EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT AND TRANSITIONAL PROVISION) REGULATIONS 2015

2015 No.58

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 make amendments to the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349) ("the 2013 Regulations") as amended. The 2013 Regulations 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 the NHS market and relocation of the most numerous types of service providers; and the contractual conditions under which most service providers are required to operate.

2.2 The most significant changes, from a practical perspective, are new service requirements relating to repeat dispensing and to the audits undertaken by pharmacy contractors as part of their clinical governance systems.

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

3.1 There are no matters of special interest for the JCSI in these Regulations.

4. Legislative Context

4.1 The 2013 Regulations carried forward changes to the legal framework and the contractual conditions introduced under the National Health Services (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909) in force from 1st September 2012 and amalgamated these with the National Health Service (Local Pharmaceutical Services) Regulations 2006 (S.I. 2006/552) to ensure both were fit for purpose in the new NHS architecture in place in England from April 2013.

4.2 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" (LPS) - 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), 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 from 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 are required to be on pharmaceutical lists, which are compiled and kept by the Board by reference to the location of the premises in relation to the area of an HWB. 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.

4.3 The changes in these Regulations relate to the market entry arrangements for pharmacy contractors and to the terms of service of those contractors and of LPS contractors.

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 the 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 to regulations 25, Schedule 2 and Schedule 3 of the 2013 Regulations are essentially drafting changes with no policy implications – they help clarify the regulations and ease implementation. The change made to regulation 32 corrects an error introduced into the 2013 Regulations by an amendment made by the National Health Service (Pharmaceutical and Local Pharmaceutical Services (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417) ("the 2014 Regulations"). The intention behind regulation 11 of the 2014 Regulations, as explained in the Explanatory Note to those Regulations, was to amend Regulation 32 of the 2013 Regulations so that the designation of an area or premises under Part 13 of the Regulations – which is a potential preliminary for a tendering exercise for a contract to provide local pharmaceutical services – would act as a ground for deferring all types of routine pharmaceutical list applications in the area or the premises covered by the designation – not just some types of routine application, as had previously been the case. Inadvertently, "may be deferred" became "must be refused", and this has now been corrected.

7.2 The changes to pharmacy contractors' terms of service arise out of negotiations on the *Community Pharmacy Contractual Framework (CPCF).* Following a negotiated settlement between the Board and the Pharmaceutical Services Negotiating Committee (PSNC), as a service enhancement the Board wish to require pharmacy contractors to support the uptake of the repeat dispensing service by informing patients of the benefits of the service. Also, currently, a pharmacy contractor must undertake two clinical audits each year – one, which is determined by the pharmacy and one specified by the Board. The Board have sought flexibility in the Regulations to allow them to vary the Board specified audit so that it is to be either one of a clinical nature, as per the current arrangements, or a policy based audit, which

is to support the development of the commissioning policies of the Board. These require two separate amendments to the Regulations.

7.3 *Local Pharmaceutical Services contract disputes* – providers of services under the statutory arrangements governing the provision of LPS may choose to be a "health service body" and so for their contract to be an NHS contract – and if they do, they may also choose to cease to be such a body and so for their contract to cease to be an NHS contract. The difference between the two types of contracts is in the dispute resolution arrangements. Disputes between bodies that are health service bodies under NHS contracts have to be resolved via the dispute resolution procedure operated by National Health Service Litigation Authority (NHSLA), rather than via the courts.

7.4 If an LPS contractor that has been a "health service body" decides to stop being a health service body, the Board must agree to that request and vary their contract accordingly. However, at the time of the variation, there may be outstanding disputes between the parties relating to the time when the contract was an NHS contract, or such disputes may emerge later.

7.5 In the case of *NHS England v Bargain Dentist.Com and others* [2014] EWHC 1994(QB), the court determined, in terms, that the relevant legislation governing contracts for NHS dental services, which contains similar provisions on this issue, did not allow for litigation in court about alleged liabilities for breaches of a contract that predated its variation from an NHS contract to a non-NHS contract.

7.6 An implication of this judgement is that if a LPS contractor owes NHS England money under an NHS contract (e.g. because of overpayments), and the contract is varied so that it is a non-NHS contract, the Board can only initiate proceedings to recover that money after the variation has taken effect with the contractor's consent. This is an anomaly that these Regulations seek to rectify.

7.7 The changes provide, in terms, that following the variation of an NHS contract to a non-NHS contract, the LPS contractor is still to be regarded as a "health service body", and accordingly the contract is to continue to be regarded as an NHS contract, for the purposes of all disputes that relate to the pre-variation period. Additionally, the Board is given the right post variation to refer disputes that relate to the time when the contract was an NHS contract to the NHSLA for determination. In this respect, NHS England is now on the same footing as the LPS contractor.

7.8 There is a significant risk to the public purse if NHS England is unable to recover money owed under an LPS contract simply because it has been required to vary the contract so that it becomes a non-NHS contract but, for whatever reason, has NHS England has not commenced proceedings for recovery of the money before it does so.

7.9 A transitional provision has been included to ensure that any pipeline cases that are already the subject of court proceedings are not affected by this change.

- ***Consolidation***

7.4 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 General Practitioners' Committee of the British Medical Association (BMA) and the Dispensing Doctors' Association (DDA) an opportunity to comment on the draft amendment regulations. We did not include representatives of dispensing appliance contractors (DACs) on this occasion as these amendment regulations are not relevant to them. We also customarily consult the Board, particularly as they lead on negotiations on the CPCF. We formally invited the views of these organisations in December 2014 and gave them three weeks to respond, which is the usual period given for responses.

8.2 All of these bodies indicated they were content with the proposed amendment regulations. However, further suggestions for clarifying the regulations were received from the NHSLA whom we also briefed on the changes and we have revised the final regulations to take account of their suggestions.

9. Guidance

9.1 As well as amending the 2013 Regulations, we will also amend the *Information for NHS England on the 2013 Regulations* when possible. This is available at https://www.gov.uk/government/publications/nhs-pharmaceutical-services-assessing-applications

10. Impact

10.1 We have considered the impact of these amendments in relation to the Impact Assessment published alongside the 2012 Regulations. 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 any substantial impact as a result of these modest changes on the policy positions that underpin these 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.

10.2 The General Public Sector Equality Duty is not simply limited to eliminating, discrimination, harassment and victimisation but also includes positive obligations to promote equality of opportunity and to foster good relations between those who are likely to suffer discrimination and those who are not. When making legislation, Ministers are obliged to have due regard to all aspects of this duty. We have not identified any specific equalities issues. We have also considered the impact of the Secretary of State's general duties under the NHS Act 2006, for example in relation to promoting autonomy and the duty in regard to improvement in the quality of services. Again, there are no specific issues. However, we consider that the proposed changes will bring benefits in terms of fairer and more effective decision-making, through, for example, the removal of potentially uncompetitive or market-distorting loopholes.

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 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

Gillian Farnfield at the Department of Health Tel: 0208 527 4532 or e-mail: gillian.farnfield@dh.gsi.gov.uk can answer any queries regarding the instrument.