EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2023

2023 No. 479

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 His Majesty.

2. Purpose of the instrument

2.1 These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended) ("the PLPS Regulations"). The principal purposes of this instrument are to introduce new regulatory flexibilities regarding the opening hours of NHS community pharmacies and to require NHS community pharmacies to have business continuity plans to deal with the suspension of the provision by them of NHS pharmaceutical services.

Amendments to the PLPS Regulations

2.2 The amendments to the PLPS Regulations in essence are:

- To permit NHS England to implement temporary local hours plans in areas where patients are experiencing or likely to experience significant difficulty in accessing NHS pharmaceutical services.
- To require all pharmacy owners to prepare business continuity plans and implement these plans in the event of temporary suspension of services for a reason beyond the control of the pharmacy owner – in order to support patient access to NHS pharmaceutical services.
- To make it easier for pharmacy owners to change their regular core opening hours in order to close the pharmacy during the day for staff breaks, as long as this does not change the total number of core opening hours on a given day.
- To permit pharmacies obliged to open for 100 hours per week to apply to NHS England to reduce opening hours to 72 or above, subject to them maintaining their pre-existing opening hours between 5pm-9pm Monday to Saturday, their pre-existing opening hours between 11am-4pm on Sundays (with an exception for rest breaks) and their pre-existing total of Sunday hours,
- To change the "needs" test that normally applies to applications to change core opening hours of pharmacies, and
- To simplify and clarify specific aspects of the market entry procedures.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instrument

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) 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 These Regulations amend the PLPS Regulations, which govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of NHS pharmaceutical and local pharmaceutical services, such as the dispensing of NHS prescriptions.

6.2 Most pharmaceutical services provision in England is by community pharmacies that are on lists, known as pharmaceutical lists. Applications for entry onto those lists are determined by NHS England (who may now delegate this type of function to integrated care boards, but the functions will remain in NHS England's name).

6.3 Arrangements with retail pharmacy businesses are made on the basis of either entry on these approved 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". 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.

6.4 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. Those arrangements are not affected by these Regulations.

6.5 Decisions by NHS England 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. Known as the Pharmaceutical Needs Assessments, these 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.

6.6 Between 2005 and 2012, a number of community pharmacies were allowed onto pharmaceutical lists if they agreed to provide services for 100 hours per week, rather than the usual 40 core hours, but the legislation permitting this was revoked in 2012. Before now, 100 hours conditions could not be removed, even if the pharmacy relocated. Whilst in theory it was possible, between 2005 and 2012, for a DAC to open subject to a 100 hours condition, in practice none did so.

7. Policy background

What is being done and why?

7.1 These Regulations allow 100 hours pharmacies, for the first time, to reduce their core opening hours. The new minimum is 72 hours per week, if the pharmacy contractor makes an application to NHS England to change their commitment. However, as part of the reduction, they are not allowed to reduce their pre-existing hours between 5pm and 9pm, Monday to Saturday, their pre-existing opening hours between 11am-4pm on a Sunday (with an exception for rest breaks) and the pre-existing total number of hours on a Sunday. The framework for imposing the new opening hours commitments will be a framework that already exists for NHS England to direct community pharmacies be open for a certain number of core hours, or on set days and set times, and this has been adapted to take account of these new core hours reductions.

7.2 Before now, there has been some uncertainty about whether or not opening hours directions survive a change of ownership of a pharmacy, and an amendment is made to state that they do. If a change of ownership is combined with a relocation, a new opening hours direction has to be issued, which will need to reflect the new minimum of 72 hours a week if the old premises were ever subject to a 100 hours condition or, going forward, to an opening hours direction that is in succession to a 100 hours condition. This will provide market certainty – as well as a stable basis for the new 72 hours arrangements to be as binding, in practice, as the previous 100 hours conditions.

7.3 There is a "needs" test, which up until now has applied to all applications to NHS England requesting a direction to change in core opening hours. This is disapplied in cases where a 100 hours pharmacy is reducing its hours to a minimum of 72 – as is a separate test relating to the reasonableness of remuneration.

7.4 This "needs" test has been relatively onerous, requiring the pharmacy owner to produce evidence that their proposed new hours will ensure that the new arrangements will continue to meet the needs of likely users of the pharmacy, with the implication that any changes to hours would need to reflect a changing pattern of needs. Going forward, in those cases in which the needs test does apply, the applicant who wants to change their core opening hours will be required either to demonstrate that they are able to maintain as necessary the existing level of service provision in that area or, if maintaining the existing level of service provision is neither a necessary nor a realistically achievable outcome, that they are able to maintain a sustainable level of adequate service provision.

7.5 Not all changes to opening hours need to follow the applications and directions procedure. Changes to supplementary opening hours (the additional hours during which a pharmacy contractor says they will provide NHS pharmaceutical services, beyond their core opening hours) can proceed by way of notification of the change to NHS England only, and this group of notification only changes is expanded to allow addition of the rest breaks up to one hour long in core opening hours, subject to caveats that include not allowing pharmacies that are subject to a 100 hours condition or directions that succeed such a condition to add or change a rest break in this way. Pharmacy contractors that are subject to a 100 hours condition or the directions that succeed it and contractors who want to reduce the duration of the existing rest breaks that are longer than one hour or increase a rest break to beyond one hour will need to make an application to make any changes to their core opening hours and a needs test will apply.

7.6 For most cases that follow the notification procedure, the notice that has to be given to NHS England of the change is five weeks, but where the pharmacy wants to increase its supplementary hours, all that has been required is that the pharmacy submits a return to NHS England informing it of the change. These Regulations specify that such return must be submitted before the change takes place.

7.7 Breach of the opening hours requirements of the PLPS Regulations ordinarily puts a pharmacy in breach of their NHS terms of service, but this has not been the case if the breach was for a reason beyond the control of the pharmacy owner, they notified NHS England as soon as was practicable and they used all reasonable endeavours to resume the provision of services as soon as was practicable. The notification requirement is amended to require advance notification, wherever possible, and a new obligation is added. From 31st July 2023, pharmacy owners will also need to use all reasonable endeavours to implement a business continuity plan. Separately, they are required to have such a plan, and there are some specified obligations related to that. However, the obligation on pharmacy owners, where practicable, to make arrangements with other providers of NHS pharmaceutical or local pharmaceutical services in their area during a temporary closure is removed.

7.8 In areas of England where patients are experiencing or likely to experience significant difficulty in accessing pharmaceutical services, NHS England is given powers to establish local hours plans with any community pharmacies that are willing to participate in them. These plans will set out revised opening hours which will temporarily override participating pharmacies' normal pharmacy opening hours.

7.9 Changes are made to the application procedure for entry onto a pharmaceutical list, which will apply not just to potential pharmacy contractors but also to potential DACs. Firstly, once an application has been granted, the applicant has a limited time to send a "notice of commencement" specifying when they will open. Provided a notice is sent before the end of that window period, the date specified as the date on which services are to be commenced, either in initial or revised notice, must be no more than 60 days after the end of that window period.

7.10 The information to be supplied by the applicant is also revised – in effect to focus on key people's (such as directors and superintendents) work histories of the previous seven years, rather than requiring a general account of these individuals' professional experience, as has been the case previously. There is also a provision to prevent unnecessary duplication of information already submitted. However, if information was sent more than seven years previously, it will need to be sent again.

Explanations

What did any law do before the changes to be made by this instrument?

7.11 Prior to these Regulations, 100 hours pharmacies were not allowed to reduce their core opening hours to below 100 hours. This commitment survived even a change of ownership or a relocation – and was imposed by a condition attached to the listing of the premises in the relevant pharmaceutical list.

7.12 The 100 hours pharmacy owner could change days on which or times at which the pharmacy was obliged to provide pharmaceutical services, but the overall total had to be at least 100.

7.13 More broadly, there were two procedures – a directions procedure and a notifications procedure – which had to be followed for changes to opening hours. Essentially, the

directions procedure applied to core opening hours and a change via notification to NHS England was only available for supplementary opening hours. As noted above, the directions procedure was subject to a "needs" test.

7.14 As noted above, breach of the opening hours requirements of the PLPS Regulations ordinarily puts a pharmacy in breach of their NHS terms of service, but there was the exception explained in paragraph 7.7. The only mitigating measures to support patients in the event of temporary suspension was an obligation on pharmacy owners, where practicable, to make arrangements with other providers of pharmaceutical or local pharmaceutical services in their area during a temporary closure. The PLPS Regulations did not specify what such arrangements needed to include.

7.15 There is no statutory precedent for the local hours plans mentioned in paragraph 7.8 above.

7.16 The changes to the applications procedures take effect in the context of very detailed requirements, in the PLPS Regulations, as to what pharmaceutical list applications must include.

Why is it being changed?

7.17 The changes relating to notification of opening hours are made to provide more flexibility for pharmacy contractors to alter their opening hours to provide rest breaks for staff during the day – and to clarify the timing of notifications of increased supplementary opening hours.

7.18 The changes relating to 100 hours pharmacies are more far reaching and relate to 100 hours pharmacies closing at a rate six times higher than 40 hours pharmacies. Allowing 100 hours pharmacies to reduce their core opening hours whilst at the same time protecting certain core opening hours for patients (evenings and Sundays, when other pharmacies and primary care providers nearby are likely to be closed), should help to protect the patient access currently provided in particular by 100 hours pharmacies. These hours are likely to be lost if a 100 hours pharmacy permanently closes. Permitting 100 hours pharmacies to reduce opening hours to 72 or above should help prevent permanent closures of these pharmacies.

7.19 Introducing a requirement for pharmacies to prepare business continuity plans that are proportionate to the needs of those patients who are anticipating or are accustomed to receiving pharmaceutical services from pharmacy premises, should help reduce impact on patients if a pharmacy has to temporarily close.

7.20 Permitting NHS England to temporarily establish local hours plans will support patients' access to services if in a particular area patients are experiencing, or are likely to experience, significant difficulty in accessing pharmaceutical services. Holiday periods or regional pressures on workforce can be an occasion of such difficulties, but the potential need for such plans is also part of the learning from the covid pandemic.

7.21 The opportunities to ease administrative burden on contractors when applying to join pharmaceutical list and clarify the permissible opening dates of a new pharmacy were identified in discussions with the sector's representative body (the Pharmaceutical Services Negotiating Committee (PSNC)).

What will it now do?

7.22 In the case of rest breaks, pharmacy contractors, with the exception of those who are subject to a 100 hours condition or have a direction that succeeds it, will be able to notify NHS England about closing the pharmacy for one hour during the day as long as this change does not alter the total number of core opening hours on any given day. This change will not require NHS England approval and could be actioned in five weeks following a notification to NHS England.

7.23 In the case of the reduction in hours of 100 hours pharmacies, pharmacy contractors obliged to open for 100 hours a week will be able to apply to NHS England and reduce their opening hours to 72 or more, as long as they remain open for their pre-existing commitments between 5pm-9pm Monday to Saturday and between 11am-4pm on Sunday (with an exception relating to including a rest break) – and they maintain their total number of pre-existing Sunday opening hours.

7.24 In the case of the change to the needs test that applies to most applications for changes to core opening hours, pharmacy contractors will need to meet the new, less onerous test described in paragraph 7.4.

7.25 In the case of changes to supplementary opening hours, notification of increased hours will simply need to be in advance of any changes.

7.26 In the case of business continuity plans, all pharmacy contractors will need to prepare them by 31st July 2023 and be required to use all reasonable endeavours to implement the plans in the event of temporary suspension of services at or from their pharmacy for reason outside of their control.

7.27 In the case of local hours plans, NHS England will be able from 25th May 2023 to implement, in agreement with participating contractors, local hours plans in areas where patients are experiencing or likely to experience significant difficulty in accessing pharmaceutical services. For the duration of the plan, contractors will be able to alter their opening hours to ensure patient access to services in the local area is maintained. Participation will be entirely voluntary.

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 currently no plans to consolidate the PLPS Regulations.

10. Consultation outcome

10.1 Customarily, the Department seeks the views of the Pharmaceutical Services Negotiating Committee (PSNC) on changes to the PLPS Regulations. The Department has been able to discuss the policy changes with PSNC and responded to their comments, making changes to the Regulations where appropriate.

11. Guidance

11.1 Departmental guidance is not required. Pharmacy contractors and DACs will be supported with guidance in their usual ways by NHS England.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The Regulations apply to small businesses, including firms employing up to 20 people. As these Regulations concern the provision of NHS community pharmaceutical services in England on the basis of what is, in all cases at least in part, 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 framework.

13.2 To minimise the impact of the requirements on small businesses (employing up to 20 people), the requirement to have business continuity plans available at the premises level is delayed until 31st July 2023. The requirements that aim to provide contractors with flexibilities to amend their opening hours are not delayed.

14. Monitoring & review

14.1 The Department monitors the implementation of the Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation.

15. Contact

15.1 Inna Kochetkova at the Department of Health and Social Care (telephone: (0113) 254 6114 or email: inna.kochetkova@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

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

15.3 Neil O'Brien MP Parliamentary Under Secretary of State for Primary Care and Public Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.