EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CHARGES AND PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (CORONAVIRUS) (AMENDMENT) REGULATIONS 2021

2021 No. 169

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 makes amendments to The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570, as amended) ("the Charges Regulations") and to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended) ("the PLPS Regulations"). The principal purpose of this instrument is to make provision for the supply and distribution of any treatments for coronavirus which are found to be effective for use outside hospitals in England.

2.2 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. This instrument amends the Charges Regulations to ensure that all supplies of prescription items for or in anticipation of pandemic disease, or in other serious emergencies, either on prescription or pursuant to a patient group direction ("PGD"), a pandemic treatment protocol ("PTP") or serious shortage protocol ("SSP"), are free of charge. To be free of charge, arrangements must have been made to that effect by the Secretary of State, or by another NHS body with the approval of the Secretary of State. Previously, the relevant exemption from charging applied in a more limited way.

2.3 The PLPS Regulations govern the arrangements, in England, for the provision of pharmaceutical services under Chapter 1 of Part 7 of the National Health Service Act 2006 ("the 2006 Act"). These arrangements enable pharmacy contractors (such as retail pharmacy outlets), holders of local pharmaceutical services contracts, appliance contractors and dispensing doctors to provide, between them, a range of NHS community pharmaceutical services to patients. This instrument amends the PLPS Regulations to require dispensing contractors other than dispensing appliance contractors to provide a home delivery option to patients for specific prescription items in a pandemic situation. This includes treatments for COVID-19, free of charge. The free of charge delivery service applies if the dispensing contractor is required to supply the item and the patient is unable to obtain it from the dispensing contractor in other specified ways.

2.4 This instrument enables the supply by pharmacy contractors and dispensing doctors of treatments relating to pandemic diseases against a pandemic treatment PGD (PTPGD)

or a PTP, where the pharmacy or dispensary provides the triage to establish entitlement.

2.5 This instrument also makes provision for supplies against PTPGDs where the pharmacy contractor or dispensing doctor receives an approved electronic message prompting supply of the drug, for example via a service linked to NHS 111. Previously, this only applied to PTPs.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument breaches the "21 day rule" and its provisions come into force on 1st March 2021. This approach has been taken in order to balance the application of the normal rules for statutory instruments coming into force with the need to act as quickly as possible to enable NHS patients to have timely access to newly established effective treatments for COVID-19.

3.2 There are a number of ongoing trials to establish the efficacy of potential treatments for COVID-19, both within and outside a hospital environment. Due to the rules which cover research into effective treatments, DHSC will not be made aware of an effective treatment in advance of it being reported to the public. Neither will DHSC, nor anyone else, be given advance notice of when news of research outcomes is going to be released. Once findings demonstrating an effective treatment for COVID-19 are published, citizens and the NHS staff caring for them will expect to have very rapid access to those potentially lifesaving treatments.

3.3 However, PTPGDs and PTPs cannot be prepared until the details of the effective COVID-19 treatment have been published. The clinical information that has been gathered in the research and any additional information about the drug and target patient group concerned must be collated and reviewed by clinicians and translated into written PTPGDs and/or PTPs. Both documents have a formal clinical sign-off process that ensures that they are robust and safe to use. In addition, the PTP must be agreed by DHSC Ministers or an NHS body, and PTPGDs by the relevant NHS commissioner. The time needed for this work means that despite the urgency of giving access to the treatments, DHSC considers that the necessary time gap between research publication and treatment deployment should be utilised for Parliamentary scrutiny. DHSC therefore wishes to bring the provisions into force on 1st March in order to balance the need for Parliamentary scrutiny with the urgency of ensuring treatment is available at the earliest possible time.

3.4 Due to the uncertainty in the timing of publication of research results, 21 or more days may have passed after the laying of this instrument before any research results describing effective COVID-19 treatments are published, or before action could in practice be taken on the basis of such results. Nevertheless, the potential need or opportunity to act with greater urgency has led to the decision to breach the 21 day rule.

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)

3.5 As this instrument is subject to 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 and Wales.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

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

6. Legislative Context

6.1 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. This instrument extends an existing exemption provision of the Charges Regulations so that it applies not just to PTP supplies but also to supplies against prescriptions, SSPs and PTPGDs, and not just to drugs but also to other prescription items.

6.2 The PLPS Regulations carried forward changes to the legal framework and the terms of service introduced by the National Health Service (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909, as amended), in force from 1st September 2012. The PLPS Regulations amalgamated these Regulations 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.

6.3 NHS community pharmaceutical services in England are provided on the basis of four sets of standard arrangements with the NHS, referred to in paragraph 2.3 above. 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". The arrangements made with dispensing doctors are solely for patients in some rural areas.

6.4 These arrangements are the responsibility of NHS England – NHS Improvement (NHSE-I), although the local plans outlining the needs and availability of pharmaceutical and local 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 1st April 2013.

7. Policy background

What is being done and why?

7.1 If a treatment for a pandemic disease such as COVID-19 is identified that is suitable for use outside hospitals, additional arrangements are needed to ensure the maximum number of eligible people possible can be given access to the treatment and will not be inappropriately charged for them.

7.2 Provision already exists in the Charges Regulations to allow the Secretary of State, in a pandemic or an emergency situation, to make arrangements to supply some drugs free of charge to all patients regardless of other exemptions, or to allow NHS bodies to do so with the Secretary of State's approval. Generally, these provisions are extended so that they apply not just to drugs but potentially to other prescription items as well. This might, for example, include spare inhalers and food supplements. The specific powers to have these exemptions in relation to a pandemic situation currently only apply, however, if the product in question is supplied under a PTP. This, in practice, is only one supply arrangement that might be contemplated in circumstances where a treatment for COVID-19 was identified as suitable for use outside hospitals. Potentially, the product in question might be ordered on prescription by a GP practice for the patient in question and supplied under that prescription (or, in certain circumstances, under a SSP). Equally, it is possible that the supply might be under a PGD in circumstances where a prescription charge was payable under regulation 8 of the Charges Regulations.

7.3 This instrument ensures that the Secretary of State can ensure that no patient pays a prescription charge for a COVID-19 treatment – or a treatment in another pandemic situation – where the Secretary of State wants the product in question to be free of charge. This would support maximum take-up of the treatment in question and may make the distribution of the product easier, limiting the administrative burdens of doing so.

7.4 Under the PLPS Regulations, drugs are not generally supplied against PGDs as part of the dispensing services that contractors are required to provide. These dispensing services are normally triggered by prescriptions – PGD supplies are generally made under advanced or enhanced services. These are additional rather than core pharmaceutical services, and broadly are optional. However, as noted above, the potential exists for pandemic treatments to be rolled out not just via prescriptions (and potentially on the back of those via SSPs), but also via PGDs and PTPs.

7.5 Arrangements already exist to support PTP supply where a pharmacy contractor or dispensing doctor receives an electronic message, approved by NHSE-I, telling them that a particular patient is to have the drug in question. Such a message could potentially be transmitted via a service linked to NHS 111. The arrangements that allow that to happen are extended to PGD supply. However, a community pharmacy or staff at a GP dispensing practice may instead be asked to assess entitlement to the drug themselves by triaging the patient and following either a PGD or a PTP. Provision is made to allow for this possibility. If the patients are suffering from the pandemic disease, all this may need to be done remotely and the drug delivered to the patient's home – both because of the condition of the patient and also to prevent wider transmission of the disease. Accordingly, NHSE-I is given powers, with the approval of the Secretary of State, to require a dispensing contractor to provide a home delivery option for specific prescription items that they are required to provide.

7.6 That home delivery option will not be necessary if an authorised person (a representative of the patient) is able to take the medicine to the patient, or the patient or the authorised representative is in fact at the pharmacy or dispensary.

7.7 As a package, these measures will support the effective roll out of a pandemic treatment that is suitable to be taken by patients outside hospitals, should such a treatment become available and be suitable for widespread distribution. This has the potential to support patient care and reduce hospital admissions and morbidity.

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 / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

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 There is no obligation to consult on the Charges Regulations and no consultation was undertaken.

10.2 Customarily, DHSC seeks the views of the Pharmaceutical Services Negotiating Committee (PSNC), the British Medical Association (BMA) and the Dispensing Doctors' Association (DDA) on changes to the PLPS Regulations that affect pharmacy contractors, local pharmaceutical services contractors and dispensing doctors. DHSC has consulted these representative bodies on these proposals in its customary way, and they are supportive of these measures.

11. Guidance

11.1 Should a treatment be identified that is to be supplied under the arrangements provided for in this instrument, guidance on the amendments to the Charges Regulations and the PLPS Regulations will be produced by NHSE-I with input from the PSNC, BMA and DDA as appropriate. DHSC is very confident that the roll-out would be done in a collaborative way – as part of the national effort against COVID-19.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies from the changes to the Charges Regulations or the PLPS Regulations. The changes are designed to ensure that members of the public can access any COVID-19 treatment that they are eligible to receive outside hospital without needing to pay a prescription charge or to attend at a pharmacy or dispensary, if the Secretary of State does decide to make or approve such arrangements. As noted above, this has the potential to support patient care, and reduce hospital admissions and morbidity. The primary care contractors will be remunerated for the services in question.

12.2 The impact on the public sector of making prescriptions for COVID-19 free could mean, depending on the treatment in question, that NHSE-I will not be able to raise

perhaps between £500,000 and £1m over 6 months. However, it very much depends on the scope of the roll-out and the patients impacted.

12.3 An Impact Assessment has not been prepared for this instrument. The provisions for pharmacies are subject to further negotiations with the PSNC on the fees for new services.

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 PSNC on any problems identified.

15. Contact

15.1 Claire Potter at DHSC telephone 0113 254 5975 or email claire.potter@dhsc.gov.uk can be contacted with any queries regarding the changes in respect of the Charges Regulations in this instrument.

15.2 Marta Senger at DHSC, telephone: 02079722922 or email: marta.senger@dhsc.gov.uk can be contacted with any queries regarding the changes to the PLPS Regulations in this instrument.

15.3 Jeannette Howe, Deputy Director for Pharmacy, at DHSC can confirm that this explanatory memorandum meets the required standard.

15.4 Nadhim Zahawi MP, Parliamentary Under Secretary of State for Covid-19 Vaccine Deployment can confirm that this explanatory memorandum meets the required standard.