

EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES, CHARGES AND PRESCRIBING) (AMENDMENT) REGULATIONS 2016

2016 No. 1077

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before the House of Commons 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 amendments create a new type of application, designed to facilitate business consolidations, in relation to the National Health Service Commissioning Board’s lists of approved providers of NHS community pharmaceutical services.
- 2.2 These Regulations also make amendments to the 2013 Regulations, National Health Service (Charges for Drugs and Appliances) Regulations 2015 (SI 2015/570) (“the Charges Regulations”), as amended, the National Health Service (General Medical Services Contracts) 2015 (S.I. 2015 No. 1862) (“the GMS Regulations”), as amended, and the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015 No. 1879) (“the PMS Regulations”), as amended, in respect of therapeutic radiographer independent prescribers and dietitian supplementary prescribers. These amendments enable providers of NHS community pharmaceutical services to dispense against NHS prescriptions issued by these new types of prescriber.
- 2.3 These Regulations also make amendments to the Charges Regulations to allow providers of pharmaceutical and local pharmaceutical services who undertake emergency supplies of medicines at the request of a patient as an additional service to levy prescription charges. A requirement in the 2013 Regulations that providers of pharmaceutical services publicise such arrangements is removed.

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 and the contractual conditions introduced under the National Health Service (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909), as amended, in force from 1st September 2012, and amalgamated these with the National Health Service (Local Pharmaceutical Services) Regulations 2006 (S.I. 2006/552), as amended, to ensure both were fit for purpose in the new NHS architecture in place in England from 1st April 2013.
- 4.2 NHS pharmaceutical services in England are provided on the basis of two sets of standard arrangements with the NHS. Both sets of arrangements – for the provision of “pharmaceutical services” and 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 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 from 1st April 2013.
- 4.3 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 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 pharmaceutical lists compiled and kept by the Board by reference to the location of the premises in the area of an HWB. Thirdly dispensing services, but not other pharmaceutical services, may be provided by “dispensing doctors” to patients in designated rural areas, under certain conditions.
- 4.4 Potential pharmacy contractors seeking entry into a pharmaceutical list, or pharmacy contractors seeking inclusion in relation to premises other than those already listed in relation to them, are subject to the “market entry” test in section 129(2)(c) of the 2006 Act, which is a test applied to “routine applications” and requires the Board to consider the ability of the applicant, having regard to the relevant PNA, to meet pharmaceutical services needs or provide improvements or better access. However, some applications are exempt from the specific requirements of this test, such as change of ownership applications, and the provision made for such “excepted applications” is in Part 4 of the 2013 Regulations.
- 4.5 Most primary medical services in England are provided on the basis of one of two forms of standard contract between general practices and the Board: a General Medical Services (GMS) contract or Personal Medical Services (PMS) agreement. A number of standard terms and conditions are set out in two sets of Regulations: the GMS Regulations and the PMS Regulations. These Regulations specify the terms under which a person, prescriber or health care worker may prescribe and dispense drugs, medicines and appliances under the relevant contract agreement.

- 4.6 The Charges Regulations provide for charges to be made and recovered for the supply of certain drugs, appliances, wigs and fabric supports, and provide for certain exemptions from charging in prescribed circumstances.

5. Extent and Territorial Application

- 5.1 This instrument extends to England.
5.2 This instrument applies to England.

6. European Convention on Human Rights

- 6.1 The Parliamentary Under-Secretary of State for Community Health and Care has made the following statement regarding Human Rights:
6.2 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 *Consolidation onto an existing site* – the amendments to the 2013 Regulations insert a new type of “excepted application” in relation to pharmaceutical lists. Two different commercial operators may decide to combine the retail pharmacy businesses carried on a different sites – or a single operator that has more than one pharmacy may decide to combine the retail pharmacy businesses carried on at two or more pharmacies onto a single site – and the current provisions of the 2013 Regulations already allow for this. In practice, the closing premises simply has to make a notification under regulation 67 of the 2013 Regulations.
- 7.2 However, a business or the businesses seeking to consolidate in this way do not know how the Board, as the commissioner of NHS pharmaceutical services, will respond to the closure. It could decide to allow another pharmacy of an rival business to open up instead. NHS efficiency savings in the 2016-17 and 2017-18 financial years mean that some pharmacy contractors, particularly in clusters of pharmacies, are more likely to want to know where they would stand if they sought to consolidate their activities with those of other businesses in their area, or sought to consolidate their own operations on a smaller number of sites.
- 7.3 The proposed new procedure will be helpful to them in the following respects. Firstly, the Board will be required to notify the application locally and seek the views of the relevant HWB, who will have to give a view on whether or not they see the application as creating a gap in provision. This is important because of the role of the HWB in producing the PNA to which the Board must have regard when assessing “routine applications” from potential rivals. Secondly, the Board will only grant the application if it considers that there is no gap, which gives the applicant a clear statement of the Board’s own position as commissioner. Thirdly, the Board then has to refuse any routine applications that purport to fill any alleged gap resulting from a closure that follows the grant of an application under the new arrangements – until the next revision of the PNA. Fourthly, the HWB must publish a supplementary statement in relation to its PNA, following the closure, if in its view that no gap has been created by the closure. Fifthly, if the application is refused, there is an appeals procedure which allows the merits of the application to be reconsidered by the Family Health Services Appeals Unit of the National Health Service Litigation Authority. Taken

together, this all provides the company or companies with valuable information which would not be available to them if the closing premises simply followed the regulation 67 procedure.

- 7.4 If the Board refuses the application but the business or businesses still want to press ahead with the consolidation, they simply have to follow the regulation 67 procedure instead. Nothing in these Regulations cuts across the availability of that procedure. However, the premises would then be closed in the light of information from the Board that an application for a new pharmacy from another business might be considered favourably.
- 7.5 These amendments are part of the Government's response to the recent consultation on proposals for Community Pharmacy in 2016/17 and beyond held between December 2015 and May 2016.
- 7.6 *Therapeutic radiographer independent prescribing and dietitian supplementary prescribing* – these amendments enable community pharmacists and dispensing doctors entitled to dispense NHS prescriptions to dispense against prescriptions issued by a therapeutic radiographer or dietitian qualified to order drugs, medicines and appliances as an independent or supplementary prescriber, respectively. These changes are part of the latest expansion of prescribing responsibilities, aimed at improving patient care by increasing capacity and flexibility, and making the best possible use of experienced health professionals' skills.
- 7.7 Including the National Urgent Medicine Supply Advanced Service in the National Health Service (Charges for Drugs and Appliances) Regulations 2015 – this amendment enables the community pharmacy supplying a medicine to a patient by means of this advance service to levy the prescription charge if appropriate.
- 7.8 A new nationally commissioned advanced pharmaceutical service is being introduced – the National Urgent Medicine Supply Advanced Service. This service enables community pharmacy to supply urgently required repeat medicines and appliances where the patient has made such a request to NHS 111 and NHS 111 has referred the patient to the community pharmacy. This requires an amendment to the Charges Regulations so that if this route of supply is used, where appropriate, a prescription charge can be levied. A further amendment is made to ensure that pharmacies are not required to publicise their participation in this new service.

Consolidation

- 7.9 There are no plans to consolidate the 2013 Regulations at present. The GMS Regulations, PMS Regulations and Charges Regulations are all recent consolidations.

8. Consultation outcome

- 8.1 *Consolidation onto an existing site* - 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 amendments to the 2013 Regulations. Of these, we have only involved PSNC on this occasion as these amendments are not relevant to the other organisations. The PSNC are content with the Regulations as are the Board. As the amendments included amendments to the 2013 Regulations concerning local authority HWBs, we also

consulted the Local Government Association. They are also content with the Regulations.

- 8.2 *Therapeutic radiographer independent prescribing and dietitian supplementary prescribing* - the Board undertook the necessary statutory public consultations on these changes during February to May 2015, following publication on the Board's consultation hub and circulation to health service, local authority, a range of patient and other representative bodies and the devolved administrations. Following analysis of the responses, the Board reported the results of consultation to the Commission on Human Medicines (CHM) for discussion at the Commission's meetings in September and October 2015. These regulations reflect CHM's recommendations. Copies of the full consultation reports are available on the Board's consultation hub.
- 8.3 *Charges amendments* – we do not customarily consult on changes such as those made to Charges Regulations but PSNC have been made aware of the changes as part of the Department's engagement with them.

9. Guidance

- 9.1 There are no plans to produce guidance.

10. Impact

- 10.1 An Impact Assessment has not been prepared for this instrument. However, the Board undertook an Impact Assessment regarding the initial proposals to enable independent prescribing by radiographers and supplementary prescribing by dietitians. This forecast net benefits from implementation of the proposals, as a result of a range of factors including: improved outcomes, reductions in referrals and a better patient experience.
- 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 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.
- 10.3 We have not identified any specific equality issues that need to be considered on the consolidation on to an existing pharmacy site. NHS England has not identified any specific equality issues on the proposals relating to prescribing by therapeutic radiographers and dietitians. However, responses to the public consultation have indicated the potential for these changes to have a positive impact on many of the protected groups.

11. Regulating small business

- 11.1 The legislation applies to activities that are undertaken by small businesses. However, as the 2013 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 8.1 above on any problems identified.

13. Contact

- 13.1 Gillian Farnfield at the Department of Health. Telephone: 0207 972 2700 or email: gillian.farnfield@dh.gsi.gov.uk can answer any queries regarding the instrument.