NHS Resolution

7 November 2024

REF: SHA/26304

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM MED-CHEM UK LIMITED ("THE APPELLANT")

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

1 **Outcome**:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £10,614.00.

1.2 I note that neither party has submitted a claim for interest with regard to this dispute so I determine that no interest is payable on the sums to be paid from one party to another.

A copy of this decision is being sent to:

Med-Chem UK Limited
NHS BSA on behalf of NHS England

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1 INTRODUCTION

1.1 The Appellant appealed the decision of NHS England to recover an overpayment relating to the Medicines Delivery Service.

1.2 The Secretary of State for Health and Social Care, pursuant to the National Health Service Litigation Authority (Pharmaceutical Remuneration – Payment Disputes) (England) Directions 2022 (the "Payment Disputes Directions"), has directed that NHS Resolution determines this type of appeal on their behalf. I, as an authorised officer of NHS Resolution, have made this determination.

2 DECISION

The NHS Business Services Authority ("NHS BSA"), acting on behalf of NHS England, sent a decision to the Appellant on 19 August 2024 in respect of Med-Chem Pharmacy (ODS code FRW62). The decision stated:

2.1 "**Medicines Delivery Service - Post Payment Verification**

2.2 The Pharmacy Provider Assurance Team, part of NHS Business Services Authority (NHSBSA), have been requested by NHS England (NHSE) to undertake a Post Payment Verification (PPV) exercise to provide assurance that pharmacy contractors have claimed correctly for the Medicines Delivery Service.

2.3 This service was originally commissioned across the country from 8th April 2020 and ran until 31st July 2020. In the months of April 2021 to March 2022 the Medicines Delivery Service (MDS) was limited to those patients who had been notified by Test and Trace to self-isolate. The Service was only available to people during their 10-day self-isolation period and who have provided their Test and Trace Account ID when requesting the service. Eligibility for Clinically Extremely Vulnerable (CEV) patients for the MDS ceased on the 31st March 2021 and therefore claims for deliveries to these patients after this date no longer qualified for a MDS payment.

2.4 Please find further information in this link to the service announcement - https://www.england.nhs.uk/coronavirus/documents/home-delivery-of-medicines-and-appliances-during-the-covid-19-outbreak-march-2021/.

2.5 As part of the verification exercise, your pharmacy has been contacted by the Provider Assurance Team to request that you review all of your Medicines Delivery Service records between the months of April 2021 to March 2022.

2.6 **To date your pharmacy has not provided evidence to demonstrate that the Medicines Delivery Service claims made during this time met the requirements set out in the service specification, i.e. that these claims for deliveries were to self-isolating patients. Therefore, the PAT are unable to verify that these claims were for deliveries to eligible patients. This is despite several attempts made by the NHSBSA Pharmacy Provider Assurance Team.**

2.7 The evidence is requested in accordance with Schedule 4 Part 4 paragraph 35 (4) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The NHSBSA Provider Assurance team have been authorised in writing by NHS England to request this information on their behalf.

2.8 Attached is a timeline of correspondence with your pharmacy to date which was passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary.

2.9 The NHS England Pharmaceutical Services Regulations Committee has now reviewed this information and noted that:

2.9.1 FRW62– Med-Chem UK Limited claimed **1,529 self-isolating deliveries and 240 CEV** claims for the Medicines Delivery Service in the months of April 2021 to March 2022.

2.9.2 The NHSBSA Provider Assurance Team did not receive any evidence which demonstrated that the Medicines Delivery Service claims made between the months of April 2021 to March 2022 were to patients who had been notified by Test and Trace to self-isolate and who had provided their Test and Trace Account ID when requesting the service, and therefore could not verify that these claims met the requirements set out in the service specification.

2.9.3 Med-Chem UK Limited was contacted on 8 separate occasions by the NHSBSA Provider Assurance Team to request evidence to demonstrate that that the Medicines Delivery Service claims made during this time met the requirements set out in the service specification.

2.10 Having reviewed the information provided by the NHSBSA Provider Assurance Team, the NHS England Pharmaceutical Services Regulations Committee has decided that an overpayment in relation to your April 2021 to March 2022 Medicines Delivery Service claims has occurred and has instructed recovery of this overpayment to be progressed in accordance with Regulation 94 (1) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.11 The tables below outline the monthly Medicines Delivery Service claims reimbursed to your pharmacy **– Med-Chem UK Limited – FRW62** in the months of April 2021 to March 2022 for Self-isolating and CEV patients, along with the associated recovery values:

2.12 **Self-isolating claims**

2.13 The table below shows MDS claims reimbursed to your pharmacy between April 2021 and March 2022 for Self-isolating patients.

	Apr 21	May 21	Jun 21	Jul 21	Aug 21	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	Total
Self-isolating	80	144	110	40	110	169	156	155	155	146	120	144	1529

claims paid													

2.14 1,529 self-isolating claims paid x £6.00 **= £9,174.00**

2.15 **CEV claims**

2.16 The table below shows MDS claims reimbursed to your pharmacy between April 2021 and July 2021 for CEV patients.

	April 2021	May 2021	June 2021	July 2021	Total
CEV claims paid	120	120	N/A	N/A	240

2.17 Subsequently this has resulted in the following payment:

2.18 240 CEV claims paid x £6.00 = £1,440.00**.**

2.19 **Total recovery for April 2021 to March 2022**:

2.20 1,529 self-isolating claims paid x £6.00 **= £9,174.00**

2.21 240 CEV claims paid x £6.00 = **£1,440.00**

2.22 **Total value to be recovered = £10,614.00 deduction**.

2.23 **Action Required**

2.24 Please respond to this correspondence at pharmacysupport@nhsbsa.nhs.uk to confirm your agreement for the overpayment to be recovered pursuant to Regulation 94(1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. **Please send this confirmation by 18th September 2024.**

2.25 Where you agree an overpayment has been made the amount over paid will be recovered by deduction from a future NHSBSA payment to you.

2.26 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by **18th September 2024.**

2.27 Once the NHSBSA has received confirmation to recover the overpayment you will be notified of when this will take place. A record of this process will be kept on your NHS England contractor file.

2.28 **Please be aware that failing to contact us by 18th September 2024 to agree that there has been an overpayment DOES NOT mean that the overpayment cannot be recovered.** Instead, where you do not agree that an overpayment has been made you have a right of appeal to the Secretary of State against NHS England's decision. Should you choose to appeal then send a concise and reasoned statement of the grounds for your appeal **within 30 days of the date of this letter** to nhsr.appeals@nhs.net or:

2.28.1 NHS Resolution, Primary Care Appeals, 10 South Colonnade, Canary Wharf, London, E14 4PU

2.29 If there is no appeal within 30 days from the date of this letter, NHS England has requested that the NHSBSA Provider Assurance Team commence overpayment recoveries under Regulation 94(1) (b) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, on the basis that the final outcome of our investigation is that there has been an overpayment.

2.30 The NHSBSA will notify you of when the overpayment recovery will take place.

2.31 A record of this process will be kept on your NHS England contractor file.

2.32 For more information or for clarification of any of the details in the letter, please contact us by email at pharmacysupport@nhsbsa.nhs.uk.

2.33 If you would prefer to speak to us via telephone/Microsoft Teams, please email pharmacysupport@nhsbsa.nhs.uk to provide your contact details and a member of the team will get in touch as soon as possible.

2.34 The proposed and future actions detailed in this letter are stipulated without prejudice."

2.35 The NHS BSA provided a copy of the timeline referred to in the decision.

3 THE DISPUTE

In an email dated 7 September 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "I am writing this email as I do not agree that an overpayment has been made and would like to appeal this.

3.2 During the period that an overpayment is suspected to have been made, the pharmacy had a delivery record book for self isolating patients. Before handing medications to the delivery driver the patients relevant information was written in this book.

3.3 We are a 100 hour pharmacy, being the only one in North London, open from 09:00-00:00 everyday for 365 days of the year we have a high demand for all services. Therefore, the demand for deliveries during this period was also very high. Haringey is a poor socio-economical area of North London, which has more vulnerable patients than other boroughs. Hence why our volume of Self-Isolating claims appear high for this period. We are certain the claims are not made incorrectly as every month we counted the number of deliveries based on the record kept in our delivery book.

3.4 At the time we were not told that this information will be needed and should be stored for a long time. The time period we are asked to supply information is during COVID. This time was a very difficult time for patients as well as us, we had to recruit a delivery driver to ensure we can provide an adequate and excellent service to the community.

3.5 I would like to mention at the time of the delivery service we did not know that we need to keep the delivery book for this many years. Also we did not recieve [sic] any confirmation from the NHS via email or letters to confirm this. Due to patient confidentiality we may have possibly shredded the list of patients we have delivered to as it is not a legal requirement to archive patient information's [sic] for delivery services, hence cannot provide evidence.

3.6 I hope you consider these points when deciding what happens next and I look forward to hear from you."

4 SUMMARY OF REPRESENTATIONS

The NHS BSA on behalf of NHS England stated:

4.1 "Thank you for your letter of the **11th of September 2024** and the opportunity to provide representations on the appeal.

4.2 **Background**

4.3 As part of the national response to the COVID-19 Pandemic, NHS England (NHSE) commissioned a delivery service from community pharmacies to those patients classed as Clinically Extremely Vulnerable (CEV) or 'Shielded Patients' who were required to self-isolate at home. This group of people were at a very high risk of serious illness from COVID-19 infection and were asked to remain indoors for their own safety.

4.4 To allow these patients to receive their prescriptions, an Advanced Service known as the Medicine Delivery Service (MDS) was created to provide funding for deliveries of prescriptions to CEV patients. The service was limited to CEV patients who could be identified on their Summary Care Record (SCR) as 'Shielded Patients'.

4.5 Contractors claimed for the service via the Manage Your Service (MYS) portal and for each delivery claimed as part of the Medicine Delivery Service, a payment of £6.00 (including VAT) was paid as part of the normal end of month process.

4.6 The Medicines Delivery Service was commissioned from both pharmacies and dispensing doctors across England from 9th April 2020 until 1st July 2020 in the first instance, but in the introductory letter – attached – it stated that this service may be extended as necessary as part of the Covid-19 response.

4.7 In its letter of 30th June 2020 – attached - NHSE announced that the service would be extended so that both pharmacies and dispensing doctors across England will be required to ensure shielded patients can receive a home delivery of their medicines until 31st July 2020. The letter informed contractors that the Government had published plans on 22nd June 2020 for a phased easing of the shielding advice to people who are clinically extremely vulnerable from 6th July 2020 however went on to explain that "the provision of this service throughout July will enable patients who are shielding time to make alternative arrangements for access to their prescription medications, after which both the essential and advanced pharmaceutical service, and both elements of the dispensing doctor COVID-19 home delivery service cease to be commissioned."

4.8 This and subsequent letters were published by NHS England on its website at: https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-community-pharmacy/.

4.9 Following the publication of each of these letters on the NHS Website the Pharmaceutical Services Negotiating Committee – the representative body for the community pharmacy sector, now known as Community Pharmacy England (CPE), also sent an update to its members highlighting the change to the service specification.

4.10 **April 2021 to March 2022 claims**

4.11 In the months of April 2021 to March 2022 the Medicines Delivery Service was limited to those patients who had been notified by Test and Trace to self-isolate. The Service was only available to people during their 10-day self-isolation period and who had provided their Test and Trace Account ID when requesting the service. Eligibility for Clinically Extremely Vulnerable (CEV) patients for the MDS ceased on the 31st of March 2021 and therefore claims for deliveries to these patients after this date no longer qualified as valid for a MDS payment.

4.12 The guidance stated that only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it. A record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision,

and for post-payment verification purposes. It also stated that pharmacies should familiarise themselves with the details of the service before making a claim.

4.13 Please find further information in this link to the service announcement - https://www.england.nhs.uk/coronavirus/documents/home-delivery-of-medicines-and-appliances-during-the-covid-19-outbreak-march-2021/.

4.14 The service specification also states that claims should only be made in the event that no friend, relative, carer or volunteer is available to collect the prescription on the patient's behalf.

4.15 The NHSBSA Pharmaceutical Provider Assurance Team (NHSBSA PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification exercise to ensure that pharmacy contractors claimed correctly for the Medicines Delivery Service between the months of April 2021 to March 2022 to ensure that all claims were for Self-Isolating (SI) patients and contractors had test and trace referral records available to substantiate those claims.

4.16 Manage Your Service (MYS) put in place new functionality to enable contractors to claim for the delivery of the MDS to SI patients. In doing so it retained the functionality for contractors to submit claims for CEV patients to future proof the system in-case the response to the Pandemic and MDS changed again at some point in the future and required the MDS provision for CEV patients. DHSE, NHSE and PSNC agreed the wording of the communication regarding this change to the service expecting that this would be sufficient for those contractors delivering the service to understand the changes in patient eligibility.

4.17 However, MYS became aware that contractors continued to claim for deliveries to CEV patients. Once it became apparent that many contractors were still submitting claims for these ineligible patients, MYS was amended to ensure these claims were no longer automatically paid. CEV claims submitted after May 2021 were not paid and only claims for deliveries to SI patients were processed for payment.

4.18 Despite the changes to the MYS functionality it remained the situation that any claims for deliveries to CEV patients submitted for April 2021 and May 2021 by contractors were paid. In effect the system continued to pay for deliveries to ineligible patient claimed by contractors. Subsequently, the NHSBSA PAT were requested to recover the identified CEV claims, as there was no regulation to allow payments for patients who were ineligible for the service.

4.19 In the Post Payment Verification exercise undertaken by the NHSBSA PAT, FRW62 – Med Chem UK Limited was contacted on eight occasions to request specific Test and Trace referral evidence to show that the 1,529 Self-Isolating patient claims made between April 2021 and July 2021 were for deliveries made to eligible patients' self-isolating in response to a positive Covid test, as specified in the NHSE service announcements.

4.20 Alongside that, NHSBSA PAT outlined that FRW62 – Med-Chem UK Limited also incorrectly claimed for 240 CEV patients during the months of April and May 2021 to enquire if they were aware of the change in the service and that these patients were no longer eligible.

4.21 Emails were sent to the pharmacy shared NHSmail address pharmacy.frw62@nhs.net as required by NHSE. All listed pharmacies must have a valid shared NHSmail account that should be regularly monitored by the pharmacy team as part of their terms of service.

4.22 Several phone calls to the pharmacy were also made, to confirm receipt of these emails and to advise the pharmacy of the final 14-day response deadline.

4.23 Med-Chem UK was unable to provide any evidence to demonstrate that the 1,529 Medicine Delivery Service deliveries claimed for between April 2021 and March 2022 were made to self-isolating patients who had provided their test and trace referral number when requesting the service as specified in the service specification at this time.

4.24 The NHSBSA PAT engaged with Med-Chem UK during the PPV process. Initially during email communication in December 2023, an email from the pharmacy explained that they did previously have a delivery book which contained patient names and addresses however this had been misplaced and could no longer be located.

4.25 Following this in further email communication it was stated by the pharmacy that *"Due to patient confidentiality we may have possibly shredded the list of patients we have delivered to as it is not a legal requirement to archive patient information's for delivery services."*

4.26 The NHSBSA PAT did remind the contractor of the requirements for keeping evidence for PPV purposes that was outlined in the service announcements. In this response the NHSBSA PAT also outlined that if no evidence was available, the case would need to be referred on to the Pharmacy Services Regulation Committee (PSRC) of the ICB area where the pharmacy was located, which was agreed with the pharmacy manager.

4.27 It should be noted that between the dates of 28th October 2021 – 12th May 2022 the NHSBSA PAT engaged regularly with Med-Chem UK as the pharmacy were involved in a previous MDS PPV activity exploring incorrectly claimed CEV claims during August to October of 2020.This is to highlight that they were thoroughly aware of the need of keeping evidence for assurance activity as this message was given to all contractors that on-going PPV activity would be taking place in regards to MDS. Between August and October 2020 MDS was commissioned only for deliveries made to patients in areas of the country subject to local lockdown restrictions, which were specified in the attached service announcements. Only pharmacies providing delivery services to patients affected by these local lockdowns were eligible to continue to claim for the delivery service.

4.28 Med-Chem UK claimed for the provision of the service, although they were not based in an area of the country affected by a regional lockdown. Over the three months where the service was not commissioned in their area the pharmacy claimed and were paid for 466 incorrect MDS claims for the months of August to October 2020. During telephone conversations throughout May 2021 and emails received by the NHSBSA PAT for this PPV period it is noted that the pharmacy stated *"we were not aware of the service announcements which detailed the extension of the Medicines Delivery Service for specific local lockdown areas only. Therefore, the pharmacy continued to provide the service to shielding and isolating patients outside of the specified local lockdown areas past the 31st July. As a result, the pharmacy is unable to provide evidence of any deliveries made to patients within the local lockdown areas."*

4.29 As a result, in July 2022 the NHSBSA PAT performed a recovery for the 466 ineligible claims totalling £2,796.00. This recovery took place with agreement from the contractor and the case was not referred onto PSRC for a decision, so Med-Chem UK have previously accepted they did not follow the service specification correctly. Alongside this as part of the completion of this engagement the NHSBSA PAT made Med-Chem UK aware we would continue to perform assurance activity on MDS claims and as part of the notification of adjustment we advised that this recovery will not mean that no further potential sampling may take place for MDS involving the pharmacy as that would depend on the national data. Therefore, contractors should ensure evidence was kept in-case they were sampled again in later reviews of the service delivery.

4.30 To avoid any doubt there is no dispute about these deliveries may having been made, the engagement with the pharmacy was to confirm that the deliveries were made to patients eligible for the Medicine Delivery Service.

4.31 With evidence not forthcoming the NHSBSA PAT have been unable to validate the deliveries claimed by the pharmacy during this time and with the agreement of the appellant, the details of the case were passed to the NHS England regional team for their PSRC to review. A decision was sought as to whether the deliveries claimed by the contractor were for deliveries eligible for a payment under the terms of the Medicine Delivery Scheme at the time that the deliveries were made; and if they were not eligible, for the delivery fees that have been paid to be recovered under regulation 94 (1) (a) as an overpayment.

4.32 **The PSRC decision**

4.33 To assist with their review, the PSRC was provided with the NHSE service announcements and the timeline of correspondence showing all contact the Provider Assurance team had with the pharmacy for review. This timeline has been provided to you in addition to this information.

4.34 The engagement showed that despite repeated requests and additional time given to the contractor by the NHSBSA PAT, the contractor was unable to locate the evidence requested and the NHSBSA PAT were unable to verify the claims made as part of our assurance activity.

4.35 Consequently, the PSRC concluded that the NHSBSA PAT had been unable to find any evidence to demonstrate that the 1529 deliveries claimed by the contractor between April 2021 and March 2022 met the requirements set out in the service specification alongside the incorrectly claimed 240 claims made for CEV patients. Following this conclusion, the PSRC determined that the pharmacy was not entitled to the payment for which it had received.

4.36 Having made this decision, the PSRC then directed that as Med-Chem UK was not entitled to the payment that the overpayment should be reclaimed pursuant to Regulation 94 (1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.37 In making this decision the PSRC relied on the information that it had before it, following the extensive investigation undertaken by the NHSBSA and the repeated requests to the contractor for evidence of how the Medicine Delivery Service claims made for April 2021 to March 2022 met the requirements set out in the service specification.

4.38 **In response to the points made in the contractor's appeal:**

4.39 The service specification states *'Only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it. A record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision, and for post-payment verification purposes.'*

4.40 The service specification is therefore clear that *a record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision, and for post-payment verification purposes. All contractors providing the service in line with the service specification would then have been aware that these records would be required should a contractor be required to provide evidence for the Post Payment Verification of service delivery eligibility.*

4.41 The request of evidence to support the MDS claims made was outlined in our engagement outlining for the self-isolating claims we require test and trace referral numbers in support of each MDS delivery. This evidence was not forthcoming, Med-Chem UK outlined in their response that the evidence was destroyed in compliance with confidentiality concerns. In their appeal Med-Chem UK made the following statements: *"During the period that an overpayment is suspected to have been made,*

the pharmacy had a delivery record book for self-isolating patients. Before handing medications to the delivery driver the patient's relevant information was written in this book.", "At the time we were not told that this information will be needed and should be stored for a long time."

4.42 In response to this the NHSBSA PAT would state we do not dispute that the deliveries took place rather it is that NHS England cannot be assured that the eligibility of the patients for which deliveries were claimed was confirmed as required for the commissioned Medicines Delivery Service. Med-Chem UK were included in the assurance activity because they had a high volume of claims alongside the fact, they had made ineligible CEV claims. Their claims were different to the majority of contractors in the fact the pharmacy MDS claims were increasing regularly while overall claims for the service were reducing sharply in the final six months of the service.

4.43 When Med-Chem UK stated they were not told they needed to keep this information this is incorrect as the service specification and the service announcements clearly stated '*Only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it. A record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision, and for post-payment verification purposes. Pharmacies and dispensing doctors should familiarise themselves with the details of the service before making a claim.'*

4.44 Med-Chem UK in their appeal also stated; *"I would like to mention at the time of the delivery service we did not know that we need to keep the delivery book for this many years. Also, we did not receive any confirmation from the NHS via email or letters to confirm this."*

4.45 In response to this point we need to state that information regarding the MDS was published regularly by NHSE on its website and following the publication of each of these letters on the NHS Website, Community Pharmacy England (CPE), also sent an update to its members. These updates highlighted the changes to the service specification, ensuring that all community pharmacies were informed of the necessary adjustments and extensions to the MDS. This comprehensive communication strategy was designed to ensure that all pharmacies were aware of the requirements and could comply accordingly. This method of communication was effective as the majority of pharmacy contractors stopped claiming for the ineligible CEV patients suggesting they were aware of the change to the service after April 2021. In support of this point for the previous three months before the change to the service of January to March 2021 the 3-month average total number of pharmacies claiming for MDS was 6,621 however after the service change the 3-month average total number of pharmacies claiming for MDS from April to June 2021 reduced to 1,048. This is almost an 85% reduction in pharmacies claiming for MDS showing the message to pharmacies around who was eligible for the service was clear.

4.46 The NHSBSA PAT appreciate and understand that the pharmacy stated they maintained a delivery record book during the period in question, however it is important to emphasize the necessity of retaining such records for verification purposes. Also, the information does not state if the relevant information was recorded on the delivery book as they made no mention nor answered questions on whether test and trace referral numbers were kept for those patients advised to self-isolate.

4.47 The lack of explicit instructions from the NHS regarding the timescales for the storage of these records does not negate the requirement in the service specification that appropriate records must be maintained. This documentation is essential to substantiate the deliveries made under the Medicine Delivery Service. The NHSBSA PAT acknowledges that whilst the service specification is clear that records need to be kept for PPV purposes, it does not advise of exactly how long contractors were required to keep such evidence. However, the NHSBSA PAT would highlight again that Med-Chem UK was aware of the PPV exercise being undertaken by the NHSBSA in October

2021 as it was asked to provide evidence of patient eligibility then. Med-Chem UK was not able to provide evidence of patient eligibility for that exercise and has been unable to do so again for this one.

4.48 Med-Chem UK argues that they were not told that this evidence will be needed and should be stored for a long time. However, the pharmacy did not outline in their engagement what record retention policy they follow instead just stated they destroyed evidence after a set period of time. In their response Med-Chem UK do not even state the evidence was destroyed down to any retention period instead rather they state, "*Due to patient confidentiality we may have possibly shredded the list of patients we have delivered to as it is not a legal requirement to archive patient information's for delivery services, hence cannot provide evidence."*

4.49 Many pharmacies provide non-NHS funded delivery services to patients who request this service. The NHSBSA PAT understand that the demand for these services increased during COVID, we also appreciate that there was no need to retain or archive these delivery records even in the short term for NHS purposes. However, it was an essential requirement that the records of eligibility for the NHS Medicines Delivery Service were retained, and that they should be available for PPV purposes. NHS England and the NHSBSA PAT are unsure what Med-Chem UK regards as a "*long time*" for the keeping of these delivery records, additionally they have not outlined when this delivery book was destroyed and therefore what retention period they followed.

4.50 Section VIC of the Drug Tariff contains the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. Throughout the directions there are repeated requirements for records to be retained for post payment verification purposes without the reference to a time scale for retention. For the New Medicines Service there is a time scale mentioned in paragraph 7- ongoing **conditions of arrangements**:

4.51 (l) P (pharmacy) ensures that a written record (which may be an electronic record) of each consultation carried out by or on behalf of P as part of P's New Medicine Service is prepared by the registered pharmacist who carried out the consultation and includes the approved data ("approved" for these purposes means approved by the NHSCB).

4.52 (m) P provides information from those records to the NHSCB or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the NHSCB; and

4.53 (n) P keeps a copy of the record mentioned in sub-paragraph (l) for at least 2 years from the date on which the service intervention is completed or discontinued.

4.54 Other advanced services such as the NHS community pharmacy hypertension case-finding advanced service requires records to be retained for 3 years.

4.55 It is therefore clear that records being kept for 2 years only is not uniform and there is the precedence that evidence would be required to be retained for longer than two years. It, therefore, appears incredulous that a contractor providing this service in accordance with the service requirements and knowing that records would be required for PPV purposes may have then shredded such records without confirming that they would not be needed for such a PPV exercise.

4.56 In their appeal response Med-Chem UK then state "*We are a 100 hour pharmacy, being the only one in North London, open from 09:00-00:00 every day for 365 days of the year we have a high demand for all services. Therefore, the demand for deliveries during this period was also very high. Haringey is a poor socio-economical area of North London, which has more vulnerable patients than other boroughs. Hence why our volume of Self-Isolating claims appear high for this period".*

4.57 Again, the NHSBSA PAT are not disputing the fact that Med-Chem UK are a 100-hour pharmacy and that flexibility and support for their patients may lead to them having a

high demand for their services. However, we are unsure whether any of the information included here would lead to an increased amount of self-isolating patients for MDS. This information seems more to suggest it would impact previous time periods of MDS for the clinically extremely vulnerable patients rather than those advised to self isolate by Test and Trace following a positive Covid test. Having potentially more patients can lead to possibly more self-isolating deliveries but again the claims from Med-Chem UK are of a consistent volume whereas the data of positive Covid tests would suggest peaks and troughs depending on national levels of infection.

4.58 We must also outline that Med-Chem UK were seen as a significant outlier for the service claims made by the pharmacy contractors. So, if a contractor was still submitting CEV claims these were included in that calculation as even if those claims were not being paid after May 2021 the contractors were still claiming these as MDS deliveries. Across the final 12 months of the service Med-Chem UK carried on claiming for CEV patients every month even though these claims were not paid after May 2021. This volume meant that Med-Chem UK across the final 12 months of the service was one of the highest claiming pharmacies nationwide for MDS. The table below shows that the claims for MDS deliveries made by Med-Chem UK Limited were consistently and significantly higher than the national average across every one of the final 12 months of MDS.

	Apr 21	May 21	Jun 21	Jul 21	Aug 21	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22
Self-isolating claims paid	80	144	110	40	110	169	156	155	155	146	120	144
Combined CEV and SI	200	264	175	84	266	289	292	299	304	301	264	264
National monthly average claims Combined CEV and SI	87.36	72.03	28.07	19.79	26.1	26.8	27.22	29.41	29.76	25.02	27.41	19.17

4.59 [Graph provided highlighting Claims vs National Average.]

4.60 In their response Med-Chem UK stated, *"We are certain the claims are not made incorrectly as every month we counted the number of deliveries based on the record kept in our delivery book."* The NHSBSA PAT in response would again state we do not dispute that deliveries took place instead rather how Med-Chem UK limited their claims for the MDS to those patients that were eligible for the service. Not only were they not able to show how they confirmed eligibility for the service or how they differentiated between SI and CEV claims. Without any evidence to support these high volumes of claims the PAT were unable to give assurance to NHS England that the claims had been made in accordance with the service specification.

4.61 Reviewing the claims made by Med-Chem UK for the service their consistently high volume of combined CEV and SI claims does not align with the national trend observed for other contractors. This pattern is also inconsistent with what we would expect from patients eligible for deliveries, as the claims imply a steady number of positive COVID-

19 cases in their local area throughout the final 12 months of the service. This is contrary to the national decline in positive cases during that period, which led to the easing of pandemic restrictions. Additionally, while the national average peaked in April 2021 Med-Chem UK's combined claims peaked in December 2021 with a combined claim which is almost nine times higher than the national average of claims across the final 12 months of the service.

4.62 Med-Chem UK also stated in their appeal *"The time period we are asked to supply information is during COVID. This time was a very difficult time for patients as well as us, we had to recruit a delivery driver to ensure we can provide an adequate and excellent service to the community."*

4.63 NHS England and the NHSBSA PAT acknowledge the many difficulties experienced by pharmacies during this period and express gratitude for their efforts to protect vulnerable patients. However, it is important to note that only those pharmacies delivering to patients covered by the NHSE announcements between April 2021 and March 2022 are eligible to claim for the MDS, so while we appreciate pharmacies considering the needs of their patients only deliveries to self-isolating patients were acceptable to be claimed under MDS. Deliveries made outside this eligibility fall outside the scope of MDS, and therefore, the associated costs must be covered through alternative means. We also appreciate all pharmacy contractors were in the same difficult situation and the majority were able to identify the correct eligible patients for the service.

4.64 The appellant states that "*Due to patient confidentiality we may have possibly shredded the list of patients we have delivered to as it is not a legal requirement to archive patient information's for delivery services, hence cannot provide evidence."*

4.65 While we understand the importance of patient confidentiality, it is crucial to note that the lack of delivery records due to shredding does not exempt the pharmacy from the requirement to provide evidence for the eligibility of the deliveries that they have submitted claims for. Proper documentation and record keeping is essential for verifying the eligibility of deliveries under the Medicine Delivery Service. Therefore, the inability to produce these records means that the associated costs cannot be claimed under this service. Before undergoing our assurance activity, the NHSBSA PAT confirmed that there is a legal obligation for contractors such as Med-Chem UK to share this information and this is in accordance with data protection legislation. - 8.1. The pharmacy contractor must maintain appropriate records to ensure effective ongoing service provision and to support post-payment verification.

4.66 NHS England maintains that Med-Chem UK was not compliant with the requirements set out in the service specification and the claims for deliveries during April 2021 to July 2021 could not be verified as deliveries to patients who were eligible for the Medicines Delivery Service. As a consequence of an overpayment had been made. The decision to then recover the £9,174.00 overpayment for self-isolating claims and £1,440.00 for ineligible CEV claims was then in accordance with the regulations.

4.67 **Key points for consideration**

4.68 NHS England respectfully asks that NHS Resolution considers the following key points when making its determination on the appeal:

4.69 The NHSE service announcement was very clear that the Medicines Delivery Service was limited to only those patients who had been notified by Test and Trace to self-isolate and was only available to people during their 10-day self-isolation period. Also, patients must have provided their Test and Trace Account ID when requesting the service.

4.70 Claims for MDS deliveries were exceptionally higher than the national average for everyone of the final 12 months.

4.71 Contractors were advised to retain evidence of deliveries made to Self-isolating patients as highlighted in the service announcements for post payment verification purposes.

4.72 From 1st April 2021 NHS England did not commission a delivery service for CEV patients. Any claims submitted for delivery to CEV patients were not then eligible for payment. Those claims submitted and paid are therefore an overpayment and have been treated as such.

4.73 NHS England has no power to make payments to pharmacy contractors outside of the statutory framework of eligible patients set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, the service specification, and the Drug Tariff.

4.74 The contractor had numerous opportunities to provide evidence to demonstrate that the deliveries claimed met the requirements set out in the service specification. Only those contractors where no or insufficient evidence of meeting these requirements were referred to the PSRC of their ICB.

4.75 The PSRC was presented with timelines of correspondence, showing all contact between the Provider Assurance team and the pharmacy.

4.76 The PSRC fully considered all information that it had before it when making its determination for the overpayment under regulation 94.

4.77 The appeal has not provided any evidence to demonstrate that the deliveries claimed for during this phase were made to patients eligible for the Medicines Delivery Service.

4.78 The decision to make an overpayment recovery is in line with regulations and there is nothing in the appeal to suggest otherwise.

4.79 Having considered these matters NHS England and Improvement respectfully suggests that NHS Resolution conclude that the decision made by the PSRC in respect of the £10,614.00 overpayment recovery from Med-Chem UK Limited was fair and in accordance with the regulations."

4.80 The NHS BSA provided the following:

4.80.1 A copy of the NHS England introductory letter dated 9th April 2020

4.80.2 A copy of the NHS England letter dated 30th June 2020

4.80.3 A copy of the NHS England Service Specification dated 16th March 2021

4.80.4 A copy of the NHS England Service Announcement which outlined the service from 16th March 2021

4.80.5 A further copy of the timeline of correspondence between the NHS BSA PAT and the contractor.

5 OBSERVATIONS

5.1 The Appellant provided a further copy of its grounds of appeal. See point 3 above.

6 CONSIDERATION

6.1 Direction 2 of the Payment Disputes Directions directs me to determine a dispute in respect of the recovery of an overpayment from an NHS pharmacist under regulation 94(1) of the NHS (Pharmaceutical and Local Pharmaceutical Services Regulations) 2013 (the "Regulations") which is in the nature of an appeal against a decision of NHS England that there has been an overpayment.

6.2 Direction 4 of the Payment Disputes Directions requires me to determine the appeal by dismissing it if:

6.2.1 NHS England has advised that an appeal must be brought within 30 days of the date the Appellant was notified of NHS England's decision and the appeal was not brought within that timescale; or

6.2.2 I am of the opinion that notification of the appeal contains no valid grounds of appeal (for example because it amounts to a challenge to the legality or reasonableness of the Payment Disputes Directions, the Regulations or the Drug Tariff).

6.3 I consider that I am not required to dismiss the appeal pursuant to Direction 4 as:

6.3.1 the NHS BSA advised the Appellant of a 30 days' timescale for appeal and the appeal was received within that timescale; and

6.3.2 the grounds of the appeal are valid.

6.4 Direction 6 of the Payment Disputes Directions states that I may determine the appeal without hearing any oral representations but if an appellant asks to make oral representations a hearing must be arranged unless I am satisfied that:

6.4.1 a hearing is unnecessary; or

6.4.2 I must dismiss the appeal by virtue of Direction 4.

6.5 The Appellant has not requested a hearing. On the basis of the information before me I have considered that it is unnecessary to hold an oral hearing.

6.6 I have before me the papers considered by the NHS BSA. I also have before me the responses to NHS Resolution's own statutory consultations.

6.7 I have considered further the requirements relating to the home delivery service referred to by the NHS BSA.

6.8 I note that the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (the "Advanced and Enhanced Services Directions") were amended on 27 March 2020 to require NHS England to commission a home delivery service from a pharmacy contractor who is to make a delivery of a prescription as mentioned in paragraph 22A(3)(a) or (b) of Schedule 4 to the Regulations. Paragraph 22A(3)(a) and (b) relate to deliveries to eligible patients in an area specified in an announcement made by NHS England with the agreement of the Secretary of State. The announcement must be to the effect that in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from pharmacy premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

6.9 The Advanced and Enhanced Services Directions go on to say that NHS England is directed to ensure there is a service specification for the home delivery service. A pharmacy contractor must comply with the requirements of the service specification.

6.10 I note that the NHS BSA has indicated that the deliveries that are covered by the decision on overpayment are those made in the period April 2021 to March 2022. These were split into 1,529 deliveries to those who were self-isolating and 240 deliveries to those who were Clinically Extremely Vulnerable (CEV).

6.11 A copy of the specifications and guidance for the 'Home delivery of medicines and appliances during the COVID-19 outbreak' dated 16 March 2021 have been provided to me by the NHS BSA.

6.12 I note the NHS BSA states that "*In the months of April 2021 to March 2022 the Medicines Delivery Service was limited to those patients who had been notified by Test and Trace to self-isolate*" and that "*Eligibility for Clinically Extremely Vulnerable (CEV) patients for the MDS ceased on the 31st of March 2021 and therefore claims for deliveries to these patients after this date no longer qualified as valid for a MDS payment.*"

6.13 One of the announcements provided to me, dated 16 March 2021, states the following:

6.13.1 "*To help provide support to people who have been notified of the need to self-isolate by Test and Trace, the Community Pharmacy Home Delivery Service and the Dispensing Doctor Home Delivery Service will be commissioned from 16 March 2021 to 30 June 2021 (inclusive) for anyone living in England who has been notified by Test and Trace to self-isolate. Upon receiving contact from Test and Trace, the individual is provided with a unique Test and Trace Account ID, which is an 8-character mix of letters and numbers.*

6.13.2 *This service is only available to people during their 10-day self-isolation period and who have provided their Test and Trace Account ID when requesting the service.*"

6.14 I do not appear to have been provided with an announcement relating to the period 1 July 2021 to March 2022. However I note that there is no dispute that the Community Pharmacy Home Delivery Service was commissioned during the period April 2021 to March 2022 inclusive and that it was only available to people during their 10-day self-isolation period who had provided their NHS Test and Trace Account ID when requesting the service.

6.15 The specifications and guidance provided state:

6.15.1 "*Pharmacy contractors should ensure that they are only delivering to eligible patients in the areas specified in the announcement in place at that time when they are acting in accordance with this service specification. Appropriate checks should be made to ensure that the patient remains eligible for this service, which may include checks on the summary care record.*"

6.16 I note the NHS BSA states that it was "*requested to conduct a Post Payment Verification exercise to ensure that pharmacy contractors claimed correctly for the Medicines Delivery Service between the months of April 2021 to March 2022 to ensure that all claims were for Self-Isolating patients and contractors had test and trace referral records available to substantiate those claims.*"

6.17 I further note the NHS BSA's comments that the Manage Your Service (MYS) system had retained functionality for contractors to submit claims for delivering to CEV patients, which had led to claims being submitted for ineligible patients during the months of April and May 2021. The MYS service had subsequently been amended to ensure such claims could not be automatically paid. The NHS BSA states that it was therefore requested to recover those CEV claims which had been paid in error, given that those patients were ineligible.

6.18 The NHS BSA has provided a timeline detailing its contact with the Appellant between 6 December 2023 and 22 May 2024, in order to request evidence that the 1,529 claims made between April 2021 and March 2022 were for deliveries made to eligible patients as details in the service specification. The NHS BSA states that it also outlined to the Appellant that it had incorrectly claimed for deliveries to 240 patients during April and May 2021 and enquired whether it was aware of the change to the service.

6.19 I note that the service specifications state:

6.19.1 "*The pharmacy contractor must maintain appropriate records to ensure effective ongoing service provision and to support post-payment verification. This should include, as a minimum, details of the eligible patients to whom a delivery was made under this service, including the postcode of the patient's address, and the date of the delivery.*"

6.20 In its appeal, the Appellant states that *"We are a 100 hour pharmacy, being the only one in North London, open from 09:00-00:00 everyday for 365 days of the year we have a high demand for all services. Therefore, the demand for deliveries during this period was also very high. Haringey is a poor socio-economical area of North London, which has more vulnerable patients than other boroughs. Hence why our volume of Self-Isolating claims appear high for this period. We are certain the claims are not made incorrectly as every month we counted the number of deliveries based on the record kept in our delivery book."*

6.21 I note that the NHS BSA has highlighted the volume of deliveries made by the Appellant compared to the national average, although it does not dispute that the deliveries were made, rather it challenges the eligibility of the claims made by the Appellant for self-isolating patients.

6.22 The Appellant continues that "*At the time we were not told that this information will be needed and should be stored for a long time. The time period we are asked to supply information is during COVID. This time was a very difficult time for patients as well as us, we had to recruit a delivery driver to ensure we can provide an adequate and excellent service to the community.*

I would like to mention at the time of the delivery service we did not know that we need to keep the delivery book for this many years. Also we did not recieve [sic] any confirmation from the NHS via email or letters to confirm this."

6.23 However I note the NHS BSA's response that *"the service specification and the service announcements clearly stated* '*Only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it. A record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision, and for post-payment verification purposes. Pharmacies and dispensing doctors should familiarise themselves with the details of the service before making a claim.'"*

6.24 Further "*information regarding the MDS was published regularly by NHSE on its website and following the publication of each of these letters on the NHS Website, Community Pharmacy England (CPE), also sent an update to its members*. *These updates highlighted the changes to the service specification, ensuring that all community pharmacies were informed of the necessary adjustments and extensions to the MDS. This comprehensive communication strategy was designed to ensure that all pharmacies were aware of the requirements and could comply accordingly. This method of communication was effective as the majority of pharmacy contractors stopped claiming for the ineligible CEV patients suggesting they were aware of the change to the service after April 2021".*

6.25 I note the NHS BSA's argument that the Appellant was previously involved in a post payment verification exercise and therefore the Appellant would have been aware of the need to retain records for any subsequent post-payment verification exercises.

6.26 It is unhelpful that the service specification did not identify a requirement for the records to be retained for a set period. I also sympathise with the challenges faced by pharmacies as referred to by the Appellant in the appeal. However I am of the view that the Appellant should have been aware of the requirement of the service specification to retain records for any post-payment verification.

6.27 Further in the absence of any specified time period, the requirement in the specification is absolute – appropriate records must be maintained. It is not reasonable to expect a pharmacy to keep records forever so it is appropriate to imply into the wording that records will be kept for a reasonable time period, taking into account the reasons expressly stated for maintaining records. Those reasons are to ensure effective ongoing service provision and to support post payment verification. The former would likely fall away once service provision ceases but the latter clearly extends after the provision of service and after payment has been received. The key question is therefore, knowing that records were to be maintained for post-payment verification, whether the policy of the Appellant to destroy records when it did was reasonable.

6.28 I note the Appellant has not provided any evidence of its retention policy for records, at its pharmacy to support any retention periods.

6.29 I do not consider it reasonable that, where a service specification expressly requires records to be maintained to support post payment verification, a pharmacy should be entitled to apply a particular retention period without confirmation that there will be no post payment verification.

6.30 I note the Appellant's comment that "*Due to patient confidentiality we may have possibly shredded the list of patients we have delivered to as it is not a legal requirement to archive patient information's for delivery services, hence cannot provide evidence."*

6.31 Whilst there is a requirement that data is kept for no longer than is necessary, there are also obligations on data controllers to ensure that retention periods are reflected in their privacy notice including any changes to data retention periods.

6.32 I consider that had any evidence, at all, relating to these months been provided then this might have enabled the Appellant to evidence that claims were made in accordance with the service specification. However, the Appellant has stated that the information "*may have been possibly shredded*". I do not consider that this destruction was in accordance with the service specification. I consider that the Appellant should have been able to provide the necessary information for post-payment verification by the NHS BSA. As it has not done so, I consider that the NHS BSA's decision to recover the overpayment is the only appropriate outcome.

7 DECISION

7.1 I have had regard to the Payment Disputes Directions which provide me with three options:

7.1.1 dismiss the appeal and confirm the decision of NHS England; or

7.1.2 substitute for the decision any decision that NHS England could have taken when it took the decision; or

7.1.3 quash the decision, with or without remitting the matter to NHS England for it to take the decision again subject to such directions as NHS Resolution considers appropriate.

7.2 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £10,614.00.

7.3 I note that neither party has submitted a claim for interest with regard to this dispute so I determine that no interest is payable on the sums to be paid from one party to another.

Head of Appeals
NHS Resolution