

**EXPLANATORY MEMORANDUM TO**  
**THE NHS (PHARMACEUTICAL SERVICES) (AMENDMENT)**  
**REGULATIONS 2006**

**2006 No. 3373**

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty. This memorandum contains information for the Joint Committee on Statutory Instruments.
2. **Description**
  - 2.1 This Instrument amends the NHS (Pharmaceutical Services) Regulations 2005 – SI 2005/641 (“the 2005 Regulations”) and the NHS (Local Pharmaceutical Services etc.) Regulations 2006 – SI 2006/552 (“the 2006 Regulations”).
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
  - 3.1 These amendments contain certain corrections to the 2005 Regulations set out in the Department's response of July 2005 to the Committee and certain corrections to the 2006 Regulations set out in the Department's response of April 2006 to the Committee.
  - 3.2 However, the Instrument has not been issued free of charge on this occasion since the principal reason for making the Instrument at this time is not to correct the earlier defective instruments, but to make required amendments to the regulatory system governing the provision of NHS pharmaceutical services.
4. **Legislative Background**
  - 4.1 This Instrument amends the 2005 and 2006 Regulations to achieve certain policy objectives and technical corrections to the operation of the regulatory system governing the provision of NHS pharmaceutical services.
5. **Extent**
  - 5.1 This instrument applies to England.
  - 5.2 Responsibility for the provision of NHS pharmaceutical services is devolved to the administrations in Scotland, Wales and Northern Ireland.
6. **European Convention on Human Rights**
  - 6.1 As the Instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## 7. Policy background

7.1 The policy background to the 2005 Regulations was set out in the Explanatory Memorandum accompanying those regulations. In brief, the 2005 Regulations:

- introduced from 1 April 2005 a new contractual framework for NHS community pharmacy services;
- implemented the Government response for England to the Office of Fair Trading (OFT) report *The control of entry regulations and community pharmacy services in the UK*; and
- introduced requirements under the Health and Social Care Act 2001, which amended the National Health Services Act 1977, for pharmacists, companies, their directors and superintendent pharmacists to make declarations as to their suitability to provide pharmaceutical services (termed “fitness to practice”).

7.2 The policy background to the 2006 Regulations was set out in the Explanatory Memorandum accompanying those Regulations. In brief, the primary legislation for Local Pharmaceutical Services (LPS), as set out in Section 28 of the Health and Social Care Act 2001, included a provision in Section 39 that, subject to certain conditions, LPS schemes could move from “pilot” to “mainstream” status. These conditions were fulfilled by December 2005 and the 2006 Regulations give effect to Section 40, which was brought into force by SI 2006/481.

7.3 This Instrument in particular:

- introduces amendments to the 2005 Regulations and 2006 Regulations requested by the Joint Committee on Statutory Instruments which the Department has accepted;
- makes consequential amendments to the 2006 Regulations, including that local pharmaceutical services schemes must include dispensing;
- allows contractors to dispense prescriptions written by independent pharmacist prescribers who work in GP, community or hospital clinics or have agreed with their local NHS primary care trust (PCT) to provide this as a local enhanced service under the new community pharmacy contractual framework;
- enables PCTs to allow contractors to begin to provide NHS pharmaceutical services sooner than the usual 30-day waiting period where this is appropriate;
- corrects procedures for notifying decisions and consequent appeal rights concerning minor relocations of contractor premises within a PCT or between neighbouring PCTs;

- corrects an error that doctors can appeal decisions about pharmacy applications in designated rural areas, known as “controlled localities”;
- removes the ability for dispensing doctors in rural areas to ask a PCT to give them special protection, if a new pharmacy were to apply to move into that area, by seeking a PCT determination that a particular area with a small population (under 2,750) should be designated a “reserved location”. This particular arrangement can, however, continue to apply where a pharmaceutical contractor makes an application to be included on the pharmaceutical list in that area;
- corrects the procedures for determining applications from dispensing doctors, including where practices amalgamate; and
- sets out the procedures and appeal rights for PCTs to recover over-payments made to contractors who are suspended from the pharmaceutical list.

### **Consultation**

- 7.4 The Department has consulted representative bodies for community pharmacy, primary medical services, dispensing doctors on the proposals regularly over the last 12 months in preparing these amendments. They are all content.

### **Guidance**

- 7.5 The Department published information for PCTs on its website to support the introduction of the 2005 Regulations which is on the Department’s website at: [http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4107573&chk=5TqNtc](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107573&chk=5TqNtc). The Department will update this information to reflect the amendments set out here.

### **Consolidation**

- 7.6 As these amendments achieve limited objectives including technical corrections to the current regulations, the Department does not propose to consolidate either set of Regulations.

## **8. Impact**

- 8.1 A Regulatory Impact Assessment (RIA) has not been prepared as these Regulations amend the main 2005 and 2006 Regulations, for which RIAs were published at the time. However, these changes may help reduce any regulatory burden by allowing pharmacists to dispense NHS prescriptions issued by pharmacist independent prescribers, by removing the 30-day waiting time for contractors before they can begin providing NHS services where there is good cause, and clarifying certain appeal rights.

## 9. Contacts

### The 2005 Regulations

Gillian Farnfield  
Department of Health  
453D Skipton House  
80 London Road  
London SE1 6LH

Telephone number 0207 972 2700 e-mail: [gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk)

### The 2006 Regulations

Chris Plummer  
Department of Health  
453D Skipton House  
80 London Road  
London SE1 6LH

Telephone number 0207 972 2715 e-mail: [chris.plummer@dh.gsi.gov.uk](mailto:chris.plummer@dh.gsi.gov.uk)