EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) REGULATIONS 2012

2012 No. 1909

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 These Regulations replace the National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641, as amended) ("the 2005 Regulations") as the Regulations which govern the arrangements, in England, for the provision of pharmaceutical services under Chapter 1 of Part 7 of the National Health Service Act 2006 ("the 2006 Act"). These arrangements enable pharmacy contractors (such as retail pharmacy outlets), appliance contractors and dispensing doctors to provide, between them, a range of NHS community pharmaceutical services to patients.

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

3.1 The attention of the Joint Committee on Statutory Instruments is drawn to the fact that on a number of occasions the word "will" is used in these Regulations, although not in contexts where the Department's intention is that "will" should confer a duty or to specify an automatic outcome. Rather, the Department's intention has been to use "will" in constructions where some form of reference to the future is necessary and its use is therefore appropriate. It is used in regulations 13(3)(a) and (b), 15(2)(f)(i) and (3)(a) and (c), 17(3)(a) and (c), 20(2)(f) and (3)(a) and (c), 24(1)(e), (2)(f), and (3)(b)(iii), 26(1)(d) and (2)(e)(i) and (ii), 27(2)(a)(ii) and (iii), 28(3)(a), 42(3), 46(6)(a)(i) and (ii) and 82(2)(c), paragraphs 1(7)(a)(ii), 9(d), (i), (ii) and (iii) and 33(1)(a) and (b) of Schedule 2, paragraphs 5(2)(b)(ii) and (3)(b)(ii), 7(1)(a) and (b), 10(1)(e), 25(1) and (3) and 26(4) of Schedule 4, paragraphs 4(2)(b)(ii) and (3)(b)(ii), 6(1)(a) and (b), 9(1)(d), 15(1), 15(3) and 16(4) of Schedule 5, and paragraph 2(2)(b)(ii) and (3)(b)(ii) of Schedule 6 (as well as some occasions in the Explanatory Note). Where it is used three times in paragraph 9(d) of Schedule 2, it is in the context of giving an undertaking, and its use does have some semblance of guaranteeing an automatic outcome. However, the Department considers that the provisos (i.e. the services in question being commissioned and the service specifications being agreed) mean that the use of "will" in this context therefore remains appropriate. In paragraph 25(3) and 26(4) of Schedule 4, and 15(3) and 16(4) of Schedule 5, its use in the construction "will need" does make reference to a duty, but in the context of describing circumstances where a future obligation will arise, rather than, in the Department's view, the word "will" itself conferring the obligation.

3.2 Ministers have decided to proceed with these Regulations so that they can be brought into force as soon as practicable, albeit at a time when Parliament is not sitting. This is to ensure PCTs are able to deal with the majority of outstanding applications under the current regulatory regime (including any appeals) before their anticipated abolition in April 2013. Further information is in paragraph 12 below.

4. Legislative Context

4.1 The great majority of NHS 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" have been governed by the 2005 Regulations, which are replaced by these 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 Both historically under the 2005 Regulations and now under these Regulations, there have been and are three types of "contractor" who may provide NHS pharmaceutical services. Firstly, and in the great majority of cases, these services may be provided by "pharmacy contractors" such as retail pharmacy outlets. 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". They too also need to be on a PCT's pharmaceutical list. They only dispense appliances (for example, incontinence aids, dressings, bandages etc.) not medicines. Thirdly, dispensing services, but not other pharmaceutical services, may also be provided by "dispensing doctors". These are general practitioners who are authorised by PCTs to dispense to patients who live in designated rural areas a distance away from pharmacies. They have to be on a dispensing doctor list kept by their local PCT.

4.3. The replacement of the 2005 Regulations with these Regulations relates to the implementation of changes to the enabling powers in the 2006 Act for arrangements for the provision of pharmaceutical services, which have been made by sections 26 and 27 of the Health Act 2009 ("the 2009 Act"). These changes relate to pharmacy contractors and appliance contractors – not to dispensing doctors. The changes provide for new arrangements for entry of contractors or additional contractor premises onto pharmaceutical lists. Entry of businesses or premises onto these lists is now generally to be on the basis of a new market entry test based around needs or benefits identified in the PCT's "pharmaceutical needs assessment" (PNA).

4.4 Section 28 of the 2009 Act, which is also being implemented in parallel with these Regulations, further provides for a new quality and performance sanctions regime for contractors on pharmaceutical lists, but again not for dispensing doctors.

4.5 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. Apart from some minor and consequential amendments, the LPS Regulations are unaffected by these Regulations.

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 Amendments made to the 2005 Regulations in 2010 (by S.I. 2010/914) required PCTs to develop, publish and update PNAs. A PNA is the statement of the assessment each PCT must make of the needs in its area for community pharmaceutical services provided as part of the NHS by all types of contractor. The PNA must describe the population profiles and local characteristics as well as providing an assessment of unmet needs for, and possible improvements and better access to, pharmaceutical services provision in the PCT's area. The 2010 changes, which have been consolidated into these Regulations, were the first part of a three-part plan to reform key elements of the arrangements under which pharmaceutical services are provided by contractors on pharmaceutical lists. The second and third parts of that plan are implemented by these Regulations.

7.2 The first of the two main changes introduced by these Regulations is a change to the way pharmacy and dispensing appliance contractors or their additional premises are included on a PCT's pharmaceutical list. The "control of entry" test as set out in the 2005 Regulations, which was based on whether new premises were "necessary or expedient" for a particular neighbourhood, has been replaced by a new market entry test. This will enable PCTs to determine applications for new entries (or certain other applications such as subsequent relocations) to its pharmaceutical list by reference to its PNA. Inevitably, PCTs will not be able to foresee every need and benefit when they complete and publish their PNAs. Therefore, the Regulations also allow for applications to be approved where applicants can demonstrate, in specified circumstances, that their application will bring "unforeseen benefits". Taken as a whole, these new arrangements are intended to bring about the following improvements:

- decision-making based on local planning will help to secure effective commissioning of adequate services which address local priorities;
- the planning process will help stimulate the market by facilitating the identification of needs and benefits that are not currently being met or secured; and
- the new decision-making process will provide a more objective basis than the current regulatory system for determining whether or not to commission services or to expand existing provision.

7.3 The second of the two main changes introduced by these Regulations is to reform the arrangements for remedial actions that PCTs can take against pharmacy and dispensing appliance contractors who breach their contractual terms of service. In so doing, these Regulations replace the enforcement system under the 2005 Regulations (dating back to 1992) which was based on reference to a PCT's discipline committee. For the first time, arrangements for local dispute resolution become part of the pharmacy and dispensing appliance contractors' terms of service. However, where local dispute resolution is inappropriate or has failed, PCTs will be able to issue breach and remedial notices, similar to those which already exist in other areas of NHS primary care. These will formally draw breaches to contractors' attention, and in the case of remedial notices, require remedial action. In the context of pharmaceutical services provision, but in contrast to other areas of NHS primary care, these notices can also provide for payment withholdings. Ultimately, there is also the sanction of removal from PCTs' pharmaceutical lists, where this is necessary.

7.4 There are, however, important safeguards, both on the face of the legislation and in terms of rights of appeal, to ensure that this system works both proportionately and fairly.

7.5 It is important that PCTs have adequate powers to take proportionate but sufficient action where pharmacy and dispensing appliance contractors may not consistently perform to the same quality levels as are widely achieved and accepted within their professions. Similarly, PCTs should be able to take similar action where the quality of contractors in performing their responsibilities under their terms of service gives grounds for concern. This can happen, for example, if there are repeated minor safety incidents or risks which individually do not pose a serious or immediate risk to the public or to public health, but cumulatively may indicate that corrective action is required.

7.6 As well as introducing new provisions made possible by the 2009 Act, the opportunity has been taken as part of the consolidation exercise to review, with the support of an Advisory Group on the NHS (Pharmaceutical Services) Regulations (see next section), those parts of the 2005 Regulations that were being carried forward into the new scheme. An exercise of rationalisation and simplification has led to a wholesale redrafting of the substantive provisions of the Regulations, and some more minor reworking of the Schedules which contain the core terms of service for contractors. The changes that have resulted from this exercise include:

- simplification of the applications procedures, replacing preliminary and full approval with a single type of approval;
- simplification of the arrangements under which applications can be made which are exempt from the main control of entry or market entry test. Three of the four exemptions introduced in 2005 are removed, although the "distance-selling" exemption, derived from the package of control of entry changes made in 2005, is retained (with tightened conditions). As before, there are other exemptions to deal with issues such as change of ownership, although the exemptions to deal with relocations to nearby premises have been simplified so that there are no longer the concepts of "minor" and "major" relocations, just a single system based on the significance of the business move in terms of service planning and provision in relation to a PCT's PNA;
- clarification and some rationalisation of the procedures for taking fitness to practise action against pharmacy and appliance contractors – these supplement the provisions in Chapter 6 of Part 7 of the 2006 Act;
- clarification and some rationalisation of the arrangements for authorising dispensing in rural areas by dispensing doctors, and the arrangements under which pharmacy contractors may open up in competition with them; and
- a change to the enforcement arrangements of dispensing doctors' terms of service. These will now be enforced using the dispute resolution and enforcement arrangements in the terms of service of the dispensing doctor's contract to provide primary medical services to their registered patients. As a consequence of this and the changes mentioned in paragraphs 7.3 to 7.5, there will no longer be any role for discipline committees of PCTs, so those committees are abolished by these Regulations.

7.7. Cumulatively, the changes made in these Regulations align with the current Government's priorities for the NHS. The NHS White Paper (*Equity and excellence: Liberating the NHS)* published in July 2010 stated (para 3.22) that: "…the community pharmacy contract . . . will incentivise and support high quality and efficient services… Pharmacists, working with doctors and other health professionals, have an important and expanding role in optimising the use of medicines and in supporting better health."

7.8 These Regulations also contain consequential amendments to other legislation as well as an amendment to the National Health Service (Charges for Drugs and Appliances) Regulations 2000 (S.I. 2000/620, as amended)("the Charges Regulations") in relation to a key measure in

the Department of Health's public health emergency preparedness response. If medicines, drugs or appliances are ordered by a GP for dispensing under arrangements for the provision of either pharmaceutical services or local pharmaceutical services a charge is generally payable, subject to some exceptions. The Charges Regulations also contain charging arrangements and exemptions from charging that relate to other routes of NHS supply of medicines. It is essential that the supply of medicines is made without a prescription charge in exceptional circumstances, where a public health emergency has arisen that poses a wide scale risk to public health. This amendment enables this and the exemption can only be triggered by the Secretary of State making arrangements to supply the medicines free of charge.

- ***Consolidation***

7.9 These Regulations are themselves a consolidation.

8. Consultation outcome

8.1 As indicated above, the draft Regulations were developed with the support of an Advisory Group on the NHS (Pharmaceutical Services) Regulations. This Group, which also advised on the development of the proposals that led to the introduction of PNAs in 2010, met regularly between 2010 and 2012 to consider draft provisions when the Regulations were under development and to consider ancillary matters arising out of the implementation of the new Regulations. Members comprise representatives of patient groups, the NHS and pharmaceutical contractors. Papers for the Group's work are available on the Department's website at http://www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/RegulationsAdvisoryGroup/index.htm.

8.2 The proposals were also subject to full public consultation from 31 October 2011 to 25 January 2012. There were 164 written responses. A report on the consultation has been published - http://www.dh.gov.uk/health/category/publications/consultations/consultation-responses/.

9. Guidance

9.1 The Department, in partnership with the NHS and in consultation with a sub-committee of the Advisory Group mentioned in the previous section, also developed draft Guidance that accompanied the above consultation. Revised guidance for the NHS and contractors drawing on comments received following consultation has been published.

10. Impact

10.1 The final Impact Assessment estimates a net benefit of the new market entry and quality and performance sanctions system over 10 years of £952 million. The Impact Assessment can be found on the Department's website at http://transparency.dh.gov.uk/category/transparency/ias/ and is also available from the postal address at the end of this memorandum. The Impact Assessment will also be published alongside this memorandum on www.legislation.gov.uk

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 the Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation. The abolition of Primary Care Trusts, expected to take place in 2013, will, in any event, require the Department to revise these Regulations to coincide with that expected abolition. This work is underway, with the support of the Advisory Group referred to in Section 8.1 above.

13. Contact

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