These notes refer to the Public Health (Wales) Act 2017 (c.2) which received Royal Assent on 3 July 2017

PUBLIC HEALTH (WALES) ACT 2017

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 7

Pharmaceutical Services

217. This Part introduces changes to the way in which Local Health Boards ("LHBs") determine applications to provide NHS pharmaceutical services. The principal changes require LHBs to prepare and publish a pharmaceutical needs assessment for their area, and to determine applications for entry onto the pharmaceutical list (or applications to amend entries on the pharmaceutical list) by reference to whether or not the application meets a need for a service or services identified in the assessment. Each LHB maintains a pharmaceutical list which includes details of the persons whose applications to provide NHS pharmaceutical services have been approved and the location from which they provide those services.

218. This new "control of entry test" replaces the test in section 83 of the National Health Service (Wales) Act 2006 ('the 2006 Act'), which requires LHBs to determine whether it is "necessary or expedient" to grant the application in question. Further changes authorise LHBs to remove a person from its pharmaceutical list for very serious or persistent breaches of terms and conditions of service.

Section 111 - Pharmaceutical needs assessments

219. This section inserts section 82A into the 2006 Act which makes provision for a new duty for LHBs in Wales to prepare and publish an assessment of need for pharmaceutical services.

220. Section 82A(2) places a duty upon each LHB to keep its most recently published assessment under review and revise it as and when it is appropriate to do so.

221. Section 82A(3) requires the Welsh Ministers to make regulations providing for:

- the date by which a LHB must publish its first assessment of pharmaceutical needs. This is to ensure that all LHBs have an assessment prepared and published by a set date and there is a smooth transition from the previous arrangements to these arrangements for determining applications;
- the circumstances in which a LHB is to revise its assessment. Regulations could, for example, require a LHB to review, and if appropriate revise, its assessment if there are significant changes to the demographics of an area which could have an impact upon the need for pharmaceutical services. Regulations could also stipulate that a LHB is required to revise its assessment every, for example, three years in order to ensure that the information remains up to date; and
- the way in which an assessment is to be published. This could, for example, include a requirement to place a copy of the assessment on the LHB's website as well as

making hard copies available in NHS pharmacies and GP surgeries, so that the assessment is accessible to people living in the LHB's area.

222. Regulations may also make provision about the preparation, publication, review and revision of an assessment under subsection (1) including, but not limited to:

- the information to be contained in an assessment. For example, regulations could specify that an assessment must contain information on the demography of the people in its area, any seasonal trends, age profiles and information about the provision of General Medical Services in the area;
- the extent to which an assessment is to take account of likely future needs and of other matters. For example, regulations could specify that an assessment must consider the impact of planned housing or commercial developments;
- the consultation to be carried out in connection with an assessment. For example, regulations may require LHBs to consult specified persons about specified matters when preparing their assessment. LHBs may, for example, be required to consult with local authorities, patient and community groups and local professional representative committees; and
- procedural requirements.

223. Section 111(2) provides that the first time the Welsh Ministers make regulations about pharmaceutical needs assessments under section 82A of the 2006 Act, these will be subject to the affirmative procedure, meaning they must be laid before, and approved by, the National Assembly for Wales. Subsequent regulations will be subject to the negative procedure.

Section 112 - Pharmaceutical lists

224. This section amends sections 83 and 84 of the 2006 Act. Section 83 of that Act sets out the principal regulation-making powers governing the provision of NHS pharmaceutical services in Wales, whilst section 84 provides for rights of appeal resulting from decisions made under section 83.

225. Section 83(2)(c) of the 2006 Act sets out the legislative criteria which a LHB must apply when considering applications to be included on a LHB's pharmaceutical list and applications for changes to the list. These criteria are often referred to as the "control of entry test".

226. Subsections (2) and (3) modify the "control of entry test" that LHBs are required to apply when considering applications to join their pharmaceutical list. Subsection (2) removes the requirement for LHBs to consider whether it is "necessary or expedient" to grant the application in order to secure "adequate" provision of pharmaceutical services within the neighbourhood.

227. In its place, subsection (3) inserts the new subsection (2B) into the 2006 Act which provides that a LHB may grant an application where it is satisfied, having regard to its most recently published pharmaceutical needs assessment, and any matters that are specified in regulations, that to grant the application would meet the need(s) identified within its assessment. This means that the "control of entry test" will be clearly based on meeting assessed local pharmaceutical needs.

228. Section 112(3) also inserts a new subsection (2A) into section 83 of the 2006 Act, which permits the Welsh Ministers to specify, in regulations, persons, or the description of persons, who are not to be included within a pharmaceutical list.

229. Section 112(3) also inserts a new subsection (2C) into the 2006 Act which makes additional provision in cases where a LHB 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 procedure which the

LHB must follow when determining an application for inclusion in a pharmaceutical list. For example, the regulations may provide that a LHB must seek representations from local patient representative bodies and other key interested parties. Second, new subsection (2C) provides that the regulations may stipulate certain matters which a LHB must or must not take into consideration when deciding whether or not to grant an application under subsection (2B).

230. Subsections (4), (5) and (6) modify the existing provisions which enable regulations to specify the circumstances in which two or more applications are considered together by a LHB.

231. Subsection (4) inserts a new subsection (3A) into the 2006 Act to provide that the regulations may prescribe the circumstances in which two or more applications may be considered together by a LHB. Subsection (5) amends section 83(4) of the 2006 Act to create a general power to make provision for the case where two or more applications, taken individually, meet the test under the new subsection (2B), but, taken together, do not.

232. Section 112(7) inserts a new subsection (6)(za) into section 83 of the 2006 Act, which permits the regulations to prescribe the circumstances in which LHBs may invite applications for inclusion in their pharmaceutical list. This will enable a LHB, if it is not receiving applications to provide the pharmaceutical services which are required to meet needs identified in its pharmaceutical needs assessment, to actively seek applications that will fulfil those needs.

233. Section 112(7)(b) inserts a new subsection (6)(fa) into section 83 of the 2006 Act, which permits the regulations to prescribe the timescale within which a LHB must determine applications for inclusion in or amendment to an inclusion in the pharmaceutical list.

234. Section 112(7)(d) makes amendments to section 83(6)(g) of the 2006 Act so that regulations under section 83 may provide grounds for removal of a person from the pharmaceutical list that are not connected with a person's fitness to practise. This power enables LHBs to remove pharmacists from the pharmaceutical list for serious and/or persistent breaches to their terms and conditions of service. Before removing a person from the pharmaceutical list an LHB must first issue the person with a notice describing the alleged breach (a so called "breach notice") and any action required by the person to rectify it. A person may only be removed from the pharmaceutical list where they fail to comply with the requirements stipulated in a breach notice. Appeals against removal from the pharmaceutical list will be to the Welsh Ministers.

235. Section 112(9) inserts subsection (10A) which requires LHBs to provide reasons for their decisions as to any matters covered within section 83.

236. The remaining subsections amend section 84 of the 2006 Act, which deals with appeals against decisions made by LHBs under the regulations provided for in section 83.

237. Section 112(10) amends section 84 of the 2006 Act so as to ensure that appeals against a LHB's determination of an application for inclusion in a pharmaceutical list are heard by the First Tier Tribunal only if they are on fitness to practise grounds. This removes the requirement relating to redetermination so that the First Tier Tribunal is not limited in the way it determines the appeal, for example, it could remit the matter back to the LHB. Appeals on other grounds are to be made to the Welsh Ministers – including appeals against a removal from the list for breaches of terms and conditions of service.

238. Section 112(11) provides that if regulations made under section 83 of the 2006 Act include provision for removal of a person or an entry in respect of premises from a pharmaceutical list, the regulations must require LHBs to give a pharmacist notice of their intention to remove him/her from the list, together with their reasons for this. The regulations must also set out the rights that a pharmacist will have to make representations prior to a LHB taking such a decision.

239. Section 112(12) removes text relating to section 83(6)(d) of the 2006 Act from the table in Schedule 6 (repeals and revocations) of the Health Act 2009.