

## GUIDANCE NOTE

### **Performance Related Sanctions: Breach Notices and Remedial Notices Regulations 70 and 71 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013**

NB – Excerpts from past decisions are included in this guidance note. The full version of a decision may not be available as NHS Resolution only retains past decisions for up to 6 years, in line with its file retention policy.

1. Breach notices and remedial notices are performance related sanctions resulting from breaches of NHS pharmacists' terms of service. The terms of service of NHS pharmacists are set out in Schedule 4 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("Regulations"). All references to regulations, schedules and paragraphs in this guidance note are references to the relevant provisions of these Regulations unless otherwise stated.
2. All references to "contractor" are to the NHS pharmacist who appealed the breach or remedial notice. References to the Commissioner or NHS England are references to NHS Commissioning Board or since 1 April 2023, integrated care boards (ICBs) unless otherwise stated, who issued the breach or remedial notices. References to NHS Resolution are references to the operating name of the NHS Litigation Authority acting on the direction of the Secretary of State for Health and Social Care to determine the appeals.
3. Regulations 70 and 71, as at [19 March 2021], are set out in the Annex to this guidance note. A large number of other provisions of the Regulations are referred to in this note but, for the sake of brevity, have not been set out in the Annex.
4. This guidance note focuses on the determination of appeals against breach notices and remedial notices. Its purpose is to provide guidance based on past decisions. As at the date of this note, there is no judicial guidance on breach notices or remedial notices.

### **Local Dispute Resolution**

5. Both the contractor and the Commissioner should seek to resolve any issue before next steps are taken. Regulation 69 requires the Commissioner to make every reasonable effort to engage in local dispute resolution with the contractor, with a view to resolving the dispute in relation to the compliance with the contractor's terms of service, prior to proceeding with the issue of the breach or remedial notices. There is a similar requirement in Regulation 68 on the contractor to engage with the Commissioner, with a view to resolving any dispute in relation to the compliance with the contractor's terms of service.
6. In SHA/18510 (27 February 2017) the contractor was issued with a breach notice for failure to provide an annual complaints report within a certain time. In this case, NHS Resolution stated:

*"The Regulations contain no definition of what constitutes "reasonable effort to communicate and co-operate".*

*I note that I have been sent copies of the generic emails which were sent by*

*NHS England to the Pharmacist in an attempt to communicate and co-operate with the Pharmacist. I further note that the Pharmacist has not commented on the information provided in this regard. I note that NHS England twice extended the deadline for submission of the annual complaints report with a view to resolving the matter. I note that the Pharmacist has still not engaged with NHS England in relation to the submission of this report. On the basis of the information before me I am of the view that NHS England has made every reasonable effort to communicate and co-operate with the Pharmacist."*

7. In SHA/22216 (6 November 2019) the contractor was issued with a remedial notice for failure to provide evidence of carrying out a public health campaign. NHS Resolution noted that:

*"...the Remedial Notice was issued to the Contractor as a result of the clinical advisor downloading a report relating to the Help Us Help You campaign from PharmOutcomes which identified the pharmacies which had not provided the required data. I note that this report was provided to NHSE&I's PSRC which concluded that remedial notices should be issued to those pharmacies which were identified in the report as not having provided required information in relation to participation the Help Us Help You campaign.*

*I consider that it is at this point that Regulation 69 applies and requires NHSE&I to "make every reasonable effort to communicate and co-operate with" the Contractor with a view to resolving any dispute between them.*

*Whilst there is no definition in the Regulations as to what constitutes "reasonable effort to communicate and co-operate", I consider that the starting point in establishing whether Regulation 69 has been complied with is whether there has been any "effort" to communicate and co-operate by NSHE&I.*

*I have not been provided with any evidence, supporting information or comments that show that NHSE&I has made "every reasonable effort to communicate and cooperate with" the Contractor to resolve the dispute relating the Contractor's alleged non-compliance with the terms of service. It appears that a report was downloaded which indicated which pharmacies had not provided data and this was referred to NHSE&I's PSRC which determined that a remedial notice was to be issued.*

*...*

*In the absence of any information to the contrary, I am of the view that NHSE&I has not made "every reasonable effort to communicate and co-operate" with the Contractor. I am of the view that NHSE&I must not disregard the clear statutory requirement to engage in local dispute resolution set out in Regulation 69 before issuing a notice in circumstances where the listed exemptions do not apply.*

*I consider that I cannot ignore non-compliance with Regulation 69. I consider that NHSE&I must engage in local dispute resolution prior to issuing a remedial notice."*

#### **Ascertaining whether a breach is capable of remedy**

### Breach not capable of remedy

8. Regulation 71 states that where a contractor breaches a term of service and that breach is not capable of remedy, the commissioner may issue a breach notice requiring the contractor not to repeat the breach.
9. The Regulations contain no definition as to what constitutes a breach of a term of service which is not capable of remedy. A common sense interpretation is that it is a breach that cannot be rectified.
10. For example, where a term of service requires an action to be done within a certain timescale and a contractor fails to do that action within that timescale, there is no action that the contractor can take in order to rectify that failure if the timescale has passed. There are past appeal decisions where a contractor failed to open during core hours and was unable, at that time and for the duration of the closure, to provide services. Depending on the reasons for closure, this may amount to a breach of the relevant term of service which is not capable of remedy as there is no action that the contractor can take to rectify the failure to open during those hours, which have now passed.
11. Another example can be found in SHA/18334 (1 June 2016). A contractor was issued with a breach notice for breach of paragraph 31(1) of Schedule 4 which requires the contractor to notify NHS England within seven days of the occurrence of a specified event. On appeal, NHS Resolution stated:

*“as the Appellant has not provided any evidence to show that it notified NHS England within 7 days of the outcome of the GPhC hearing, I am of the view that a breach of the Appellant’s Terms of Service did occur for the reasons given above and the breach notice issued by NHS England was therefore appropriate”*

### Is the breach capable of remedy?

12. The distinction between a breach which is capable of remedy and a breach which is not capable of remedy is not always obvious.
13. In SHA/19867 (4 July 2018), NHS England issued a breach notice to the contractor for a failure to provide various information by the deadline previously communicated to the contractor. In particular, one of the breaches identified in the breach notice was a breach of paragraph 28(2)(e)(iv) of Schedule 4 of the Regulations, which relates to clinical governance. The contractor was required to provide certificates for dispensing in relation to its staff. In the course of the appeal, the contractor provided the required certificates.
14. NHS England had asked on several occasions prior to issuing a breach notice to provide it with the required certificates. The contractor did not do so and, as the contractor could not evidence compliance with paragraph 28(2)(e)(iv), NHS England concluded that the contractor did not have the certificates and so the breach could not be remedied by producing the certificates. NHS Resolution, however, with the knowledge that the certificates had been provided during the course of the appeal, stated:

*“I consider that paragraph 28(2)(e)(iv) requires the contractor to participate in a system of clinical governance which includes a staffing and staff management programme which itself includes arrangements for identifying*

*and supporting the development needs of all staff engaged in the provision of NHS services.*

*I consider that a breach of this provision can be remedied by putting in place such arrangements. There is no timescale set out in this provision. I therefore consider that a remedial notice should have been issued.”*

15. In SHA/18510 (27 February 2017), the contractor was issued with a breach notice under paragraph 34 of Schedule 4 of the Regulations for failing to provide an annual submission of its patient complaints report. Paragraph 34 provides that a contractor must have in place arrangements which comply with the requirements of the Local Authority Social Services and National Health Services Complaints (England) Regulations 2009. NHS Resolution stated:

*“I have considered whether the breach of paragraph 34 is capable of remedy. On one hand, it could be argued that the breach is not capable of remedy as the obligation to provide the report [as set out in the Complaints Regulations] is to send it as soon as reasonably practicable after the end of the year to which the report relates. As it is now almost a year after the end of the year to which the report relates (the 12 months ending 31 March 2016), provision of the report now could not reasonably be considered as provision as soon as possible after 31 March 2016. As such it could be reasonable to consider that the breach cannot be remedied.*

*On the other hand, the wording of paragraph 34 relates specifically to having in place arrangements to comply with the Complaints Regulations. I consider that it would be more appropriate to consider that a failure to have in place arrangements can be remedied by putting in place such arrangements. As the breach can be remedied, a remedial notice is appropriate.”*

16. It is worth noting, that the breach notice in 18510 contained a remedial action and a notice period within which the remedial action must be taken by. As further discussed below, these are requirements of a valid remedial notice. A breach notice should not include requirements relating to remedial actions or remedial period as a breach notice is appropriate for issue against a breach not capable of remedy.
17. Similarly in SHA/18507 (26 April 2017), the contractor was issued with a breach notice for a failure to provide an annual patient complaints report. The breach notice also contained a remedial action and a notice period within which that remedial action must be taken. During the course of the appeal, NHS England acknowledged that a remedial notice should have been issued in place of a breach notice.
18. Whether or not a breach is capable of remedy depends on the relevant term of service. In the above examples, the Regulations did not prescribe a time frame within which a contractor had to carry out the relevant action. As such, the contractor could remedy the breach by carrying out the action. The breach was therefore capable of remedy and so a remedial notice was appropriate.

#### Breach capable of remedy

19. Compared to the number of appeals against the issue of breach notices, there has only been a small number of appeals relating to the issue of remedial notices.
20. In SHA/18479 (10 January 2017), a remedial notice was issued for breach of paragraph 35(3) of Schedule 4 of the Regulations which, in summary, requires the

contractor to allow NHS England access to information NHS England requests in order to check that the contractor is complying with the requirements of Schedule 4. NHS England requested information to evidence the contractor's participation in at least three public health campaigns (paragraph 18 of Schedule 4). The contractor provided some of the information within the deadline prescribed by NHS England but not all and so NHS England issued a remedial notice. The contractor provided the missing information two days after the date of the remedial notice but appealed nevertheless. NHS Resolution noted that by providing the missing information the contractor remedied the breach.

21. In SHA/19988 (4 January 2019), NHS Resolution considered whether it is appropriate to issue a breach notice if a contractor has failed to comply with a remedial notice. NHS Resolution stated:

*"I note that the Regulations do not expressly state that if a remedial notice is not complied with then a breach notice can be issued. I do note, however, that regulation 73 expressly states that NHS England can remove a contractor from the pharmaceutical list if the contractor fails to take the steps set out in a remedial notice. Although [regulation] 73 sets out additional criteria to be met before this right can be exercised, it is clear to me that the Regulations envisage a specific possible consequence of non-compliance of a remedial notice. This consequence is not the issue of a breach notice.*

*I consider that the issue of a remedial notice carries the same weight as the issue of a breach notice. It is not the case that issue of a breach notice is more serious than the issue of a remedial notice."*

22. The above examples illustrate that it is not always clear whether a breach is capable of remedy. The term of service to which the breach relates must first be identified before it can be considered whether it is capable of remedy.

#### Who is in breach?

23. Both Regulation 70 and Regulation 71 apply where an NHS chemist i.e. the contractor, breaches a term of service. It is the contractor who is accountable and responsible for the compliance with its terms of service; a failure by an employee of the contractor does not render the contractor not in breach.

24. In SHA/23339 (16 July 2020) the contractor was issued with a breach notice for failure to provide evidence of patient consent for medicine use reviews. In its appeal, the contractor stated that the reason for this failure was an oversight by its practice manager who was under a performance management procedure at the time. NHS Resolution stated that:

*"while the Pharmacy Manager appears to have failed to respond to the requests for information, it is ultimately the Appellant that is responsible for ensuring that it complies with the terms of service and that it is aware of the procedures and protocols which it is expected to be following".*

25. In SHA/22119 (9 August 2019) the contractor was issued with three separate breach notices. The facts of this matter are complex but in essence, the contractor was receiving electronic prescriptions and dispensing medicines for another pharmacy in its group which had been temporarily suspended from providing services due to damage to its premises. The suspended pharmacy continued to receive payments in respect of these prescriptions despite it being suspended from providing

pharmaceutical services. NHS Resolution determined that the contractor to whom the notice was issued was not in breach of the specific Regulation referred to in the breach notice but noted:

*“...in my view, if [the suspended pharmacy] were still open, it would likely have been in breach of the Regulations by claiming payment for services it has not provided. I am not required to make a determination on this point in this matter but I consider it likely that it would be a breach of the rules for claiming payments set out in the Drug Tariff.*

*...Had [the suspended pharmacy] remained open, then I consider that it is likely that NHS England could have taken action against it to ensure the activity that occurred did not continue”*

26. The above cases illustrate that the breach notices and the remedial notices may only be issued against the contractor on a pharmaceutical list, despite the existence of circumstances which may point otherwise.

### **Formalities of a breach and a remedial notices**

#### Breach notice

27. Regulation 71(2) states that, to be valid, the breach notice must include:
- i) the nature of the breach; and
  - ii) an explanation of how the contractor’s right of appeal may be exercised.
28. In SHA/18720 (29 August 2017), one of the contractor’s grounds of appeal was that the breach notice was not valid. The contractor queried both of the above elements which must be satisfied under Regulation 71(2) for the breach notice to be valid.
29. In this case the contractor stated that the *“breach notice is not precise and does not contain the relevant information to allow it to be valid”* and that it must reference the specific term of service which has been allegedly breached.
30. The contractor further stated that, although the breach notice references the contractor’s right to appeal, it did not explain *“under which regulation this can be applied under”*.
31. In this case, the breach notice, under the sub heading “Nature of the breach” stated *“Failure to fulfil contractual hours under the Terms of Service, which resulted in the disruption to provision of pharmaceutical services”*. It was determined that this statement was sufficient to describe the nature of the breach and so satisfied the requirements of Regulation 71(2)(i).
32. In SHA/19988 (4 January 2019), the contractor was issued with a breach notice. The nature of the breach set out in the breach notice was *“failure to remedy the remedial notice issued on 15 August 2018, regarding submission of complaints...via an Annual Complaints report”*. NHS Resolution noted:

*“..although this appeal is not against the issue of the Remedial Notice, I consider that the Remedial Notice is relevant to this appeal to ascertain the nature of the breach referred to in the Breach Notice...I consider that NHS England was of the view that the nature of the breach was the failure to*

*comply with the Remedial Notice as evidenced by the failure to provide the annual report by 31 August 2018”.*

33. Although a failure to remedy a remedial notice is not a term of service capable of being breached under the Regulations, in the above case, NHS Resolution was able to ascertain the nature of the breach by reference and review of the remedial notice (which was referred to in the breach notice).
34. In SHA/18281 (June 2016), the breach notice referred to “*Schedule 3, Part 4 (28) 92 (b)*”. It was determined that this reference was a typographical error and that the correct term of service breached was Schedule 4, Part 4, paragraph 28(2)(b). As NHS England had explained the nature of the breach in the breach notice, NHS Resolution determined that the typographical error “*does not have the effect of invalidating the breach notice*”.
35. In SHA/18791 (17 January 2018), the contractor appealed the issue of a breach notice on the basis that NHS England cited the wrong paragraph when describing the nature of the breach. NHS Resolution determined that the contractor had breached a term of service which accorded with the explanation provided by NHS England but that the breach was of a different term of service to that referred to in the breach notice. In its determination, NHS Resolution substituted the issued breach notice with a breach notice citing the correct term of service.
36. With regard to the contractor’s right of appeal, in SHA/18720 (29 August 2017) it was decided that whilst the breach notice did not specifically reference Regulation 77 “Appeals against decisions in Part 10”, NHS England provided the contractor with the name of the organisation and address to send the appeal to, the time frame for such an appeal and that the appeal should contain a concise reasoned statement of the grounds of appeal.

#### Remedial notice

37. There are additional requirements that a remedial notice must satisfy to be valid. Regulation 70(2) states that a remedial notice must include:
  - i) the nature of the breach;
  - ii) steps a contractor must take to remedy the breach;
  - iii) the notice period during which the steps must be taken; and
  - iv) an explanation of how the contractor’s right of appeal may be exercised.
38. Regulation 70(3) further states that the notice period must be at least 30 days unless a shorter period is appropriate to protect the safety of the patients or to protect the Commissioner from material financial loss.
39. In SHA/21018 (9 May 2019), one of the grounds of appeal was that the remedial notice was not valid as the notice period during which steps to remedy the breach must be taken was less than 30 days. There was no explanation why it was shorter than 30 days. NHS Resolution determined that it could not confirm the remedial notice. This was due to the lack of explanation as to why NHS England had considered that a shorter notice period was appropriate.
40. The question of a “valid notice” also applies to a contractor’s notice of appeal, which

is discussed below.

#### Contractor's right of appeal

41. Regulation 77 "Appeals against decision under Part 10" sets out a contractor's right to appeal the issue of a breach notice or a remedial notice. In relation to remedial notices, a contractor has two additional elements which it may appeal, which do not apply to breach notices. These are: the duration of the notice period, and the steps required to remedy the breach.
42. A contractor may only appeal a breach or remedial notice if it notifies NHS Resolution with a valid notice of appeal within 30 days of the date on which it was notified of the decision that is being appealed. NHS Resolution does not publish details of appeals that it determines have been notified to NHS Resolution outside this timescale as these are not valid appeals.
43. In relation to what constitutes a valid notice of appeal, Regulation 77(2) provides that a notice of appeal is valid if it includes a concise and reasoned statement of the grounds of appeal.
44. In SHA/19988 (4 January 2019), NHS England stated that:

*"it is unclear on what basis the breach notice is being appealed...as the contractor has neither challenged NHS England's actions in issuing the breach notice, nor have they disputed that due process has not been followed by NHS England in this respect, NHS England does not believe that the contractor has grounds for appealing the decision to issue the breach notice".*
45. The grounds of appeal in the appeal notice were that the contractor was on annual leave for a while and they forgot about submitting the annual complaints report. NHS Resolution determined that:

*"Although NHS England may consider that the reason for the non-provision of information is not a valid reason, in order for the notice of appeal to be valid it must include a concise and reasoned statement of the grounds of appeal...I consider that Regulation 70(2) is broad and allows for a statement such as the statement the contractor provided in its appeal letter".*

#### Determination of the appeals

46. The Regulations contain processes and procedures to follow in various circumstances. This includes the determination of appeals. The powers to determine appeals are set out in paragraph 9(5) of Schedule 3 of the Regulations.
47. There are two options. NHS Resolution may either confirm the decision to issue a breach notice or a remedial notice or it may substitute for that decision, any decision that the Commissioner could have taken when it took its decision to issue the breach notice or remedial notice.
48. If NHS Resolution confirms the decision, the contractor must comply with the breach notice or remedial notice and that notice will be recorded against the contractor. The Regulations set out further actions that the Commissioner can take should the contractor fail to comply with a breach notice and / or a remedial notice or if the contractor has a number of breach and / or remedial notices recorded against its performance. These are set out in Regulation 73. These actions are outside of the



scope of this note.

49. In SHA/18510 (27 February 2017) NHS Resolution determined that the contractor was in breach of the relevant term of service but instead of confirming the breach notice issued by NHS England, NHS Resolution substituted the breach notice with a remedial notice. This was on the basis that issuing a remedial notice was a decision that NHS England could have taken at the time it issued the breach notice. The contractor was required to comply with the actions set out in the remedial notice instead.
50. If NHS Resolution determines that the contractor is not in breach of any term of service, it will substitute the Commissioner's decision to issue the notice with a decision to **not** issue a notice. This has the effect of "cancelling" or "rescinding" the notice and so the issue of the notice should not be recorded against the contractor.
51. Prior to 26 November 2018, if NHS England issued a notice in error or otherwise no longer wished to impose a notice, the Regulations did not permit NHS England to rescind a notice. The contractor's only remedy would be to appeal the notice and for NHS Resolution to substitute NHS England's decision to issue the notice with a decision to **not** issue a notice.
52. In SHA/19953 (12 October 2018) NHS England issued a breach notice to the contractor for failure to provide information requested by NHS England regarding the contractor's opening hours. The contractor appealed on the basis that it had provided the requested information prior to the date of the breach notice. In its representations, NHS England confirmed that it had made an error in issuing the breach notice. NHS Resolution noted that NHS England no longer challenged the position and stated:

*"I note that there are no provisions to rescind a breach notice in the [Regulations]. Therefore even though NHS England is no longer challenging the position, there would still be a record of a breach notice being issued.*

*Given that NHS England is no longer challenging the position, as well as the fact that I have evidence before me which demonstrates that the reporting forms were submitted on time, I have considered the most appropriate approach to this matter in order to ensure the formal removal of the breach notice. I determine that that the decision of NHS England to issue a breach notice shall be replaced by a decision not to issue a breach notice."*
53. From 26 November 2018, the Regulations permit the Commissioner to rescind both a breach notice and a remedial notice at any time (Regulations 71(5) and 70(8) respectively). With this new power, the Commissioner is able to "cancel" the notice without the need for the contractor to appeal. The use of the power to rescind has been noted by NHS Resolution in SHA/22206 (25 October 2019) which concerned appeals against a breach notice and a remedial notice. As a result of the remedial notice being rescinded, the contractor withdrew its appeal in respect of that notice which led NHS Resolution to make no finding on it:

*"I note that NHS England originally issued a remedial notice and that the appellant appealed against this remedial notice. Since then it appears that NHS England has rescinded the remedial notice and further the appellant has withdrawn the appeal against the remedial notice. I therefore make no finding*

*in this regard.”*

## **Information and communication**

54. NHS Resolution determines each appeal on its own facts and merit. There are however certain similarities in certain appeals which makes it possible to extrapolate common themes.
55. Paragraph 35 of Schedule 4 enables the Commissioner to monitor a contractor's compliance with the terms of service set out in the Regulations. The Commissioner may require a contractor to submit certain information to the Commissioner to evidence compliance. The Regulations do not specify in detail how the information should be submitted.
56. In SHA/21047 and SHA/21050 (28 March 2019), the contractor was issued with a breach notice under paragraph 35(3) of Schedule 4 for failure to submit required data regarding the new medicines service. The submission was required to be made via a portal and within a prescribed time frame. The contractor appealed on the basis that it did not receive the email reminders from NHS England upon which it relied to submit the data on time. The reason given was that the contractor's records had not been updated since the change of ownership and so the emails were sent to a wrong email address. NHS Resolution stated that:

*“Although it is unfortunate that the pharmacist did not receive the reminder emails; I am of the view that it is a matter for the Pharmacist to ensure that NHS England is provided with the correct contact details. I am of the view that in any case, that it is a matter for the Pharmacist to know what is required under the terms of service.”*

57. In SHA/18793 (12 January 2018), the contractor was issued with a breach notice for failure to submit required data regarding medicines use review. The system for submitting the required data was changed and the contractor was made aware of this by way of a letter and several subsequent emails. The contractor stated that it did submit the data correctly and received an email, which appeared to be confirming submission. Nevertheless, it transpired that the required information was not in fact received. NHS Resolution noted:

*“I have some sympathy with the contractor in that the email of 4 August 2017 appears to acknowledge receipts of submissions. Further that the email from NHS England quoted at 5.9.1 is somewhat confusing in that it states initially that the required information has not been received, and then later states that “if you have submitted the data...please disregard...”...*

*Given that it is accepted [that] NHS England did communicate with the contractor, and despite the contents of the email being confused, I would have expected the contractor to contact NHS England to clarify the position, particularly given that three separate emails were sent to the contractor advising that [the] data had not been received.”*

58. In SHA/18684 (23 August 2017), the contractor was issued with a remedial notice for failure to submit weekly declarations regarding its opening hours. The contractor appealed on the basis that there has been a lack of guidance for completing the online declarations. NHS Resolution noted however that assistance was offered to the contractor on two occasions by way of a letter and then again at a meeting, which

the contractor attended. NHS Resolution stated:

*"I am of the view that this is a matter for the pharmacy and that there has been plenty of opportunities for the contractor to raise any issues that they may have had with the PharmaOutcomes system since NHS England advised that they were introducing this...and that they would be using a more robust approach...for the reporting of hours."*

59. In SHA/18282 (6 May 2016), the contractor was issued with a breach notice for failure to provide information to demonstrate that it undertook a pharmacy based audit. In its appeal, the contractor stated that it set up and agreed the practice based audits centrally for all its branches. The contractor stated that it was concerned that the correspondence "linked to the alleged breach" was sent direct to the branch rather than to the corporate body and its registered address. NHS Resolution considered that:

*"I am of the view that NHS England was obligated to communicate with the pharmacist as listed in the entry on the pharmaceutical list. It is not a matter for NHS England to establish whether or not the pharmacist as listed would prefer correspondence to be sent to an alternative address. It is a matter for the pharmacist to arrange its own internal communications as appropriate."*

60. The above appeals illustrate that miscommunication, even if attributable to both the contractor and the Commissioner may, depending on the specific facts, lead to the contractor being in breach of a term of service. Ultimately, the contractor is responsible for ensuring that it complies with the terms of service and that it is aware of the procedures and protocols which it is expected to be following.
61. Similarly, the Regulations state that the contractor must provide the Commissioner access to the information which the Commissioner reasonably requires. To that effect, the Regulations do not always specify what information exactly is required from the contractor or how that information is provided to the commissioner.
62. In SHA/18281 (2 June 2016), the contractor stated that there is considerable variation *"in how NHS England regional teams want this action plan submitting from fax, email, post to just retaining a copy in branch"*. In addition, the contractor stated that *"no confirmation is sent by NHS England and therefore the contractor has no mechanism of confirming if it has actually been received"*. With its appeal, the contractor provided a copy of a screenshot showing the date and time of the completed audit and the action plan. NHS Resolution was satisfied, based on a number of emails provided to it, that NHS England had requested the required information on several occasions and that the contractor had not provided it to NHS England.
63. In relation to the screenshot provided by the contractor as part of the appeal and in the absence of information from NHS England in this regard, NHS Resolution was not able to ascertain whether a screen shot would be satisfactory evidence to evidence that the contractor provided the required information. In this instance, NHS Resolution substituted the breach notice with a remedial notice and required NHS England to inform the contractor of the information it required to enable NHS England to be satisfied that an audit had been carried out.
64. In SHA/18501 (10 March 2017), the contractor was issued with a breach notice for failing to participate in at least three public health campaigns. The contractor made a

number of administrative errors in attempting to email the evaluation forms for the three public health campaigns and as a result NHS England did not receive the evaluation forms on time. During the course of the appeal the contractor provided the missing evaluation forms. NHS Resolution stated:

*"I am of the view that NHS England made the correct decision based upon the information provided by the contractor at the time. However, I am mindful that I have now been provided with a copy of the completed form relating to the 'Stay Well' campaign. I have considered the information and I am of the view that the contractor appears to have made an honest mistake. I am also mindful that a result of not providing information [it] has meant that both parties spent a considerable amount of time dealing with this when it could have easily been avoided with effective record keeping.*

*I am of the view that it is unreasonable of me to confirm the breach notice (which is about not participating in the campaign) when I now have evidence before me which demonstrates that the breach did not in fact occur."*

65. In SHA/18282 (6 May 2016), an appeal with similar facts to SHA/18281 (2 June 2016) (the contractor was a branch pharmacy of a corporate body), the contractor also provided in the course of the appeal a screenshot showing the date and time of the completed audit and action plan. In its representations, NHS England stated that, following the issue of the breach notice and prior to the appeal, the contractor *"provided by fax, audit documentation which following review by NHS England...has been deemed adequate to demonstrate that...the branch did undertake the clinical audit within the required time period"*. It is not clear whether the information provided by the contractor to NHS England before the appeal was the same screen shot that was provided during the course of the appeal and so it is still unknown exactly what information and in what format would be deemed appropriate to satisfy the commissioner that the contractor carried out the audit.
66. Similarly to the outcome in SHA/18281 (2 June 2016), NHS Resolution determined to substitute the breach notice for a remedial notice and as the contractor provided the required information after the date of the breach notice, the contractor effectively remedied the breach but the remedial notice still stood.
67. In SHA/22228 (4 December 2019) a contractor was issued with a breach notice relating to paragraph 35(3)(a) of Schedule 4 of the Regulations for failure to provide evidence to demonstrate that it participated in public health campaigns. The contractor was a distance selling pharmacy and stated that its non-compliance was due to the lack of guidance provided to distance selling pharmacies on data collection strategies. NHS Resolution noted the evidence provided to it with regard to the guidance actually provided and determined that the contractor was in breach of the relevant term of service. It stated:
- "I am mindful that distance selling pharmacies are by virtue of the regulations obliged to provide: "... the safe and effective provision of essential services without face to face contact between any person receiving the services". In the circumstances, the Appellant's Standard Operating Procedures (SOPs) should already contain procedures to ensure that patients have access to information by various means including via the internet."*
68. In SHA/21018 (9 May 2019), a contractor was issued with a remedial notice relating to paragraph 28(2)(c)(v) of Schedule 4 of the Regulations, which requires the

contractor to “*participate in the manner reasonably required by the [commissioner] in an acceptable system of clinical governance*” and where “*acceptable*” means where it is considered acceptable by NHS England and comprises of a risk management programme which includes appropriate standard operating procedures.

69. Without clear guidance from NHS England, a contractor may find it difficult to comply with the Regulations due to the somewhat subjective standard imposed by this provision. In this appeal, NHS Resolution noted on several occasions the lack of information provided by both parties in the course of the appeal which would evidence the compliance or non-compliance with paragraph 28(2)(c)(v) of Schedule 4 of the Regulations.
70. As illustrated above, NHS Resolution is not always able to ascertain whether the evidence provided to it is evidence that the Commissioner would have deemed appropriate to satisfy itself of the contractor’s compliance with its terms of service. Often, the reason why these types of appeals progress to the appeal stage is due to inadequate communication and failure to clarify matters when they arise. Where a contractor is required to provide information to the Commissioner, it is important that the parties understand what is required of them and that they invest in effective record-keeping to avoid finding themselves engaging in dispute resolution.

## **Opening hours**

71. A significant number of appeals of breach notices or remedial notices relate to paragraph 23 of Schedule 4 of the Regulations in relation to pharmacy opening hours.
72. Paragraph 23(1) requires the contractor to ensure that the pharmaceutical services are provided at its premises for a certain number of hours per week and paragraph 23(7) requires the contractor to ensure that the pharmaceutical services are provided at its premises at the days and the times set out in the notification for inclusion on a pharmaceutical list.
73. The fact matrix of this category of appeals is broadly the same; a contractor has failed to provide pharmaceutical services during its core opening hours and/or supplementary opening hours which resulted in the Commissioner issuing a breach notice to the contractor for breach of paragraphs 23(1) and /or 23(7) of Schedule 4 of the Regulations.
74. As an example, in SHA/18843 (27 March 2018) the contractor failed to open and provide pharmaceutical services for 5 of its contracted hours due to a locum pharmacist, who was booked to provide services during that time, cancelling on short notice as a result of a family emergency. The contractor notified NHS England of the unplanned closure. The Contractor explained that it immediately made attempts to book another locum cover but with no success despite offering a higher rate per hour. The contractor put up a notice and remained open, albeit without a pharmacist, so that its staff were at the premises to speak with customers and sign post them to the nearest pharmacy. The contractor explained that there were no complaints received from any customers. NHS England, however, deemed this to be a closure that was within the contractor’s control and therefore found the contractor to be in breach of its terms of service. As the nature of the breach is one that is not capable of remedy, the contractor was issued with a breach notice.
75. In an appeal of the above type, NHS Resolution may need to consider a number of

factors including, but not limited to:

- i) the reasons submitted for the unplanned closure;
- ii) any mitigating circumstances;
- iii) whether there was a notification by the contractor of the unplanned closure; and
- iv) whether the contractor signposted customers to the nearest pharmacy to access pharmaceutical services.

76. Most of the previous determinations of this type of appeal cover the above factors. This guidance note considers how these factors have been approached by NHS Resolution.
77. Paragraphs 23(1) and 23(7) of the Regulations state that the contractor “*must ensure that pharmaceutical services are provided*” at its premises during its contracted hours and at the days and times set out in its application for inclusion in a pharmaceutical list. The Regulations do not refer to a grace period during which the contractor may not provide pharmaceutical services unless there has been a prior agreement for a temporary suspension of services, where the Commissioner has received three months’ notice of the proposed suspension.
78. Paragraph 23(10) however, makes clear that the contractor is not in breach of paragraphs 23(1) and 23(7) where the temporary suspension in the provision of services (or the unplanned closure) is for a reason beyond the control of the contractor and the contractor notifies the Commissioner of the suspension and resumes the provision of services as soon as possible.
79. Paragraph 23(10) therefore must be considered where the contractor has failed to provide pharmaceutical services during its contracted hours. It sets out a “checklist”, satisfaction of which leads to a conclusion that despite the unplanned closure, the contractor is not in breach of paragraphs 23(1) and 23(7).
80. The “checklist” in paragraph 23(10) can be summarised as follows:
- i) has there been a temporary suspension in the provision of services?
  - ii) was the suspension in the provision of services for a reason beyond the control of the contractor?
  - iii) did the contractor notify the commissioner of the temporary suspension as soon as practical?; and
  - iv) did the contractor use “all reasonable endeavours” to resume provision of pharmaceutical services as soon as practicable?

#### Temporary suspension

81. In SHA/19908 (27 July 2018), the contractor notified the commissioner of the temporary suspension of services and was issued with a breach notice. On appeal, the contractor explained that the notification sent to the commissioner was sent in error in that although one of the pharmacists did not arrive on time, there was in fact another pharmacist on premises providing services and so there was no suspension of services. As NHS Resolution was presented with evidence to that effect it noted that the commissioner was no longer challenging the position and substituted the

decision to issue a breach notice with a decision not to issue a breach notice.

“Beyond the control”

82. The Regulations do not define an event that is deemed to be “beyond the control” of a contractor which results in temporary suspension of services. The review of previous determinations indicates that the reasons provided by the contractors on appeal to explain the temporary suspensions are largely due to locum pharmacists who have been booked for shifts, cancelling their booked shifts on short notice or not honouring their bookings at all and failing to attend the contractor’s premises to provide pharmaceutical services.
83. In SHA/18849 (27 March 2018), the contractor stated on appeal that “*the Appellant had confirmation of booking for the Locum who failed to turn up for the shift at 7am*” and that “*the Appellant considers that the failure of the locum to arrive is “outside the control” of the pharmacy*”. In SHA/18789 (4 January 2018), the contractor explained that the booked locum mistakenly attended the wrong pharmacy resulting in the contractor being unable to provide services at its premises.
84. Other reasons however, include system errors resulting in a locum being booked incorrectly (SHA/18703 (4 August 2017)), family emergencies (SHA/18717 (29 August 2017)) and pharmacists unable to attend and provide services due to an illness (SHA/19925 (24 August 2018)).
85. In all of the above scenarios, NHS Resolution considered that staffing issues are not “beyond the control” of the contractor and determined that paragraph 23(10) does not apply on this basis. In SHA/19991 (3 January 2019), a pharmacist had not arrived for a scheduled shift and so the contractor was unable to provide pharmaceutical services. The contractor considered the subsequent suspension in the provision of services to be beyond its control. NHS Resolution stated:

*“...a problem with the staffing of a pharmacy is not good cause as to why the Pharmacist is not able to provide pharmaceutical services during core (or supplementary) hours. Staffing levels of the Pharmacist are not beyond the control of the Pharmacist. The arrangements and number of pharmacists employed are a commercial consideration and a matter for the Pharmacist to ensure that there is sufficient cover. It is open to the Pharmacist to employ more than one pharmacist to work during the same hours thus limiting the need for locums to be found to cover the employed pharmacist if they should be unavailable for some reason; to not do so is a commercial decision under the control of the Pharmacist.”*
86. The reasons provided by the contractor to justify the unplanned temporary suspension are often accompanied by additional mitigating factors. In SHA/18242 (8 April 2016), the contractor stated that it had “*provided NHS England with detail of extenuating circumstances that they feel have been overlooked with the issuing of a breach notice being premature and inappropriate in light of the circumstances*”. The facts of this appeal were that due to human error, the contractor mixed up the dates on when it had to renew its GPhC registration and this resulted in the contractor being unable to provide pharmaceutical services until the registration was re-instated. The contractor explained that they had been spending some time at the hospital visiting their father who had undergone an operation and missed the deadline for re-instatement. Although sympathetic to the contractor’s mitigating circumstances, NHS Resolution concluded that the contractor, as a body corporate,

should have had measures and procedures in place to ensure *“the wholly foreseeable lapsing of the pharmacy’s registration with the GPhC was realised and acted upon in good time”*.

87. In SHA/18668 (31 May 2017), the contractor was directed to provide pharmaceutical services on Christmas Day between the hours of 2pm and 4pm which it failed to do due to a booked locum not attending the confirmed booking. The contractor set out its mitigating circumstances by explaining that the booked locum did not cancel their shift, they simply did not attend; there were staff present at the premises but they were not qualified to provide pharmaceutical services and that due to it being Christmas Day it had proved impossible to find alternative cover on such a short notice. Despite these mitigating factors, NHS Resolution determined that the failure to provide pharmaceutical services was:

*“not beyond the control of the contractor as this relates to general management of the pharmacy, which includes having appropriate levels of staffing to ensure there is cover on any given day when the pharmacy is required to be open.”*

88. It can therefore be seen that where staff, be it locums or employed pharmacists, fail to attend the pharmacy and fail to provide pharmaceutical services, this is not likely to be deemed to be “beyond the control” of the contractor by NHS Resolution. The reasons for the failure to attend may contribute towards a set of mitigating circumstances carrying weight towards the Commissioner’s decision whether to issue a breach notice or not.
89. In SHA/18701 (29 August 2017), the contractor was issued with a breach notice for failure to provide pharmaceutical services on 7 separate occasions. The reasons stated for the unplanned closures were illness, late arrival and a flood from premises above the contractor’s premises. NHS Resolution stated that in relation to the closures which resulted from illness and late arrival, such failure *“was not beyond the control of the contractor, as it relates to the general management of the pharmacy, which includes having appropriate levels of staffing to ensure there is cover on any given day when the pharmacy is required to be open”*. NHS Resolution concluded:

*“For the purposes of this determination, I agree with the issue of the breach notice to the extent that it relates to the closures of the Broseley branch as set out in paragraph 5.17 above (apart from the incident on 24 January 2017 when there was a flood from the premises above the pharmacy)”*.

90. The above indicates that an event such as flooding would be deemed to be beyond the control of the contractor.
91. This is supported to an extent by Regulation 29(1)(b) of the Regulations, which relates to temporary arrangements because of circumstances beyond the control of the contractor. Regulation 29(1)(b), when referring to a reason that is beyond the control of the contractor provides an example of such a reason, which is fire or flooding. Although paragraph 23(10) of Schedule 4 does not contain similar wording, it is reasonable to extend the examples set out in Regulation 29(1)(b) to paragraph 23(10) of Schedule 4 on the basis that both of these provisions relate to a temporary suspension of services for reasons beyond the control of the contractor.

#### Notification of unplanned closure and resuming services

92. Previous determinations show that the requirements to notify the Commissioner of



temporary suspension and to use reasonable endeavours to resume service provision as soon as practicable, are largely met by the contractors and are not controversial on appeal. The issue here is that in order for the contractor to rely on paragraph 23(10) of Schedule 4 where there has been an unplanned temporary suspension of services, it must also show that the reason for the unplanned closure was one that is beyond its control. This issue is frequently the main subject matter of the appeals relating to breaches of paragraphs 23(1) and / or 23(10).

93. Ultimately, the Commissioner becomes aware of the temporary suspension upon the contractor notifying it of the temporary suspension and therefore there is an opportunity for the contractor to rely on paragraph 23(10) of Schedule 4 before it is issued with a breach notice. The Commissioner may choose not to issue a breach notice for breach of paragraphs 23(1) and/or 23(7) and so the requirements to notify the Commissioner of the unplanned temporary suspension of services and to resume the provision of services as soon as reasonably practicable are important steps for the contractor to take in seeking to avoid being issued with a breach notice.
94. In SHA/20007 and SHA/20008 (15 February 2019) joint appeal, the contractor sought to rely on paragraph 23(8) of Schedule 4 of the Regulations on the basis that the temporary suspension in the provision of services was due an illness of a pharmacist. In its appeal, the contractor stated that unplanned closure due to illness is a “*reasonable cause for failure to open*” and so it considered that it should not have been issued with a breach notice. NHS Resolution stated that:

*“unlike the provisions of paragraph 23(10), I consider that paragraph 23(8) is not a provision which “excuses” the Appellant from being in breach of another provision, it is rather a requirement that where the Appellant fails to provide pharmaceutical services ... it must, where practicable, make arrangements with another NHS pharmacist in the area to provide service during the time of temporary suspensions. It is an additional obligation on the Appellant.”*

95. NHS Resolution was therefore of the view that illness, as a reason for failure to provide services during the contractor’s contracted hours, is not a reason “beyond the control” of the contractor as paragraph 23(8) does not have the same effect as paragraph 23(10), it is an additional obligation on the contractor in the event that it is prevented from providing pharmaceutical services. Paragraph 23(8) requires the contractor to facilitate continuation of services where possible to ensure that patients are aware of where to access pharmaceutical services.

### **Withholding of payment**

96. Regulations 71 and 70 provide that where the breach related to a failure to provide, or a failure to provide to a reasonable standard a service that the contractor is required to provide, the breach or remedial notice may provide for the Commissioner to withhold all or part of the remuneration due to the contractor under the drug tariff. The supplementary matters relating to the withholding of payment are set out in Regulation 72.
97. Regulation 72 states that a remedial or a breach notice may only provide for the withholding of remuneration where the Commissioner is satisfied that the breach to which the withholding relates was without good cause, the amount to be withheld is justifiable and proportionate and the Commissioner includes justifiable reasons for both the decision to withhold and the amounts to be withheld.

98. In SHA/18414 (2 September 2016) the contractor was issued with a breach notice for failure to open. NHS England stated in the breach notice that a payment withholding was appropriate as the contractor did not provide services during the period it was closed. On appeal, the contractor did not dispute the payment withholding. Because the payment withholding flowed from the breach of a term of service and as NHS Resolution determined that the contractor was in breach of a term of a term of service, it considered that the payment withholding was appropriate.
99. In SHA/18359 (27 July 2016), the facts of which are similar to the above appeal, NHS England issued a breach notice for failure to open and stated in the breach notice that it would withhold payment from the contractor. NHS England calculated the payments to be withheld comprising salary costs and administrative costs of NHS England in investigating the breach.
100. In determining whether the proposed withholdings were appropriate, NHS Resolution noted that the Regulations do not attach values to the withholding but also noted that guidance is provided at paragraph 40 of the Department of Health (as it then was) guidance entitled “Regulations under the Health and Social Care Act 2012: Performance sanctions including market exit for contractor providing pharmaceutical services”. NHS Resolution stated:

*“Mindful of the guidance, I consider that it is reasonable for the amount of withholding to be based on an average hourly rate of a locum pharmacist that has been applied consistently in this sector.*

*I consider that the sum based on the administration costs incurred by NHS England is the costs of the investigations and, being mindful of the guidance, may not be recovered from the contractor or used to increase the withholding.*

*I am therefore of the view that the amount that NHS England has chosen to withhold that is based on the hourly rate for locum pharmacist is justifiable and proportionate within the context of Regulation 72 but that the sum based on the administration costs incurred by NHS England is not.”*

101. Regulation 72(3) states that the withholdings of payments provided for in the breach or remedial notices are without prejudice to the arrangements in place for recovering overpayments under Regulation 94. There is therefore a conceptual difference between withholding of payments pursuant to Regulations 71 or 72 and the recovery of overpayments pursuant to Regulation 94.
102. In SHA/19869 (31 May 2018) the contractor was issued with a breach notice for failure to meet the terms of the NHS Drug Tariff Part II Clause 12 on the grounds that it had not taken all reasonable steps to avoid claiming out of pocket expenses. In addition, the breach notice stated that NHS England is now seeking to recover the out of pocket expenses claimed by the contractor under Regulation 94. NHS Resolution stated:

*“I note that NHS England’s breach notice to [the Contractor]...referred to the Appellant’s failure to meet the terms of the NHS Drug Tariff Part II clause 12 as evidenced by the finding that the Appellant did not take all reasonable steps to avoid claiming out of pocket expenses (“OOP Expenses”). I further note that the breach notice included reference to NHS England’s intention to recover the amounts paid to the Appellant for the relevant OOP Expenses.*

*In my view the reference to NHS England’s intention to recover the amounts*

*was a consequence of the breach rather than part of the breach itself. I conclude that there are two different matters included in the breach notice, the decision to issue a breach notice as a result of not taking all reasonable steps to avoid claiming out of pocket expenses and the consequential decision to recover the amounts paid to the contractor the relevant OOP Expenses.”*

103. NHS Resolution went on to explain:

*“I consider that recovery of overpayments is not “withholding”. I consider that “withholding” is holding back payments that a contractor has claimed or (or may claim for) but have not yet been paid.*

*In the present matter, the breach notice does not refer to “withholding” of the monies that would otherwise be paid for the OOP Expenses. The breach notice refers to the recovery of overpayments which I consider is a reference to recovering payments already made.*

*As a result I consider that Regulation 77 cannot be used to appeal a decision of NHS England to recover overpayments”.*

104. In this case, the contractor was not appealing NHS England’s decision to recover the out of pocket expenses, rather the contractor appealed the amount NHS England sought to recover and the length of time provided to it to satisfy the recovery of the overpayment. A contractor’s right to appeal the recovery of overpayment is outside of the scope of this note as it is not contained in Regulation 77.
105. NHS Resolution has previously determined however, that it is possible to draw attention to the overpayment using a breach notice. This is particularly the case in the matters where the breach of a term of service was a failure to comply with the NHS Drug Tariff in the context of claiming for out of pocket expenses.
106. In SHA/19976 (6 March 2019) the contractor was issued with a breach notice on the grounds that it has claimed out of pocket expenses inappropriately and in contravention of NHS Drug Tariff part II clause 12. NHS Resolution noted that compliance with the NHS Drug Tariff is a term of service under Regulation 11(1)(b) which makes it clear that the terms of service include the provisions of the NHS Drug Tariff.
107. Part II clause 12 of the NHS Drug Tariff permits a contractor to claim out of pocket expenses for drugs and appliances ordered, provided certain criteria are met. This criteria are listed below and all must be met:
- i) that there are exceptional circumstances;
  - ii) that the product is a type of product for which out of pocket expenses claims can be made, with reference to parts and categories of the Drug Tariff;
  - iii) that the product is not required to be frequently supplied; and
  - iv) that the contractor has taken all reasonable steps to avoid claiming out of pocket expenses.
108. NHS Resolution noted that there are no definitions for ‘exceptional circumstances’, ‘frequently supplied’ or ‘take all reasonable steps to avoid claiming’ in the Drug Tariff

and stated:

*“I consider that the use of these unquantified expressions is deliberate by those drafting the Drug Tariff to enable specific circumstances to be considered. If the intent was to give these expressions a quantifiable meaning, this would have been set out.”*

109. In this case, NHS Resolution went on to consider each criteria against the specific set of circumstances unique to this particular appeal.
110. In its consideration of ‘exceptional circumstances’, NHS Resolution took into account the particular set of mitigating circumstances that was unique to this contractor, namely that the contractor could not source the products using its usual line of suppliers and so it had to source the products using a more expensive supplier in order to provide services. NHS Resolution considered that in the context of this appeal and based on the evidence, the out of pocket expenses were claimed in exceptional circumstances.
111. In its consideration of whether the products were ‘frequently supplied’, NHS Resolution once again noted that this criterion must relate to how frequently the contractor supplied a particular product, without comparison to the frequency of supply by other pharmacists. In order to determine whether a product is ‘frequently supplied’ it is important to analyse the data and so availability of a decent sample is imperative.
112. In consideration of whether the contractor took ‘all reasonable steps to avoid claiming’ NHS Resolution noted that in this case the contractor had shown that it had attempted to source the products from a number of other suppliers but with no success and so it considered that the contractor took all reasonable steps to avoid claiming.
113. The lack of clear guidance on the interpretation of Part II Clause 12 of the Drug Tariff makes it difficult to extract a solid principle relating to how to approach these appeals. The SHA/19976 appeal however emphasises the importance of considering a particular set of circumstances on an individual basis. Although this appeal provides some guidance on this type of appeal, this should not be taken in isolation as a blanket approach.

#### Document Control - Change Record

Date	Author	Version	Reason for Change
21 May 2024	Technical Case Manager	3	Amended to reflect recent changes to commissioning arrangements  Annex A wording updated to reflect Regulations in force as at 6 November 2023



## **Annex**

### **Regulation 70 (Breaches of terms of service: remedial notices)**

- (1) Where an NHS chemist (C) breaches a term of service and the breach is capable of remedy, NHS England may by a notice (“a remedial notice”) require C to remedy the breach.
- (2) To be valid, the remedial notice must include—
  - (a) the nature of the breach;
  - (b) the steps C must take, to the satisfaction of NHS England, in order to remedy the breach;
  - (c) the period (“the notice period”) during which the steps must be taken; and
  - (d) an explanation of how C's rights of appeal under regulation 77(1)(a) may be exercised.
- (3) The notice period must be not less than 30 days, unless NHS England is satisfied that a shorter period is appropriate—
  - (a) to protect the safety of any persons to whom C may provide pharmaceutical services; or
  - (b) to protect NHS England from material financial loss.
- (4) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C is required to provide, the remedial notice may provide that—
  - (a) as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, NHS England is to withhold all or part of the remuneration due to C in respect of that period under the Drug Tariff or a determination as mentioned in regulation 91(6);
  - (b) pending C taking the steps that C must take, to the satisfaction of the NHS England, in order to remedy the breach, NHS England is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(6), and in these circumstances—
    - (i) as regards any period for which C remains in breach, any withholding that is attributable to that period is to be permanent, and
    - (ii) once C has taken the steps that C must take, to the satisfaction of NHS England, any withholding that has taken place which is attributable to a period when C is no longer in breach is to be restored to C, provided that C submits a claim, in accordance with the Drug Tariff or a determination as mentioned in regulation 91(6), for restoration of the withheld remuneration attributable to that period.
- (5) The remedial notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 91(6) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.

- (6) The period referred to in paragraph (4)(b)(i) may be a longer period than the notice period.
- (7) If NHS England refuses to restore all or part of any withheld remuneration which is claimed under paragraph (4)(b)(ii), it must notify C of that decision as soon as is practicable, and that notification must include—
  - (a) a statement of the reasons for the decision; and
  - (b) an explanation of how C's rights of appeal under regulation 77(1)(b) may be exercised.
- (8) NHS England may rescind a remedial notice at any time.

**Regulation 71 (Breaches of terms of service: breach notices)**

- (1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, NHS England may by a notice (“a breach notice”) require C not to repeat the breach.
- (2) To be valid, the breach notice must include—
  - (a) the nature of the breach; and
  - (b) an explanation of how C's rights of appeal under regulation 77(1)(c) may be exercised.
- (3) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C is required to provide, the breach notice may provide that, as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, NHS England is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(6) in respect of that period.
- (4) The breach notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 91(6) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.
- (5) NHS England may rescind a breach notice at any time.