EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2016

2016 No. 296

1. Introduction

1.1 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 in England for the provision of NHS community pharmaceutical services, which include the dispensing of NHS prescriptions. The changes mainly affect the terms of service of community pharmacists under the Community Pharmacy Contractual Framework (CPCF). They include new requirements relating to the use of summary care records and to the advice to be given where entitlement to non-payment of NHS prescriptions is claimed but evidence of entitlement is not supplied.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 The 2013 Regulations carried forward changes to the legal framework introduced by 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 schemes 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"). The Board and HWBs took over these responsibilities following the abolition of NHS Primary Care Trusts from April 2013.

4.3 Under Sections 28 to 32 of the Small Business, Enterprise and Employment Act 2015, Ministers are required to ensure that new regulatory provisions affecting businesses and voluntary or community bodies generally include a review provision that requires them to publish a report setting out the conclusions of a review of the new provisions within five years of the legislation coming into force, and on a five year cycle thereafter (starting from the date of the publication of the most recent report). The report must contain an assessment of the extent to which the original objectives of the new provisions have been achieved, whether they remain appropriate, and (if so) whether they could be achieved in a less burdensome way.

5. Extent and Territorial Application

5.1 This instrument extends only to England.

5.2 This instrument applies only to England.

6. European Convention on Human Rights

6.1 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 Regulation 75 - regulation 75 relates to the removal of premises or a contractor from the pharmaceutical list as the result of a relocation that does not result in a significant change. The changes made to Regulation 75 correct 2 cross-references and do not have any policy implications.

7.2 Point of dispensing checks – the Board is responsible for the commissioning of NHS pharmaceutical services in England and for negotiating changes to arrangements for the provision of services with the Pharmaceutical Services Negotiating Committee (PSNC), a representative body of pharmacy and LPS contractors. The changes to pharmacy contractors' terms of service with regard to point of dispensing checks arise out of a negotiated settlement between the Board and the PSNC with which Ministers concur. As a service enhancement, it has been agreed that pharmacy contractors are to be required to point out to patients, who claim exemption from prescription charges but who do not provide the required evidence, that the NHS routinely checks claims for exemption and takes action whenever inappropriate claims are made. This is part of an ongoing programme of work to help bring about a reduction in prescription fraud.

7.3 Access to the Summary Care Record - A summary care record (SCR) is a centrally held electronic record containing key clinical information including a patient's medication, known allergies and any adverse reactions to medication. At the end of March 2015, over 94% of the population of England have an SCR available to be viewed by care professionals 24 hours a day, seven days a week. Subsequent to a successful pilot, the Government announced in summer 2015 that professionals working in community pharmacies would be given access to a patient's SCR.

7.4 The Board and PSNC have reached an agreement about the use of SCR by community pharmacies with which Ministers concur. Access to the SCR is not a service in itself: it is a tool which pharmacists and pharmacy technicians may use to provide a safer more efficient pharmaceutical service. It is recognised that pharmacy professionals may access the SCR when providing NHS services generally – pharmaceutical services as well as local authority commissioned public health services. However, the Board are keen that pharmacists and pharmacy technicians take advantage of their ability to refer to it when providing pharmaceutical services and so use of SCRs, where this accords with the professional clinical judgement and the relevant NHS guidance, is made a requirement of pharmacy and LPS contractors' terms of service.

7.5 Review – the review clause in the 2013 Regulations has been amended to align it with the duties in the Small Business, Enterprise and Employment Act 2015. Although secondary legislation with existing review provisions is exempt (section 28) we consider it is useful to follow the Act's approach, particularly in relation to reviewing the Regulations at least every five years and what should be involved in those reviews.

Consolidation

7.6 These changes are relatively small in scale and there are no plans to consolidate the 2013 Regulations at present.

8. Consultation outcome

8.1 We customarily give key representative organisations, the PSNC, the General Practitioners' Committee of the British Medical Association (BMA) and the Dispensing Doctors' Association (DDA) an opportunity to comment on draft regulations amending the 2013 Regulations. We have only involved the PSNC on this occasion as these amendment regulations are not relevant to the other organisations. We also customarily consult the Board, particularly as they lead on negotiations on the CPCF. The Board is content with the Regulations.

9. Guidance

9.1 There are no plans to produce guidance.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies.

10.2 There is no impact on the public sector.

10.3 An Impact Assessment has not been prepared for this instrument.

10.4 We have considered the impact of the market entry amendment 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.

10.5 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. A reduction in prescription charge fraud should bring financial benefits to the NHS and increased use of SCRs should help improve the quality of NHS services. People who share some protected characteristics (e.g. the elderly and the disabled) are more likely to use NHS pharmaceutical services compared to the population at large and so service improvements may benefit them particularly. Their greater use of NHS services may also mean they are more aware of the changes than the population at large, particularly as both changes will mean greater interaction between pharmacy professionals and some patients. However, as regards prescription charges, people exempt by way of age do not have to provide evidence of entitlement because of the inclusion of their date of birth on the prescription is sufficient, so the additional fraud checks will not affect them.

10.6 When exercising his functions in relation to the NHS, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS. It is important to emphasise that this duty is separate from the Public Sector Equality Duty, and is about a need to reduce inequalities that may or may not be based on protected characteristics. Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation. As mentioned above, reduction in prescription charge fraud should bring financial benefits to the NHS and increased use of SCRs should help improve the quality of NHS services. Some causes of social deprivation may be linked to an increased use of NHS pharmaceutical services compared to the population at large, so service improvements may benefit people affected by these causes particularly. Their greater use of NHS services may also mean they are more aware of the changes than the population at large, particularly as both changes will mean greater interaction between pharmacy professionals and some patients. For example, those eligible to prescription charge exemption also include people on low income, but the impact on them of being better informed about NHS checks of claims for exemption from prescription charges is not in the Department's view a disproportionate burden.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses.

11.2 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 nationwide 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

13.1 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.