

GUIDANCE NOTE
Pharmacy Opening Hours
Part 3 of Schedule 4 of the National Health Service
(Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1. The terms of service for NHS pharmacists are set out in Schedule 4 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations"). All references to regulations, schedules and paragraphs in this guidance note are references to the relevant provisions of the Regulations unless otherwise stated.
2. The terms of service in relation to a pharmacy's opening hours are set out in Part 3 of Schedule 4 which is set out in Appendix 1.
3. This guidance note:
 - 3.1 provides an overview of the provisions in the Regulations relating to pharmacy opening hours; and
 - 3.2 outlines certain issues that commonly arise in pharmacy opening hours appeals and indicates how these issues have been determined by NHS Resolution.
4. This guidance note does not cover potential breaches of the Regulations where a pharmacy fails to open.
5. As at the date this guidance note was drafted, 26 March 2019, there is no judicial guidance on the interpretation of Part 3 of Schedule 4.

Overview of pharmacy opening hours

6. Paragraph 23 of Schedule 4 states that an NHS pharmacist must ensure that pharmaceutical services are provided at the relevant pharmacy premises:
 - 6.1 for 40 hours each week;
 - 6.2 if a "100 hours condition" applies pursuant to regulation 65(1), for not less than 100 hours each week; or
 - 6.3 if there has been a direction that pharmaceutical services are to be provided at the premises for greater or fewer than 40 hours per week on specified days and times, at the times and on the days specified.
7. These are the pharmacy's "core opening hours". A direction in relation to core opening hours may be made pursuant to regulation 65 or paragraphs 25 and 26 of Schedule 4 (or may have been made pursuant to previous versions of the Regulations).
8. If a pharmacy is to be open at hours that are more than its core opening hours, the pharmacist must notify NHS England of these other hours. These are the pharmacy's "supplementary opening hours".
9. A pharmacy's "additional opening hours" are those core opening hours it is directed to be open which are additional to the 40 hours it would otherwise be required to

open if such a direction were not in place.

10. NHS England is required to issue a direction as to a pharmacy's opening hours in certain circumstances pursuant to regulations 65(4) and 65(5). These apply where:
 - 10.1 the pharmacy's application for inclusion in a pharmaceutical list was granted having regard to the pharmacy:
 - 10.1.1 giving an undertaking to open for a specified number of core opening hours greater than 40 hours each week; and
 - 10.1.2 the pharmacy agreed with NHS England that it would be open during the additional opening hours on set times and on set days,

in which case NHS England must issue a direction when it includes the premises in a pharmaceutical list; or
 - 10.2 NHS England invited the pharmacy to increase its total number of core opening hours and agreed the increased number and the set days and set times for the additional opening hours with the pharmacy.
11. An application for inclusion in a pharmaceutical list must specify the proposed core opening hours and total proposed opening hours for the pharmacy. In addition, at NHS England's request, a pharmacist must submit a return to NHS England setting out the days and times at which the pharmacy is to be open. Changes to supplementary opening hours require a return to be submitted to NHS England informing it of the change.
12. Paragraph 25 enables NHS England to instigate a change to a pharmacy's core opening hours where it appears to NHS England that the days and times at which the pharmacy is open will not meet, or no longer meets, the needs of the people in its area or other likely users of the pharmacy premises.
13. Paragraph 26 provides that a pharmacy may apply to NHS England to change the days on which or times at which it is obliged to open. This may be an application to reduce the total number of hours at which the pharmacy is open each week or it may be an application to keep the total number of hours the same but change the days and times at which it is to open.
14. The remainder of this note considers various issues that have arisen in relation to pharmacy opening hours appeals and sets out how those issues have been determined by NHS Resolution.

NHS Resolution's approach to a change of core hours

15. Where:
 - 15.1 NHS England looks to instigate a change to a pharmacy's core opening hours under paragraph 25; or
 - 15.2 a pharmacy applies to change core hours under paragraph 26,
the Regulations require the decision maker to consider the needs of the people in the area, or other likely users of the pharmacy, for pharmaceutical services and any changes to those needs.

16. In an appeal of a decision by NHS England on changing opening hours, NHS Resolution will consider the relevant information provided by the parties as to the needs of the people and whether there has been a change in need.
17. The approach adopted by NHS Resolution was outlined in SHA/18144 (4 December 2015) which stated:

"The "area" referred to is the area of NHS England (as is clear from its use in paragraphs 24 and 26, as distinct from the description of 'area' in paragraph 25). I do not consider that it is for the applicant to make an assessment of the needs either generally of the people in England or specifically in relation to users of the pharmacy. If NHS England considers that there have been (or will be) changes in need since the Applicant's hours were set out in the pharmaceutical list, it may specify them and ask the applicant to address such changes as part of its application (if they are relevant to it).

In the absence of any information in that regard (either when NHS England considered the matter or on appeal), I have proceeded on the basis that NHS England considered there were no changes in relation to the needs of people for pharmaceutical services which the Applicant needed to address.

In the absence of any information being requested from the Applicant regarding specific changes in need, I have approached the general question of whether the application should be granted by reference to whether, if it were, pharmaceutical services provided at the times proposed would continue to "meet the needs of ... people in its [NHS England's] area; or ... other likely users of the pharmacy premises, for the pharmaceutical services available at or from those premises".

Those words appear in paragraph 25(1) of Schedule 4 to the Regulations, which relate to any situation in which NHS England instigates a re-determination of core hours. They are similar to the wording used in paragraph 24 (relating to directions requiring fewer or greater than 40 hours provision) and represent an appropriate touchstone for consideration of whether an application under Regulation 26 should be granted.

Information provided to support a change of core hours

18. NHS Resolution will consider whether enough information has been provided to satisfy it that the change in hours meets the needs of the people, whether there has been a change in those needs or not.
19. In SHA/18472 (17 November 2016) a pharmacy applied to change its core hours by closing on Saturdays and Sundays. NHS Resolution determined that no information had been provided in respect of needs:

"I have not been provided with any information to indicate why patients would be best served by the applicant's request for a change in core hours, or how such a change would satisfy the needs of patients. I have however been provided with statements as to why it is more convenient for the Applicant; such consideration is not part of the regulations.

In light of the proposed changes (which are particularly significant for two of the days in question) and the lack of information available to me, I am not satisfied that the pharmaceutical services provision that would result from the

Applicant's proposed hours would meet the needs of people in the NHS England area or other likely users of the pharmacy for pharmaceutical services."

20. Information put forward purporting to indicate that the change in hours meets the needs of the people takes different forms. In SHA/18432 (26 October 2016) a pharmacy, looking to reduce its Saturday core hours, provided dispensing figures to support its view that needs had changed and it was no longer necessary for the pharmacy to open on a Saturday. The determination stated:

"I note that the Applicant has provided details of the dispensing figures for the last three years (going back to August 2013) which the Applicant states shows that the dispensing on a Saturday is negligible.

Whilst I note that dispensing overall on a Saturday is low and I accept that the dispensing over the last few years on a Saturday has been sporadic, from the information provided to me by the Applicant it demonstrates that there has been some dispensing of prescriptions on a Saturday. The Applicant has provided details of the dispensing figures in relation to the periods for which it is proposing to close, no information has been provided (either in relation to this table, or generally) as to how this evidences a change in the needs of the people more generally particularly those requiring other essential pharmaceutical services other than dispensing of prescriptions. I have not been provided with data regarding the demand for other services or any change in need in relation to those services."

21. Even where dispensing information indicates that no prescriptions have been dispensed during the days and times at which the pharmacy wishes to close, NHS Resolution may not be satisfied that this indicates that the pharmacy will meet the needs of the people in the area. In SHA/18252 (1 April 2016), NHS Resolution stated:

"I note that the Applicant provided NHS England with purported Trading Data in the form of a spread sheet which shows the number of prescriptions presented at the pharmacy, the number of items dispensed the number of OTC Sales during the times which the pharmacy wishes to now close for the period 18 September 2015 to 18 October 2015. I note that all of these three columns show a nil return and the pharmacy states that this demonstrates that there is no need for pharmaceutical services at such times that they are currently open. I am mindful, however, that the provision of pharmaceutical services is wider than the filling of prescriptions, and the dispensing of items.

I note that the data from the Applicant, which was provided to NHS England in support of their proposal to change their hours, is not accompanied by any explanation as to how they were drawn up, from where the data was taken, any identification of the person or persons responsible for compiling the data or any independent confirmation of content. As such this information lacks persuasive weight."

22. In SHA/18432 (26 October 2016), the pharmacy relied on statements made in a previous determination of an application to open a new pharmacy in the area. NHS Resolution stated:

"I note the comments from the Applicant with regard to the PNA and a

decision made by the NHS LA in 2011 in which an application to open a new pharmacy in the area was refused. I note that the Applicant quotes from the reply from the then Cheshire Health Agency (on behalf of St Helens PCT) in that pharmaceutical services in the area were "more than adequate". I further note the comment from the Applicant that three 100 hour pharmacies have opened since this decision was made. The Applicant seeks to argue that this demonstrates that their hours on a Saturday mean that there is currently more than adequate provision for those who wish to access pharmaceutical services on a Saturday morning. I am mindful that the application to which the Applicant refers was made under different Regulations to those that are currently in force and further that different criteria apply for a new pharmacy to open as opposed to an existing pharmacy to change their hours. I take no view on these comments as they were made in relation to a different application and a different set of circumstances that applied at the time the application was made."

23. Pharmacies often cite the availability of nearby pharmacies to indicate that needs will be met if its opening hours are changed. In SHA/18090 (28 October 2015), NHS Resolution stated:

"I note the applicant's letter of 28 April 2015 also included details of the opening hours of other pharmacies within a three miles radius of the applicant's Bailgate pharmacy. The applicant has not provided me with any indication of the distribution of the opening hours of these pharmacies (or whether these are core hours) during the week and on Saturday, to show that patients requiring access to essential pharmaceutical services during the hours that would not now be core hours for the applicant, could reasonably access services elsewhere. I considered that the applicant has failed to support the inference that patients requiring access to essential pharmaceutical services during those times which the applicant will no longer be providing core hours, could reasonably access services elsewhere."

24. SHA/19886 (1 August 2018) is an example of NHS Resolution being satisfied on the basis of the information provided by the pharmacy that there has been a change in needs. The determination states:

"I note the reasons given by the Applicant, in both their original application and subsequent appeal, for the change in hours is that:

- patients who require services out of hours have nominated the Lloyds pharmacy, situated in the town centre;*
- the out of hours clinic is now in the town centre and patients are using the town centre pharmacies after a visit to this clinic;*
- New Road surgery has changed its prescription turn around times, which has introduced a new pattern of the dispensing of prescriptions;*
- New road surgery no longer opens every Saturday but has introduced a "commuter clinic" opening 1 Saturday in 4;*

I note that the Applicant has not provided details of the dispensing figures in relation to Saturday mornings for which it is proposing to close. This type of evidence can sometimes be used to support an argument that there has been

a change in the use of the pharmacy by the local population.

I note that NHS England has provided no information in support of their decision and further that they chose not to provide representations on the information provided by the Applicant in their appeal.

I note the comments from the Applicant that since the out of hours service is operated out of the town centre patients requiring pharmaceutical services following a visit to the out of hours service are now visiting one of the 3 pharmacies which are located within walking distance of the out of hours service in the town centre. I further note the comment from the Applicant that the pharmacy at New Road is a 45 minute walk from the town centre. I note the information provided by the Applicant which shows the extended opening hours of both Knights Central Pharmacy, located in the town centre, as well as the Lloyds Pharmacy, which is located at the BHI centre where the out of hours service is also based. I am of the view that it is reasonable to conclude that those attending the out of hours service in the town centre are now more likely to access pharmacies close to that service, given that their needs are likely to be more urgent than those who attend surgery during normal working hours.

I note the comments from the Applicant with regard to the location of the pharmacy and the lack of other facilities and amenities which are in the vicinity of the surgery, which now only opens 1 Saturday in 4 and which contribute to the Applicant's assertion that there has been a change in need of the population.

I note that the moving of the out of hours service and the closing of the surgery on most Saturdays has not been disputed by NHS England.

I am of the view therefore that the Applicant has demonstrated that there has been a change 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."

Changes of core hours for specific days of the year

25. The appeals cited above relate to permanent changes to core hours. NHS Resolution receives a large number of appeals relating to temporary changes of hours for specific periods. Most common are appeals relating to the Christmas period.
26. NHS Resolution's approach to these appeals is the same as for those appeals listed above: it will consider the information provided by the pharmacy and by NHS England in relation to the needs of the people and determine whether it is satisfied that the change in hours will meet the needs of the people.
27. These appeals are either appeals of NHS England's decision to refuse applications by pharmacies to change hours made under paragraph 26 or appeals of NHS England's decision to direct a pharmacy to open on specific days and times made under paragraph 25.
28. SHA/20016 (20 December 2018) is an example of NHS Resolution determining an application to temporarily reduce core opening hours from 40 hours to 39 hours by closing an hour early on Christmas Eve. NHS England had refused the application and, on appeal, the pharmacy argued that there was a nearby 100 hours pharmacy

that would be open during this hour which would continue to meet the needs of people in the area for the limited duration that the pharmacy would be closed. However, it was determined that this argument related to the current provision of pharmaceutical services in the area rather than changes in needs of the people in the area. As such, it was determined that the application had not addressed the test set out in paragraph 26(2) and should be refused.

29. This determination is also of relevance as NHS England had argued that the application was for a temporary suspension of services for a set period pursuant to paragraph 23(1), which may be agreed by NHS England "*in appropriate circumstances*". This was on the basis that the application was for a change that would only apply on that specific day. This argument was rejected by NHS Resolution on the basis that:
 - 29.1 the application form submitted by the pharmacist was a template form populated with information by the pharmacy and contained a question specifically referring to the test set out in paragraph 26(2) (i.e. whether there had been a change in the needs of people in the area or other likely users of the premises), which does not apply to paragraph 23(1); and
 - 29.2 there is no apparent restriction in the Regulations which restricts an application made under paragraph 26 to temporary changes.
30. In appeals against NHS England's decision to direct a pharmacy to open, there are several additional matters that NHS Resolution will consider.
31. Under paragraph 25(6), when NHS England notifies a pharmacy that it is directing that pharmacy to open, NHS England must give reasons for the decision. NHS Resolution will therefore consider whether NHS England has given sufficient reasons for the determination, including whether it has taken into account any representations from the pharmacy.
32. SHA/18616 (24 April 2017) is an example of NHS Resolution determining that the reasons provided by NHS England were not sufficient:

"I am mindful that NHS England 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.

...

The letters [from NHS England to the pharmacy] 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.

The letters explain the process which has taken place and the conclusions reached, but not the reasoning that lies behind the direction, in particular what regard was had to the days and times of opening and how these will no longer be such as they will meet the pharmaceutical needs of relevant persons and the assessment that led to the direction which is a requirement of the regulations."

33. It is therefore important to distinguish between:
- 33.1 notification which sets out what the decision is and the process that has been followed in reaching that decision; and
 - 33.2 notification which explains the actual reasoning behind how a decision has been reached.
34. SHA/18819 (26 February 2018) is an example of NHS Resolution upholding NHS England's direction to a pharmacy to open on a day on which the pharmacy would otherwise be closed. The determination referred to a range of matters relied on by the pharmacy to challenge NHS England's decision to direct the pharmacy to open:

"I note that NHS England states that it has reviewed which pharmacies have opened on previous bank holidays and have tried where possible to ensure that directing pharmacies to open has taken place on a fair shares basis according to local need. I also note that NHS England refers to its powers under paragraph 25 of the Terms of Service to direct pharmacies to open. I take no view on how NHS England has organised cover for bank holidays previously however I am mindful that it is the needs of people in its area or other likely users of the pharmacy premises which should be taken in to account when the assessment is made.

I note the comments from the Appellant regarding previous bank holidays that they have opened, however I note NHS England's comment that in each case the opening of the pharmacy has been due to a business decision by Tesco and not as a result of a direction or request from NHS England. I take no view on previous bank holidays in which the pharmacy was open, whether that was voluntary or directed by NHS England.

I note that NHS England has carried out an assessment prior to directing the appellant to open. In its assessment I consider that NHS England has demonstrated that there is a need for pharmaceutical services in the area by way of activity reports from the East Devon area last New Year, although I note that I have not been provided with a copy of those reports, however they are not challenged by the appellant and it is noted that NHS England refers to the Appellant's comment that "clearly a dispensing service may be required for emergencies" which in its view supports its assessment that there is a need for a pharmacy in Seaton to be open on New Years Day.

I note the Appellants comments that it has lived in Seaton for 21 years and the town is very quiet on New Years day until about 2pm and therefore suggested that a later time might be more appropriate to meet local needs, however no information is provided in support of this. However I also note the Appellant's comments to NHS England that it provided a dispensing service from 10am to 4pm in similar circumstances and actually it only did 2 prescriptions, although the appellant has not provided any detail as to the timing of the dispensing of these prescriptions. I am mindful also that the provision of services is wider than the dispensing of prescriptions.

I note that NHS England has made a subjective decision that 10 miles is the maximum distance that patients should have to travel in order to access a pharmacy on New Years Day. Without information to the contrary I am of the view that this is a reasonable assumption in the circumstances of this appeal.

I also note that NHS England has considered where the next nearest pharmacies are open on New Years Day and the distances and travel times to those pharmacies, and there is some merit in having pharmacies open so that the majority of the population is equidistant to those pharmacies.

I note the Appellants concerns regarding the opening of its pharmacy due to the location within the main store, and that it considers it "more suitable for the customer journey to have a stand alone pharmacy open". However I am of the view that this is a matter for the Appellant to arrange appropriate security and staffing to facilitate access, in the event that they are required to open.

I also note the Appellant's concerns regarding it's stock levels, however again I am of the view that this would be a matter for the Appellant to arrange for appropriate stocking levels as it would be at any other time.

I am of the view that NHS England has provided sufficient reasoning to support its decision to issue a direction to the Appellant to open on New Years Day."

35. The determination above includes a number of matters that the pharmacy sought to rely on which are summarised below with an indication of how NHS Resolution considers such matters:
- 35.1 Arrangements in previous years – NHS Resolution usually determines that this is not relevant;
 - 35.2 NHS England's assessment of needs – NHS Resolution will be looking for evidence that an assessment was carried out and that this indicated a change in needs;
 - 35.3 Level of use of the pharmacy in previous years for the specific day – NHS Resolution will be looking for evidence to support the pharmacy's comments on this;
 - 35.4 Other pharmacies' opening hours – NHS Resolution will consider information such as how far away those pharmacies are, when they are open and how persons access those other pharmacies.

Reducing hours where a 100 hours condition applies

36. A pharmacy may not apply to reduce the total number of hours at which it will be open each week to the extent that such hours are required by a 100 hours condition. A 100 hours condition will apply if the pharmacy's application for inclusion in a pharmaceutical list was granted on the basis that the pharmacy agreed to open for at least 100 hours per week pursuant to regulation 13(1)(b) of the National Health Service (Pharmaceutical Services) Regulations 2005. Regulation 65(3) of the Regulations is clear that a 100 hours condition may not be varied or removed by NHS England.
37. In SHA/18122 (11 November 2015), followed in subsequent determinations, the 100 hours condition applied. It was confirmed that:

"the pharmacy is included on the pharmaceutical list by virtue of being a 100 hour pharmacy and as such, in accordance with the Regulations, the pharmacy is not able to apply for a change in its hours which would reduce

the total number of hours for which the Pharmacist is obliged to provide pharmaceutical services at those premises each week."

38. In determining any application where the 100 hours condition applies, NHS Resolution will consider whether the application would reduce the pharmacy's opening hours to fewer than the number of hours it is required to be open.

Determining applications by pharmacies to a change of core hours

39. Paragraph 26(4) sets out the manner in which applications by pharmacies to change opening hours made under paragraph 26 are determined. Paragraph 26(4) states:

"(4) When it determines the application, the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5) and which has the effect of either granting the application under this paragraph or granting it only in part;

(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), where this has the effect of granting the application under this paragraph or granting it only in part, 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."

40. Applications by pharmacies under paragraph 26 to change opening hours often fall into one of two types:

40.1 the first type is where the current number of core hours is 40 and the pharmacy wishes to change the days and times at which those 40 hours are provided; and

40.2 the second type is where the current number of core hours is over 40 and the pharmacy wishes to reduce those hours.

41. The manner in which NHS Resolution considers these types of applications is set out below.

Determining applications to change the days and times at which 40 core hours are provided

42. NHS Resolution routinely receives appeals of refusals of applications made under

paragraph 26 from a pharmacy wishing to change the days and times at which it provides its 40 core hours.

43. Where NHS Resolution is satisfied that the proposed change in hours meets (or continues to meet) the needs, it is not immediately obvious how NHS Resolution should determine the application. This is because Regulation 26(4) does not explain how to determine the days and times at which pharmaceutical services are to be provided when the pharmacy has 40 core hours.
44. This issue arose in SHA/19886 (1 August 2018). NHS Resolution determined the issue as set out below:

"The Regulations expressly state that no direction is to be issued where the core hours of a pharmacy are 40 hours a week. I therefore determine that no direction is to be issued.

Paragraph 26 of Schedule 4 is silent on how to determine the days and times of a pharmacy that has 40 core hours. I therefore consider it reasonable to either accept or refuse the application to change hours. As I have determined that I am satisfied that the pharmaceutical services provision that would result from the Applicant's proposed hours would meet the needs of people in the NHS England area or other likely users of the pharmacy for pharmaceutical services, I therefore determine that the Applicant's application to change its hours is granted."

45. In respect of applications made under paragraph 26 to change the days and times at which the 40 core hours are provided, NHS Resolution will therefore accept or refuse the application depending on NHS Resolution's consideration of any changes in needs and/or whether the change in hours meets (or continues to meet) the needs of people.

Determining applications to reduce core hours over 40 or change the days and times at which over 40 core hours are provided

46. Where a pharmacy, at the time of making an application, provides pharmaceutical services for over 40 core hours a week, the Regulations envisage that a direction will be in place specifying the days and times at which pharmaceutical services must be provided for those hours over 40.
47. A number of determinations have considered directions in further detail.
48. In certain situations, NHS Resolution may adopt the presumption that a direction must have been issued even if no paperwork is provided. In SHA/18396 (25 August 2016), NHS Resolution explained the rationale for this approach:

"I note in its appeal letter, the Applicant states that it purchased the pharmacy approximately 18 months ago, and that there does not appear to be any original documentation of the number of opening hours that were agreed at the point of these contracts being issued. I note that I have not been provided with any copies of directions issued under the Regulations or under any previous pharmacy regulations in respect to the premises.

However, I note that neither NHS England nor the Applicant dispute that the Applicant's core opening hours total 41 hours 45 minutes. In fact both the Applicant and NHS England appear to accept that there is a such a direction

in place by the very fact that an application has been made by the Applicant (and considered by NHS England under the Regulations) to change its core opening hours. To this end I note the application form provided is titled 'Application to change core hours', the Applicant has ticked the box in relation to 'permanently change core opening hours' and in its decision letter, NHS England also refers to amendments to core opening hours.

In light of the above, I have proceeded on the assumption that a direction has been issued by NHS England requiring the Applicant to open for 41 hours and 45 minutes in respect of its core opening hours (although I note the Applicant's comments regarding a lack of original documentation and that such a direction may have been misplaced)."

49. Where NHS England specifically states that no direction has been issued or where the pharmacy disputes whether a direction has been issued, NHS Resolution will consider the information provided and determine whether it considers a direction has or has not been issued.

50. In SHA/18770 (30 November 2017) NHS England expressly stated that there was no direction:

"I also note that in the minutes of the PSRC meeting on 24 July 2017, NHS England expressly states:

"NHS England confirms there is no existing direction in place for this pharmacy."

51. Where NHS Resolution considers that there is no direction in place, it usually results in NHS Resolution determining that Regulation 23(1)(a) applies. An example of this is SHA/17584 (4 July 2014) which stated:

"In the absence of any direction in this case, I have started from the position that the Applicant is operating in accordance with Regulations and is providing services during 40 "core" opening hours: the remaining opening hours therefore being "supplementary" opening hours."

52. Arguments have been made in appeals as to why there appears to be no direction in place requiring pharmaceutical services to be provided for over 40 core hours.

53. In SHA/19874 (20 June 2018), NHS England argued that the reason why no direction was in place in relation to the pharmacy's core hours (which exceeded 40) was that the 2005 Pharmacy Regulations did not require such a direction. NHS Resolution did not agree. The determination stated:

"I note that NHS England states in its representations dated 3 May 2018 that the Applicant has always had extended core opening hours, that the Applicant's core opening hours were extended under the National Health Service (Pharmaceutical Services) Regulations 2005/641 (the "2005 Regulations") to 51.5 hours, that a previous application to amend the Applicant's core opening hours was refused in June 2014, and that the reason no direction was made in relation to the Applicant's core opening hours was that the 2005 Regulations did not require such a direction.

Paragraph 22 of Schedule 1 of the 2005 Regulations and paragraph 23 of Schedule 4 of the Regulations both contain general provisions regarding pharmacy opening hours. Paragraph 22 of Schedule 1 of the 2005 Regulations does not refer to "core opening hours" at all. The concept of "supplementary opening hours" was introduced in a new paragraph 22(1A) of Schedule 1 of the 2005 Regulations from 17 September 2009 until the 2005 Regulations were repealed. This introduced a requirement for a pharmacy to give notice of the "other hours" during which the premises from which the pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open.

The 2005 Regulations also required a pharmacist to submit a return to give notice if it changes the days on which or times at which pharmaceutical services are to be provided at premises from which the pharmacist has undertaken to provide pharmaceutical services. The only restriction on making such change is that the change should not be made for a period of 3 months after the return was received.

Paragraph 22 of Schedule 1 of the 2005 Regulations stated that a pharmacist must provide pharmaceutical services at the relevant premises at set times and on set days, at the times and on the days so set, for more than 40 hours per week, where directed to do so under Part 3 of Schedule 1 of the 2005 Regulations or paragraph 4 of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992. Paragraphs 23, 24 and 25 set out the matters to be considered when issuing directions in respect of pharmacy opening hours and how pharmacy opening hours may be determined.

The 2005 Regulations provided a power allowing directions to be made requiring a pharmacy to open at set times and on set days in excess of 40 hours per week. While there is no specific reference to "core opening hours" in the 2005 Regulations, a pharmacy could be directed to open for more than 40 hours under the 2005 Regulations but, unless such a direction was made, there was no obligation for the pharmacy to do so.

NHS England has not explained when or how a pharmacy, that previously provided greater than 40 hours a week under previous versions of the Regulations, can be considered to have those same (greater than 40) hours treated as core hours under the present Regulations without there being a direction in place.

Without this information, I have to reject NHS England's argument that the reason no direction was made in relation to the Applicant's core opening hours was that the 2005 Regulations did not require such a direction."

54. In SHA/19910 (10 August 2018) NHS England argued that the approval letter, sent by NHS England to the pharmacy when NHS England granted the pharmacy's application to be included on the pharmaceutical list at the relevant premises, was the direction. NHS Resolution did not agree. The determination stated:

"I consider that, during the application process, where an applicant undertakes to provide more than 40 hours a week, the Regulations envisage

that there will be an agreement between NHS England and the applicant as to the days and times the pharmacy will be open for its "additional opening hours", i.e. the hours which are the difference between the total number of hours specified and 40.

In relation to Regulation 65(4)(a)(i), the Applicant originally undertook to provide 58.5 hours a week. There is no dispute between the parties in relation to this.

In relation to Regulation 65(4)(a)(ii), from the information provided to me in relation to the Applicant's 2014 application to be included on the pharmaceutical list, I cannot find any agreement between NHS England and the Applicant as to the days and times the pharmacy will be open for its additional opening hours, i.e. the 18.5 hours which are the difference between the 58.5 hours undertaken by the Applicant and 40.

In relation to Regulation 65(4)(a)(iii), from NHS England's letter sent to the Applicant indicating that NHS England granted the application, it is clear that the application was granted having regard to the Applicant's undertaking to provide 58.5 hours but, given there doesn't appear to have been an agreement as to the additional opening hours, it can't be the case that the application was granted having regard to that agreement.

I note that Regulation 65(4)(a) indicates that where:

- an undertaking has been given by the Applicant to provide more than 40 hours;*
- an agreement has been reached as to the additional opening hours; and*
- the application is granted having regard to the above,*

then a direction is to be issued by NHS England when it includes the premises on the pharmaceutical list.

Notwithstanding that the second point above appears not to be fulfilled, I consider that the final point above is important. The direction is to be issued when the premises are included on the pharmaceutical list.

I therefore consider that the issue of a direction is an action that is separate to the notification that an application has been granted.

I note that NHS England indicates that its notification to the Applicant that the Applicant's application was granted should be considered a direction. I do not agree with this for the reason given above."

55. Where a pharmacy has been providing over 40 core hours but it is determined that, in the absence of any direction, it is only required to have 40 core hours, the Regulations do not indicate how to determine the days and times at which the pharmacy must provide pharmaceutical services.

56. This issue was directly addressed in SHA/19911 (19 September 2018), which stated:

"I consider that NHS England is asking how the days and times at which the

40 core hours are provided is determined. I note that the Regulations do not envisage this situation arising and therefore there is no guidance in the Regulations to determine the days and times at which core hours are provided in these circumstances. I also note that, while NHS England states in its representations that it may wish to propose 40 core hours that are different to those proposed by the Applicant, NHS England has not indicated what those different hours may be and why, except for a reference to 2 hours on a Sunday. This leads to an unsatisfactory situation in which neither party is clear as to the days and times at which the 40 core hours are to be provided.

I therefore strongly suggest that it is appropriate for NHS England and the Applicant to look to agree:

- the days on which and the times at which the Applicant is required to provide the 40 core hours;*
- whether any supplementary hours are to be provided in which case they will need to be recorded in accordance with the Regulations; and*
- whether Regulation 65(5) is applicable and so whether NHS England should issue a direction to require the pharmacy to have core hours in excess of 40 and if so, the days and times at which the Applicant is required to be open during the additional opening hours.*

If the parties cannot agree the days and times at which the Applicant is to provide the 40 core hours and this is because it appears to NHS England that the days on which or times at which the pharmacy premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of people in its area or other likely users of the pharmacy premises, for the pharmaceutical services available at or from those premises, NHS England will need to consider carrying out an assessment in accordance with paragraph 25 of Schedule 4 of the Regulations as to whether to issue a direction which requires the Applicant's core opening hours to be extended beyond 40."

57. Following the determination of SHA/19911, the pharmacy submitted an appeal which made clear that the parties had not agreed the days and times at which the pharmacy is to provide the 40 core hours. NHS Resolution considered that it did not have jurisdiction to consider the appeal. This was because the pharmacy was effectively seeking to appeal NHS England's decision to refuse to agree the pharmacy's proposal as to the days and times at which it would provide the 40 core hours. This was not an action taken by NHS England under paragraph 26(4) and therefore the right of appeal in paragraph 26(9) did not apply. In notifying the pharmacist of this outcome, NHS Resolution reiterated the wording quoted above in SHA/19911 that if the pharmacist and NHS England cannot agree the days and times at which the 40 core opening hours are to be distributed then NHS England will need to consider whether to issue a direction as to the pharmacy's opening hours.

Appendix 1
Part 3 of Schedule 4 of the National Health Service
(Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The wording below is correct as at 26 March 2019.

23. Pharmacy opening hours: general

(1) An NHS pharmacist (P) must ensure that pharmaceutical services are provided at P's pharmacy premises—

(a) for 40 hours each week;

(b) for not less than 100 hours each week, in the case of premises in respect of which a 100 hours condition applies;

(c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;

(d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set; or

(e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours—

(i) for the total number of hours each week required by virtue of that direction, and

(ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

but the NHSCB may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

(2) The hours during which pharmacy premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as “core opening hours”.

(3) P must notify the NHSCB of other hours during which P's pharmacy premises are to be open, which are hours in addition to P's core opening hours (and which are referred to in these Regulations as “supplementary opening hours”).

(4) Unless P is a distance selling chemist, at P's pharmacy premises P must exhibit—

(a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances (including times at which P is providing pharmaceutical services during supplementary opening hours); and

(b) at times when the premises are not open, a notice based on information provided by the NHSCB, where practicable legible from outside the premises, specifying—

(i) the addresses of other NHS pharmacists and the days on which and times at which drugs and appliances may be obtained from those addresses, and

(ii) the addresses of LPS chemists in the area, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.

(5) P must, on request, submit a return to the NHSCB setting out—

- (a) the days on which and times at which pharmaceutical services are provided at P's pharmacy premises (including times at which P is providing pharmaceutical services during supplementary opening hours); and
- (b) the pharmaceutical services which P ordinarily provides at those premises.

(6) Where P changes—

- (a) the supplementary opening hours of P's pharmacy premises; or
- (b) the pharmaceutical services which P ordinarily provides at those premises,

P must supply the NHSCB with a return informing it of the change.

(7) Where P has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and times at which pharmaceutical services are to be provided at P's pharmacy premises (for example, in a return under sub-paragraph (5) or (6) or in an application for inclusion in a pharmaceutical list)—

- (a) P must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the times set out in the notification (unless the notification has been superseded by a return, or a further return, under sub-paragraph (6)); and
- (b) P must not change—

- (i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours which are neither additional opening hours nor in total less than 40 (if those core opening hours are additional opening hours, or are in total less than 40, regulation 65(5) to (7) and paragraphs 25 and 26 apply),

- (ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 25 and 26 apply to changes to the total number of core opening hours),

- (iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or

- (iv) the pharmaceutical services which P is ordinarily to provide at those premises,

for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

(8) Subject to sub-paragraph (9), where P is prevented by illness or other reasonable cause from complying with P's obligations under sub-paragraph (1), P must, where practicable, make arrangements with one or more NHS pharmacists or LPS chemists whose premises are situated in the same area for the provision of pharmaceutical services or local pharmaceutical services during that time.

(9) P may only make an arrangement with an LPS chemist under sub-paragraph (8) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which P ordinarily provides.

(10) Where there is a temporary suspension in the provision of pharmaceutical services by P for a reason beyond the control of P, P is not in breach of sub-paragraphs (1) and (7), provided that—

- (a) P notifies the NHSCB of that suspension as soon as practical; and
- (b) P uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(11) Planned refurbishment of pharmacy premises is neither a “reasonable cause” for the purposes of sub-paragraph (8) nor a “reason beyond the control of P” for the purposes of sub-paragraph (10).

(12) For the purposes of calculating the number of hours that 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.

(13) For the purposes of this Part, “additional opening hours”, where they are required, are hours during which P is required to provide pharmaceutical services pursuant to sub-paragraph (1)(e) which are in addition to the hours during which P would be required to provide pharmaceutical services, if P were subject instead to the condition set out in sub-paragraph (1)(a).

24. Matters to be considered when issuing directions in respect of pharmacy premises core opening hours

(1) Where the NHSCB issues a direction setting any days or times for the opening hours of pharmacy premises under this Part, 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 are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in its area or other likely users of the pharmacy premises.

(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.

(3) The NHSCB may only direct that an NHS pharmacist (P) may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in its area is likely to be adequate to meet the need for such services at times when P is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that P must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that P is to receive reasonable remuneration in respect of the additional opening hours for which P is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is “reasonable remuneration” for these purposes).

25. Determination of pharmacy premises core opening hours instigated by the NHSCB

(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.

26. Determination of pharmacy premises core opening hours instigated by the NHS pharmacist

(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 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 (but not those required under any 100 hours condition); or
- (b) keeps that total number of hours the same.

(2) 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 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.

(3) The NHSCB must determine the application within 60 days of receiving it (including any information required of P in accordance with sub-paragraph (2)).

(4) When it determines the application, the NHSCB must—

- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (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 (5) and (6); 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), where this has the effect of granting the application under this paragraph or granting it only in part, 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.

(5) Where the NHSCB issues a direction under sub-paragraph (4) 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 premises, and

(ii) as regards any 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 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.

(6) The NHSCB must not issue a direction under sub-paragraph (4) 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).

(7) Where the NHSCB is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee for the area in which the pharmacy premises are situated before determining the application.

(8) The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send P a statement setting out—

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) P's right of appeal under sub-paragraph (9).

(9) P may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) 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 sub-paragraph (4).

(11) The Secretary of State must notify the pharmacist of the determination and must include with the notification a statement of the reasons for the determination.

(12) 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 (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (4); or
- (b) if P has appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (11).

(13) This paragraph does not apply where regulation 65(5) to (7) applies.

27. Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

(1) Notwithstanding the provisions of this Part, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS pharmacist (“P”), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at pharmacy premises, or permit temporary closure of those premises, if—

- (a) P gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by P for the request are, in the opinion of the NHSCB, adequate reasons.

(2) The NHSCB need not approve the request in advance of the change or closure, but if it does not do so and decides subsequently that P's reasons are not, in its opinion, adequate reasons, then the days on which or times at which P is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to P.