EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT AND TRANSITIONAL PROVISION) REGULATIONS 2014

2014 No. 417

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 (JCSI).

2. Purpose of the instrument

2.1 These Regulations make amendments to the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349) ("the 2013 Regulations") which set out the overarching national legal framework and most of the contractual requirements in England for the provision of NHS community pharmaceutical services, such as the dispensing of NHS prescriptions. The changes affect the arrangements under the 2013 Regulations for entry to this NHS market and relocation of the most numerous types of service providers, and the contractual conditions under which some of those service providers are required to operate.

2.2 The 2013 Regulations carried forward changes to that legal framework and the contractual conditions introduced under the National Health Services (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909, as amended), in force from 1st September 2012 until 31st March 2013, and amalgamated these with the National Health Service (Local Pharmaceutical Services) Regulations 2006 (S.I. 2006/552, as amended), the provisions of both of which were revised to ensure they were fit for purpose in the new NHS architecture in place in England from 1st April 2013.

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

3.1 This instrument includes amendments that relate to criticisms of the Department made by the Committee in its Fourth Report of Session 2013-14. In that Report, the Committee reported regulation 34(1) of the 2013 Regulations for defective drafting. As a consequence, the Department has made amendments to correct the defective drafting which it acknowledged. However, it has reviewed regulation 34 and has also made other changes which go beyond a correction. These changes are explained in paragraph 7.7 below.

3.2 Appendix 1 of that Report included a memorandum from the Department on a point raised by the Committee in relation to regulations 17(1) and 20(1) of the 2013 Regulations. In paragraph 7 of the memorandum, the Department indicated that it considered that the same point also arose in relation to regulations 13(1) and 15(1). Although the Committee did not report the Department for the drafting of regulations 17(1) and 20(1), the Department has decided, in all four cases, to adopt the improvements to which the Committee's point alluded.

3.3 Because these Regulations include a significant number of provisions that correct errors in the 2013 Regulations, the Department has concluded that it is appropriate in this instance to apply the free issue procedure.

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. Both sets of arrangements – for the provision of "pharmaceutical services" and for the provision of "local pharmaceutical services" – are governed by the 2013 Regulations. These arrangements are the responsibility of the National Health Service Commissioning Board ("the Board", known as NHS England), 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), are developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs). HWBs took over this responsibility following the abolition of NHS Primary Care Trusts with effect from 1st April 2013.

4.2 There 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 and individuals responsible for these businesses have to be on pharmaceutical lists, which are compiled and kept by the Board by reference to the location of the premises in relation to areas of HWBs. Secondly, a more limited range of pharmaceutical services may be provided by "appliance contractors". They too need to be on the Board's pharmaceutical lists. Thirdly, dispensing services, but not other pharmaceutical services, may be provided by "dispensing doctors" to patients in designated rural areas, under certain conditions and provided they too are listed on the Board's relevant dispensing list.

4.3 The changes in these Regulations relate to the market entry and relocation arrangements for pharmacy contractors and appliance contractors, and to the terms of service of sub-groups of those contractors and to a specific matter concerning applications in designated rural areas.

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 changes in regulations 3, 4, 5, 7, 9(a), 17(a) and (b) and 20 are all purely drafting changes with no policy implications.

7.2 The 2013 Regulations are based on a market entry test, originally introduced on 1st September 2012, the effect of which is that applicants applying to be included on a pharmaceutical

list are required to meet a need for, or secure improvements or better access to, pharmaceutical services with reference to the relevant HWB PNA. There are two exceptions to this. The first is an "unforeseen benefits application", where applicants need to prove that their new pharmacy or service would meet a need not foreseen when the PNA was drawn up – such as services for a specific group of patients or the public or an innovative service. The second is an "excepted application". This is a group of different types of application including applications for wholly mail order or internet pharmacies (known as "distance-selling pharmacies"), applications to move an existing pharmacy to another location where there is no significant change to local service provision, and change of ownership applications, etc.

7.3 The market entry arrangements are relatively new and some of the changes arise out of the early experience of the Board, the Appeals Unit at the NHS Litigation Authority and others involved in operating them. As regards unforeseen benefits applications, a clarification has been introduced to make it clear that particular regard need only be had by the Board to one of three desirable characteristics for such applications, listed in the Regulations (i.e. reasonable choice, supporting innovation, and improving access for people who may face discrimination), and not to all three, when considering such applications. This is to enable greater use of this type of application and to improve the Board's discretionary decision-making powers. Similarly, a change is made to allow for greater use to be made of the "excepted application" that allows for relocations to be made where there is no significant change to service provision locally, where detriment to proper planning is an issue. Both these changes support market flexibility.

7.4 Experience has also shown that distance-selling pharmacies may seek to relocate or to change ownership using forms of "excepted application" that were not specifically tailored for them. Changes are made, in the interests of maintaining a level playing field in the market, so that all applications that relate to distance-selling premises have to meet the same general conditions (which include not applying to be on the same site as a GP practice with an NHS patient list) – and also so that, generally speaking, all distance-selling premises have to comply with the same terms of service (which include not actually being on the same site as GP practices with NHS patient lists). A transitional provision has been put in place to ensure that distance-selling pharmacies that may have received approval to relocate or have relocated to the same site as a GP practice with an NHS patient list before the changes come into effect do not have to reapply or to close because of these new conditions.

7.5 Also, the Department has been advised that, because restrictions on operating two pharmacies on the same site did not apply to all types of application, or in certain situations after the grant of an application, this was creating or could create future market distortions. These distortions have been removed. A provision that limited the effect of a designation of an area as an area for the provision of local pharmaceutical services has also been amended to prevent potential market distortion.

7.6 Experience of the operation of the 2013 Regulations has also shown that the arrangements requiring the refusal of applications for new pharmacies in certain rural areas for a period of five years after the refusal of an application for a new pharmacy, a rule designed to protect the interests of dispensing doctors, have also created the potential for market manipulation and 'gaming'. Two changes are made to prevent this. Firstly, it is made clear that the refusal of new applications within an existing 'five year rule' period does not restart the five year 'clock'. Secondly, the Board is allowed to not start that 'clock' if it is satisfied that the application that would otherwise start a five year period running was motivated wholly or partly by a desire for the application to be refused.

Together these changes allow for the continuing protection of the legitimate interests of dispensing doctors, whilst ensuring that the potential for market manipulation is removed and that the market remains open to new entrants where appropriate.

7.7 The opportunity has also been taken to end a long standing anomaly, by virtue of which the arrangements for refusing or deferring applications for inclusion in a pharmaceutical list on fitness to practise grounds only applied to applications from individuals or bodies corporate but not to applications from partnerships where there are fitness to practise concerns about any of the partners. Refusal or deferment is now possible where such concerns arise, in the interests of public protection as well as ensuring a level playing field as between different types of applicant.

7.8 The common themes of ensuring market flexibility and ensuring a level playing field for current and potential providers of services, and preventing market distortions, characterise the bulk of the changes in these Regulations. The changes are, in practice, relatively small in scale so as to enhance effective implementation and allow these relatively new arrangements sufficient time to 'bed down' successfully.

7.9 There are also two amendments to take account of the anticipated abolition of the NHS Direct National Health Service Trust from 1st April 2014. Where a pharmacy or an appliance contractor supplies certain types of specialist appliance and provides a telephone care line for patients, then the contractor must ensure outside normal business hours that the care line provides advice for patients or gives contact details for NHS Direct. Contractors now have to provide contact details via those care lines for alternative sources of NHS advice. Essentially this is to ensure that advice is available to patients who use these appliances and are unable to contact the suppliers.

- ***Consolidation***

7.10 As these changes are relatively small in scale, there are no plans to consolidate the 2013 Regulations at present.

8. Consultation outcome

8.1 We customarily give key representative organisations, the Pharmaceutical Services Negotiating Committee (PSNC), the British Medical Association (BMA), the Dispensing Doctors' Association (DDA) and the British Healthcare Trades Association (BHTA) an opportunity to comment on draft amendment Regulations of this sort. We advised these organisations in late 2013 of the impending amendments, and subsequently formally invited their views (with the exception of those related to the abolition of NHS Direct) in January 2014 and gave them three weeks to respond, which is the customary, agreed period for consultations of this nature.

8.2 These representative organisations were in broad agreement with the draft Regulations. The PSNC, in their response, also asked for several clarifying amendments to be made to the 2013 Regulations to cover the inclusion of notifications of changes of address in paragraph 31 of Schedule 2 of the 2013 Regulations and suggested other minor amendments to the draft Regulations. We have either accepted their suggestions or will look to cover them by revising the supporting guidance referred to in paragraph 9.1 below. The Department also consulted the Board, who queried the amendment of regulation 40 of the 2013 Regulations, which will again lead to revision of that guidance.

9. Guidance

9.1 As well as amending the 2013 Regulations, we will also revise the guidance for NHS England, published on 8th November 2013 - *NHS pharmaceutical services: assessing applications* - in response to the comments from various stakeholders. This is available at https://www.gov.uk/government/publications/nhs-pharmaceutical-services-assessing-applications. The Department intends to update this by the date these amendments come into force.

10. Impact

10.1 We have considered the impact of these amendments in relation to the original Impact Assessment published alongside the 2012 Regulations. This is available at http://www.legislation.gov.uk/uksi/2012/1909/impacts. Copies may also be obtained by writing to Gillian Farnfield, Department of Health, Room 453D Skipton House, 80 London Road, London SE1 6LH. We have not identified any significant quantifiable costs or benefits arising from these changes and therefore consider no amendment is needed to that Impact Assessment. Similarly, we have not identified, having had due regard to the relevant duties of the Secretary of State, any substantial impact as a result of these modest changes on those duties or the policy positions that underpin the 2013 Regulations. We keep these matters under regular review as set out in paragraph 12 below and will revisit our assumptions if new evidence emerges, for example, of further quantifiable costs or benefits.

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 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 and efficient operation of the 2013 Regulations and has regular discussions with interested parties including the NHS and contractors' representatives mentioned in paragraph 8.1 above on any problems identified.

13. Contact

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.