EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2022

2022 No. 930

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 National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended) which set out the framework for market entry and exit for dispensing contractors and their terms of service.

2.2 The amendments enable new reimbursement arrangements for Covid-19 vaccinations and antivirals, introduce a requirement for all pharmacy contractors to complete an annual workforce survey and make changes to the market entry process.

2.3 The amendments provide that:

- Where the Government has centrally purchased Covid-19 vaccines or Covid-19 antivirals and makes those products available to community pharmacies at no cost, the determinations for pharmaceutical remuneration are to set a zero or nominal NHS reimbursement price for those products, if certain conditions are met.
- Completion of an annual workforce survey by pharmacy contractors is mandatory and that the requirement to complete a patient satisfaction survey is removed.
- The required 45-day notice period is reduced to 30 days for the notification of consolidation of community pharmacies on to one site.
- Updates of fitness to practise information about superintendents are to be provided up until they are included on such a list, or the application can no longer proceed.
- Contractors are permitted to decrease supplementary hours with five weeks' notice to NHS England and increase supplementary hours with no advance notice.
- NHS England is no longer required to keep lists of all NHS chemists that provide the Electronic Prescription Service (EPS).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is to 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 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations") govern the arrangements in England, under Part 7 of the National Health Service Act 2006 ("the NHS Act"), for the provision of pharmaceutical and local pharmaceutical services. The core pharmaceutical or local pharmaceutical service is the dispensing of NHS prescriptions.

6.2 The scheme for payment for pharmaceutical and local pharmaceutical services in Part 7 of the NHS Act is predicated on the basis that the determining authorities for pharmaceutical remuneration will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients.

6.3 However, there are statutory exemptions to remunerating service providers when they provide pharmaceutical services and local pharmaceutical services. Section 161 of the Health and Care Act 2022 made amendments to the NHS Act increasing the exemptions to cover:

a) vaccinations and immunisations; and

b) medicinal products used for the prevention or treatment of disease in a pandemic or an anticipated pandemic; and

c) associated products such as diluents and syringes.

6.4 The changes in this instrument are not intended to radically change NHS pharmaceutical service provisions or payment mechanisms. The aim is to strengthen the legal basis for scenarios when the usual supply routes need to be bypassed to address a public health need.

6.5 The additional regulations make a small number of relatively minor amendments to the PLPS Regulations.

6.6 The scheme for market entry is, for most community pharmacies and all dispensing appliance contractors, based on a "pharmaceutical list" system. Potential providers apply to be on these lists, held by NHS England, and submit applications in accordance with the requirements of the PLPS Regulations. This includes some information about the fitness of companies, and their directors and superintendents, to provide services. Each body corporate that runs a community pharmacy has to have a "superintendent", who performs a key role in ensuring the safe and effective supply of medicines by that business. Applicants will now be required to provide updates of the fitness information about this key individual up until they are actually included on such a list or the application can no longer be proceeded with. Consequential amendments are made to provide for redetermination of applications where this is necessary on fitness grounds.

6.7 Retail pharmacy businesses that own more than one business in a particular area may wish to consolidate their activities onto one site. Potentially, this might create an opportunity for a rival business in the area and so there is a special type of application that allows businesses to obtain some reassurance about that before proceeding. A local notification process is embedded in the process of making this type of consolidation application, as it is for other, more standard types of market entry applications, so that representations can be made in relation to an application. The period for making such representations, in the case of consolidation applications, is reduced by this instrument.

6.8 The requirement for NHS England to keep lists of NHS chemists (community pharmacies on pharmaceutical lists and dispensing appliance contractors) that use the EPS, the NHS service that is used to for the transmission of electronic prescriptions, most notably from GP practices to community pharmacies, is removed.

6.9 The notice period where a community pharmacy on a pharmaceutical list wants to reduce its supplementary hours, which are ordinarily the hours it is open above 40 hours per week, is reduced – and the notification requirement is removed altogether where the pharmacy wants to increase its supplementary hours.

6.10 There is a new requirement for community pharmacies on pharmaceutical lists to undertake an annual workforce survey as part of their clinical governance obligations, but the existing requirement to undertake a patient satisfaction survey is removed from those clinical governance obligations.

7. Policy background

What is being done and why?

Zero or nominal reimbursement of coronavirus vaccines and coronavirus antivirals

7.1 Covid-19 vaccinations have been centrally secured and supplied free of charge directly to pharmacies who are providing Covid-19 vaccination services. In turn, pharmacies have been paid for the enhanced service of administering them ("enhanced services" are a type of additional pharmaceutical service that is directly commissioned by NHS England), but there has been no reimbursement for the basic cost of the vaccines that are administered, and none is currently proposed. There has been uncertainty about the legal basis for the approach taken to reimbursement to date, although the position has now been put beyond doubt by amendments made to the NHS Act by the Health and Care Act 2022, and now to the PLPS Regulations by this instrument.

7.2 To date, centrally purchased Covid-19 antivirals have not been made available to community pharmacies for onward supply to patients, but this instrument would support such deployment in the future by supporting either zero or nominal NHS reimbursement prices for antivirals that a pharmacy had received for free from the central stock.

7.3 Accordingly, in the future, in relation to both COVID-19 vaccines and antivirals, there could be:

a) Zero reimbursement. This is the simpler scenario. The pharmacy would not be able to claim anything for the basic cost of the vaccine or antiviral that it had supplied or administered, although it would be paid for the service that it

provided, in the course of which the vaccine or antiviral was supplied or administered.

b) Nominal reimbursement. Ordinarily when a community pharmacy supplies a medicine or drug to a NHS patient it makes an amount that is known as "margin". "Margin" is the term used to describe the difference between the amount that a pharmacy purchases a product for, and the NHS reimbursement price they are paid for dispensing/administering it. The changes made by this instrument will allow the determining authorities that set the NHS reimbursement arrangements for prescription items and services (the Department and NHS England) to set a reimbursement price that essentially cover the cost of the margin that the pharmacy would potentially lose because it had sourced the product from a central stock rather than purchasing the product itself.

However, it is not necessarily the case that zero or nominal reimbursement would be the model followed in any future deployment of Covid-19 vaccines or antivirals. The amendments made by this instrument have been worded to provide for other reimbursement options where the precise conditions for zero or nominal reimbursement of centrally purchased stock are not followed. For example, deployment models that involve the "selling on" of a product, where the pharmacy buys the centrally purchased stock, or that anticipate the centrally purchased stock not being the only source of supply for community pharmacies, are also possible.

The adoption of any particular deployment and reimbursement model would be the subject of further discussions with the representative body for community pharmacies, the Pharmaceutical Services Negotiating Committee (PSNC), which is consulted on all determinations of pharmaceutical remuneration under section 165(1)(a) of the NHS Act 2006.

Community Pharmacy Workforce Survey (CPWS)

7.4 Health Education England has committed to conduct an annual Community Pharmacy Workforce Survey (CPWS) which provides up to date information about the current workforce numbers and skill mix in community pharmacy teams. Participation in the survey is currently voluntary and completion rate is low – 47% last year, undermining credibility of the findings. We have therefore decided to make completion of the HEE survey mandatory and, to balance this, to remove the current requirement to conduct a patient satisfaction survey. Mandating completion will ensure more robust data is available to inform future planning and investment.

Notification of consolidation applications

7.5 Prior to the amendments made by this instrument, the PLPS Regulations required a 45-day notice period for the local notification of consolidation of community pharmacies on to one site, as described in paragraph 6.6 above. A reduced consultation period of 30 days is intended to accelerate the consolidation process. As is indicated above, that process allows businesses to reduce down to a smaller number of sites, with some reassurance that if they do so, NHS England will not simply allow new competitors into the market. Consolidations reduce the number of pharmacies in a particular area overall, which is in keeping with our desire that pharmacies should not simply be "clustered" at favourable locations.

Superintendents of new entrants onto pharmaceutical lists

7.6 A loophole has been identified in the PLPS Regulations that a Superintendent of a business (see paragraph 6.5 above) who takes over after an application to join a pharmaceutical list after the application has been made but before the opening of the new premises is not required to submit any fitness information as part of the applications process, such as information relating to criminal convictions. We have closed this loophole.

7.7 This also has implications for the procedures to be followed after NHS England or Integrated Care Boards (ICBs) decide an application but it is under appeal, or *when* the appeals process has reached its final outcome, but the successful business is in the window period that is allowed between the decision and actual opening. In these circumstances, it is possible that NHSE or the ICB may be told information of serious concern and they may need to re-determine the application – or at least that aspect of it that relates to fitness to provide pharmaceutical services. The changes will allow for new flexibility to deal with this type of situation, essentially allowing the same sort of action that could have been taken before the initial decision, to be taken *instead* after the initial decision but prior to opening.

Supplementary hours

7.8 The PLPS Regulations require 3 months' notice of changes to supplementary opening hours (pharmacies are generally open for a core 40 hours every week, and anything above that is treated as supplementary hours). Changes are proposed to permit contractors to decrease supplementary hours with five weeks' notice to NHSE and increase supplementary hours with no advance notice. In practice this would still require patient notification for reduction of hours within the ordinary 28-day prescription cycle, whilst at the same time supporting businesses by allowing greater flexibility over opening.

EPS lists

7.9 Currently NHS England is required to keep lists of all NHS chemists (community pharmacies on pharmaceutical lists and dispensing appliance contractors) that provide the EPS. Whilst not all dispensing appliance contractors have to be connected to the EPS, previous regulation changes made it mandatory for all community pharmacies to be connected, and so the requirement therefore no longer serves the original practical purpose that it was intended to serve and can be removed.

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 2018.

9. Consolidation

9.1 DHSC does not consider that there is a current need to further consolidate this instrument.

10. Consultation outcome

10.1 Customarily, DHSC seeks the views of the Pharmaceutical Services Negotiating Committee (PSNC) on changes to the PLPS Regulations. DHSC has met with the

PSNC to discuss the policy changes and draft instrument, and responded to their comments, making changes to this instrument where appropriate.

11. Guidance

11.1 There will not be any guidance issued in connection with the zero/nominal reimbursement regulations.

11.2 The relevant guidance for the workforce survey and market entry regulations connected to the CPCF will be published by NHS England.

12. Impact

12.1 An Impact Assessment has not been prepared for the amendments regarding the supply of |Covid-19 vaccines and Covid-19 antivirals. This instrument is enabling and facilitative in that, principally, it will allow for the NHS to pay zero or nominal reimbursement for coronavirus vaccines and coronavirus antivirals where they have been provided free of charge to pharmacies.

12.2 The generally beneficial nature of this instrument means that no adverse impacts are foreseen in the context of the discharge of the Secretary of State's Public Sector Equality Duty or his general duties under the National Health Service Act 2006. In particular, these changes will support the continuous improvement in the quality of NHS services, as mentioned in section 1A of the 2006 Act.

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 As the PLPS Regulations concern the provision of NHS 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 nation-wide standards and practices in the provision of such services as part of the nationally determined contractual frameworks.

14. Monitoring & review

14.1 DHSC monitors the implementation and efficient operation of the PLPS Regulations. It has regular discussions with interested parties including the NHS and PSNC as mentioned in paragraph 10.1 above on any problems identified.

15. Contact

15.1 Natasha Padam at the Department of Health and Social Care Telephone: 0207 972 1570 or email: Natasha.Padam@dhsc.gov.uk can be contacted with any queries regarding the zero or nominal reimbursement of coronavirus vaccines and coronavirus antivirals provision in this instrument.

15.2 Stefan Politowicz at the Department of Health and Social Care Telephone: 0113 254 6949 or email: Stefan.Politowicz@dhsc.gov.uk can be contacted with any queries regarding all other provisions in this instrument.

15.3 Ed Scully, Director for Primary Care, at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.

15.4 James Morris MP, The Parliamentary Under-Secretary at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.