

## EXPLANATORY MEMORANDUM TO

### THE NATIONAL HEALTH SERVICE (CHARGES AND PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2020

2020 No. 1126

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

#### 2. Purpose of the instrument

- 2.1 This instrument amends the following sets of Regulations by including new provisions relating to new services and service updates for community pharmacies to meet the year 2 ambitions of the 5-year Community Pharmacy Contractual Framework (CPCF) deal, and by including some further changes related to the Covid-19 pandemic:
  - The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013/349, as amended) (“the PLPS Regulations”) which set out the framework for dispensing contractors’ terms of service.
  - The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (SI 2015/570, as amended) (“the Charges Regulations”) which set out charges to be made and recovered for the supply as part of the National Health Service in England of certain drugs, appliances, wigs and fabric support, and provides for certain exemptions from charging in prescribed circumstances.

#### *Amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013*

- 2.2 The amendments to the PLPS Regulations can be divided into those that introduce changes, which were agreed with the Pharmaceutical Services Negotiating Committee (PSNC – the representative body of pharmacy contractors), for year 2 of the 5-year CPCF deal, and those that are related to the pandemic.
- 2.3 The CPCF amendments mainly enable the introduction of new essential services requirements for community pharmacies, in particular the new Discharge Medicines Service (DMS) and putting a framework in place for requiring all community pharmacies to adhere to the ethos of Healthy Living Pharmacies (HLPs). There are also amendments to help facilitate community pharmacies transition to be more information technology (IT) orientated.
- 2.4 The amendments relating to the pandemic essentially relate to more flexible provision of immunisation services and distribution of potential Covid-19 or other pandemic illness treatments in primary care through dispensing contractors (this is an enabling provision which might not be used during the current pandemic).

*Amendments to the National Health Service (Charges for Drugs and Appliances) Regulations 2015*

- 2.5 The Charges Regulations are being amended to allow the supply of influenza and Covid-19 vaccines to all eligible patients free of prescription charges, including when these are supplied under the new “national immunisation protocols”.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 None.

*Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)*

- 3.2 As the instrument is subject to the negative resolution procedure, there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

**4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is England.  
4.2 The territorial application of this instrument is England.

**5. European Convention on Human Rights**

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

**6. Legislative Context**

*Amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013*

- 6.1 The mandatory NHS pharmaceutical services provided by community pharmacies, dispensing appliance contractors and dispensing doctors are set out in the PLPS Regulations, and some additional services are set out in Directions. The PLPS Regulations contain four different sets of terms of service:
- the services provided by the retail pharmacy businesses on pharmaceutical lists held by NHS England and NHS Improvement (NHS E&I) – these businesses are generally known as “pharmacy contractors”, and they are responsible for providing most of the community pharmaceutical services provided to NHS patients in England;
  - the services provided by retail pharmacy businesses that hold local pharmaceutical services contracts (“LPS contractors”) – who hold contracts with NHS E&I for dispensing and other services;
  - the services provided by dispensing appliance contractors, who supply appliances but not drugs; and
  - the dispensing services provided by the general practitioners (“dispensing doctors”) in some rural areas.
- 6.2 Related Directions under section 127 of the NHS Act 2006 deal with the “additional pharmaceutical services” that pharmacy contractors and dispensing appliance

contractors may but are not generally required to provide. These are sub-divided into “advanced services”, commissioned nationally, and (in the case of pharmacy contractors) “enhanced services” commissioned locally.

***Amendments to the National Health Service (Charges for Drugs and Appliances) Regulations 2015***

- 6.3 Section 1(4) of the National Service Act 2006 provides that NHS services must be provided free of charge, subject to express legislative provision to the contrary. The Charges Regulations contain such contrary provision. They set out a scheme for charges for drugs, appliances and some other items supplied to NHS patients in England, and the arrangements for exemption from those charges in prescribed circumstances.

## **7. Policy background**

- 7.1 DHSC (on behalf of Ministers), the PSNC and NHS E&I concluded a joint agreement<sup>1</sup> in July 2019 which described a joint vision of how community pharmacy would support delivery of the NHS Long Term Plan. This agreement was supplemented in February 2020 by a guidance document for year 2 of the agreement<sup>2</sup>. Both of these documents are available on the Gov.uk website and by post from DHSC<sup>3</sup>. The amendments to the PLPS Regulations will enable the following service enhancements, which have been agreed as part of year 2 of the CPCF deal but which have been delayed because of the demands of dealing with the Covid-19 pandemic:

- digital improvements which were previously part of the pharmacy quality scheme (an optional scheme that was set out in a publication known as the Drug Tariff<sup>4</sup>) now become essential for all pharmacy contractors, and the first two mentioned also become essential for LPS contractors:
  - to have NHS mail shared mailboxes for every community pharmacy with linked personal NHS mail accounts for pharmacy staff. This is primarily to facilitate referral and exchange of other patient confidential information;
  - Access to and appropriate use of Summary Care Records (networked NHS summary patient records), which is to support patient care;
  - Building and updating, as necessary, community pharmacy profiles for the NHS 111 Directory of Services (DoS), which is to facilitate referral;
  - Keeping pharmacy profiles for the NHS.uk (previously NHS Choices) DoS, including opening times, facilities and service information up-to-date, which is to facilitate efficient patient access to services, and evidence checking of this information at least quarterly.
- Patient safety – both pharmacy contractors and LPS contractors are required to register and keep up to date with the Medicines and Healthcare products Regulatory Agency (MHRA) Central Alerting System (CAS), which is an alert system to be aware of safety information on medicines. It is also used to cascade other health information.

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<sup>1</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/819601/cpcf-2019-to-2024.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/819601/cpcf-2019-to-2024.pdf)

<sup>2</sup> <https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024/year-2-detail>

<sup>3</sup> Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU

<sup>4</sup> <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

- Electronic Prescription Service (EPS) – Pharmacy contractors and LPS contractors are required to have, and have constant and reliable access to, the EPS, in so far as this is within their control. This is the system via which GP (general practitioners) practices (and others) can submit prescriptions electronically to community pharmacies. If the system is temporarily unavailable, the pharmacy is required to take steps such as providing details of other pharmacies in their area.
- Insolvency – pharmacy contractors and dispensing appliance contractors are required to notify NHS E&I of entering administration – it is important that NHS E&I is made aware of this situation so that it can maintain its statutory duties in respect of ensuring that there is adequate access to pharmaceutical services.
- Requirement for contract management and monitoring data to be submitted electronically by pharmacy contractors to NHS E&I – this amendment will significantly improve efficiency within NHS E&I to perform its obligation of assuring itself that pharmacy contractors comply with their terms of service.
- Health campaigns – the requirement for pharmacy contractors to participate in public health campaigns is made, more flexibly, a requirement to participate in health campaigns, and the data sharing requirements in respect of the campaigns are changed to enable NHS E&I to perform appropriate evaluation of the campaigns.
- Changes to learning requirements – pharmacy contractors will no longer be required to undertake training on repeat dispensing (this requirement had been around for a considerable amount of time and DHSC understands that it no longer needs to be specified as separate training). Although this is not stated in the Regulations, pharmacy contractors will instead be expected to undertake safeguarding level 2 training, which focuses on the safety and wellbeing of the young and vulnerable people in society.
- Digital relationship with a patient who does not present in the pharmacy – in the light of Covid-19, DHSC has included an overarching obligation on pharmacy contractors, to the extent reasonable, to facilitate remote access to the pharmacy.
- There are also some administrative changes relating to the notices that are filled in, and the notice period given, when a new pharmacy contractor or dispensing appliance contractor premises are opened.
- Owings – pharmacy contractors and LPS contractors are given the option of giving an electronic note of “owings”, for the prescription items that they are not immediately able to dispense, informing the patient of when it is expected that the item will become available.

7.2 The amendments to the PLPS Regulations also contain three sets of amendments that are part of year 2 of the CPCF deal, which have a delayed start date until 1 January 2021:

- Requirement on all pharmacy contractors, brought about largely by changes to the clinical governance requirements, to follow the ethos of HLPs. The objective of an HLP is to create teams that are aware of local health issues, trained in change behaviour and are consistently proactively promoting healthy lifestyles by tackling the health problems their populations face. Additionally, distance selling pharmacies are required to have a health promotion zone on their website.

- Introduction of a new DMS focusing on medicine optimisation and safety where patients, who have been identified as being at risk from adverse effects or needing support with their medicines, are referred, on hospital discharge or transfer between care settings, by an NHS trust or foundation trust for advice and support to their usual community pharmacy. A three-stage process has to be followed, culminating in a discussion between a pharmacy professional and the patient or their carer in which they are to be offered appropriate advice, assistance and support, and for the purposes of addressing any issues of concern.
- Partly linked to the new DMS, most pharmacy contractors will be required to have a consulting room (previously, this was only mandatory if the pharmacy contractor was providing advanced services) – although distance selling pharmacies will instead be required to provide live audio (e.g. telephone) and video links.

7.3 There are also the following pandemic response related amendments to the PLPS Regulations:

- the distribution of potential Covid-19 treatments (or treatments for other pandemic diseases) through community pharmacies and dispensing doctors by using “pandemic treatment protocols” under the Human Medicines Regulations 2012 (S.I. 2012/1916) – pandemic treatment protocols can be used to authorise supply of prescription only medicines without a prescription, on the basis of a protocol approved by Ministers or NHS bodies. This is essentially an enabling provision, i.e. if a Covid-19 treatment became available that was suitable for distribution via community pharmacies, it is possible that supply to patients would be done under ordinary arrangements for GP practices issuing prescriptions. Pandemic treatment protocols would be an option where it was not necessary for the decision to treat to be made by an authorised prescriber at the patient’s GP practice;
- flexible provision of immunisation services during the pandemic – under this provision community pharmacies will be allowed, with the agreement of NHS E&I, to close their premises for a few hours just to focus on the delivery of flu or Covid-19 vaccinations. Much larger numbers of patients than is usual will need to be vaccinated, and this measure will support both the expansion of the national flu vaccination programme and any future national Covid-19 vaccination programme.

7.4 The Charges Regulations are being amended to allow the supply of influenza and Covid-19 vaccines to all eligible patients free of prescription charges, including when these are supplied under the “national immunisation protocols” that are being introduced by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, which are being made at the same time as these Regulations.

7.5 Vaccinations against influenza and (in the future) Covid-19 are not available on the NHS simply to anyone who asks for them. Before each influenza season, the categories of persons eligible to receive NHS flu vaccinations are normally established by the Department, Public Health England and NHS E&I for the purposes of the annual NHS flu vaccination programme, and then feature in the national patient group direction that is used by community pharmacies as the basis for the flu vaccinations that they deliver to NHS patients. In 2020/21, subject to vaccine supply availability, the eligible groups will be expanded during the course of the vaccination programme as part of the Covid-19 pandemic response. Although community

pharmacies only administer a relatively small proportion of the number of flu vaccinations given annually as part of the NHS programme, they are an integral part of the programme, so national protocols for them will be published, each year, of the people who are eligible to receive NHS immunisations. Once a Covid-19 vaccination becomes available, the groups who are eligible to receive free immunisations will similarly be identified in a national patient group direction for community pharmacies – or in a “national immunisation protocol” using powers being included in the Human Medicines Regulations 2012 by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, or both. It is anticipated that, as with the use of flu vaccine in 2020/21, any Covid-19 vaccine would be made available progressively to different eligible groups, subject to the availability of supplies.

- 7.6 If someone is identified as needing to be immunised against influenza or Covid-19, it is important that they are not dissuaded from receiving the vaccine by a prescription charge, regardless of the NHS commissioning route by which that vaccine is supplied. The amendment makes it clear that, in all cases, NHS supply to eligible patients will be free of charge – regardless of whether any other exemptions would apply.

## **8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union**

- 8.1 This instrument does not relate to withdrawal from the European Union.

## **9. Consolidation**

- 9.1 There are no plans to consolidate the PLPS Regulations. There are no plans to consolidate the Charges Regulations in the near future, but this will be kept under review.

## **10. Consultation outcome**

- 10.1 Customarily, the DHSC seeks the views of the PSNC, the British Medical Association and the Dispensing Doctors’ Association on changes to the PLPS Regulations. The Department has been able to discuss the policy changes and draft Regulations, and responded to their comments, making changes to the Regulations where appropriate.
- 10.2 The DHSC is not required to consult on changes to the Charges Regulations.

## **11. Guidance**

- 11.1 Guidance for the amendments relating to the PLPS Regulations will be produced by NHS E&I with input from the PSNC.

## **12. Impact**

- 12.1 A high-level Impact Assessment (IA) was conducted, setting out the rationale for intervention and describing the main impact of the proposed legislation in comparison to taking no action.
- 12.2 There will be no additional cost of the DMS to the NHS since its introduction is agreed as part of the 5-year CPCF deal, and the funding relating to the provision of the service is included within the CPCF funding envelope. The main cost will be to community pharmacies through the staff time required to deliver the service. The main benefits of the service will be the freed-up NHS capacity through avoided

hospital readmissions. There will also be health benefits to patients from avoided adverse events.

- 12.3 The requirement for all pharmacies to adhere to the ethos of an HLP creates a small cost for community pharmacies. The main benefits will be the health impacts of patients leading healthier lifestyles and the NHS cost savings associated with a reduced workload burden for GPs.
- 12.4 The amendments introducing administrative changes and helping to facilitate community pharmacies transition to be more IT orientated are expected to have no significant costs. The main benefits will be better contract management and commissioning decisions. There will also be better flow of information leading to efficiency gains and an improvement in patient care, access and experience, particularly for patients who cannot easily access a community pharmacy.
- 12.5 There is no significant cost impact of the amendments relating to the pandemic to provide for flexible provision of immunisation services. The flexible provision enables vaccination programmes to be delivered across the NHS in the most effective way.
- 12.6 The regulations relating to the distribution of potential Covid-19 treatment in primary care through dispensing contractors are enabling. At this stage it is impossible to quantify the impacts, so they are not considered in the IA. Any future utilisation of the provisions and associated impacts will be considered separately.
- 12.7 The Charges Regulations ensure that charging exemptions apply regardless of the delivery mechanism of administering vaccines. There will be no loss of income to the NHS of the regulation changes. The vaccines in question are vaccines that the Department would always intend to be free of charge to eligible patients.
- 12.8 The IA contains broad assumptions and costings on how services could develop, which are subject to further policy development and negotiation with the PSNC. As such, the IA contains sensitive information and has not been published alongside this instrument so not to prejudice current and future negotiations with the PSNC.

### **13. Regulating small business**

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

### **14. Monitoring & review**

- 14.1 DHSC monitors the implementation and efficient operation of all the Regulations amended by this instrument, and in the case of the amendments to the PLPS Regulations has regular discussions with the pharmacy contractors' representative body – the PSNC - on any problems identified.

### **15. Contact**

- 15.1 Marta Senger at DHSC, telephone: 02079722922 or email: [marta.senger@dhsc.gov.uk](mailto:marta.senger@dhsc.gov.uk) can be contacted with any queries regarding the instrument.
- 15.2 Jeannette Howe, Deputy Director for Pharmacy, at DHSC can confirm that this explanatory memorandum meets the required standard.

15.3 The Secretary of State for Health and Social Care, Matt Hancock at DHSC can confirm that this explanatory memorandum meets the required standard.