These notes refer to the Health and Social Care Act 2001 (c.15) which received Royal Assent on 11 May 2001

HEALTH AND SOCIAL CARE ACT 2001

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 2: Pharmaceutical Services

Chapter 1: Local Pharmaceutical Services

160. Chapter 1 of Part 2 provides for new arrangements under which community pharmacy and related services may be provided on a piloted basis. At present, pharmaceutical services, including the dispensing of NHS prescriptions, are provided by community pharmacies, appliance contractors and dispensing doctors under arrangements made with Health Authorities in accordance with Part 2 of the 1977 Act, and in particular regulations made under sections 41 and 42 of that Act. These arrangements are referred to below as "Part 2 pharmaceutical services".

161. The new arrangements will be known as Local Pharmaceutical Services and will provide an alternative legal framework for the provision of pharmaceutical services, under locally agreed contracts. Local Pharmaceutical Services will first be provided under pilot schemes, which are intended to develop and demonstrate innovative ways of providing high quality, cost-effective services to patients. They will be similar to PMS and PDS pilot schemes, established under the NHS (Primary Care) Act 1997. Many of the provisions in this Part of the Act (and in particular s*ections 31 to 34)* are modelled on the equivalent provisions in that Act.

Preparation and making of pilot schemes

Section 28: Pilot Schemes

162. *Section 28* deals with the general nature of Local Pharmaceutical Services pilot schemes. *Subsection (2)* provides that a pilot scheme may consist of one or more agreements between a Health Authority and any other person or persons (other than another Health Authority) under which Local Pharmaceutical Services are to be provided. The Health Authority may not itself provide Local Pharmaceutical Services.

163. Unlike Personal Medical and Dental Services pilots, provision of Local Pharmaceutical Services is not to be restricted to particular classes of person (although nothing in these provisions will alter restrictions in the Medicines Act 1968 and other legislation on who may supply medicines). The parties to pilot schemes may therefore include, amongst others, individual pharmacists, retail pharmacy businesses and dispensing appliance contractors. They may also include NHS trusts and Primary Care Trusts, and *subsection (7)* provides that NHS trusts and Primary Care Trusts have the necessary powers to provide services under a pilot scheme.

164. *Subsection (8)* defines Local Pharmaceutical Services as such services prescribed in regulations which are of a kind that may be provided under section 41 or 41A of the NHS Act 1977 (that is, Part 2 pharmaceutical services). However, *subsection (9)* means that Local Pharmaceutical Services may not include the dispensing of drugs, medicines and appliances by doctors or dentists to their own patients.

165. Under section 41 of the NHS Act 1977, Health Authorities have a duty to arrange Part 2 pharmaceutical services for their area. Since Local Pharmaceutical Services pilot schemes will be providing similar services, *subsection (6)* permits Health Authorities to take into account such schemes in determining how to meet their duty under section 41.

166. *Subsection (3)* provides that a pilot scheme may also include health services which are not Local Pharmaceutical Services, but which may be provided under Part 1 of the NHS Act 1977. This could include, for example, diagnostic testing, therapeutic monitoring and health education. It need not be restricted to services normally associated with pharmacies. So it could, for example, include the provision of chiropody or similar services. Pilot schemes may also include the provision of training and education. However, *subsection (4)* provides that schemes may not combine arrangements for Local Pharmaceutical Services with those for Personal Medical or Dental Services.

167. *Subsection (5)* defines piloted services as services provided under a pilot scheme, which therefore include not only Local Pharmaceutical Services but any other services included within a scheme.

Section 29: Making Pilot Schemes

168. *Section 29* introduces Schedule 2, which makes provision about the making of pilot schemes. In particular, that Schedule provides that pilot schemes may only be established with the approval of the Secretary of State or, in relation to Wales, the National Assembly for Wales.

Section 30: Designation of priority neighbourhoods or premises

169. *Section 30* permits the Secretary of State or National Assembly for Wales to make regulations allowing Health Authorities to designate neighbourhoods, particular premises, or particular descriptions of premises for the purposes of Local Pharmaceutical Services pilot schemes. Under *subsection (2)* the regulations may, in particular, make provision about which such places Health Authorities may designate and in what circumstances. The regulations may allow Health Authorities to defer applications to provide Part 2 Pharmaceutical Services relating to designated places. To avoid designations being prolonged inappropriately, regulations may also deal with the cancellation of designations, and may permit the Secretary of State or the National Assembly for Wales to direct that a designation be cancelled.

Reviews, variation and termination of pilot schemes

Section 31: Reviews of Pilot Schemes

170. *Section 31* deals with the review of pilot schemes. *Subsection (1)* requires that each pilot scheme be reviewed at least once by the Secretary of State or National Assembly for Wales, and *subsection (2)* requires that this be done within three years of services first being provided under the scheme. *Subsection (3)* requires the Secretary of State or National Assembly for Wales to give the relevant Health Authority and the people providing services under each scheme an opportunity to comment as part of the review, but otherwise *subsection (4)* allows the procedure for the review to be at the discretion of the Secretary of State or National Assembly for Wales.

Section 32: Variation and Termination of Pilot Schemes

171. *Section 32* deals with the variation and termination of pilot schemes. In particular *subsection (1)* permits the Secretary of State or National Assembly for Wales to issue directions to Health Authorities giving them a general authority to vary pilot schemes in specified circumstances and subject to specified conditions. The Secretary of State or National Assembly for Wales may also issue directions under *subsection (2)* to require Health Authorities to vary particular schemes. If for any reason the Secretary of State or National Assembly for Wales is satisfied that a pilot scheme is

unsatisfactory, *subsection (3)* permits them to issue directions requiring the Health Authority concerned to bring the scheme to an end.

NHS contracts and financial provision

Section 33: NHS Contracts

172. Under s*ection 33,* persons providing pilot services may apply to become a health service body. The effect of such an application being granted is that the contracts entered into between the Health Authority and the health service body will be NHS contracts within the meaning of the National Health Service and Community Care Act 1990, rather than legal contracts.

173. Where a pilot scheme involves a single individual or body corporate, *subsection (1)* provides for that individual or body to apply to become a health service body. Where a pilot scheme involves more than one person, *subsection (2)* permits all the people involved to apply collectively. In both cases, applications must be made in accordance with regulations under *subsection (3)*. Regulations under *subsection (4)* may provide for applications to be granted except in specified cases. If an application is granted, *subsection (5)* requires the Secretary of State or National Assembly for Wales to specify when it is to come into effect.

174. From a specified day following grant of an application, the applicant or applicants are to be treated as a health service body for the purposes of section 4 of the 1990 Act. *Subsection (7)* provides that where an application has been granted to pilot scheme providers collectively, it is the providers in that scheme at any given time who are to be considered the health service body, even if they have changed since the original application. Regulations under *subsection (9)* may provide for people to cease to be health services bodies in specified circumstances.

175. *Subsections (10) and (11)* require the Secretary of State and National Assembly for Wales to maintain and keep up to date a list of pilot scheme providers who have been awarded health service body status, and to publish it in such manner as they consider appropriate.

176. *Subsection (6)* has the effect that contracts between pilot scheme providers which have been granted the status of health service bodies and other health service bodies (including other pilot scheme providers) are to be treated as NHS contracts if they are for the provision of goods or services in connection with the scheme .

177. NHS contracts are not normally enforceable in the courts. Instead, any disputes can be put to the Secretary of State or National Assembly for Wales for resolution. However, because most pilot scheme providers will be rather different from other health service bodies, *subsection (8)* provides that the County Court may enforce directions issued as a result of that dispute resolution procedure in favour of or against a pilot scheme provider.

Section 34: Funding of preparatory work

178. *Section 34* deals with financial support for people developing proposals for pilot schemes and preparing to provide services under them. *Subsection (1)* provides that regulations may make provision for Health Authorities to give people financial assistance in respect of preparatory work, as defined by *subsection (2)*. S*ubsection (3)* sets out matters which may in particular be included in those regulations.

Section 35: Charges, recovery of payments and penalties

179. *Section 35* deals with charges. The Government's policy is that arrangements for prescription charges under Local Pharmaceutical Services will be the same as those which apply in relation to Part 2 Pharmaceutical Services. People who are exempt,

or who otherwise are not required to pay prescription charges, will receive free prescriptions whether they use a pilot scheme provider or a Part 2 provider. Similarly, there will be no difference in the level of prescription charges, or in the cost of pre-payment certificates. Such certificates will be valid for both services interchangeably. To that end, *subsection (1)* provides that regulations may be made about the making and recovery of charges for Local Pharmaceutical Services. *Subsection (2)* specifies matters which may in particular be included in regulations, including the application to Local Pharmaceutical Services of sections 122A and 122B of the 1977 Act, which deal with the recovery of certain charges and the imposition of penalty charges in certain cases. *Subsection (3)* requires the regulations to secure that any charges in respect of Local Pharmaceutical Services will be the same as those which would apply had the service been provided under Part 2 of the 1977 Act.

General

Section 36: Effect of the 1977 Act

180. *Section 36* makes general provision about the status of the functions of the Secretary of State, National Assembly for Wales and Health Authorities in respect of Local Pharmaceutical Services pilot schemes. In particular, *subsection (2)* provides that, unless otherwise specified, the 1977 Act applies to services provided under pilot schemes as if the Secretary of State or National Assembly for Wales had directed a Health Authority to arrange those services on his behalf. One effect of this is that Health Authorities may, subject to directions from the Secretary of State or National Assembly for Wales under section 17A of the 1977 Act, delegate their functions in respect of pilot schemes to a Primary Care Trust. (For that reason, references in these explanatory notes to Health Authorities should be read to include Primary Care Trusts unless the context demands otherwise).

Section 37: Premises from which pilot services may be provided

181. *Section 37* deals with the relationship between pilot schemes and pharmaceutical services provided under Part 2 of the NHS Act 1977. S*ection 37(a)* permits regulations to be made preventing the provision of pilot scheme services from the same premises as pharmaceutical services under Part 2 of the 1977 Act, except as provided in the regulations. *Section 37(b)* permits regulations to make provision about the inclusion, re-inclusion, removal and modification of entries in pharmaceutical lists held under Part 2 of that Act. It is envisaged that such regulations may be used to establish arrangements for determining whether, and to what extent, pilot scheme providers are to have a preferential right to return (or transfer) to Part 2 services in respect of particular premises on ceasing to provide services under a pilot scheme.

Section 38: Control of Entry Regulations

182. Section 42 of the 1977 Act requires regulations to be made about (amongst other things) the preparation and publication by Health Authorities of lists of people who have undertaken to provide Part 2 Pharmaceutical Services. Except as provided for in those regulations, applications by people wishing to join such a list (or to change the services or premises in respect of which they are already entered in the list) are granted only if the Health Authority is satisfied that it is necessary or desirable to do so in order to secure in the neighbourhood in question the provision of adequate pharmaceutical services by people on the list.

183. *Section 38* provides that regulations under section 42 of the 1977 Act may include provision about the extent which services provided under Local Pharmaceutical Services pilot schemes are to be taken into account when determining such applications.

Assessing the result of pilot schemes

Section 39: Assessing pilot schemes

184. *Section 39* provides that the Secretary of State or National Assembly for Wales may not bring into effect *section 40* (which deals with the provision of Local Pharmaceutical Services otherwise than under pilot schemes) unless they are satisfied that pilot schemes have shown that the continued provision of Local Pharmaceutical Services would be in the interests of the health service (or any part of it). The Secretary of State or National Assembly for Wales must have regard, in particular to the results of reviews of pilot schemes required under *section 31*.

Provision for local pharmaceutical schemes

Section 40: Provision for LPS schemes

185. *Section 40* makes provision for Local Pharmaceutical Services schemes which are not pilot schemes by inserting a new section 28J and a new Schedule 8A into the NHS Act 1977. The new Schedule 8A is set out in Schedule 3 to this Act. *Subsection (3)* inserts a new subsection (2A) in section 42 of the 1977 Act, which has the same effect in relation to Local Pharmaceutical Services schemes which are not pilot schemes, as s*ection 38* has in relation to pilot schemes.

Corresponding provision, etc.

Section 41: Corresponding provision and application of enactments

186. *Section 41* provides a power to make regulations in relation to local pharmaceutical services (or the people involved in providing them) whose provisions correspond to equivalent statutory provision in relation to personal medical or dental services (or the people involved in providing them). The provisions may be applied with such modifications as are considered appropriate.

Schedule 2: Pilot Schemes

187. This Schedule deals with arrangements for establishing Local Pharmaceutical Services pilot schemes (see explanatory notes to Chapter 1 of Part 2 of the Act and in particular *section 29*).

188. *Paragraph 1* provides that a pilot scheme may be established on a Health Authority's own initiative or at the request of a person wishing to participate in a scheme. A request from a prospective participant must be made in writing and must conform to any requirements set out in regulations.

189. *Paragraph 2* deals with the preparation of proposals for pilot schemes both for preliminary and final approval. Before establishing a pilot scheme Health Authorities are to be required to prepare proposals for submission to the Secretary of State or National Assembly for Wales, who may issue directions about the issues to be dealt with and the information to be included in such proposals. They may also issue directions requiring Health Authorities to consult on proposals before submitting them (and any such requirement would be in addition to any other obligation to consult imposed by or under any other legislation).

190. In some cases, it may be that Health Authorities will be required to include with proposals a recommendation about whether it should, or should not, be approved. The Secretary of State or National Assembly for Wales is therefore to be able to issue directions specifying the factors that Health Authorities should take into account in making any recommendation and the form in which the recommendation is to be made. Like other directions under this paragraph, such directions may be general, or particular to specific schemes.

191. Health Authorities are not generally to be required to submit proposals at the request of potential participants. However, sub-paragraph (5) will allow the Secretary of State and National Assembly for Wales to direct Health Authorities to submit summaries of such requests, prepared and presented in accordance with the directions, and to specify circumstances in which Health Authorities must submit proposals for consideration.

192. *Paragraph 3* deals with approval. The Secretary of State or National Assembly for Wales will not be able to approve a proposal unless satisfied that there are adequate arrangements for participants (other than the Health Authority) to withdraw. Otherwise, they may approve proposals as submitted, or with modifications, or reject them. They must notify the relevant Health Authority of their decision and the Health Authority must notify the other participants without delay.

193. *Paragraph 4* will permit a Health Authority to apply for preliminary approval for a scheme, before it has identified who the participants are to be. This could be used, for example, by a Health Authority wishing to establish services in an area that is not adequately served either by Local Pharmaceutical Services or Part 2 Pharmaceutical Services. It could first obtain preliminary approval for a scheme, and then invite bids from people to become the pilot scheme provider. As with full proposals, the Secretary of State and National Assembly for Wales will be required either to approve preliminary approvals as they stand or subject to modifications, or else reject them. If the preliminary proposal is approved, Health Authorities may be required to prepare full proposals in accordance with directions from the Secretary of State or National Assembly for Wales. Preliminary approval will not guarantee final approval of the scheme.

194. *Paragraph 5* requires Health Authorities to include in their proposals for pilot schemes an assessment of the likely effect of the schemes on other services. Those other services are pharmaceutical services provided under Part 2 of the 1977 Act, local pharmaceutical services provided under other pilot schemes, general medical services and personal medical services. Where necessary, the Health Authority making the proposals must consult any other Health Authority whose area may be affected, and that Health Authority must provide an assessment of the effects on services in its area.

195. *Paragraph 6* permits the Secretary of State and National Assembly for Wales to issue guidance about the criteria they are likely to apply when considering both full and preliminary proposals.

196. *Paragraph 7* deals with the establishment of schemes once approved. It will require Health Authorities to implement proposals that have been approved, in accordance with directions from the Secretary of State or National Assembly for Wales. The Health Authority may not withdraw from the scheme before it is established, but any of the other parties may at any time. A pilot scheme may only differ from the proposals as approved if the Secretary of State or National Assembly for Wales agree the particular change, or if the change falls within the scope of any directions they have issued permitting variations. As soon as possible after implementing a scheme, Health Authorities will be required to publish details of the scheme, in accordance with any directions issued by the Secretary of State or National Assembly for Wales.

Schedule 3: Local Pharmaceutical Services

197. Schedule 3 sets out the new Schedule 8A which is inserted into the 1977 Act by *section 40*. The Schedule makes provision for Health Authorities to make arrangements for Local Pharmaceutical Services schemes on a substantive (rather than a pilot basis).

198. *Paragraph 1* makes provision for Local Pharmaceutical Services schemes, equivalent to those in *section 28* for pilot schemes.

199. *Paragraph 2* allows regulations to be made permitting Health Authorities to designate locations in which they may give priority to Local Pharmaceutical Services. The provision is equivalent to that in *section 30* for pilot schemes.

200. *Paragraph 3* provides for the Secretary of State or National Assembly for Wales to make regulations about Local Pharmaceutical Services. Paragraph 3(2) requires that those regulations must include provision for participants in schemes (other than Health Authorities) to withdraw if they wish. Regulations may also impose conditions to be satisfied by people providing Local Pharmaceutical Services. By virtue of paragraph 3(3), regulations may make provision about other matters, including in particular the items specified in sub-paragraphs (a) – (k). Sub-paragraphs (i) and (j) provide for regulations to make arrangements similar to those provided for in respect of pilot schemes by *section 33* (NHS contracts). Sub-paragraph (k) provides for regulations to make provision for payments by Health Authorities of financial assistance in respect of preparatory work, and is similar in effect to *section 34* for pilot schemes.

Chapter 2: Changes to existing arrangements

England and Wales

Section 42: Dispensing of NHS prescriptions and provision of pharmaceutical services

201. *Subsection (1)* of *section 42* substitutes a revised section 41 in the 1977 Act relating to the arrangements for pharmaceutical services.

202. *Subsection (1)(a)* of new section 41 requires Health Authorities, in accordance with regulations, to make arrangements for the supply to persons who are in their area, of drugs, medicines and listed appliances to those people for whom they have been prescribed by medical practitioners under the national health service (including the Scottish and Northern Ireland health services).

203. *Subsections (1)(b) and (c)* require Health Authorities similarly, in accordance with regulations, to make arrangements for the supply to persons who are in their area, of drugs and medicines to those people for whom they have been prescribed by dental practitioners.

204. *Subsection (1)(d)* makes provision for items prescribed by certain other categories of prescriber also to be dispensed as part of NHS pharmaceutical services. This subsection gives the Secretary of State powers to specify in regulations the categories of person whose prescriptions will be dispensed and any conditions in accordance with which they must prescribe. It also provides the Secretary of State with powers to determine the particular drugs, medicines and appliances which each of them may prescribe for NHS dispensing. In relation to prescription only medicines, this subsection needs to be read in conjunction with *section 63*, which deals with the related issue of extension of the right to prescribe such medicines.

205. *Subsection (1)(e)* allows the Secretary of State to make regulations extending the scope of the services for which Health Authorities are required to make arrangements.

206. *Subsection (2)* of new section 41 defines these services together with the additional pharmaceutical services provided for under section 41A as “pharmaceutical services”.

207. *Subsection (3)* of new section 41 provides that the categories of persons under subsection (1)(d) whose prescriptions may be dispensed must be professionals regulated by law. It includes provision to ensure that prescriptions written by health professionals regulated under Scottish and Northern Irish legislation can be dispensed in England and Wales. *Subsection (4)* of new section 41 relates to the Secretary of State’s powers to determine the particular drugs, medicines and appliances which each category of prescriber may prescribe for NHS dispensing. It provides that a determination may make different provision for different cases; specify the circumstances or cases in which

a drug, medicine or appliance may be prescribed and allow for the dispensing of such items as the prescriber thinks necessary, in the exercise of their discretion.

208. *Subsection (5)* of new section 41 provides that the arrangements made by a Health Authority can include arrangements for the provision of a service by 'remote' means, so that the person receiving the service does so otherwise than at the premises from which it is provided. *Subsection (6)* of new section 41 makes provision to the effect that (subject to any limitations imposed by the Secretary of State in regulations) people with whom a Health Authority has made arrangements may also provide pharmaceutical services to people who are outside the Authority's area. This might happen, for example, where patients send their prescriptions by post to the pharmacy of their choice, or where a pharmacy collects a prescription from a GP's surgery on a patient's behalf and then delivers the dispensed medicine to the patient's home. The intention is to facilitate, and provide a means to control, the development of internet, mail order, home delivery and other arrangements. This will provide patients with greater flexibility in the way they can present their prescriptions and obtain the drugs or appliances that have been ordered for them.

Section 43: Remote provision of pharmaceutical, etc. services

209. Section 41A of the 1977 Act concerns the provision of "additional pharmaceutical services" which are in addition to those required by section 41. *Section 43* amends this section to give the Secretary of State powers to give directions to Health Authorities authorising or requiring them to arrange for the provision of services to any person, whether or not in their area. *Subsection (1)(b)* (of *section 43*) adds a new subsection (1A) to section 41A of the 1977 Act to allow the Secretary of State to authorise or require Health Authorities to arrange for the provision of these services by remote means so that the service is received otherwise than at the premises from which it is provided.

210. Section 42 of the 1977 Act provides powers to make regulations governing the arrangements made by a Health Authority for the provision of pharmaceutical services. In accordance with section 42(2), regulations require all Health Authorities to prepare and publish lists of persons (other than for medical and dental practitioners) who undertake to provide pharmaceutical services from premises in their area. Applications for inclusion in a pharmaceutical list are only to be granted if the Health Authority is satisfied that it is necessary or desirable to do so to secure the adequate provision of services in the neighbourhood in which the premises are located. *Subsection (3)* provides that regulations may be made exempting people from the 'necessary or desirable' test where they are to provide services solely by remote means.

211. *Subsection (4)* of *section 43* adds new subsections (3A) and (3B) to section 42 of the 1977 Act.

212. New subsection (3B) allows regulations to be made requiring people providing remote services to be approved for that purpose. It also provides a power to prescribe conditions to be imposed on the grant of an application for inclusion in a pharmaceutical list, where the applicant is to provide services by remote means.

213. *Subsection (5)* (of *section 43*) amends section 43(2A) of the 1977 Act, under which regulations are required to provide for the preparation by Health Authorities of lists of medical practitioners who supply drugs, medicines and appliances. The effect is to ensure that such dispensing doctors are included in the list of each Health Authority with whom they have arranged to dispense, even if they dispense from premises in another Health Authority's area.

214. Section 44 of the 1977 Act permits a Health Authority to recognise a Local Pharmaceutical Committee (LPC) which it is satisfied is representative of persons providing pharmaceutical services in its area. S*ubsection (6) (of section 43)* amends section 44 to clarify that notwithstanding that people in the Health Authority's area may receive pharmaceutical services from people whose premises are outside that area, the

LPC need only be representative of persons who are included in a Health Authority's own pharmaceutical list, in order to be recognised by it.

Scotland

Section 44: Dispensing of NHS prescriptions

215. *Section 44* amends section 27 of the National Health Service (Scotland) Act 1978 to make provision for items prescribed by certain categories of prescriber to be dispensed as part of NHS community pharmaceutical services in Scotland. This section was requested by the Scottish Executive and approved by the Scottish Parliament on 17th January 2001. Section 27(1)(cc) as amended, gives Scottish Ministers powers to specify in regulations the categories of person whose prescriptions will be dispensed and conditions in accordance with which they must prescribe. Scottish Ministers may also determine the drugs, medicines and appliances which each of them may prescribe for NHS dispensing. Paragraph (cc) applies to persons other than doctors and dentists, for whom separate provision is made at paragraphs (a) to (c) of Section 27.

216. *Subsection (3)* limits the categories of person who may be prescribed in regulations under Section 27(1)(cc) to certain professionals regulated under statute. It includes provision to ensure that prescriptions written by health professionals regulated under legislation in Northern Ireland can be dispensed in Scotland. It also provides that determinations under that section may make different provision for different cases, specify the circumstances or cases in which a given drug, medicine or appliance may be prescribed, and specify types of prescriber who may prescribe such drugs, medicines and listed appliances as they see fit, in the exercise of their discretion.