EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) REGULATIONS 2012 (AMENDMENT) REGULATIONS 2012

2012 No. 2371

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. Purpose of the instrument

2.1 These Regulations make amendments to the National Health Service (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909) ("the 2012 Regulations") which came into force on 1st September 2012 to:

- restore rights of appeals included in the National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641 as amended) ("the 2005 Regulations") but not included in the 2012 Regulations;
- make it clear that members of limited liability partnerships are to be treated, for information providing purposes, in the same way as directors of bodies corporate; and
- correct the list of conditions that have to be met if a dispensing doctor is to dispense a repeatable prescription in Schedule 6 to the 2012 Regulations (terms of service for dispensing doctors).

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

3.1 This instrument has been made in consequence of defects in the 2012 Regulations. Because of this it is being issued free of charge to all known recipients of the 2012 Regulations.

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 (PCTs): arrangements for the provision of "pharmaceutical services", which are governed by the 2012 Regulations; and arrangements for the provision of "local pharmaceutical services", which are governed by the National Health Service (Local Pharmaceutical Services etc) Regulations 2006 (S.I. 2006/552, as amended) ("the LPS Regulations").

4.2 Under the 2012 Regulations, there are three types of "contractor" who may provide pharmaceutical services. Firstly, and in the majority of cases, these services may be provided by "pharmacy contractors" such as retail pharmacy outlets – and the companies, partnerships or individuals responsible for these businesses have to be on a pharmaceutical list kept by their local PCT. Secondly, a more limited range of pharmaceutical services may be provided by "appliance contractors", who also need to be on a PCT's pharmaceutical list and who dispense appliances (for example, incontinence aids, dressings, bandages etc.) but not medicines. Thirdly, dispensing services but not other pharmaceutical services may also be provided by "dispensing doctors". These are general practitioners who are able to dispense, generally speaking, to patients who live in designated rural areas a distance away from pharmacies, and who have to be on a dispensing doctor list kept by

their local PCT. The applications procedures for entry onto pharmaceutical lists are set out in Schedule 2 to the Regulations, which also includes provisions relating to rights of appeals against granted applications. Schedules 4 to 6 contain specific terms of service for contractors – a separate Schedule for each of the three types of contractor.

4.3 If a pharmacy contractor wishes to provide pharmaceutical services, the premises at or from which they provide those services, and which will be listed alongside them in the PCT's pharmaceutical list, have to be registered under Part 4 of the Medicines Act 1968. This sets out a threefold division of who may carry on a retail pharmacy business: individuals, partnerships and bodies corporate. The Department's view is that for the purposes of this registration requirement, limited liability partnerships are to be treated as bodies corporate rather than as partnerships and so limited liability partnerships have to meet the requirements in respect of bodies corporate rather than partnerships under that Part.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

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 Applications for inclusion of new pharmacy premises in pharmaceutical lists and for inclusion of new pharmacy contractors essentially fall into two categories, "routine applications" and "excepted applications". "Excepted applications" are applications, which do not have to meet the "market entry" test. In order to make a successful "routine application", an applicant has to fulfil a need or to secure improvements or better access identified in the PCT's pharmaceutical needs assessment (PNA), a local plan relating to the provision of pharmaceutical services, or prove an unforeseen benefit not identified in the PNA. If the routine application is for new premises in a rural area, there may be an additional requirement that the applicant may have to meet. For applications in certain rural areas (known as "controlled localities"), if the premises are not in a "reserved location" (which essentially are areas below a certain population threshold), applicants must also pass a "prejudice" test. The PCT must refuse the application unless it is satisfied that granting it would not prejudice the proper provision of "relevant NHS services", which are the NHS services of other chemists or of primary medical services providers (in the main, GP practices) in the area.

7.2 The 2012 Regulations replaced the the 2005 Regulations, with effect from 1st September 2012. Under the 2012 Regulations, providers of primary medical services and individual GPs on a PCT's dispensing doctor list could appeal a decision on "prejudice" that went against their interests, but this right of appeal was inadvertently left out of the 2012 Regulations. It has been restored, and with transitional arrangements to ensure that no provider or doctor loses out as a consequence of this inadvertent omission.

7.3 Providers of local pharmaceutical services under the LPS Regulations also had appeal rights against decisions to grant pharmacy applications, which were inadvertently left out of the 2012 Regulations, and these have also been restored – again with transitional arrangements to ensure that no provider loses out as a consequence of this inadvertent omission.

7.3 The 2012 Regulations require pharmacy and appliance contractors to send the PCT certain "fitness to practise" information – both with some applications to join pharmaceutical lists, and once they are on the list, when certain fitness to practise issues arise such as criminal convictions. In the case of pharmacy contractors, people can apply and be registered as individuals, partnerships or bodies corporate. However, the 2012 Regulations do not address a misunderstanding that has arisen about how members of limited liability partnerships (LLPs) should be treated. The 2012 Regulations are being amended to include a new definition of "director", which indicates that the term is to include members of LLPs. The Department is in effect ensuring that members of LLPs will be treated as directors of bodies corporate rather than as partners in partnerships for the purposes of the notification requirements relating to fitness to practise information under the 2012 Regulations.

7.4 The terms of service for dispensing doctors in Schedule 6 to the 2012 Regulations include a provision, which sets out the circumstances in which a dispensing doctor is entitled to dispense drugs or appliances ordered on a repeatable prescription. An amendment is being made to include the word "not" which was inadvertently omitted – this will correct the list of conditions that have to be met if a dispensing doctor is to dispense a repeatable prescription.

- ***Consolidation***

7.5 The Department intends that these Regulations will be included in a consolidated version of the 2012 Regulations, which it hopes will come into force on 1st April 2013, subject to parliamentary scrutiny.

8. Consultation outcome

8.1 Key stakeholders have been consulted on these amendments and are in agreement to this.

9. Guidance

9.1 The abolition of PCTs, expected to take place in 2013, will require the Department to revise the 2012 Regulations to coincide with that expected abolition. We will be discussing the issue of guidance on the 2012 Regulations and the Regulations that replace them with the NHS Commissioning Board Authority and the Local Government Association.

10. Impact

10.1 We have considered the impact of these amendments on the Market Entry Exit Impact Assessment which was published alongside the 2012 Regulations and consider no amendment is needed to them as these amendments do not impact on the overall policy.

11. Regulating small business

11.1 The Regulations apply to small businesses, including firms employing up to 20 people. As these Regulations concern the provision of NHS pharmaceutical services in England on the basis of nationally determined terms of service, it is not possible to differentiate between

contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practices in the provision of such services as part of the nationally determined contractual framework.

12. Monitoring & review

12.1 The Department monitors the implementation of pharmaceutical services Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation. The abolition of PCTs, expected to take place in 2013, will, in any event, require the Department to revise the 2012 Regulations to coincide with that expected abolition. This work is underway, with the support of an external Advisory Group.

13. Contact

13.1 Catriona Patterson at the Department of Health Tel: 0113 254 5780 or e-mail: catriona.patterson@dh.gsi.gov.uk. can answer any queries regarding the instrument.