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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations govern the arrangements for the provision of local pharmaceutical services in England under agreements, known as LPS schemes, between Primary Care Trusts, who commission the services, and independent contractors, who provide them. LPS schemes have to be made in accordance with the provisions of these Regulations and of Schedule 8A to the National Health Service Act 1977 (“the 1977 Act”). Previously, local pharmaceutical services could only be provided under pilot schemes established under Chapter 1 of Part 2 of the Health and Social Care Act 2001, but as a result of these Regulations, most pilot schemes will become LPS schemes, and new proposals for pilot schemes will no longer be accepted.

Part 1 contains general provisions, including interpretation provisions – and, together with Schedule 1, provides for the application with modifications of certain provisions of the 1977 Act and the Health Service Commissioners Act 1993 that already deal with arrangements for personal medical or dental services (and with local pharmaceutical services pilot schemes) so that those provisions apply in relation to LPS schemes in a similar way.

Part 2 deals with designation of priority neighbourhoods or premises, and the review, variation and cancellation of such designations. Where a neighbourhood, premises or type of premises are designated, Primary Care Trusts may defer consideration of applications for inclusion in a pharmaceutical list (under the National Health Service (Pharmaceutical Services) Regulations 2005 (“the 2005 Regulations”)) in relation to the same neighbourhood or premises. Notice of designations, and of the variation and cancellation of designations, has to be given to the interested parties listed in regulation 4(5).

Part 3 sets out the general requirements in relation to contractors. Specified categories of individuals, partnerships and companies are prevented from entering into LPS schemes (regulation 7) and if the Primary Care Trust determines that an applicant falls within one of those categories, the applicant has a right to the reasons for that determination and a right of appeal (regulations 8 and 9). Contractors are given health service body status, meaning that their contract is an NHS contract, unless they elect otherwise (regulation 10).

Part 4 sets out the general requirements in relation to LPS schemes. These include a requirement for certain information relating to the suitability of the applicant to be included in the proposal (regulation 12) and requirements as to the terms to be specified (regulation 14). The latter include the mandatory terms in Schedule 2, which relate to such matters as the dispensing arrangements, clinical governance, professional standards, inducements, the provision of information about fitness to practise matters, NHS charges, remuneration, complaints, dispute resolution and termination. The Primary Care Trust must also determine whether any potential contractor is to be given a right of return to its pharmaceutical list kept under the 2005 Regulations (regulation 15). The pharmaceutical list is a list of providers of pharmaceutical services who provide such services on the basis of the statutory terms of service set out in the 2005 Regulations rather than on the basis of a locally negotiated LPS scheme. Determinations of rights of return have to be sent to a list of interested parties.

There are arrangements which allow Primary Care Trusts to share information that they receive about the suitability of contractors or the fitness to practise of pharmacists under the Regulations with other Primary Care Trusts and, where appropriate, the Royal Pharmaceutical Society of Great Britain (regulation 16).

**Status:** *This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

Part 5 contains transitional and consequential provisions. These include a duty on former pilot scheme contractors to provide Primary Care Trusts with certain information about their suitability to be a contractor, although some corporate bodies are exempt from this requirement (regulation 17). Generally, pilot scheme agreements all become LPS schemes (or for a transitional period, transitional agreements), but pilot schemes that come under the special arrangements for essential small pharmacies will continue as pilot schemes. The pilot schemes that become LPS schemes must, however, be modified so that they comply with the requirements of these Regulations (regulation 18). There are also transitional arrangements for the scheme for the designation of neighbourhoods and premises (similar to the scheme in Part 2) that was in operation for pilot schemes. A number of consequential amendments are also made to other secondary legislation to take account of the arrangements set out in these Regulations. In addition, some consequential amendments are made to the 2005 Regulations to take account of the replacement of the Prescription Pricing Authority and the NHS Counter Fraud and Security Management Service by the NHS Business Services Authority, and the definition of “supplementary prescriber” is updated (regulation 20 and Schedule 3).

A full regulatory impact assessment of the effect that this instrument will have on the costs to business is available from the Medicines, Pharmacy and Industry Division, Department of Health, Skipton House, 80 London Road, London SE1 6LH. Copies have also been placed in the libraries of both Houses of Parliament.