

2023 No. 479

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical and Local
Pharmaceutical Services) (Amendment) Regulations 2023**

Made - - - - - *26th April 2023*

Laid before Parliament *27th April 2023*

Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State for Health and Social Care makes these Regulations in exercise of the powers conferred by sections 126, 129 and 272(7) and (8) of the National Health Service Act 2006(a).

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023.

(2) These Regulations, apart from regulations 9(6) to (8) and 13, come into force on 25th May 2023.

(3) Regulations 9(6) to (8) and 13 come into force on 31st July 2023.

(4) These Regulations extend to England and Wales and apply in relation to England only.

Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(b) are amended in accordance with regulations 3 to 13.

Amendment of regulation 65

3.—(1) Regulation 65 (core opening hours conditions) is amended as follows.

(2) Omit paragraph (3).

(3) Before paragraph (4) insert—

(a) 2006 c. 41. Section 126 has been amended by: the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63; the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraph 30 and 47(j); and the Health and Care Act 2022 (c. 31) (“the 2022 Act”), Schedule 1, paragraph 1. Section 129 has been amended by: the Health Act 2009 (c. 21), sections 26, 27 and 38, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraphs 120 and 121; the 2022 Act, Schedule 1, paragraph 1; and S.I. 2010/231. *See* section 275(1) of the National Health Service Act 2006 (“the 2006 Act”) for the meanings given to “prescribed” and “regulations”, which are relevant to the powers being exercised. The powers conferred by these sections are exercisable by the Secretary of State only in relation to England, by virtue of section 271(1) of the 2006 Act.

(b) S.I. 2013/349, as amended.

“(3A) NHS England may remove a 100 hours condition in respect of premises of an NHS pharmacist and replace it with a direction under paragraph (4) or (5) or paragraph 25 or 26 of Schedule 4, but that direction, and any subsequent direction which replaces that direction (whether it is in respect of those premises or any premises to which that NHS pharmacist, or any NHS pharmacist that is in succession to that NHS pharmacist, relocates), must specify a total number of core opening hours of not less than 72.”.

(4) In paragraph (4)(a)—

- (a) in paragraph (i), omit “(other than as a consequence of a 100 hours condition)”;
- (b) in paragraph (ii)—
 - (i) after “the NHSCB agreed” insert “, or the NHS pharmacist undertook,”;
 - (ii) for “the additional” substitute “any additional”, and
 - (iii) for from “(that is” to “and 40)” substitute “, or any core hours specified that replace (at any distance in succession) a 100 hours condition,”;
- (c) in paragraph (iii), for “that undertaking and that” substitute “any such undertaking or”;
- (d) after “hours so undertaken, and” omit “during the additional opening hours”; and
- (e) after “set days so agreed” insert “or undertaken”.

(5) In paragraph (5)—

- (a) in sub-paragraph (b)(ii)(aa), for from “(that is” to “and 40)” substitute “, or any core hours specified that replace (at any distance in succession) a 100 hours condition,”;
- (b) after “hours so undertaken, and” omit “during any additional opening hours”; and
- (c) after “set days so agreed” insert “or undertaken”.

New regulation 65A

4. After regulation 65 (core opening hours conditions) insert—

“Continuity in respect of opening hours directions

65A.—(1) In this regulation, “opening hours directions” means directions that have been given under regulation 65(4) or (5), or issued in accordance with paragraph 25 or 26 of Schedule 4 or paragraph 15 or 16 of Schedule 5, or given under or issued in accordance with earlier provisions which that regulation and those paragraphs have (at any distance in succession) replaced.

(2) Opening hours directions given or issued in respect of premises included in a pharmaceutical list apply to any NHS chemist listed in relation to those premises, not just to the NHS chemist to whom they were given or issued.

(3) Where, by virtue of regulation 24 or 26(2), an excepted application may be granted in circumstances where the applicant is undertaking to provide the same pharmaceutical services as those that are already being provided, but at premises that are not already included in a pharmaceutical list, that application must be refused where opening hours directions apply in respect of the premises from which the applicant is relocating the relevant business, unless—

- (a) the applicant, as part of their undertaking, undertakes to provide pharmaceutical services for any total number of core opening hours, and on any set days and at any set times, specified in those opening hours directions, taking into account any variation in respect of a rest break in accordance with paragraph 23(7)(bd) of Schedule 4; and
- (b) NHS England is, accordingly, required to give directions under regulation 65(4) in the same terms as those given in those opening hours directions, but in respect of the premises to which the applicant is relocating the relevant business and taking into account any variation in respect of a rest break in accordance with paragraph 23(7)(bd) of Schedule 4.

(4) In circumstances where, in respect of any premises, there are opening hours directions that have replaced (at any distance in succession) a 100 hours condition, whether that condition applied in respect of those premises or other premises, any routine application to relocate from those premises must be refused unless—

- (a) the applicant undertakes to provide pharmaceutical services, at the premises to which the applicant is relocating the relevant business, for any total number of core opening hours, and on any set days and at any set times, specified in those opening hours directions; and
- (b) NHS England is, accordingly, required to give directions under regulation 65(4) in the same terms as those given in those opening hours directions but in respect of the premises to which the applicant is relocating the relevant business.”.

Amendment of regulation 67

5. In regulation 67 (conditions relating to voluntary closure of premises)(a), in paragraph (2)(b), for paragraph (i) substitute—

- “(i) 6 months in advance of that date, in the case of premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, or”.

Amendment of paragraph 3 of Schedule 2

6. In Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed), in Part 1 (information to be included in routine and excepted applications), in paragraph 3 (fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list), in sub-paragraph (7), for paragraph (b) substitute—

- “(b) personal work history for the previous 7 years from the date on which the application is submitted, together with a declaration by P (where it can be made, in the case of sub-paragraphs (ii) and (iii)) that—
 - (i) the details provided are a complete and accurate account of that personal work history,
 - (ii) P has not been dismissed in that time, and if P cannot make this declaration, the reasons for being unable to do so must be covered in P’s personal work history,
 - (iii) P has not had a break of more than 6 months from work in that time, and if P cannot make this declaration, the reasons for being unable to do so must be covered in P’s personal work history, and
 - (iv) if P is an NHS chemist, or is a partner in or a director or superintendent of a NHS chemist, P or the NHS chemist in which P is a partner or of which P is a director or superintendent, has complied with the requirements of paragraph 31 of Schedule 4 and paragraph 21 of Schedule 5 that are applicable to P.”.

Amendment of paragraph 5 of Schedule 2

7. In Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed), in Part 1 (information to be included in routine and excepted applications), in paragraph 5 (fitness information that has already been provided under pharmaceutical or local pharmaceutical services), after sub-paragraph (2) insert—

- “(3) Unless sub-paragraph (4) applies, information is only to be considered missing for the purposes of sub-paragraph (2)(b) if, having regard to the fact that the fitness of the

(a) Amended by S.I. 2016/1077.

applicant to be included in a pharmaceutical list has already been established (or if the applicant's fitness is under investigation, that investigation is being taken forward separately), it is nevertheless material to the consideration of the application.

(4) Information is to be considered missing for the purposes of sub-paragraph (2)(b) if it has previously been provided to NHS England or a Primary Care Trust by the applicant, but more than 7 years prior to the date of the application.

(5) If a declaration that is required to be included in an application has never previously been provided to NHS England or has previously been provided but it is no longer up to date—

- (a) an up to date declaration, together with any information that the applicant needs to provide in support of that declaration; or
- (b) any information that needs to be provided because the applicant is unable to make that declaration,

is to be considered as missing information for the purposes of sub-paragraph (2)(b).”.

Amendment of paragraph 34 of Schedule 2

8.—(1) In Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed), in Part 5 (notification, taking effect of decisions and rights of appeal to the Secretary of State), paragraph 34 (taking effect of listing decisions: general)(a) is amended as follows.

(2) In sub-paragraph (3B), for “both dates” substitute “the date on which the provision of services is to commence”.

(3) After sub-paragraph (3B) insert—

“(3C) A notice of commencement is invalid if the date included in it (on or after 25th May 2023), whether when the notice is given or after a change in accordance with sub-paragraph (3B), as the date on which the provision of services is to commence is more than 60 days after the end of the period within which the notice, if it is to be valid, must be sent, as determined in accordance with sub-paragraph (4).”.

Amendment of paragraph 23 of Schedule 4

9.—(1) In Schedule 4 (terms of service of NHS pharmacists), in Part 3 (hours of opening), paragraph 23 (pharmacy opening hours: general)(b) is amended as follows.

(2) In sub-paragraph (1)—

- (a) before “An NHS pharmacist (P)” insert “Subject to paragraph 23A,”;
- (b) in paragraph (d), after “days so set” insert “, subject to any variation in respect of a rest break in accordance with sub-paragraph (7)(bd)”;
- (c) in paragraph (e)—
 - (i) after “the additional opening hours”, at the first place where it occurs, insert “, or the core opening hours where paragraph 26(4A) applied to the issuing of the direction”, and
 - (ii) in sub-paragraph (ii), after “set out in that direction” insert “, subject to any variation in respect of a rest break in accordance with sub-paragraph (7)(bd)”.

(3) In sub-paragraph (6), after “the change” insert “before the change takes place”.

(4) In sub-paragraph (7), omit “and” at the end of paragraph (a) and for paragraph (b) substitute—

(a) Amended by S.I. 2016/1077 and 2020/885 and 1126.

(b) Amended by S.I. 2022/930.

“(ba) P must not change the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours, except for making a change that—

(i) amounts to the inclusion of a rest break which is no longer than one hour, or a change to such a rest break—

(aa) on a Monday to Saturday, which starts at least 3 hours after the start of the pharmacy’s opening hours and ends at least 3 hours before the end of the pharmacy’s opening hours, or

(bb) on a Sunday, and

(ii) does not change the total number of P’s core opening hours on a particular day,

otherwise than as provided for, and in accordance with the procedures set out in, paragraphs 25 and 26;

(bb) P must not change P’s supplementary opening hours in a way that reduces the time for which P’s pharmacy is open before or after a rest break on a Monday to Saturday to less than 3 hours (if P wants to change the supplementary opening hours affected by this requirement, P must also change the time of the rest break);

(bc) P must not change—

(i) the total number of P’s supplementary opening hours in a way that either reduces or leaves the same the total number of P’s supplementary opening hours, or

(ii) unless the change relates to an increase of the total number of supplementary opening hours, the days on which or the times at which pharmaceutical services are to be provided at P’s premises during supplementary opening hours,

for a period of at least 5 weeks after the day on which that notification was received by NHS England, unless NHS England agrees otherwise; and

(bd) P must not change the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours, in the case of making a change that—

(i) amounts to the inclusion of a rest break which is no longer than one hour, or a change to such a rest break—

(aa) on a Monday to Saturday, which starts at least 3 hours after the start of the pharmacy’s opening hours and ends at least 3 hours before the end of the pharmacy’s opening hours, or

(bb) on a Sunday, and

(ii) does not change the total number of P’s core opening hours on a particular day,

for a period of at least 5 weeks after the day on which that notification was received by NHS England, unless NHS England agrees otherwise.”.

(5) After sub-paragraph (7) insert—

“(7A) Paragraphs (ba) and (bd) of sub-paragraph (7) do not apply to changes to core opening hours of premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, and accordingly the core opening hours of such premises may only be changed in accordance with paragraph 25 or 26.”.

(6) Omit sub-paragraphs (8) and (9).

(7) In sub-paragraph (10)—

(a) for “for a reason” substitute “because of illness or another reason”;

(b) after “(1) and (7),” insert “or of paragraph 23A(5)(a),”;

(c) in paragraph (a), for “as practical; and” substitute “as practicable, in the manner required by paragraph 29D(2)(a) and wherever possible before the start of the suspension;”; and

(d) after paragraph (a) insert—

“(aa) P uses all reasonable endeavours to implement the business continuity plan that P is required to have by virtue of paragraph 29D; and”.

(8) In sub-paragraph (11), for “neither a “reasonable cause” for the purposes of sub-paragraph (8) nor” substitute “not”.

New paragraph 23A in Schedule 4

10. In Schedule 4 (terms of service of NHS pharmacists), in Part 3 (hours of opening), after paragraph 23 insert—

“Local hours plans

23A.—(1) Where NHS England is satisfied that people in a particular area are experiencing, or are likely to experience, significant difficulty in accessing pharmaceutical services on a temporary basis for an identified period, NHS England may establish a local hours plan with the NHS pharmacists in that area that are willing to participate in a local hours plan for that area.

(2) NHS England must, prior to establishing a local hours plan, consult any local pharmaceutical committee for the area that comprises or includes the area of the plan, unless NHS England decides that it is not practicable to do so.

(3) NHS England must notify any local pharmaceutical committee for the area that comprises or includes the area of a local hours plan that it establishes of the contents of that plan and any changes to it, including where further NHS pharmacists join or any NHS pharmacists cease to participate in the plan.

(4) The local hours plan is to be of a specified duration, determined by NHS England, and is to contain the temporary opening hours agreed between NHS England and each of the participating NHS pharmacists (each participating NHS pharmacist agrees their own but not other participants’ temporary opening hours).

(5) NHS pharmacists that have agreed to participate in a local hours plan—

(a) must ensure that pharmaceutical services are provided at their pharmacy premises during the agreed temporary opening hours; and

(b) may cease to participate in the plan and return to their core and supplementary opening hours, provided that, subject to sub-paragraph (8), they have given the notice period for doing so that they have each agreed with NHS England as part of the plan.

(6) NHS England may revise a local hours plan from time to time, including by allowing further NHS pharmacists to join, but any change to the plan that is a change to the temporary opening hours of an NHS pharmacist that is participating in the plan, or of their notice period as referred to in sub-paragraph (5)(b), must be agreed with that NHS pharmacist.

(7) A local hours plan ceases to have effect on the expiry of its specified duration, determined by NHS England in accordance with sub-paragraph (4), unless NHS England revises the specified duration, in which case the new specified duration becomes the specified duration of the plan, and further revisions are then also permissible pursuant to this sub-paragraph.

(8) If NHS England revises the specified duration of a local hours plan, an NHS pharmacist may cease to participate in the plan on the date that was the plan’s expiry date, having given prior notice of their intention to do so, which may be of a shorter period than their agreed notice period where—

- (a) the NHS pharmacist does not wish to participate in the plan beyond the expiry date that has been extended;
- (b) the timing of the revision means it is not possible, or not reasonably practicable, for prior notice to be given for the agreed notice period; and
- (c) the NHS pharmacist gives notice of their intention to cease to participate in the plan on the date that was the plan's expiry date as soon as it is reasonably practicable for them to do so.

(9) While a local hours plan has effect, the core and supplementary opening hours that have temporarily been suspended may be changed in accordance with paragraphs 23(6) and (7), 25 and 26.”.

Amendment of paragraph 24 of Schedule 4

11.—(1) In Schedule 4 (terms of service of NHS pharmacists), in Part 3 (hours of opening), paragraph 24 (matters to be considered when issuing directions in respect of pharmacy premises core opening hours) is amended as follows.

(2) For sub-paragraph (1) substitute—

“(1) Subject to paragraph 26(2A), where NHS England issues a direction for setting any days or times for opening hours under this Part, or determines them without issuing a direction, it must in doing so seek to ensure that the days and times at which pharmacy premises are open for the provision of pharmaceutical services in the area in which the premises that are the subject of the direction are located are such as—

- (a) to maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises; or
- (b) to maintain a sustainable level of adequate service provision for the people in that area or other likely users of the pharmacy premises, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.”.

(3) After sub-paragraph (4) insert—

“(5) Sub-paragraph (4) does not apply in circumstances where the direction is in respect of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies.”.

Amendment of paragraph 26 of Schedule 4

12.—(1) In Schedule 4 (terms of service of NHS pharmacists), in Part 3 (hours of opening), paragraph 26 (determination of pharmacy premises core opening hours instigated by the NHS pharmacist) is amended as follows.

(2) In sub-paragraph (1)—

- (a) before “at P’s pharmacy premises” insert “during core opening hours”; and
- (b) in paragraph (a), omit “(but not those required under any 100 hours condition)”.

(3) In sub-paragraph (2)—

- (a) before “Where P makes” insert “Except where sub-paragraph (2A) applies,”; and
- (b) for from “any changes” to “material to the application” substitute “the matters that NHS England must seek to ensure pursuant to paragraph 24(1)”.

(4) After sub-paragraph (2) insert—

“(2A) In the case of an application for a direction under sub-paragraph (4) that has the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, the total number of core opening hours to 72 or above, but without changing any or all of the following—

- (a) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (b) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—
 - (i) is no longer than one hour, and
 - (ii) starts at least 3 hours after the start of the pharmacy’s opening hours and ends at least 3 hours before the end of the pharmacy’s opening hours; and
- (c) the total number of core opening hours on a Sunday,

NHS England must grant that application, and paragraph 24(1) does not apply to such an application.

(2B) In the case of a valid application for a direction under sub-paragraph (4) to which sub-paragraph (2A) applies, if—

- (a) the date included in the application as the date on which P wishes to change P’s core opening hours is five weeks or more after the day on which the application is received by NHS England; and
- (b) NHS England has not determined the application by that date,

pending the determination of the application, P’s core opening hours are the core opening hours that P requested in the application.”.

(5) In sub-paragraph (4)—

- (a) in paragraph (a), before “(5) and (6)” insert “(4A),”; and
- (b) in paragraph (c), omit from “in which case” to the end of that paragraph.

(6) After sub-paragraph (4) insert—

“(4A) NHS England must not issue a direction under sub-paragraph (4), or revoke without replacing it an existing direction under that sub-paragraph, if doing so would have the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, any or all of the following—

- (a) the total number of core opening hours to below 72;
- (b) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (c) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—
 - (i) is no longer than one hour, and
 - (ii) starts at least 3 hours after the start of the pharmacy’s opening hours and ends at least 3 hours before the end of the pharmacy’s opening hours; and
- (d) the total number of core opening hours on a Sunday,

and an application seeking such a change is not a valid application for the purposes of sub-paragraph (2B).

(4B) On and after 25th May 2023, NHS England must not issue a direction under sub-paragraph (4), or revoke without replacing it an existing direction under that sub-paragraph, pursuant to an application made before 25th May 2023 for a direction pursuant to this paragraph as it had effect before 25th May 2023, if doing so would have the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies, any or all of the following—

- (a) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (b) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—
 - (i) is no longer than one hour, and
 - (ii) starts at least 3 hours after the start of the pharmacy’s opening hours and ends at least 3 hours before the end of the pharmacy’s opening hours; and

(c) the total number of core opening hours on a Sunday.”.

(7) In sub-paragraph (5)(a), before “it must not set out” insert “except in a case to which sub-paragraph (4A) applies,”.

New paragraph 29D of Schedule 4

13. In Schedule 4 (terms of service of NHS pharmacists), in Part 4 (other terms of service), after paragraph 29C (contact via NHSmail, pharmacy profiles and the Central Alerting System)(a) insert—

“Business continuity plans to deal with temporary suspensions

29D.—(1) An NHS Pharmacist (P) must have at all times an up to date business continuity plan for P’s pharmacy premises, which is available at those premises, to deal with the temporary suspension because of illness or another reason beyond the control of P of the provision of pharmaceutical services at or from those premises that—

- (a) is proportionate to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P; and
- (b) includes the components set out in sub-paragraph (2).

(2) The components are—

- (a) arrangements for notifying NHS England, in the approved manner—
 - (i) about the prospect of a temporary suspension, whenever such a suspension becomes likely, and
 - (ii) about a temporary suspension and its anticipated duration, wherever possible before the start of the suspension;
- (b) arrangements for updating the pharmacy profile mentioned in paragraph 29C(3) about the suspension, including in due course about the resumption of the provision of pharmaceutical services at the pharmacy premises;
- (c) if P provides directed services that provide people with urgent care services, arrangements for ensuring, to the extent practicable, that people are not referred to P’s pharmacy premises for those services during the temporary suspension;
- (d) arrangements, where practicable and to an extent that is reasonable having regard to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P, for notifying other providers of pharmaceutical and local pharmaceutical services and providers of primary medical services about the suspension and its anticipated duration;
- (e) arrangements for displaying information about the suspension and its anticipated duration—
 - (i) in the case of distance selling pharmacies, on the website for the distance selling pharmacy, clearly promoted to any user of the website when they first access it, or
 - (ii) in any other case, on a notice at P’s pharmacy premises visible from outside the premises, which also provides information, where appropriate in the approved manner and to an extent that is reasonable having regard to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P, about the availability of pharmaceutical or local pharmaceutical services at or from other pharmacy premises nearby; and
- (f) arrangements, where practicable, for the continuity of care for the people who are anticipating or are accustomed to receiving pharmaceutical services from P, including for any people who—

(a) Paragraph 29C was inserted by S.I. 2020/1126 and amended by S.I. 2023/98.

- (i) have booked appointments, or
- (ii) attend the pharmacy premises regularly for the supervised administration of medicines.

(3) For the purposes of sub-paragraph (2), “approved” means approved by NHS England.

(4) In the event of the temporary suspension, or the likely temporary suspension, of pharmaceutical services provision at or from P’s pharmacy premises, P must use all reasonable endeavours to implement P’s business continuity plan, and in the case of a likely temporary suspension, in a manner proportionate to that likelihood.”.

Signed by authority of the Secretary of State for Health and Social Care

Neil O’Brien
Parliamentary Under Secretary of State,
Department of Health and Social Care

26th April 2023

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the PLPS Regulations”). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical and local pharmaceutical services, such as the dispensing of NHS prescriptions.

Most pharmaceutical services provision in England is by community pharmacies that are on lists, known as pharmaceutical lists, held by NHS England. Applications for entry onto those lists are determined by NHS England (who may now delegate this type of function to integrated care boards). 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. Prior to these Regulations, those 100 hours pharmacies had not been allowed to reduce their 100 hours commitment. These Regulations allow them to reduce it to 72 hours per week (or to between 72 and 100 hours), if they make an application to NHS England to that effect. However, as part of the reduction, they are not allowed to reduce their hours between 5pm and 9pm, Monday to Saturday, or 11am to 4pm on a Sunday (with a limited exception for a rest break), or to reduce their overall number of hours on a Sunday. Any such evening or Sunday commitment that they had before these Regulations came into force becomes (with a limited exception for Sunday rest breaks) irreducible (regulation 12(1) and (2) and (4) to (7)).

The applications process that will allow for the reduction from 100 to 72 hours is a process which has applied to all opening hours changes for community pharmacies, apart from a specified group of changes that can proceed by way of notification only. Ordinarily, the applicant has been required to show that the new core opening hours are such as to ensure that pharmaceutical services provision in the area in which the pharmacy is located is on such days and at such times as are necessary to meet the needs of likely users of the pharmacy – and to provide information about any changes to those needs. This “needs” test is disapplied in cases where a pharmacy that is or ever was a 100 hours pharmacy is reducing its hours in the manner permitted – as is a separate test relating to the reasonableness of remuneration (regulations 11(3) and 12(3)).

In other cases, the “needs” test has itself been changed so that, going forward, the applicant who wants to change their core opening hours must either demonstrate that they are able to maintain as necessary the existing level of service provision for the people in that area, or, if maintaining the existing level of service provision is neither a necessary nor a realistically achievable outcome, they must instead show that they are able to maintain a sustainable level of adequate service provision (regulation 11(1) and (2)).

Routine applications for inclusion in a pharmaceutical list are assessed against a local plan known as a pharmaceutical needs assessment, but there are exceptions to this process that include some minor relocation applications and some minor relocation applications that are combined with changes of ownership. 100 hours conditions survive both relocation of a pharmacy business and

changes of ownership, and the provisions that already provide for core opening hours directions to be restated if a pharmacy business relocates have been amended to accommodate the core opening hours directions that replace 100 hours conditions. At the same time, provision has been made to ensure that all core opening hours directions survive a change of ownership where the business does not move, and to ensure that where pharmacy businesses do relocate, the applications process requires undertakings to maintain existing hours where there are directed hours (regulations 3 and 4). The notice period that has to be given in cases of voluntary closures of premises that have core opening hours directions that replace 100 hours conditions becomes the same as it is for premises that are subject to 100 hours conditions, which is six months (regulation 5).

The specified group of changes to opening hours that can proceed by way of notification only is expanded to allow for rest breaks in core opening hours to be changed in this way, 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. 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 was required before these Regulations was that the pharmacy submitted a return to NHS England informing it of the change. These Regulations specify that such a return must be submitted before the change takes place (regulation 9(1) to (5)).

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 about the cessation of services 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 of this set of obligations is amended to advance notification, wherever possible, and a new obligation is added. Pharmacy owners will, going forward, also need to use all reasonable endeavours to implement a business continuity plan. Separately, they are required to have such a plan, and some of the components of business continuity plans are specified. However, the obligation on pharmacy owners, where practicable, to make arrangements with other providers of pharmaceutical or local pharmaceutical services in their area during a temporary suspension is removed (regulations 9(6) to (8) and 13).

In areas of England where people are experiencing or likely to experience significant difficulty in accessing pharmaceutical services, NHS England is given powers to establish local hours plans with community pharmacies that are willing to participate in them. These plans will set out revised opening hours for the participating pharmacies and will temporarily override their normal opening hours. There are arrangements for consultation in some circumstances, and notification in others, of local pharmaceutical committees – and for the revision and duration of the plans (regulation 10).

A small number of changes are made to the application procedure for entry onto a pharmaceutical list, which will apply not just to entry onto the lists of community pharmacies but also to entry onto the separate lists of dispensing appliance contractors. Firstly, once an application has been granted, the applicant has a limited time to send a “notice of commencement” specifying when it will open. Provided a notice has been sent before the end of that window period, the applicant is able to revise its notice of commencement. Going forward, the date specified as the date on which services are to be commenced, either in the notice initially or on revision, must be no more than 60 days after the end of that window period (regulation 8).

Separately, the information to be supplied by the applicant when their application is initially made is revised in three respects. Firstly, the information to be supplied about a key individual’s (usually a director’s or a superintendent’s) professional experience is limited to a work history covering the previous seven years, together with a supporting declaration about related matters. Secondly, in the case of applicants who are already on pharmaceutical lists, provision is made to clarify that the information that needs to be supplied by them about fitness matters is limited to information that NHS England does not already hold but is nevertheless material to the application, and a further amendment is made to make it clear that this includes up to date declarations. Thirdly, if information has been provided before by applicants who are already on pharmaceutical lists but

more than seven years previously, this is to be treated as missing information and has to be submitted again (regulations 6 and 7).

An impact assessment in relation to these Regulations is available from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. A copy of it is also published alongside this instrument on www.legislation.gov.uk.

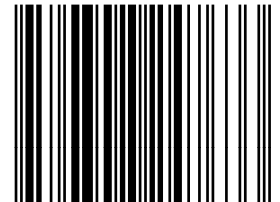
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£6.90

<http://www.legislation.gov.uk/id/uksi/2023/479>

ISBN 978-0-34-824763-3



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