

14 December 2020

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FILE REF: SHA/24437

DECISION MAKING BODY: NHS ENGLAND AND
NHS IMPROVEMENT – NORTH
EAST AND YORKSHIRE
("NHSE/I")

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PHARMACIST: LLOYDS PHARMACY LTD
("THE APPELLANT")

PREMISES: INSIDE SAINSBURYS,
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TEAM VALLEY TRADING ESTATE,
GATESHEAD, NE11 0JY

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) REGULATIONS 2013

**SCHEDULE 4 [Terms of Service of NHS Pharmacists]
PART 3 [Hours of Opening]**

1 Outcome

1.1 The appeal is granted and, pursuant to paragraph 25(3)(c)(ii), no direction is issued.

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SCHEDULE 4 [Terms of Service of NHS Pharmacists]
PART 3 [Hours of Opening]

DIRECTION OF ADDITIONAL CORE OPENING HOURS

1 Introduction

- 1.1 Relying on Paragraph 25 of Schedule 4, NHSE/I has requested that the Appellant open from 18:00 – 20:00 on Friday 25 December 2020.
- 1.2 The Appellant seeks to appeal to NHS Resolution.

2 Consideration

Rights of appeal

- 2.1 Where NHSE/I has directed a pharmacist to provide pharmaceutical services for its premises at set times and on set days in accordance with paragraph 25 of Schedule 4 of the Regulations, paragraph 25(7) provides a right of appeal to the Secretary of State for Health and Social Care ("the Secretary of State").
- 2.2 The Secretary of State has directed NHS Resolution to determine such appeals. As an authorised officer of NHS Resolution, I have considered the appeal and have determined it, in accordance with my delegated powers.

Opening hours

- 2.3 A pharmacy's opening hours may be categorised as:
 - 2.3.1 'core' opening hours (days on and times at which the pharmacy is obliged to be open), which may incorporate a direction of NHSE/I requiring fewer or greater than 40 hours; or
 - 2.3.2 'supplementary' opening hours (other days on and times at which the pharmacy undertakes to provide pharmaceutical services, as notified to NHSE/I).

Alteration of 'core' (including 'directed') opening hours

- 2.4 In accordance with paragraph 1(7)(c) of Schedule 2 to the Regulations, the pharmacy must provide, as part of an application for entry in the pharmaceutical list, the proposed core opening hours in respect of the premises during which it will be obliged to provide pharmaceutical services under paragraph 23(1) of Schedule 4 to the Regulations. These may be subject to a direction under paragraph 23(1)(c), (d) or (e)

Alteration of 'supplementary' opening hours

- 2.5 Other days or times at which services are to be provided (as set out in the original application for entry in the pharmaceutical list pursuant to paragraph 23(3) of Schedule 4 as "supplementary hours") may be altered by giving notice to NHSE/I, in accordance with paragraph 23(6)(a) without the need to make an application.
- 2.6 Notices under paragraph 23(6)(a) are not subject to review by NHS Resolution

NHSE/I's Request

- 2.7 NHSE/I wishes the Appellant to open from 18:00 – 20:00 on Friday 25 December 2020, a day on which it would otherwise be closed.

Information provided by parties

- 2.8 In a letter to the Appellant dated 25 August 2020, NHSE/I stated:
- 2.8.1 NHSE/I considers that the current core opening hours for pharmacies may not meet the needs of people in the area or other likely users of the pharmacy premises during the Christmas festive period.
- 2.8.2 NHSE/I are carrying out an assessment as to whether to issue a direction pursuant to paragraph 25(1) of Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 requiring the Appellant to provide pharmaceutical services at the following dates and times:
- 2.8.2.1 **Christmas Day, Friday 25 December 2020**, between the hours of **18:00 – 20:00**, for which you will be remunerated.
- 2.8.3 **Rationale for Direction:** According to NHSE/I records, since the inception of NHS England, the Appellant has never provided pharmaceutical services on a public / bank holiday. The Appellant is being requested to open as there are no other pharmacies open in the Gateshead area on this day at this time and it is possible that patients may require access to a pharmacy during this 2-hour period. Additionally, there are health bodies which can generate prescriptions open until late into the evening. Furthermore you are one of only 3 pharmacies which stock end of life medications which access may also be required.
- 2.8.4 If you want to make written representations about the proposed changes, they should be sent to NHSE/I at the above address within 30 days of the date of this letter, i.e. by 23 September 2020.
- 2.8.5 **Sunday 26 December 2020 – reminder:** NHSE/I would also like to take this opportunity of reminding you that Saturday 26 December 2020 (Boxing Day) is a normal working day and if your pharmacy usually opens on a Saturday, then it must do so on this day, unless you have submitted either a change of core hours application or a change to supplementary hours.
- 2.9 In a letter to the Appellant dated 22 October 2020, NHSE/I stated

- 2.9.1 Further to the letter of 24 August 2020, NHSE/I has concluded its assessment as to whether or not the provision of pharmaceutical services during the Bank Holidays, including Christmas Day, meets the reasonable needs of patients and members of the public in the Gateshead Health and Wellbeing Board Area. Pursuant to paragraph 25(1) of Schedule 4 of the NHS Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, the following direction is now issued.
- 2.9.2 This is to notify you, the contractor, of NHSE/I's proposed changes to the days on which and times at which your premises are to be open.
- 2.9.3 The pharmacy is directed to be open on **Friday 25 December 2020** between the hours of **18:00 – 20:00**, for which you will be paid **£209.30** per hour. To claim your payment, please complete the attached audit form and submit this within 28 days of providing this service.
- 2.9.4 Any direction that is issued will meet the requirements of paragraph 25, schedule 4 or paragraph 15, schedule 5 of the NHS Pharmaceutical Services Regulations 2013.
- 2.9.5 You have the right of appeal to the Secretary of State against our direction, in accordance with Schedule 4, Part 3, regulation 7 of the NHS Pharmaceutical Services Regulations 2013. Should you choose to appeal, then you should send in writing a concise and reasoned statement of the grounds for your appeal, within 30 days of the date of this letter (ie **17 November 2020**) to: appeals@resolution.nhs.uk or to: Primary Care Appeals, 4th Floor, Arena Point, Merrion Way, Leeds, LS2 8PA.
- 2.10 In a letter to NHS Resolution dated 17 November 2020 the Appellant stated:
- 2.10.1 With regard to the attached direction to open Teamvalley in Sainsburys fmg80 on 25th December – please could the Appellant request to move the open times to another store.
- 2.10.2 The reasons are that this store would be difficult to cover with regard to the actual Sainsburys store being closed. This would mean management and security of Sainsburys would have to be present alongside Lloydspharmacy team and pharmacist. The Appellant has opened previously and did not have any patients attend.
- 2.10.3 The Appellant would like to propose a more suitable community pharmacy to be put forward to open that would be accessible to the public with ample parking and easier access to be able to access.
- 2.10.4 The Appellant has a few options that are close to this store geographically, all offer nearby parking and would be more easily accessed by the public
- 2.10.4.1 Lloydspharmacy Wrekenton NE9 7JN – 1.9 miles away
- 2.10.4.2 Lloydspharmacy Harras Bank DH3 2PH – 3 miles away
- 2.10.4.3 Lloydspharmacy Concord Heworth Road NE37 2PY – 4 miles away
- 2.11 In a letter to NHS Resolution dated 19 November 2020 NHSE/I stated:
- 2.11.1 In August – initial notice of its intention to commission the pharmacy and invitation to comment on this- the Appellant made no comments within the 30 day period. If they have contacted NHSE/I with the offer of alternative stores (as suggested in the appeal), NHSE/I would have worked with the Appellant to open an alternative branch (as done in previous years). It is always open to

pharmacies to negotiate with an alternative branch of even different provider, to undertake the Direction on their behalf. The email was also notified to the Regional Manager, Mr Qureshi, who also made no comments.

2.11.2 In August, a summary of Lloyds directions across the CNE area was also provided to Mr Qureshi, who confirmed these had been sent to the rota co-ordinators – which included the Appellant.

2.11.3 In October – NHSE/I letter of Direction and audit/claim form.

2.12 No observations on the representations were received by NHS Resolution.

Assessment

2.13 I note that the letter from NHSE/I dated 22 October 2020 indicates that NHSE/I is directing the Appellant to open for the hours in question in accordance with paragraph 25 of Schedule 4.

2.14 I have considered paragraph 25 of Schedule 4 (Determination of pharmacy premises core opening hours instigated by the NHSCB), which reads as follows:

1. *Where it appears to the NHSCB, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee for the area in which the premises are situated, that the days on which or times at which pharmacy premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—*

- (a) *people in its area; or*
- (b) *other likely users of the pharmacy premises,*

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS pharmacist (P) whose premises they are to provide pharmaceutical services at the pharmacy premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

2. *Before concluding the assessment under sub-paragraph (1) the NHSCB must—*

- (a) *give notice to P of any proposed changes to the days on which or times at which the pharmacy premises are to be open; and*
- (b) *allow P 30 days within which to make written representations to the NHSCB about the proposed changes.*

3. *When it determines the outcome of its assessment, the NHSCB must—*

- (a) *issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);*
- (b) *confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5); or*
- (c) *either—*

(i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

4. *Where the NHSCB issues a direction under sub-paragraph (3) in respect of pharmacy premises that are to be required to be open—*
 - (a) *for more than 40 hours each week, it must set out in that direction—*
 - (i) *the total number of hours each week for which P must provide pharmaceutical services at the pharmacy, and*
 - (ii) *as regards the additional opening hours, the days on which and the times at which P is required to provide those services during those hours,*

but it must not set out in that direction the days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening hours; or
 - (b) *for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at the pharmacy premises.*
5. *The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring pharmacy premises to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring pharmacy premises to be open for either more or less than 40 hours each week).*
6. *The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which P is to provide pharmaceutical services at pharmacy premises, it must include with the notification a statement of—*
 - (a) *the reasons for the change; and*
 - (b) *P's right of appeal under paragraph (7).*
7. *P may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which P is to provide pharmaceutical services.*
8. *The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under paragraph (3).*
9. *The Secretary of State shall notify P of the determination and shall in every case include with the notification a statement of the reasons for the determination*
10. *If the days on which or times at which P is to provide pharmaceutical services at pharmacy premises have been changed in accordance with this paragraph, P must introduce the changes—*
 - a. *if P has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (6); or*
 - b. *if P has appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (9).*
11. *This paragraph does not apply where regulation 65(5) to (7) applies*

2.15 I am mindful that paragraph 23(12) of Schedule 4 states:

For the purposes of calculating the number of hours that a pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

2.16 I am of the view that the pharmacy would normally be closed on Christmas Day and that this would be in accordance with the Regulations.

- 2.17 I am conscious that paragraphs 25(1) and (2) require that before any direction is made, an assessment must be undertaken and that, before the assessment is concluded, the pharmacist providing services from the premises must be given of the proposed changes and given 30 days to make written representations about the proposed changes.
- 2.18 I note that the Appellant was notified of the proposed changes under cover of the letter dated 25 August 2020. I am mindful that the Appellant does not appear to have engaged in this process as I have not been provided with any correspondence demonstrating that the Appellant responded to the request from NHSE/I to make representations about the proposed changes.
- 2.19 I am mindful that NHSE/I is required by paragraph 25(6) of Schedule 4 to provide reasons for its decision. In my view, these reasons should set out the basis of any determination that days and times of opening will no longer be such as will meet the pharmaceutical needs of relevant persons and (if they are, such that a direction *may* be made) the assessment that led to the direction, taking into account any written representations from the pharmacist.
- 2.20 I note the undisputed comment from NHSE/I in its letter of 25 August 2020 which states that the Appellant has not opened on any public / bank holiday since the inception of NHS England. However, I am mindful that a direction from NHSE/I to open a pharmacy should be based on an assessment of whether or not the provision of pharmaceutical services will meet the needs of people in the area or other likely users of the pharmacy and should not be reliant on which pharmacies have opened in previous years.
- 2.21 I note that NHSE/I has stated that *“there are no other pharmacies open in the Gateshead area on this day at this time and it is possible that patients may require access to a pharmacy during this 2-hour period”*, that *“there are health bodies which can generate prescriptions open until late into the evening”* and further that the Appellant is *“one of only 3 pharmacies which stock end of life medications to which access may also be required”*. However I note that NHSE/I has not provided any evidence to indicate a historical need for these services and have not been provided with any information to indicate why the Appellant's pharmacy will be best placed in terms of access, geography or any other factor to meet any such demand for services.
- 2.22 I consider that whilst NHSE/I has provided some information to support the conclusion reached, it has not set out the reasoning that lies behind the direction to this particular pharmacy, which is a requirement of the Regulations.
- 2.23 On appeal, I may (in accordance with paragraph 25(8) of Schedule 4) either confirm the action of NHSE/I or take such other action as it could have taken.
- 2.24 The letters dated 25 August 2020 and 22 October 2020 provide me with no information which I consider sufficient to provide reasons on the basis of which I can confirm the decision, nor information upon which I might rely to make a direction for alternative reasons.
- 2.25 On the basis of the information available to me, I am not satisfied that NHSE/I has demonstrated that the needs of people in its area or other likely users of the pharmacy for pharmaceutical services will not be met on 25 December 2020.

3 **Determination**

- 3.1 The appeal is granted and, pursuant to paragraph 25(3)(c)(ii), no direction is issued.