

10 January 2024

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FILE REF: SHA/26099

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DECISION MAKING BODY: Derby and Derbyshire ICB (“the Commissioner”)

PHARMACIST: Clinical Care Limited
 (“the Applicant”)

PREMISES: Medicine Stop
Church Street,
Alfreton,
DE55 7BD

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) REGULATIONS 2013 [“THE REGULATIONS”]

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

Outcome

- 1.1 Based on the information provided, I am not satisfied that the pharmaceutical services provision that would result from the Applicant’s proposed hours would maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises. I am satisfied that maintaining the current level of service is a realistically achievable outcome and therefore the Applicant cannot rely on paragraph 24(1)(b).
- 1.2 The action taken by the Commissioner to refuse the application is confirmed.

A copy of this decision is being sent to:

Clinical Care Limited t/a Medicine Stop
Derby and Derbyshire ICB

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

1 Introduction

- 1.1 The Applicant has applied to the Commissioner to change the days and times at which it is obliged to provide pharmaceutical services at the above premises. The Applicant seeks to keep the total number of core opening hours the same while offering a different distribution of these hours during the week.
- 1.2 The Commissioner has refused the application. The Applicant seeks to appeal to NHS Resolution.

2. Consideration

Rights of appeal

- 2.1 Where the Commissioner has determined an application under paragraph 26 of Schedule 4 of the Regulations and has granted it in part only or has taken an action that has the effect of refusing it, paragraph 26(9) 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” (at the hours during which the pharmacy must be open by virtue of paragraph 23(1) of Schedule 4 of the Regulations), which may incorporate a direction of the Commissioner requiring fewer or greater than 40 hours and at set times and days; or

- 2.3.2 “supplementary” opening hours (other hours during which the pharmacy premises are open which are in addition to the core hours), pursuant to paragraph 23(3) of Schedule 4 of the Regulations.

Alteration of core opening hours

- 2.4 In accordance with paragraphs 1(7)(c) and 1(7)(d) of Schedule 2 of the Regulations, the pharmacy must provide, as part of an application for entry in the pharmaceutical list:
- 2.4.1 the proposed core opening hours in respect of the premises; and
- 2.4.2 the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).
- 2.5 The Commissioner maintains pharmaceutical lists that include the days on which and times at which, at those premises, the listed person is to provide those services during the core opening hours and any supplementary opening hours of the premises.
- 2.6 The days on which or times at which a pharmacy is obliged to provide pharmaceutical services at the premises may only be altered by the pharmacy on application under paragraph 26(1) of Schedule 4 of the Regulations, so long as the effect of that application is to reduce the total number of hours for which a pharmacy is obliged to provide, or keep the total number of hours the same.

Alteration of supplementary opening hours

- 2.7 Supplementary opening hours may be altered by the pharmacy giving notice to the Commissioner, in accordance with paragraph 23(6)(a) of Schedule 4 of the Regulations, without the need to make an application to the Commissioner.
- 2.8 There is no specific right of appeal to NHS Resolution in respect of notices given under paragraph 23(6)(a).

The Applicant's proposals

- 2.9 In its application form, the Applicant indicates that it currently has core opening hours totalling 40 hours per week.
- 2.10 The Applicant wishes to:
- 2.10.1 Open earlier on a Wednesday at 8:30am rather than 10:30am;
- 2.10.2 Close earlier on a Wednesday at 4:30pm rather than 6:30pm;
- 2.10.3 Open earlier on a Thursday at 8:30am rather than 9:30am; and
- 2.10.4 Close earlier on a Thursday at 4:30pm rather than 5:30pm.

Assessment

- 2.11 In this case, the Applicant provided the following information in its application form and supporting information dated 22 August 2023:
- 2.11.1 “This is an application to permanently change core opening hours.
- 2.11.2 Current opening hours for these premises:

Monday	08:30 – 16:30
Tuesday	08:30 – 16:30
Wednesday	10:30 – 18:30
Thursday	09:30 – 17:30
Friday	08:30 – 16:30
Saturday	Closed
Sunday	Closed

2.11.3 Proposed core opening hours for these premises:

Monday	08:30 – 16:30
Tuesday	08:30 – 16:30
Wednesday	08:30 – 16:30
Thursday	08:30 – 16:30
Friday	08:30 – 16:30
Saturday	Closed
Sunday	Closed

2.11.4 If this is a permanent change, please state below the date from which you would like the change to take effect: 21 November 2023

2.11.5 We are redistributing the core and slightly increasing the supplementary hours and there is no significant change in the times or hours the pharmacy opens daily other than Wednesday and Thursday where we will open from 08:30am. As we are only redistributing the core and supplementary hours there is no change or effect on patients and this will allow us to maintain a sustainable level of adequate service provision for the people in the area of the pharmacy. This application requires to be reviewed with the supplementary hours to show that the total pharmacy hours are being maintained.”

2.12 In a letter to the Applicant dated 21 September 2023 the Commissioner stated:

2.12.1 “Thank you for your application to make a permanent change to the core opening hours at Health Serve Pharmacy Limited [sic], received on 22 August 2023.

2.12.2 The Pharmaceutical Services Regulations Committee (PSRC) met on 19 September 2023 and a decision was made to refuse the request to change the core opening hours at the above pharmacy from 21 November 2023.

2.12.3 The Committee felt that the pharmacy had not provided the relevant information to demonstrate the changes to the needs of people in the area of the Health and Wellbeing Board, or other likely users of the premises, for pharmaceutical services.

2.12.4 You have the right of appeal to the Secretary of State against our decision. 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 to: nhsr.appeals@nhs.net

2.12.5 NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU

2.12.6 If you have any questions, please do not hesitate to contact me”

2.13 In an email to NHS Resolution dated 19 October 2023 the Applicant stated:

- 2.13.1 “We would like to appeal the below NHS refusal and will send over the weekend the result of the survey we have done to support the application. The NHS did not request any further information to consider the application in detail to make an informed decision.”
- 2.14 In an email to NHS Resolution of 20 October 2023 the Applicant stated:
- 2.14.1 “Attached surveys and additional information to support any decision.”
- 2.14.2 The survey is enclosed at Appendix A and the additional information is at Appendix B.
- 2.15 In a letter to NHS Resolution dated 17 November 2023 the Commissioner stated:
- 2.15.1 “Thank you for your letter dated 27 October 2023; The East Midlands Primary Care Team on behalf of Derby and Derbyshire Integrated Care Board would like to make the following representations;
- 2.15.2 Schedule 4, Part 3 paragraph 26 (1) states that an NHS Pharmacist may apply to the commissioner for it to change the days on which or times at which the pharmacy are obliged to provide pharmaceutical services at the pharmacy premises in a way that.
- Reduces the total number of hours for which the pharmacy is obliged to provide pharmaceutical services at those premises each week.
 - Keeps the total number of hours the same.
- 2.15.3 Schedule 4, Part 3 paragraph 26 (2) states that where the pharmacy makes an application under paragraph (1), as part of that application the pharmacy must provide the commissioner with such information as the commissioner may reasonably request in respect of any changes to the needs of the people in its area or other likely users of the pharmacy, for pharmaceutical services that are material to the application.
- 2.15.4 You make reference within the letter to Schedule 4, Paragraph 24 of the regulations however this was not applicable for this application as this was not in relation to directed hours.
- 2.15.5 An application to change core opening hours at Medicine Stop was received on 22 August 2023. The application was considered at Pharmaceutical Services Regulations Committee (PSRC) on 19 September 2022 and the decision was made to refuse the request to change the core opening hours at the above pharmacy, as the committee felt that the application failed to provide information in respect of any changes to the needs of the people in the area, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.
- 2.15.6 Chapter 36 paragraph 19 of the Pharmacy Manual April 2020 clearly states that when determining the application to change core hours the decision maker (PSRC) must bear in mind that applications to change core opening hours should only be approved where they reflect a change in the needs of people in the area, or other likely users of the premises, for pharmaceutical services. As the application did not show any engagement or consultation with patients then the only option available to the PSRC was to refuse the application.
- 2.15.7 I would like to take this opportunity to respond to any further representations provided by Medicine Stop (FEQ63) Church Street, Alfreton, DE55 7BD.”
- 2.16 I note the following:

- 2.16.1 The Applicant's core opening hours total 40 hours and the Applicant proposes to redistribute its 40 core opening hours pursuant to paragraph 26 of Schedule 4. The Applicant seeks to provide services as per its proposed changes in the table at 2.11 above.
- 2.17 The Applicant proposes to:
- 2.17.1 Open earlier on a Wednesday at 8:30am rather than 10:30am;
- 2.17.2 Close earlier on a Wednesday at 4:30pm rather than 6:30pm;
- 2.17.3 Open earlier on a Thursday at 8:30am rather than 9:30am; and
- 2.17.4 Close earlier on a Thursday at 4:30pm rather than 5:30pm
- 2.18 The Regulations, which came into force on 1 April 2013, have been amended a number of times. Certain amendments, relating to pharmacy premises opening hours, came into force with effect from 25 May 2023.
- 2.19 The application to change the hours was made by the Applicant on 22 August 2023 and a decision was made by the Commissioner on 21 September 2023. The decision was appealed to NHS Resolution by email of 19 October 2023.
- 2.20 I note the reference in the representations of the Commissioner to the Pharmacy Manual April 2020 and the relevant quote from the Pharmacy Manual. As stated above, the original Regulations which came into force on 1 April 2013 have been amended a number of times and that the latest amendments, came into force with effect from 25 May 2023. The Regulations, as quoted and referred to by the Commissioner, are not the amended Regulations and the references to the Pharmacy Manual do not reflect these changes. Based on the information before me I am of the view that the application and subsequent appeal should be considered against the Regulations as amended with effect from 25 May 2023.
- 2.21 I further note the comment from the Commissioner that *"You make reference within the letter to Schedule 4, Paragraph 24 of the regulations however this was not applicable for this application as this was not in relation to directed hours."*
- 2.22 The Commissioner makes reference to paragraph 26(2) and *"the pharmacy must provide the commissioner with such information as the commissioner may reasonably request in respect of any changes to the needs of the people in its area or other likely users of the pharmacy, for pharmaceutical services that are material to the application."* The Commissioner has misquoted the Regulations; an applicant is not required to demonstrate a change to the needs of the people or other likely users. I am of the view that as the application is being considered afresh, my consideration of this application will resolve any issues with regard to the incorrect Regulations being referred to by the Commissioner.
- 2.23 Further, whilst I concur that the application before me is not with regard to directed hours, the Applicant has sought to change the days and times at which it is obliged to provide pharmaceutical services under paragraph 26 of Schedule 4, Part 3, "Hours of opening".
- 2.24 Paragraph 26(1) states:
- "26.— (1) An NHS pharmacist (P) may apply to the NHSCB for it to change the days on which or times at which P is obliged to provide pharmaceutical services during core opening hours at P's pharmacy premises in a way that—*
- (a) reduces the total number of hours for which P is obliged to provide pharmaceutical services at those premises each week ...; or*

(b) keeps that total number of hours the same."

- 2.25 I have first considered paragraph 26(2) of Schedule 4 of the Regulations, which reads as follows:

"Except where sub-paragraph (2A) applies, where P makes an application under sub-paragraph (1), as part of that application P must provide the NHSCB with such information as the NHSCB may reasonably request in respect of the matters that NHS England must seek to ensure pursuant to paragraph 24(1).

- 2.26 Paragraph 24(1) reads as follows:

"24 (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 as 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.*

- 2.27 Paragraph 24(2) states:

(2) In considering the matters mentioned in sub-paragraph (1), the NHSCB –

- (a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided, and*
- (b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.*

- 2.28 Given the direct reference in paragraph 26 to paragraph 24, I will start by considering the application of paragraph 24(1)(a) and whether the proposed hours are such as to maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises. I will then consider the application of paragraph 24(1)(b) if that is required.

- 2.29 To properly assess the application against paragraph 24(1)(a), I need to determine the existing level of service provision. I then need to consider whether it is necessary to maintain the existing level of service provision. If it is necessary to maintain the existing level of service provision, I need to consider whether, despite the proposed change of hours, the existing level of service provision to people in the area or other likely users would be maintained, e.g. by nearby pharmacies being open and providing the same level of service provision.

- 2.30 If I consider it unnecessary to maintain the existing level of service provision or that it is necessary to maintain the existing level of service provision but doing so is not a realistically achievable outcome, then I need to consider paragraph 24(1)(b) and determine whether the proposed change of hours are such that a sustainable level of adequate service provision would be maintained.

- 2.31 I therefore need to be provided with sufficient information to understand a range of matters, starting with the existing level of service provision. The references to days and times in paragraph 24(1) leads me to consider that the reference to "level" of

service provision in paragraph 24(1)(a) is mainly focused on the days and times services are provided. I would point out that "level" of service provision could also refer to other characteristics of the service, such as types and range of services provided, geographical access to services provided, other aspects of physical access aside from location, and the quality of services provided.

- 2.32 The existing level of service provision has been outlined by the Applicant, in its own core hours provision.
- 2.33 I have next considered whether it is necessary to maintain the existing level of service provision. It could be argued that as the Applicant is not looking to reduce the number of hours each week that services are provided, then from a pure "number of hours of service provision each week" perspective, the existing level of service provision is maintained such that consideration of whether it is necessary to maintain the level of service provision is not needed.
- 2.34 However, the Applicant is applying to change the days and times that services are provided. Taking Wednesday as an example, the level of service provision at the Applicant's premises on a Wednesday afternoon is not being maintained. Similarly, the level of service provision on a Thursday afternoon, is not being maintained. I consider it appropriate to determine if it is necessary to maintain the existing level of service provision and then, if deemed necessary, consider if the opening hours of other pharmacies mean that level is maintained.
- 2.35 To determine whether it is necessary to maintain the existing level of service provision, I have had regard to the comments by the Applicant of those using the pharmacy. If I am satisfied that there is reliable evidence indicating no users of the pharmacy on/at the relevant days/times that the pharmacy wishes to close, this might support an argument that maintaining the existing level of service provision is not necessary.
- 2.36 The Applicant has provided 22 completed patient surveys in support of its application. The survey is limited in terms of quality, the quantity of responses and there is no indication of when and over what period it was carried out. Further, it is noted that "proposed core opening hours" as stated on the survey (which are until 5.30pm Monday to Friday) do not match the proposed core opening hours on the application form of 22 August 2023, which are proposed to be until 4:30pm Monday to Friday.
- 2.37 I am mindful that the survey may have included supplementary hours which the Applicant currently provides. However, I am of the view that supplementary hours are not a relevant part of this consideration as they can be amended by giving notice to the Commissioner under paragraph 23(6)(a). I further note that there is no right of appeal against an application to change supplementary hours and as such I take no view on this.
- 2.38 From the information provided in the surveys, it is difficult to specifically establish if anyone is using the pharmacy between the hours which they are wishing to close, which is compounded by the core hours as stated on the survey not reflecting the core hours which the Applicant is seeking adopt. It is difficult to draw conclusions about the necessity of maintaining the existing level of service provision if there is only limited information on what services persons are using and on/at what days/times.
- 2.39 Without more detailed information it is difficult to make an assessment of whether it is necessary to maintain the existing level of service provision and this in turn makes it difficult to apply paragraph 24(1)(a). I consider it reasonable to take the position that unless I am provided with evidence to the contrary, I should consider that it is necessary to maintain the existing level of service provision.
- 2.40 Having determined that it is reasonable to assume that maintaining the existing level of service provision is necessary, I now need to consider if, despite the changes to hours, there is maintenance of the existing level of service provision. The Applicant

cannot maintain this as it is changing its hours. Whilst I have been provided with information from NHS Choices regarding the addresses of medical practices in the area as well as an overview of the closest surgery, also from NHS Choices, I have no information from the Applicant with regard to other pharmacies in the area that have opening hours during the times that the Applicant is proposing to close.

- 2.41 If I consider that the characteristics of other pharmacies, e.g. where they are located, their access, the services provided and the times they are open, means that the level of service provision is maintained for people in the local area or other likely users of the pharmacy, then I am able to grant the application under paragraph 24(1)(a).
- 2.42 Given the lack of information surrounding other pharmacies in the area, I am therefore struggling to be satisfied that the existing level of service provision would be maintained by virtue of the existence of other local pharmacies.
- 2.43 I have decided that it is necessary to maintain the current service provision but, due to the cumulative effect of:
- 2.43.1 the survey not assuring me that it is representative of the use of the pharmacy;
- 2.43.2 a lack of information about the services being provided during the hours the Applicant is proposing to close; and
- 2.43.3 a lack of information about access to alternative pharmacies in the area;
- I am not satisfied that there will be maintenance of the existing level of service provision, whether by virtue of other pharmacies in the area or by the Applicant swapping hours to earlier in the morning.
- 2.44 I therefore next consider if I need to have regard to paragraph 24(1)(b) which states that I must seek to ensure that the changed hours are such as 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”.*
- 2.45 I have already determined that it is necessary to maintain the existing level of service provision so reference in paragraph 24(1)(b) to *“in circumstances where maintaining the existing level of service provision is ... unnecessary”* is not relevant.
- 2.46 On the point of whether maintaining the existing level of service provision is not a realistically achievable outcome, I consider that no evidence has been put forward in respect of this criteria.
- 2.47 The wording of paragraph 24(1)(b) is such that maintaining existing service levels must not be realistically achievable before considering a sustainable level of adequate provision. I consider that this sets a fairly high bar as to the level of difficulty that the Applicant must find themselves in. I do not consider that sufficient evidence has been provided to indicate that the economic and practical viability of the current opening hours has been compromised for example. I therefore consider that maintaining the existing level of service is a realistically achievable outcome and therefore the Applicant cannot rely on paragraph 24(1)(b).
- 2.48 I am mindful that the provision of pharmaceutical services is greater than the dispensing of prescriptions and that maintaining a level of service provision includes all services that the pharmacy may offer, including additional enhanced and advanced services that may be commissioned. I am of the view that I have not been provided with sufficient information to demonstrate how the proposed change of hours would maintain, as necessary, the existing levels of service provision.

3. Determination

- 3.1 Based on the information provided, I am not satisfied that the pharmaceutical services provision that would result from the Applicant's proposed hours would maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises. I am satisfied that maintaining the current level of service is a realistically achievable outcome and therefore the Applicant cannot rely on paragraph 24(1)(b).
- 3.2 The action taken by the Commissioner to refuse the application is confirmed.

**Head of Appeals
NHS Resolution**