EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) REGULATIONS 2013

2013 No. 349

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 2012 (S.I. 2012/1909, as amended) ("the 2012 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. The 2012 Regulations are being replaced by these Regulations to take account of the new NHS structure from 1 April 2013.

2.2 The Regulations also replace the Local Pharmaceutical Regulations 2006 (S.I. 2006/552, as amended)("the 2006 Regulations"), again to take account of the new NHS structure. Those Regulations governed the arrangements for the provision of local pharmaceutical services in England. Agreements to provide local pharmaceutical services, known as LPS schemes, are an alternative basis for the provision of NHS community pharmaceutical services to those mentioned in paragraph 2.1.

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 (b), 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, paragraph 2(2)(b)(ii) and (3)(b)(ii) of Schedule 6, and paragraphs 3(1)(b)(ii) and (2)(b)(ii), 5(1)(a) and (b), 8(c), 22(9)(b), 26(3)(b) and 31(5) of Schedule 7 (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 might appear to guarantee 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.

4. Legislative Context

4.1 NHS community pharmaceutical services in England are provided on the basis of one of two sets of standard arrangements with the NHS. As indicated above, arrangements for the provision of "pharmaceutical services" have been governed by the 2012 Regulations, and arrangements for the provision of "local pharmaceutical services" have been governed by the 2006 Regulations. Prior to 1 April 2013, the arrangements were made by Primary Care Trusts (PCTs), but as from 1 April 2013, these arrangements will become the responsibility of the National Health Service Commissioning Board ("the Board"), although the local plans outlining the needs and availability of NHS community pharmaceutical services in an area, which are known as pharmaceutical needs assessments (PNAs), will be developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs).

4.2 Both historically under the 2012 Regulations and now under these Regulations, there have been and are three types of "contractor" who may provide "pharmaceutical services" as opposed to "local 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. These used to be kept by PCTs and will now be kept by the Board. Secondly, a more limited range of pharmaceutical services may be provided by "appliance contractors". They too will also need to be on the Board's pharmaceutical lists. 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 currently authorised by PCTs, and in future will be authorised by the Board, to dispense to patients who live in designated rural areas a distance away from pharmacies. Under these Regulations, they will have to be on a dispensing doctor list kept by the Board.

4.3. The Health and Social Care Act 2012 ("the 2012 Act") provided both for the abolition of PCTs and for the establishment of the Board. It is by virtue of amendments made by that Act to the 2006 Act that the Board has become responsible for arrangements for the provision of pharmaceutical services.

4.4 There have been and remain two forms of contract for the provision of "local pharmaceutical services". The 2006 Regulations contained an alternative, less prescriptive set of arrangements for the provision of NHS community pharmaceutical services to the listing arrangements described in paragraph 4.2. This is a contractual framework, and most of the terms of the contracts are for local negotiation. However, there have also been some common standard terms and conditions set out in the 2006 Regulations. The other type of arrangements for the provision of local pharmaceutical services are the arrangements for "pilot schemes". These arrangements are subject to directions given by the Secretary of State, and the current pilot schemes are arrangements for the provision of what are known as "Essential Small Pharmacies".

4.5 It is also by virtue of amendments made to the 2006 Act by the 2012 Act that the Board has become responsible for commissioning all local pharmaceutical services – both the arrangements covered by the 2006 Regulations and the pilot schemes.

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 The NHS (Pharmaceutical Services) Regulations 2012 came into force on 1 September 2012. These introduced a new market entry regime based on PNAs administered by PCTs as well as a new performance sanctions regime. As part of the NHS reforms under the 2012 Act, responsibilities for the development and updating of PNAs passes to local authority HWBs and responsibility for administering the rest of the arrangements or providing pharmaceutical and local pharmaceutical services passes to the Board.

7.2 The key changes to the 2012 Regulations are:

- requiring PNAs to be developed and published by HWBs of local authorities. Pending the publication of the first HWB PNA, there are transitional arrangements extending the PNAs of PCTs;
- a timetable is set for HWBs to produce their first PNAs. There is a backstop date of 1st April 2015, but HWBs will be under an obligation to make a revised assessment as soon as reasonably practical, once they have identified significant changes to local needs;
- simplification of the matters to be taken into consideration when producing PNAs;
- the Board is to take over responsibility for pharmaceutical lists and dispensing doctor lists from PCTs. This means that it will become responsible for dealing with applications for market entry in England, and the related matters such as determining controlled localities (areas that are rural in character, where potentially services may be provided by dispensing doctors) and reserved locations (areas around pharmacies in places with a low population density where potentially services may be provided by both dispensing doctors and pharmacy contractors);
- when dealing with applications for market entry by pharmacy contractors and appliance contractors, unlike PCTs, the Board will have discretion where a PNA identifies a need for services. It will not be obliged to fill that gap as there will be other factors it needs to take into account;
- there are new arrangements allowing for contractors to relocate on a temporary basis for up to a year where there has been a temporary suspension in the provision of services for a reason (for example, fire or flooding) that is beyond the control of the contractor;
- the Board to take over from PCTs the responsibility for fitness to practise matters relating to pharmacy contractors and appliance contractors. As regards dispensing doctors, these issues are dealt with under the arrangements for the provision of primary medical services that need to be in place if dispensing services are to be provided by doctors;
- as regards fitness to practise matters, there are updated arrangements arising from the end of the “home PCT” principle that allowed some contractors only to submit fitness

information once, to a single PCT. With a single Board now taking over all commissioning of pharmaceutical services, this principle can be extended more widely, reducing the occasions on which contractors and potential contractors will need to submit the same fitness information on more than one occasion;

- there are provisions about the internal handling of fitness information by the Board to ensure that access is strictly on a need to know basis; and
- although the Secretary of State will remain responsible for the reimbursement costs relating to products dispensed as part of community pharmaceutical services, the Board will become responsible for service remuneration. This has led to some new obligations relating to how remuneration is determined and the data collection that underpins some decisions.

7.3 The opportunity has been taken, to consolidate all the regulations relating to pharmaceutical and local pharmaceutical services into a single instrument. This has allowed for some standardisation, for example in relation to definitions, and it is anticipated that it could facilitate further standardisation in the future.

7.4 We are also specifically amending pharmacy contractors, dispensing appliance contractors' and LPS contractors' terms of service in order to:

- require community pharmacy contractors to co-operate with Health Education England duties in relation to planning education and training for their workforces;
- ease the restrictions on the arrangements for supply of methadone, to allow for greater application of clinical judgement;
- allow contractors to refuse to supply drugs and appliances if the prescription does not include the necessary information to allow for costs to be recharged in the appropriate way. This change does not affect the long standing arrangements for urgent supply without prescription;
- where there is a change of ownership of contractors using the electronic prescription service, require the new owner to ask patients who use the service if they want to maintain their nomination of that location as their nominated dispenser. This will have to be done within six months of the new contractor taking over.

These service changes are part of the regular updating of the terms of service, reflecting both experience of contractors and users of the services and the need for the services to be as cost effective as possible.

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- ***Consolidation***

7.5 These Regulations consolidate the NHS (Pharmaceutical Services) Regulations 2012, amended by the NHS (Pharmaceutical Services) Regulations 2012 (Amendment) Regulations 2012 and the NHS (Local Pharmaceutical Services etc.) Regulations 2006, as amended on a number of occasions.

8. Consultation outcome

8.1 The draft Regulations were developed and amended with the support of an Extended Advisory Group. This Group, which also advised on the development of the proposals that led to the introduction of the 2012 Regulations, was extended to include representatives of

local government and the Board. Members also comprised representatives of patient groups, the NHS and pharmaceutical contractors. Papers for the Group's work are available on the Department's website at http://transparency.dh.gov.uk/category/minutes-2/pharmaceutical-services-regulations/

8.2 The 2012 Regulations were 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/. We therefore only carried out a limited consultation on these draft Regulations between December 2012 and January 2013 with the major stakeholders. All the major stakeholders responded to the short consultation and were content with the draft Regulations concerning PNAs, market entry by means of PNAs and the transfer of functions to HWBs and the Board.

8.3 NHS Employers expressed a concern that it was likely some existing PNAs will be out of date fairly quickly and given the deadline for HWBs first PNAs of 1 April 2015, this could weaken the NHSCB's ability to manage applications. Whilst this could to be the case, the Department was no persuaded that this is likely to become a problem for the NHSCB. There is also nothing to stop HWBs publishing their PNAs earlier. Indeed, we would expect them to issue interim supplementary statements on any changes to services identified as soon as possible after April 2013. NHS Employers also commented that we did not define "pharmaceutical services". This is deliberate as Section 126 of the NHS Act 2006 defines "pharmaceutical services" and it is not necessary to restate that definition in the 2013 Regulations.

8.4 The PSNC made comments on aspects of the Schedules to the 2013 Regulations, in particular pharmacists' terms of service. We have made provision to allow local authorities and CCGs to commission services that use NHS prescriptions, dispensed under NHS pharmaceutical services, to supply medicines to patients. This arrangement already exists for hospitals. We have made changes to the terms of service to enable the proper recharging of the costs of pharmaceutical services and to ensure the NHSCB does not end up meeting costs that rightly fall to other commissioners. In agreement with PSNC, we have amended the terms of service so that contractors are given the option to dispense or not if the information necessary for correct recharging is missing. Alongside this, it is anticipated that the payment arrangements in the Drug Tariff will allow a prescription submitted with the information missing to be returned to the contractor who would then be expected to seek out and supply the missing information. However, if after a suitable period the information could not be identified then the prescription would be resubmitted for payment. We have agreed that we with the NHSCB will consider whether to revisit these provisions once information about the scale of the potential problem of missing recharging information is available.

8.5 We will be formally responding to NHS Employers and PSNC's comments.

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 guidance for the NHS and contractors alongside the 2012 Regulations. This guidance is being revised for the use of the Board and an information pack is being produced for local authority HWBs.

10. Impact

10.1 These Regulations are being laid as a consequence of changes brought by the Health and Social Care Act. The impact was considered during the passage of the Health and Social Care Bill and conclusions published in that Impact Assessment - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583

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 community pharmaceutical services in England on the basis of what is, in all cases at least in part, 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.

13. Contact

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