EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CHARGES, PRIMARY MEDICAL SERVICES AND PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (CORONAVIRUS) (FURTHER AMENDMENTS) REGULATIONS 2021

2021 No. 1346

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.

2. Purpose of the instrument

2.1 This Instrument amends the following sets of England only Regulations by including new provisions relating to the year 3 agreed changes for the 5-year Community Pharmacy Contractual Framework (CPCF) deal, by including some further changes relating to the Covid-19 pandemic, and by including changes to provisions relating to medical and maternity certificates in respect of prescription charges:

- 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 market entry and exit for dispensing contractors and their terms of service.
- The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570, as amended) ("the Charges Regulations"), which set prescription charges and set out the framework for exemptions from them.
- The National Health Service (General Medical Services Contracts) Regulations 2015 (SI 2015/1862) ("GMS Contracts Regulations") which set out the framework for General Medical Services (GMS) contracts for general practitioner (GP) practices.
- The National Health Service (Personal Medical Services Agreements) Regulations 2015 (SI2015/1879) ("the PMS Agreements Regulations") which set out the framework for Personal Medical Services (PMS) agreements for GP practices.

Amendments to the PLPS Regulations

2.2 The amendments to the PLPS Regulations reflect the agreement reached with the Pharmaceutical Services Negotiating Committee (PSNC), the representative body for pharmacy contractors, for year 3 (2021/22) of the CPCF 2019-24 5-year deal, and in essence:

- Require NHS England & Improvement (NHSE&I), the commissioner of NHS pharmaceutical services, to refuse applications for new pharmacy or dispensing appliance contractor (DAC) premises where the benefit being offered by the applicant is in respect of the days on which or the times at which essential services are provided, if granting it would lead to the undesirable increase of essential services (such as dispensing services) in the area.

- Require pharmacy contractors to participate in a pandemic response programme if requested to do so by NHSE&I – after consultation with the PSNC.
- Change the consultation requirements for remuneration for enhanced services.
- Implement a change to the pharmaceutical needs assessment (PNA) publishing cycle – the next PNAs are generally now due for publication by October 2022.
- Specify that a new Health and Wellbeing board (HWB) has 12 months from their creation to publish their first PNA, and permit them, in the interim, to issue supplementary statements in relation to the PNA of any HWB they replace.

2.3 The amendments to the PLPS Regulations also lay the ground for distributing a potential Covid-19 antiviral medication by modifying the array of options for deployment in primary care of pandemic treatments and treatments for public health emergencies.

Amendments to the Charges Regulations

2.4 The amendments to the Charges Regulations align the Regulations with existing operational procedures and address some discrepancies in the scheme for medical and maternity prescription charge exemption certificates, in particular in the arrangements for mothers of still born children and those whose children have later than expected birth dates. The amendments will enable the digitising of the application processes for medical and maternity exemption certificates and will enable the national roll out of the piloting of digital application processes for maternity exemption certificates.

Amendments to the GMS Contracts and PMS Agreements Regulations

2.5 The amendments to the GMS and PMS Regulations relate to the use of vouchers as a means for ordering pandemic treatments and treatments for public health emergencies. These changes are being made in preparation for the potential use of Covid-19 antiviral medications in community settings by providing that listed prescription item vouchers may be issued by GP practices by electronic means.

2.6 Amendments are also made to the GMS and PMS Regulations to replace references to 'listed medicines' and 'listed medicines vouchers' with 'listed prescription items' and 'listed prescription items vouchers' respectively. This will ensure these references correspond with changes made previously to regulation 13 of the Charges Regulations by the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) Regulations 2021 (S.I. 2021/169).

3. Matters of special interest to Parliament

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

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

The PLPS Regulations

6.1 The PLPS Regulations carried forward changes to the legal framework for NHS community pharmaceutical services initially introduced by the National Health Service (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909), but adapted to take account of the creation of what has become NHSE&I.

6.2 NHS community pharmaceutical services in England are now provided on the basis of four sets of standard arrangements with NHSE&I.

6.3 Arrangements with retail pharmacy businesses are made on the basis of either entry on approved lists known as pharmaceutical lists or, much less often, on the basis of a contract for local pharmaceutical services (LPS). Businesses that are party to these arrangements are known as, respectively, "pharmacy contractors" and "LPS contractors".

6.4 Arrangements with dispensing appliance contractors (DACs) are made on the basis of separate pharmaceutical lists especially for them, but they share with pharmacy contractors common arrangements for market entry and market exit.

6.5 The arrangements made with dispensing doctors are solely for patients in some rural areas, and usually for patients who live more than a certain distance from a pharmacy.

6.6 Decisions by NHSE&I on new market entry by pharmacy contractors or DACs are based, with some exceptions, on the local plans outlining the needs and availability of pharmaceutical and local pharmaceutical services in an area, the PNAs, which are developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs) HWBs. HWBs took over this responsibility following the abolition of NHS Primary Care Trusts from 1st April 2013.

6.7 The Terms of Service in the PLPS Regulations require pharmacy contractors and DACs to provide "essential services", such as dispensing services. Related Directions under section 127 of the NHS Act 2006 deal with the "additional pharmaceutical services" that pharmacy contractors and DACs may but are not generally required to provide. These are sub-divided into "advanced services", which NHSE&I must commission from willing providers who meet the gateway criteria and are commissioned nationally, and (in the case of pharmacy contractors) "enhanced services" which historically have been commissioned locally and which NHSE&I are authorised but not required to commission from willing providers. At the moment, only pharmacy contractors, not DACs, provide enhanced services.

The Charges Regulations

6.8 Part 9 of the 2006 Act allows regulations to be made for the making and recovery, in such manner as may be prescribed, of charges for the supply of drugs, medicines and appliances under the 2006 Act. The Charges Regulations set out a scheme for charges for drugs and appliances and some other items supplied to NHS patients in England, and the arrangements for exemption from those charges.

The GMS Contracts and PMS Agreements Regulations

6.9 The GMS Contract Regulations set out the framework for General Medical Services ("GMS") contracts. The PMS Agreements Regulations set out the framework for

Personal Medical Services ("PMS") agreements. Essentially, both are types of NHS GP contract.

6.10 Every GP practice (individually, corporately or as a partnership) must hold an NHS GP contract to run an NHS commissioned general practice. There are three different types of GP contract arrangements in England: GMS contracts, PMS agreements and Alternative Provider Medical Services (APMS) contracts. All three types of contract are managed by the NHS commissioner, which may be NHSE&I or a Clinical Commissioning Group.

7. Policy background

What is being done and why?

Amendments to the PLPS Regulations

7.1 As indicated above, the amendments to the PLPS Regulations essentially reflect the agreement reached with the PSNC for year 3 (2021/22) of the CPCF 2019-24 5-year deal and include some further changes related to the pandemic response.

7.2 After they have published their first PNA, HWBs must publish a full revision every three years. Most HWBs last published PNAs in 2018, and the end date for publication date for the next PNAs was originally set for April 2021, but because of the pressure of Covid-19, we have now agreed to delay this until October 2022.

7.3 Other essentially technical changes have also been identified to improve the regulatory framework for PNAs. New HWBs are now given 12 months to publish their first PNA. In addition, it is already the case that HWBs can, pending a full revision, publish "supplementary statements" for their PNAs, but new powers are given to new HWBs so that they can publish supplementary statements in relation to the PNAs that they inherit from the previous HWB for a particular area, pending the new HWBs first PNA. The previous HWB's PNA, together with any supplementary statements that it issued an any supplementary statements issued by the new HWB, then form the basis of the PNA that NHSE&I is to use in that area for commissioning decisions.

7.4 A PNA may identify longer or different pharmacy opening hours as something that would provide better access to pharmaceutical services in a particular area but may already have sufficient provision of essential services, such as dispensing services, and be hoping essentially for longer or different opening hours from existing contractors. Granting an application to a new pharmacy in that area simply because it was offering more supplementary hours of opening might be to the overall detriment service provision in that area. If NHSE&I conclude that granting the application would lead to an undesirable increase in the provision of essential services, NHSE&I will be required to refuse the application.

7.5 The experience of the Covid-19 pandemic has led to the inclusion of an additional requirement in the clinical governance and promotion of healthy living provision in the terms of service for pharmacy contractors. This will put an obligation on them to participate in a pandemic response programme developed by NHSE&I and consulted on with the PSNC, where requested to do so by NHSE&I.

7.6 The nature of the pandemic response programme would need to reflect the precise threat, but some specific needs, based on recent and current experience are identified in the legislation, such as appropriate infection control measures and arrangements for

communicating with potential service users. Fundamentally, the programmes would deal with how services are to be delivered, taking into account the challenges presented by the pandemic, not what services would be delivered. The overarching aim would be to help ensure that services could continue to be delivered safely.

7.7 As mentioned above, historically enhanced services have been commissioned locally but the planning for the distribution of any potential COVID-19 antiviral medication has shown that deployment may be more suited to a national service rather than a local service – if the enhanced service model were to be used for deployment. Before now, NHSE&I have had to consult Local Pharmaceutical Committees on remuneration for enhanced services, but NHSE&I will be required to consult a national body, in practice the PSNC, instead of Local Pharmaceutical Committees if they want to commission a national enhanced service rather than a local enhanced service.

7.8 The aforementioned planning to prepare for any potential Covid-19 antiviral medication has also identified two further sets of the amendments to the PLPS Regulations:

- including as part of the dispensing services provided by pharmacy contractors, LPS contractors and dispensing doctors, obligations to dispense against vouchers for the supply of an antiviral medication against a voucher created for that purpose. This new obligation will not apply where there is an advanced or enhanced service in place for dispensing against the vouchers. Such a service might be put in place, for example, if there was only limited distribution of the treatment as a way of targeting supplies. Use of vouchers was already covered in the GP contract standard terms of service but not in those for dispensing contractors.
- supply of an antiviral medication might instead be against a Pandemic Treatment Protocol or Pandemic Treatment Patient Group Direction (where a treatment decision of an authorised prescriber was not the trigger for supply) – and the PLPS Regulations already addressed that possibility. However, further amendments have been made so that if an advanced or enhanced service is in place for supply in accordance with such protocols or directions, supply will be under those arrangements and not ordinary terms of service. As above, an advance or enhanced service might be put in place in order, for example, to target supplies.

Amendments to the Charges Regulations

7.9 The amendments to the Charges Regulations enable changes to be made to the mechanisms for applying and issuing the exemption certificates which are required in order to claim a medical or maternity exemption. The amendments:

- Enable all registered health care professionals to apply for a medical exemption and/or maternity exemption certificate on behalf of the patient. This is intended to make the application processes easier for patients and to ensure that patients benefit from any exemptions to which they are entitled. Piloting of a digitised application process for maternity exemption certificates has been welcomed by health care professionals and patients
- Remove the restriction of only using a named medical exemption form (FP29A) to support digitisation i.e. the Regulations simply refer to an approved form provided by the Secretary of State.

- Revise the rules on the duration of maternity exemption certificates to allow the issuing of certificates that will be valid from one month before the date of application until the child's first birthday (or what would have been the child's first birthday). This will allow the date of delivery to apply to the maternity exemption for both live and stillbirths. This amendment will enable women who applied as expectant mothers to request an extension to their certificate, so that it is valid for a year after the child is born or still born, rather than for a year after the expected date of confinement. If the application for the maternity exemption certificate is not made until after the mother has given birth, if the birth was a registrable still birth, the mother can choose for the 12 months end date to be calculated either from the expected date of confinement or the date of birth. These amendments will also enable the national rollout of the current piloting of a digitised application process for these certificates, as mentioned above.
- provide for a statutory gateway to support the handling of information for the purposes of processing applications for medical and maternity exemption certificates, and managing those processes. That statutory gateway also ensures that a duty of confidentiality is owed by the persons handling the data for the specified purposes, whether or not they would otherwise owe such a duty.

7.10 The above changes align the rules on maternity exemption certificates for live and still births and give all mothers the ability to request an extension for their certificates later than expected births. They address discrepancies between the regulations and operational procedures, allow existing processes to be digitised and enable the national roll out of the piloting of digital application processes for maternity exemption certificates.

Amendments to the GMS Contracts and PMS Agreements Regulations

7.11 The purpose of the changes to the GMS Contracts Regulations and PMS Agreements Regulations is described in paragraphs 2.5 and 2.6 above. Essentially, these changes are happening now in case vouchers issued by GPs, and in particular electronic vouchers, are needed as part of the arrangements for the supply of Covid-19 antivirals.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 There are no plans to consolidate the PLPS Regulations, the Charges Regulations, the GMS Contracts Regulations or the PMS Agreements Regulations.

10. Consultation outcome

Amendments to the PLPS Regulations

10.1 Customarily, the Department seeks the views of the PSNC, the British Medical Association (BMA) and the Dispensing Doctors' Association (DDA) 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.

Amendments to the Charges Regulations

10.2 There is no obligation to consult on the Charges Regulations, however views were sought from key stakeholders to ensure there were no unintended consequences with the proposed amendments.

Amendments to the GMS Contracts and PMS Agreements Regulations

10.3 The Department and NHSE&I have, as is customary, discussed the policy changes that will be made to the GMS Contracts and PMS Agreements Regulations with the General Practitioners Committee of the BMA.

11. Guidance

11.1 PNA guidance is available on the gov.uk website. Should an antiviral treatment be identified that is to be supplied under the arrangements provided for in this instrument, or the pandemic provision be utilised, guidance and or service specification on the amendments to the GMS and PMS Regulations and the PLPS Regulations will be produced by NHSE&I with input from the PSNC, BMA and DDA as appropriate. DHSC is confident that the roll-out would be done in a collaborative way as part of the national effort against COVID-19.

11.2 Guidance for patients on prescription charge exemptions and how to apply for exemption certificates is available on the NHS and NHS Business Services Authority websites. Digital application processes will be developed with input from healthcare professionals and guidance to support these changes will be issued accordingly.

12. Impact

Amendments to the PLPS Regulations

12.1 There is no, or no significant, impact on business, charities, or voluntary bodies, as a consequence of these measures. In the case of the changes to terms of service, they are enabling, but they take effect in the context of the general impact of the COVID-19 pandemic on primary care contractors, the impact of which at this stage is impossible to quantify.

12.2 There is no, or no significant, impact on the public sector as a consequence of these measures which apply to them, but again they take effect in the context of the general impact of the COVID-19 pandemic on Local Authorities, NHSE&I and primary care contractors, the impact of which at this stage is impossible to quantify.

12.3 A full Impact Assessment has not been prepared for remuneration change relating to the possible introduction of a national enhanced service because the regulatory change is permissive and does not meet the conditions for conducting an Impact Assessment. However, before any of these powers will be used, if the circumstances so permit, we will discuss the broader implications of doing so with the representative bodies of the affected contractors.

12.4 A high-level Impact Assessment (IA) was conducted for the year 3 negotiated agreement under the CPCF 5-year deal, which included the pandemic provision, PNA changes and over-provision of essential services, setting out the rationale for intervention and describing the main impact of the proposed legislation in comparison to taking no action. 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.

Amendments to the Charges Regulations

12.5 There is no significant impact on patients, healthcare professionals or the public sector as a consequence of these changes. A full Impact Assessment has not been prepared for these minor amendments as they mainly affect the processes involved in administering the medical and maternity prescription charge exemption certificates which have been or will be improved and streamlined.

Amendments to the GMS Contracts and PMS Agreements Regulations

12.6 There is no, or no significant, impact on business, charities, or voluntary bodies, as a consequence of these measures which are enabling, but they take effect in the context of the general impact of the COVID-19 pandemic on primary care contractors, the impact of which at this stage is impossible to quantify.

12.7 A full Impact Assessment has not been prepared for these minor amendments because the regulatory change is permissive and does not meet the conditions for conducting an Impact Assessment.

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.

13.3 The basis for the final decision on what action to take to assist small businesses is based on consultation with the representative body for pharmacy contractors, the PSNC, and the representative body of general practitioners, the General Practitioners Committee of the BMA, who represent all types of business. The amendments in this SI that will apply to small businesses are enabling. If these amendments are utilised, the PSNC and BMA will be consulted again and the impact on small businesses will be taken into consideration.

14. Monitoring & review

14.1 The Department monitors the implementation and efficient operation of all the Regulations amended by this instrument, and in the case of the changes to the PMS Regulations, GMS Regulations, PLPS Regulations and the Charges Regulations, has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified.

15. Contact

15.1 Maia Goree at the Department of Health and Social Care Telephone: 020 7104 7797 or email: Maia.Goree@dhsc.gov.uk can be contacted with any queries regarding the amendments to the PLPS Regulations in this instrument.

15.2 Carol Walker at the Department of Health and Social Care Telephone: 0113 25 46384 or email: carol.walker@dhsc.gov.uk can be contacted with any queries regarding the amendments to the Charges Regulations in this instrument.

15.3 Joshua Bradlow at the Department of Health and Social Care Telephone: 07707 281 535 or email: joshua.bradlow@dhsc.gov.uk can be contacted with any queries

regarding the amendments to the GMS Contracts and PMS Agreements in this instrument.

15.4 Alette Addison, Deputy Director for Pharmacy, Dentistry and Eye Care, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.5 Maria Caulfield, Parliamentary Under-Secretary of State for Primary Care and Patient Safety, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.