

**EXPLANATORY MEMORANDUM TO**  
**THE NATIONAL HEALTH SERVICE (MISCELLANEOUS AMENDMENTS**  
**RELATING TO COMMUNITY PHARMACEUTICAL SERVICES AND**  
**OPTOMETRIST PRESCRIBING) REGULATIONS 2009**

**2009 No. 2205**

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
  - 2.1 This Instrument makes miscellaneous amendments to the framework legislation which governs the provision of NHS community pharmaceutical services and NHS primary medical services in England. Amongst other matters, the amendments enable pharmacists and dispensing doctors to dispense against prescriptions from optometrists who are qualified as independent prescribers, contain measures allowing for temporary changes to the arrangements for the provision of community pharmaceutical services during an emergency, and make various technical changes to improve the functioning of the framework legislation for community pharmaceutical services. These technical changes cover matters such as opening hours, inducements, the handling of applications, and the provision of information to Primary Care Trusts (“PCTs”) about officers of companies that are providing community pharmaceutical services.
3. **Matters of Special Interest to the Joint Committee on Statutory Instruments**
  - 3.1 None.
4. **Legislative Context**
  - 4.1 The great majority of community pharmaceutical services in England are provided on the basis of one of two sets of standard arrangements with Primary Care Trusts. Arrangements for the provision of “pharmaceutical services” are governed by the National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641, as amended) (“the PS Regulations”). Arrangements for the provision of “local pharmaceutical services” are governed by the National Health Service (Local Pharmaceutical Services etc) Regulations 2006 (S.I. 2006/552, as amended) (“the LPS Regulations”).
  - 4.2 The PS Regulations set out the statutory terms of service of the majority of retail pharmacy outlets providing “pharmaceutical services”. The companies responsible for these outlets have to be on a pharmaceutical list, kept by the local PCT. Two additional categories of people may provide “pharmaceutical services”. First, dispensing doctors, who are general practitioners (“GPs”), are able dispense to patients who live in designated rural areas a distance away from pharmacies. Second, appliance contractors, who dispense appliances (for example, incontinence aids, dressings, bandages etc.) but not medicines. Generally, all these providers of

pharmaceutical services are known as “contractors”, and are referred to in this memorandum as such, even though they do not have a formal contract with their PCT. The PS Regulations were implemented on 1st April 2005 and followed negotiations and agreement between the Department, the NHS Confederation (which represented the interests of PCTs) and the Pharmaceutical Services Negotiating Committee (PSNC) which represented pharmacy contractors.

- 4.3 The LPS Regulations contain an alternative, less prescriptive set of arrangements for the provision of community pharmaceutical services. This is a contractual framework, and most of the terms of the contracts are for local negotiation. However, there are also some common standard terms and conditions set out in the LPS Regulations. The LPS Regulations also contain a scheme for designating areas where the PCT is to make arrangements for the provision of services on the basis of the LPS Regulations rather than the PS Regulations.
- 4.4 Most primary medical services in England are provided on the basis of one of two forms of standard contract between GP practices and PCTs: a general medical services (GMS) contract; or personal medical services (PMS) agreement. A number of standard terms and conditions for GMS contracts and PMS Agreements are set out in two sets of Regulations: the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291, as amended) (“the GMS Regulations”); and the National Health Service (Personal Medical Services Agreements) Regulations 2004 (S.I. 2004/627, as amended) (“the PMS Regulations”). The GMS contract is generally speaking the more prescriptive of these two types of agreement, but in relation to prescribing and dispensing, both sets of Regulations – and so both types of agreement – contain provisions imposing detailed obligations on GP practices with regard to prescribing and dispensing, for example with regard to who may be considered as authorised prescribers for the purposes of the practice’s agreement with its PCT.

## **5. Territorial Extent and Application**

- 5.1 This instrument applies to England.

## **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**

*What is being done and why*

- 7.1 The amendments made in these Regulations can be grouped as follows:
- 7.1.1 amendments which flow from the Government White Paper *Pharmacy in England – Building on Strengths, Delivering the Future* published in April 2008 and consultation on legislative and structural changes in autumn 2008. A series of amendments have been made to improve the current working of the PS, LPS, GMS and PMS Regulations, pending the anticipated replacement of

the PS Regulations as a consequence of measures contained in the Health Bill that is currently before Parliament;

- 7.1.2 further amendments to remove loopholes or improve the working of the PS and LPS Regulations that have been identified since but which were not part of that consultation; and
  - 7.1.3 changes to contractual and legislative requirements to help PCTs and contractors deal with developing situations during an emergency such as the swine flu pandemic.
- 7.2 These Regulations achieve the following changes which were the subject of consultation in autumn 2008.
- 7.2.1 Removal of remaining references to Patients' Forums or Community Health Councils as these no longer exist and are replaced by Local Involvement Networks.
  - 7.2.2 Including references to optometrist independent prescribers in the definitions in the PS, LPS, GMS and PMS Regulations to enable contractors to dispense NHS prescriptions written by registered optometrists who have gained qualifications that entitle them to act as independent prescribers.
  - 7.2.3 Inserting provisions enabling a PCT to complete any investigations concerning a contractor's "fitness to practise" where the contractor is selling the business. If a contractor who is not under investigation completes such a sale and has no other pharmaceutical services outlets in the area of the PCT, normally they are removed from the PCT's pharmaceutical list. However, where a contractor is under investigation, such a removal means there is no basis left for the investigation. Under the new arrangements, the contractor will be able to complete the sale but the PCT will be able to bring the investigation to a conclusion, and as a consequence record and notify as required any adverse findings about the contractor.
  - 7.2.4 Replacing the phrase "necessary or desirable" in the PS Regulations where indicated with "necessary or expedient". This reflects updated language now adopted in the NHS Act 2006 but does not alter the original sense of the wording.
  - 7.2.5 Clarifying the circumstances under the PS Regulations in which a contractor who is required to open at least 100 hours per week (because they went through a special applications process) is able to apply to the PCT to change their usual opening hours, although they are not allowed to reduce their total number of hours to below 100. All pharmacy contractors will be required to distinguish between their formal opening hours and their supplementary opening hours. Changes to supplementary opening hours require the filling in of a return to the Primary Care Trust. Changes to formal opening hours are the subject of an applications process, and a PCT is able to approve, reject in part or fully such applications, but there is a right of appeal against adverse decisions.

- 7.2.6 Tightening up a pharmacy contractor's terms of service in the PS and LPS Regulations so that no pharmacy contractor can offer inducements to other providers of NHS services in return for particular forms of recommendations. The PS Regulations are also being changed to permit items with a small value to be given to patients (e.g. fruit, exercise DVDs) and so not to be treated as inducements. This is a proposal originally put forward by the PSNC and applies in relation to items given away in the context of certain forms of additional services, such as special services offered by pharmacy contractors to assist in the treatment of obesity.

Further improvements to the PS Regulations have been made, including the following:

- 7.2.7 Schedule 4 to the Regulations sets out the information to be provided with applications for inclusion in pharmaceutical lists, or changes to the services provided or pharmacy premises of existing contractors. Applications for inclusion in a pharmaceutical list have to include information from companies and their individual directors and their superintendent pharmacist (a requirement of Section 71 of the Medicines Act 1968) regarding their fitness to practise. An amendment is being made to correct a loophole so that, once a company has been approved to join a PCT pharmaceutical list, any subsequently appointed directors or superintendent pharmacists must also provide, as did the original officers, information about their "fitness to practise" e.g. whether they have convictions, details of any regulatory investigation etc. In the case of people appointed before the regulations come into force, companies will be given up to 17<sup>th</sup> March 2010 to supply the up-to-date information;
- 7.2.8 Easter Sunday is included alongside other days already named in the Regulations (e.g. Christmas Day and bank holidays in accordance with the Banking and Financial Dealings Act 1971) so that contractors are treated as being open on those days whether they do or not;
- 7.2.9 PCTs are given the discretion to allow contractors a shorter waiting period than 3 months to change their supplementary opening hours. This would only apply where the PCT was satisfied there is good cause (e.g. so that a pharmacy can better match opening times if a local GP surgery changes its hours).
- 7.2.10 A loophole is removed which enabled a contractor to apply to provide NHS services at, or move NHS services to, a site where NHS services are already being provided. This can lead to a PCT paying up to twice the normal NHS allowances for what is in effect a single pharmacy. The PCT will retain a discretion to grant an application where it is satisfied the two contractors would be distinct independent operations.

To help the NHS and contractors deal with emergencies such as the swine flu pandemic, the following changes have been made to the PS and LPS Regulations:

- 7.2.11 Introduction of a definition of “emergency requiring the flexible provision of pharmaceutical services”. This enables the Secretary of State to declare such an emergency by means of directions to PCTs. The directions will enable PCTs to exercise a range of new functions under the PS and LPS Regulations, subject to any conditions or limitations that the Secretary of State imposes. .
- 7.2.12 Enabling PCTs to authorise contractors to relocate existing premises or to acquire new temporary NHS premises from which to provide pharmaceutical services. During severe impacts, contractors may want to combine one or more premises to provide any service at all. A PCT may wish a contractor to move to a “central” site from which to provide services – however, this would only be with the contractor’s agreement. These flexibilities will apply to all types of contractor.
- 7.2.13 Enabling a PCT to authorise dispensing doctors temporarily to provide patients who normally are not eligible to receive dispensing services from their doctor to do so, where other dispensing facilities have closed locally and it is necessary to provide additional capacity in order to secure adequate provision of pharmaceutical services in the PCT’s area. In more rural areas, a lack of pharmacies may mean they close during a pandemic if staff are unavailable. This will enable PCTs to authorise dispensing doctors temporarily to fill a gap until the normal pharmacy service resumes.
- 7.2.14 Enabling pharmacies and appliance contractors to amend their opening hours or to close during an emergency without giving the usual 3 months’ notice to a PCT. Contractors will be able to respond flexibly according to which staff are available during the pandemic by giving a PCT 24 hours’ notice of any such changes.

In all cases to deal with the emergency, any changes will only be temporary and the contractors will revert to previous arrangements, once either the emergency comes to an end or the PCT discontinues the temporary arrangements, unless the previous arrangements have changed during the emergency via the normal applications process.

### *Consolidation*

- 7.3 There are no immediate plans to consolidate any of the Regulations amended by these Regulations. However, new provisions in the Health Bill currently before Parliament will change the basis on which a PCT grants the right to provide NHS pharmaceutical services. The Department proposes to replace the PS Regulations with a new set of Regulations as part of the implementation of the pharmaceutical services provisions of the Bill, if enacted.

## **8. Consultation outcome**

- 8.1 The proposals in paragraph 7.2.1 – 7.2.6 were included in a larger consultation in autumn 2008. Of 1,150 responses overall, 759 replied with comments on these proposals. Overall there was some uncertainty about whether the proposed amendments should be accepted. In purely numeric terms a minority (195) were in

favour with 285 disagreeing and 267 unsure. Despite this, the Department has concluded there was sufficient support from key organisations including the NHS Confederation and the PSNC to proceed with these changes.

- 8.2 The proposals in paragraphs 7.2.7 – 7.2.10 have arisen more recently and were not subject to a general public consultation. However, the Department sought views from the NHS, the PSNC and representatives of dispensing doctors and dispensing appliance contractors. As a result of this, the Department has fine tuned the wording in the amendments to reflect the views received and none of the organisations consulted is opposed to these proposals.
- 8.3 The proposals in paragraphs 7.2.11 – 7.3.14 build on a wider consultation led by the Medicines and Healthcare products Regulatory Agency (MHRA), which took place in 2008 on a series of measures to ease requirements in both medicines and NHS legislation regarding the supply of medicines across the UK during a pandemic. Respondents to that consultation were in favour of introducing amendments aimed at enabling more flexible provision of pharmaceutical services in a pandemic situation. The detail of these new provisions has also been the subject of further consultation with the PSNC and the General Practitioners' Committee of the British Medical Association.

## **9. Guidance**

- 9.1 The Department has published information for primary care trusts on its website to support the 2005 Regulations. It is at:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4107573](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4107573).
- 9.2 The Department has completed with the NHS a major overhaul of this guidance and a revised version, which incorporates further advice for the NHS and for contractors on the amendments in these Regulations as appropriate, is scheduled for publication later in August 2009.

## **10. Impact**

- 10.1 The Department considers these amendments are largely technical in effect. The original consultation in autumn 2008 did not identify any significant impact on business nor on the NHS from these regulatory amendments. An Impact Assessment (IA) has therefore not been prepared.
- 10.2 There is no negative impact on equality issues.

## **11. Regulating Small Business**

- 11.1 The Regulations apply to small businesses, including firms employing up to 20 people. As the Regulations concern the provision of NHS pharmaceutical services, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed universal standards and practices in the provision of such services.

11.2 However, it is anticipated that the flexibilities being introduced to help contractors deal with an emergency such as pandemic flu will be of particular help to smaller contractors who may not have access to the same staffing reserves and resources of larger contractors.

## **12. Monitoring and Review**

12.1 The Department monitors the implementation of the Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation.

## **13. Contact**

Peter Dunlevy  
Department of Health  
453D Skipton House  
80 London Road  
London SE1 6LH

Telephone number 0207 972 2881 e-mail: [peter.dunlevy@dh.gsi.gov.uk](mailto:peter.dunlevy@dh.gsi.gov.uk)