

**EXPLANATORY MEMORANDUM TO**  
**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES**  
**AND LOCAL PHARMACEUTICAL SERVICES) AMENDMENT**  
**REGULATIONS 2009**

**2009 No. 599**

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 These Regulations amend the National Health Service (Pharmaceutical Services) Regulations 2005 (“the PS Regulations”) (S.I. 2005/641) and the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (“the LPS Regulations”) (S.I. 2006/552).

2.2 These Regulations refer to local pharmaceutical services provision in England. They clarify elements of existing LPS Regulations and bring these Regulations into line with existing PS Regulations.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

4. **Legislative Background**

4.1 The PS and LPS Regulations regulate the provision of pharmaceutical services in England.

5. **Extent**

5.1 These Regulations apply to England.

6. **European Convention on Human Rights**

As the instrument is subject to the negative resolution procedure and it does not amend primary legislation, no statement is required.

7. **Policy Background**

7.1. Local Pharmaceutical Services (LPS) Schemes are an alternative to the national pharmaceutical statutory arrangements through which the majority of pharmaceutical services are provided. LPS contracts are made locally by PCTs and must include an element of dispensing, but may include a range of other services not traditionally associated with pharmacy, including training and education.

The purpose of these regulations is to include certain processes in the development of LPS schemes to support transparency and good practice. As part of the process to develop an LPS scheme, Primary Care Trusts (“PCT”s) may select an area or a premises as a priority area for the provision of local pharmaceutical services. This process is referred to in the LPS and PS Regulations as “designating” an area or premises, or as a “designation”. An example of where a PCT might wish to designate an area is where it wished to have a combination of certain pharmaceutical services provided or services provided to one specific group and not to others. Once the area has been designated, the PCT will develop an LPS Scheme, and will invite providers to tender to provide the service under an LPS contract. The policy intention behind the LPS legislation is to ensure adequate provision of pharmaceutical services throughout England, and to provide PCTs with enough flexibility to be able to target areas or groups for provision of specific pharmaceutical services, should such be required. This degree of specificity is not possible under the current national statutory arrangements.

7.2 Once an area has been designated, the PS and LPS regulations provide that the PCT may, apart from certain types of applications, defer consideration of applications to join their pharmaceutical list. The pharmaceutical list is the list the PCT keeps of community pharmacy contractors who provide services under national statutory arrangements. A separate list is kept of LPS providers. As soon as an area has been designated, any new applications to join the pharmaceutical list are essentially frozen for as long as the designation lasts. The designation may remain in place until cancelled by the PCT or until the LPS scheme commences. This is to provide time for the LPS scheme to be developed and to prevent ‘spoiling’ by, for example other contractors setting up and cherry picking services, which might affect the package of services to be provided under the LPS scheme.

7.3 At present, the designation process permits deferral of all applications to join the pharmaceutical list, or in relation to relocations or changes of ownership, received by the PCT within 30 days of the date on which the designation was made. Regulation 4 of these Regulations amends existing LPS Regulations to set out a number of circumstances, similar to those set out in regulation 25(2) of the PS Regulations, where a PCT may not defer consideration of an application to join the pharmaceutical list following a designation being made. This list includes, for example, an application for a change of ownership of the same pharmacy premises, or an application to return to the pharmaceutical list to provide pharmaceutical services following a period when a pharmacist may have provided local pharmaceutical services. It also provides for extending the period of deferral from 30 to 120 days.

7.4 These changes will allow applications from service providers for certain changes to existing services to be considered, thus avoiding adverse effect on existing services, while at the same time permitting PCTs sufficient time to properly consider the applications relating to the LPS scheme being developed in accordance with the legislation and the required procedures.

7.5 Regulation 2(a) of these Regulations amends the PS Regulations to reflect the changes as explained above in paragraph 7.3. Regulation 2(b) amends regulation 67(5)(e) of the PS regulations to take account of the establishment of local involvement networks.

7.6 Regulation 4(3) of these Regulations expands the list of those to be notified in cases of designation to include local involvement networks and any other PCTs that may be affected by a designation, and brings this regulation into line with the new regulation 14B.

7.7 The result of the amendments referred to in paragraphs 7.1 to 7.6 is that the PS Regulations and the LPS Regulations mirror each other in relation to how applications to join the pharmaceutical list are considered and dealt with. The policy intention behind this legislation is to ensure that the two systems dovetail with each other effectively.

7.8 Regulation 3 inserts into the interpretation section of the LPS regulations definitions for “relevant local authority” and “relevant local involvement network” to take account of the establishment of local involvement networks.

7.9 Regulation 5 of these Regulations inserts new regulation 14A into the LPS Regulations to provide for pharmacists, doctors, local involvement networks and any other PCT likely to be affected, to be informed when a PCT has selected an LPS proposal for development. This is to ensure that those persons and bodies providing healthcare services in the area of the PCT are aware of any plans to develop an LPS scheme in the area and can take account of the proposal when making plans for healthcare provision.

7.10 Regulation 6 of these Regulations updates regulation 15 of the existing LPS Regulations, again in line with regulation 2(b) and 3, to take account of the establishment of local involvement networks.

## **8. Consultation Outcome**

8.1. The Department consulted with the Pharmaceutical Services Negotiating Committee (PSNC), as representatives of pharmaceutical services contractors. Issues raised by PSNC were resolved satisfactorily.

## **9. Guidance**

Local Pharmaceutical Services Guidance Notes were prepared by the Department of Health and published in March 2008 on the DH website.

## **10. Impact**

10.1 As the amendments described earlier are designed to strengthen the process for development of LPS schemes and will not negatively affect

existing pharmaceutical services, there is no impact on business, charities or voluntary bodies.

10.2 It is for PCTs to decide whether it wishes to develop LPS schemes. The processes dealt with by these regulations mirror the processes used in the national statutory framework legislation. The impact on PCTs is marginal or not applicable depending on whether LPS is used.

10.3 An Impact Assessment has not been prepared for this instrument, as the proposed changes are designed to make aspects of the LPS process and decisions more explicit and robust, where a PCT makes a decision to use LPS.

## **11. Regulating small business**

11.1 The legislation applies to small businesses but does not place additional requirements on small businesses.

## **12. Monitoring & review**

12.1 Not applicable.

## **13. Contact**

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