) pharmaceutical list;
- or a person already included in the PCT's (or LHB's) pharmaceutical list in respect of pharmaceutical services or premises other than those listed in relation to him.

173. The applications must relate to the same neighbourhood as each other. Accordingly, the provision does not apply where a PCT (or LHB) receives and determines a single application alone, or two or more applications each relating to different neighbourhoods.

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

175. Thirdly, the PCT (or LHB) must be satisfied that, if each application was considered separately, each would meet the "necessary or desirable test" (as described above). However, the PCT (or LHB) must also be satisfied that if all the applications were taken together, the necessary or desirable test would not be met (subsection (2B)(c)).

176. Where the conditions of subsection (2B) are met (and assuming the Secretary of State or the Assembly makes Regulations), *subsection (2C)* enables the PCT (or LHB) to take into account, in their assessment of which application or applications to grant, the proposals in such applications relating to the sale or supply of over-the-counter medicines or other healthcare products or advice related thereto (other than by way of NHS services or in accordance with a private prescription). Sale or supply of over-the-counter medicines are not usually pharmaceutical services since such products are not supplied as part of NHS pharmaceutical services (unless ordered as part of a NHS service – for example by means of a NHS prescription). Over-the-counter medicines do not include the supply of medicines against a private prescription. Healthcare products are products and services for the diagnosis, prevention, monitoring or treatment of illness or handicap or for the promotion or protection of health.

Section 36: Arrangements for dispensing of medicines

177. Section 36 of the Act amends section 43 of the National Health Service Act 1977, which concerns the persons who may be authorised to provide NHS pharmaceutical services in England and Wales. Section 36 makes provision in relation to the supervision of transactions by pharmacists, in addition to those in section 26 of the Act (requirements about supervision in the Medicines Act).

178. The existing section 43(2) of the 1977 Act provides that, except as may be provided for by or under regulations, arrangements for the dispensing of medicines shall be made only with persons who are registered pharmacists, or are persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act, and who undertake that all medicines supplied by them under arrangements for the provision of pharmaceutical services shall be dispensed by or under the direct supervision of a registered pharmacist. Section 36(1) substitutes a new subsection (2), to clarify that regulations made by the Secretary of State under section 43(2) may provide for exemptions from the second requirement; i.e. that the registered pharmacist, or the person lawfully conducting a retail pharmacy business, undertakes that medicines will be dispensed by or under the supervision of a pharmacist. The policy intention is that the regulations would allow arrangements under which medicines are to be dispensed by registered and suitably trained pharmacy staff, without the supervision of a pharmacist.

179. Section 36(2) relates to NHS legislation in Scotland concerning the eligibility to be a contractor under a pharmaceutical care services contract. Amendment of section 17S of the NHS (Scotland) Act 1978 will allow regulations to be made in Scotland which will bring NHS legislation in Scotland into line with the proposed changes to the Medicines Act 1968 implemented by Part 2 of the Health Act. This will allow arrangements under which medicines are to be dispensed by registered and suitably trained pharmacy staff, without the supervision of a pharmacist.