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6 March 2025

REF: SHA/26362

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM NORTH WALSHAM PHARMACY (FN670) ("THE APPELLANT")

1 **Outcome**:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £9,013.71.

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:

North Walsham Pharmacy
NHS BSA on behalf of NHS England

8th Floor
10 South Colonnade
Canary Wharf
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E14 4PU

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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM NORTH WALSHAM PHARMACY (FN670) ("THE APPELLANT")

1 INTRODUCTION

1.1 The Appellant appealed the decision of NHS England to recover an overpayment relating to Out of Pocket Expenses ("OOPE") – Post Payment Verification

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 27 September 2024 in respect of North Walsham Pharmacy (ODS code FN670). The decision stated:

2.1 **"Out of Pocket Expenses (OOPE) - Post Payment Verification**

2.2 The Pharmacy Provider Assurance Team (PAT), 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 Out of Pocket Expenses between February 2020 and January 2021.

2.3 As part of the verification exercise, your pharmacy has been contacted by the Provider Assurance Team to request that you review all of your Out of Pocket Expense claims between February 2020 and January 2021.

2.4 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 211 OOPE claims totaling £9.013.71 met the three conditions for claiming OOPE, as outlined in the Drug Tariff. It was therefore our recommendation that an overpayment had been received as a result.

2.5 This recommendation, along with the two attached timelines of correspondence with FN670 were passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary.

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

2.6.1 FN670 – North Walsham Pharmacy submitted 294 Out of Pocket Expense claims, totalling £12,591.42 between February 2020 and January 2021.

2.6.2 FN670 – North Walsham Pharmacy was contacted on multiple occasions by the NHSBSA Provider Assurance Team to request evidence to substantiate the claims or agree to the recovery but did not receive sufficient evidence.

2.7 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 February 2020 to January 2021 Out of Pocket Expense 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.

2.8 The below table outlines the total number of claims and the associated recovery value:

2.9 Table:

Number of claims	Total recovery value
211	£9,013.71 deduction

2.10 **Action Required**

2.11 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 27th October 2024.**

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

2.13 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 27th October 2024.

2.14 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.

2.15 **Please be aware that failing to contact us by 27th October 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:

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

2.17 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.

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

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

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

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

2.22 Your co-operation is very much appreciated."

2.23 [Enclosures:

2.23.1 Spreadsheet timeline FN670 – 2021-22

2.23.2 Spreadsheet timeline FN670 – 2023-24]

3 THE DISPUTE

In an email dated 26 October 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "Thank you for your email, I would like to appeal the decision and set out my points on this below.

3.2 Please kindly note that the number of items OOP has been claimed for is about 0.1% of items dispensed in the pharmacy during that period. This is a very busy Pharmacy, operating under extremely challenging conditions during the worst months of the COVID pandemic, when the supply chain was under extreme breaking point, and we are located in a very rural location. Please see attached letter from the Chief Officer of the Norfolk Local Pharmaceutical Committee reflecting the difficulties in obtaining stock. Our priority was getting patients their medication. It should also be noted that it is very hard for us to provide detailed replies as the period in question starts almost five years ago.

3.3 These are also costs that have been quite clearly incurred by the pharmacy and this stock has been purchased and OOP claimed in good faith, as we genuinely believed that the conditions for claiming reimbursement had been met, as the primary reason was to provide medication to patients promptly, where we experienced supply issues.

3.4 The vast majority of the claims (nearly all) are for Metoject and Methotrexate Injections.

3.5 Kindly note, it is commonly known that during this period (the worst months of the pandemic) the supply chain was unreliable and at sometimes broken - and this affected most suppliers - including mainline wholesalers during this period. The timeframe was during the peak of the pandemic and for example, Metoject is a solus distribution available from only one wholesaler. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.

3.6 Please see the following links which give an idea of the disruption we faced to the regular supply chain - I hope this provides helpful context to the environment our team was working in.

3.7 https://www.chemistanddruggist.co.uk/CD006402/COVID19-AAH-moves-to-once-a-daydelivery-to-protect-staff

3.8 https://www.alliance-healthcare.co.uk/alliance-healthcare-news-updates/servicedisruption

3.9 https://www.alliance-healthcare.co.uk/alliance-healthcare-news-updates/covidabsence-and-driver-shortages-continue-across-country-and

3.10 We have a requirement to supply stock in a timely manner. I think solus distribution models (where medicines are only available from a single primary wholesaler) are to blame for these OOP claims - if Metoject was available from more than one mainline wholesaler, there would have likely been no need to purchase this stock as a special obtain. It is a real difficulty to source stock at times, especially during an unprecedented pandemic.

3.11 We also genuinely believed Pharmacy was included in the pledge to support the NHS, particularly around the costs in supporting pharmacies to continue providing frontline services, such as the releases below:

3.12 Prime Minister, Boris Johnson, in March 2020 regarding the government's commitment to funding the NHS during the COVID-19 pandemic:

3.13 ***"We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy."***

3.14 Rishi Sunak, pledged to address the outbreak in his first Budget and said the impact of the virus on business "could be significant, but for a temporary period of time".

3.15 He said: "I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis."

3.16 Coronavirus: NHS will get whatever it needs, says chancellor - BBC News

3.17 £300 million announced for community pharmacies to support them during coronavirus outbreak - GOV.UK

3.18 I think the suggestion that there has been an overpayment of £9013.71 is concerning in this context. I respectfully ask you to look at this figure again, I do not believe it is fair.

3.19 We gave staff the option to order this stock as obtain, due to missing/late deliveries from a specific mainline wholesaler and they were only trying to do what was right by the patient. It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler."

Letter from Community Pharmacy Norfolk and Suffolk to the Appellant dated 8 October 2024

3.20 "You have asked for my recollections, as the then Chief Officer of the Norfolk Local Pharmaceutical Committee, of the issues our pharmacies were facing during that first year of the pandemic. Clearly I am unable to comment on very specific circumstances without significant investigations into my emails and records, so the following comments are my general reflections.

3.21 This was an immensely challenging time for all healthcare providers. During the early part of that period there was evolving and changing advice on a wide range of matters, from appropriate isolation of patients and staff, to PPE availability and usage etc. Our pharmacies were desperately trying to maintain patient services against the above backdrop, further complicated by distancing guidelines and their own staffing issues due to illness, isolation etc. One must also remember that the community pharmacy workforce in this area had already been disproportionately affected by the already concerning cuts to funding, but also by the rapid uptake of the Additional Roles Reimbursement Scheme (ARRS).

3.22 As such our pharmacies were struggling to cope on a daily basis. This included having to deal with a supply network which naturally faced very similar issues itself. While specifics are hard to evidence, I was aware that wholesaler deliveries could be considerably less reliable than under normal circumstances, and it was not unusual, as far as I was made aware of, for deliveries to be cancelled or delayed. This is no criticism, this was an exceptionally difficult time for everyone.

3.23 There is no doubt that, as a large rural area, our pharmacies and medication supply logistical network faced greater challenges than elsewhere. I was frequently on regional and national calls that constantly underlined that.

3.24 I also recall that the core message we seemed to be getting from Government and NHSE at that time was basically (and I paraphrase) “Keep things going the best you can, do what’s right for patients and we’ll support that”. At the time I genuinely believed that to be a laudable sentiment that could and should be trusted.

3.25 As above, I am clearly unable to provide evidence regarding specific wholesalers on specific dates, nor on the day-to-day availability of specific medication. I am, though, immensely proud of the amazing lengths our pharmacies and pharmacy contractors went through to keep their businesses open and operational, seeing patients face-to face in a way almost no other healthcare professions did. The challenges, especially in this area, often appeared insurmountable, yet somehow our pharmacies protected patients from all the worst-case scenarios which could so easily have come to pass.

3.26 I cannot comment further on the matters you raise, but I would hope and expect that anyone looking at such things accepts that these were exceptional times, that this area was particularly hard hit, and that our pharmacies were often acting on trust that they would be supported.”

4 SUMMARY OF REPRESENTATIONS

This is a summary of representations received on the appeal.

4.1 The NHS BSA on behalf of NHS England stated:

4.1.1 “Thank you for your letter of the 31st October 2024 and the opportunity to provide representations on the appeal.

4.1.2 **Background**

4.1.3 An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.

4.1.4 Out of Pocket Expenses should only be claimed in exceptional circumstances, where items are not to be frequently supplied, and the pharmacy has taken all reasonable steps to avoid claiming. If additional expenses were necessary obtaining necessary eligible drugs, appliances or chemical reagents, as per Part II, clause 12 of the [Drug Tariff | NHSBSA]

4.1.5 Part II, Clause 12 of the Drug Tariff sets out the 3 conditions which must be met when submitting a claim for OOPE:

4.1.6 *'Where, **in exceptional circumstances**, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and products not listed and **not required to be frequently supplied** by the contractor, or where out-of-pocket expenses have been incurred in obtaining from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate that **the contractor has taken all reasonable steps to avoid claiming**.'*

4.1.7 OOPE claims can only be submitted for items which fall within the following Drug Tariff categories:

4.1.7.1 Part VIIIA Category C

4.1.7.2 Readily available medicinal products outside of Part VIIIA (including ACBS)

4.1.7.3 Part IXB

4.1.7.4 Part IXC

4.1.8 Only actual costs incurred during the process of obtaining specific items to fulfil specific prescriptions can be claimed. These costs can cover things such as:

4.1.8.1 Postage and Packaging

4.1.8.2 Handling

4.1.8.3 Cost of phone calls to manufacturers or suppliers to order products

4.1.9 It is important that any charges incurred can be linked back to an order for a specific product on a specific prescription by the pharmacy claiming OOPE. VAT can be included in an OOPE claim as long as the normal criteria for claiming expenses are met i.e. VAT can be claimed on expenses incurred in obtaining that product and not on the cost of the product.

4.1.10 **February 2019 – January 2021 OOPE PPV**

4.1.11 NHSBSA Pharmaceutical Provider Assurance Team (NHSBSA PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification (PPV) exercise to ensure that pharmacy contractors were claiming correctly for Out-of-Pocket Expenses (OOPE). The assurance activity commenced following a number of cases raised by different Integrated Care Boards (ICB's) which resulted in contractors having money recovered for over-claiming for OOPE following determinations made by NHS Resolution.

4.1.12 The Counter Fraud Authority (CFA) also raised concerns around how the allowance was being claimed by a small number of pharmacy contractors following these high profile cases. In response, PAT was asked to perform a small-scale pilot engaging with a small number of the highest claimers for the service. This pilot resulted in contractors admitting they had not followed the Drug Tariff requirements in claiming OOPE allowances, and therefore a review of other claims and other contractors ensued.

4.1.13 PAT began the assurance activity by reviewing OOPE claims over a two-year period, from February 2019 to January 2021. To define and limit the scope of our engagement, we included contractors in the sample that had claimed more than £10,000 in OOPE over a 12 month period, focusing on the largest claimers of OOPE. The CFA also requested that a number of additional pharmacies be included too due to concerns around their claims. With this stipulation in place, PAT had three separate samples for the proposed assurance activity:

4.1.13.1Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)

4.1.13.2Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 in (referenced as Sample Two)

4.1.13.3Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three).

4.1.14 North Walsham Pharmacy was included in Sample Three which covered February 2020 to January 2021 as their total OOPE claims for the period totalled £12,591.42.

4.1.15 The approach taken for this assurance activity was, in the first instance, to request contractors perform a self-review of the relevant OOPE claims and the items they had claimed against and ask for confirmation and evidence that the claims were meeting the conditions outlined in the Drug Tariff focusing on the three cumulative conditions necessary: -

4.1.15.11. Claims were made only in 'exceptional circumstances'

4.1.15.22. Claims were made only where the item was not required to be frequently supplied

4.1.15.33. The contractor took all reasonable steps to avoid claiming for OOPE

4.1.16 NHSE and the PAT understood that these 3 conditions were cumulative conditions and that each needed to be met for an OOPE to be considered valid. However, the PAT also recognised that the 3 conditions were not quantified and were therefore subject to the individual circumstances within each pharmacy. This therefore required the contractor engagement in the assurance activity and an opportunity for them to provide information and detail in support of their submitted OOPE claims.

4.1.17 The response to PAT's initial engagement around self-reviews was mixed and it was ignored by some contractors included in the sampling. Therefore, PAT took the findings away and several working groups were convened between the PAT, NHSE and CFA to outline an approach for assurance activity on OOPE that would provide a fair, consistent and national approach. A key part of the revised approach was that PAT would highlight claims of OOPE that, upon review of the data, would suggest failing to meet the conditions outlined in the Drug Tariff. The expectation was that contractors would then need to share the evidence and individual circumstances that showed these claims were meeting the Drug Tariff conditions and if this wasn't the case then the recommendation would be to the ICB's that the contractors had claimed incorrectly for OOPE.

4.1.18 As part of the proposed reengagement, it was decided that the PAT would also show a recommended recovery value for any items which fell into the below categories, as the data did not suggest that the items warranted the OOPE claims; these were:

4.1.18.1 **Frequently supplied items** – includes any items which were claimed by the pharmacy on more than 12 occasions in the 12 months reviewed. Any items which fell into this category would be entitled to the first 12 claims, however, it would be recommended that any claims in addition to the initial 12 would be recovered. These items appear to have been supplied frequently throughout the year.

4.1.18.2 **100% of the National claims for an item** – includes any items in which the contractor was the only pharmacy nationally to submit an OOPE claim for an item. It was also considered how many pharmacies had dispensed the item without an OOPE claim, and the number of occasions it had been dispensed nationally without an OOPE claim. Therefore, a minimum of 500 pharmacies must have dispensed the item on a minimum of 12,000 occasions nationally, before any 100% claims would be considered in a recommendation for recovery.

4.1.18.3 **Commonly dispensed items** – includes any items which NHSE considered to be extremely common items, therefore the pharmacy should not have encountered any additional fees when obtaining the item. As a minimum, these items were required to have been dispensed by 10,000 pharmacies, on a minimum of 2.5 million occasions nationally for the item to have been considered commonly dispensed.

4.1.19 Also included in the PAT's recommendation, were any claims the pharmacy had highlighted as having been claimed incorrectly in their initial self-review. The PAT provided North Walsham Pharmacy with an overview, containing all the pharmacy's claiming data alongside national claiming data.

4.1.20 Once this was agreed upon, a further phase of engagement with contractors was started – this shows in the 2 different timelines provided for this case – the timelines also demonstrate the gap between the engagement for each. The first phase of engagement began in November 2021 and ended in July 2022 while the following phase lasted from July 2023 to July 2024. The goal of the engagement was for the contractor to show that they had evidence to support their claims or agreed to the proposed recovery. If neither was achieved, the case details would then be passed to the NHS England regional team for their Pharmacy Services Regulations Committee (PSRC) to review for a final decision on whether the claims met the Drug tariff conditions for claiming OOPE, and if not to recover overpayments from the contractor.

4.1.21 **North Walsham Pharmacy**

4.1.22 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. Therefore, emails were sent to the pharmacy shared NHSmail address (pharmacy.fn670@nhs.net) as required by NHSE.

4.1.23 During the initial phase of correspondence, North Walsham Pharmacy was contacted on numerous occasions between 10th November 2021 and 22nd June 2022. During this time, North Walsham Pharmacy was contacted on multiple occasions via emails and telephone calls, however only one response was received from the pharmacy which included a completed appendix on the 27th January 2022 advising that all claims apart from one claim for Colecalciferol 50,000unit tablet, were correctly claimed. It did not give any further explanations or supporting evidence as to how all other items met all three cumulative conditions for claiming OOPE as outlined in the Drug Tariff.

4.1.24 Following the intermission while NHSE and PAT finalised the assurance activity process previously referenced, the second phase of correspondence commenced, and North Walsham Pharmacy were contacted on 6 occasions via email and telephone between 25th July 2023 and 16th July 2024 to request evidence that the OOPE claims made in the period February 2020 - January 2021 met all three cumulative conditions for claiming OOPE.

4.1.25 On the 22nd January 2024, PAT sent an email advising North Walsham pharmacy that PAT were in the process of collating information to be reviewed by their NHSE local Pharmaceutical Regulations Committee (PSRC), and that the NHSBSA PAT were currently in discussions with their ICB to ask if they would require any further information to review the case in its entirety.

4.1.26 After reviewing the data and limited information provided by the contractor, PAT found that the pharmacy had submitted OOPE claims for five items (Metoject pre-filled pens and Methotrexate disposable devices of varying strengths) on more than 12 occasions within the 12 months reviewed. The PAT therefore had no evidence or information, provided by the contractor, to support that these claims were not required to be frequently supplied. Therefore, after allowing the first 12 occasions of these claims for each item, PAT found that the contractor had received an overpayment of £8,971.72 for these items.

4.1.27 In addition to this, the contractor had previously highlighted that 1 claim for Colecalciferol 50,000unit tablets totalling £41.99 in OOPE had been claimed incorrectly.

4.1.28 PAT therefore concluded that a total recommended recovery figure of £9,013.71 should be reclaimed for OOPE claims not meeting the three conditions of the Drug Tariff.

4.1.29 Despite the PAT's attempts to communicate with North Walsham Pharmacy, the pharmacy did not respond to any of the requests for information until the PAT sent confirmation of the conclusion of the review with the final proposed recovery figure of £9,013.71. This was calculated from items claimed above the assurance activity parameters where no further evidence was provided alongside the item they admitted to claiming incorrectly, ultimately covering 6 separate items with OOPE claims.

4.1.30 This notification was sent on 2nd July 2024 giving the pharmacy 28 days until (30th July 2024) to respond with any evidence or representations that they wished to provide to PSRC for consideration.

4.1.31 On the 29th July 2024 North Walsham Pharmacy responded and detailed that the number of items that OOPE had been claimed for was around "*0.1% of items dispensed in the pharmacy during that period.*" They specify that they are in a rural location and their priority was getting patients their medication. They go on to advise that the claims were made in good faith and they *"genuinely believe that the conditions for claiming reimbursement had been met".* They state that the vast majority of claims were for Metoject and Methotrexate injections, and that it is commonly known that during this period the supply chain was unreliable and *"sometimes broken",* during the peak of the pandemic. They go on to specify that Metoject is a *"solus distribution*" available from only one wholesaler, and that this created friction with Doctor's surgeries due to missed deliveries. Therefore, the pharmacy opted to order from other suppliers and incurred the extra charge. The pharmacy also included various links to articles around supply and covid issues. They went onto explain they think a *"solus distribution model is anti-competitive and creates so many difficulties for contractors."* North Walsham Pharmacy also went on to state, "*other contractors may not have been aware these specific lines could be ordered in this way and just accepted unreliable deliveries of certain mainline wholesalers".*

4.1.32 The PAT appreciate that the engagement occurred over an extended period of time, but despite the numerous attempts made, North Walsham Pharmacy did not provide any specific evidence to demonstrate that the 6 items highlighted in the data overview provided met the conditions outlined in the Drug Tariff. Therefore, the PAT were unable to provide assurance that the claims were made in accordance with the conditions specified in the Drug Tariff. As a result, the case was referred onto their PSRC with the recommendation that the value of £9,013.71 for 211 OOPE claims is recovered.

4.1.33 For the avoidance of doubt, NHSE and the PAT recognises that OOPE claims are difficult to quantify and are open to the individual circumstances of each pharmacy. However, the information provided by North Walsham Pharmacy was very limited and did not support that the claims were meeting the cumulative conditions required before an OOPE claim should be considered.

4.1.34 As PAT were unable to validate that 211 OOPE claims submitted by North Walsham pharmacy during the specified time period met the requirements of the Drug Tariff, a recommended recovery of £9,013.71 for these 211 claims was proposed to the contractor. However, North Walsham Pharmacy did not accept the proposed recovery and therefore 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 claims made by the contractor were eligible for a payment under the strict conditions of the Drug Tariff or whether they felt the 211 identified claims did not meet the cumulative conditions and therefore should be recovered under regulation 94 (1) (a) as an overpayment.

4.1.35 **The PSRC decision**

4.1.36 To assist with their review, the PSRC was provided with the dispensing and claim data, along with the timelines of correspondence showing all contact the PAT had with North Walsham pharmacy for review. These timelines have been provided to you in addition to this response.

4.1.37 The engagement showed that despite repeated requests by the NHSBSA PAT, North Walsham Pharmacy was still unable to provide evidence to support their claims and the PAT were therefore unable to provide assurance that the OOPE claims met all three cumulative conditions required for an OOPE claim as part of the assurance activity.

4.1.38 Consequently, the PSRC concluded that the PAT had been unable to find any evidence to demonstrate that the 6 items (211 claims) claimed by North Walsham Pharmacy between February 2020 and January 2021 met the requirements set out in the Drug Tariff for claiming OOPE.

4.1.39 Following this conclusion, the PSRC determined that North Walsham Pharmacy was not entitled to the payment which it had received.

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

4.1.41 In making this decision the PSRC relied on the information that it had before it, following the extensive investigation undertaken by the PAT and the repeated requests to North Walsham pharmacy for evidence of how the Out of Pocket Expense claims made between February 2020 and January 2021 met the requirements set out in the Drug Tariff.

4.1.42 **Response to the points made in the contractor's appeal: -**

4.1.43 For OOPE claiming the Drug Tariff states:

4.1.44 *'Where, **in exceptional circumstances**, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and products not listed and **not required to be frequently supplied** by the contractor, or where out-of-pocket expenses have been incurred in obtaining from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate that **the contractor has taken all reasonable steps to avoid claiming**.'*

4.1.45 Each of the points highlighted are conditions that need to be met before an OOPE claim should be submitted. For the 6 items (211 claims) highlighted, North Walsham Pharmacy have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.46 In their response, North Walsham Pharmacy state that *"the number of items OOP has been claimed for is about 0.1% of items dispensed in the pharmacy during that period*". Although the volume of claims does not appear to be a large amount in relation to the total number of items dispensed by the pharmacy, the conditions specified in the Drug Tariff relate only to items in which an OOPE is to be claimed on. All of the items highlighted in yellow on the Data Overview, PAT believe were frequently supplied. They submitted OOPE claims on more than 12 occasions within a 12 month period. All of these items highlighted in yellow for FN670 submitted OOPE claims in each of the

12 of the months sampled. PAT has not received any evidence to support that these items were not required to be frequently supplied by the pharmacy.

4.1.47 North Walsham Pharmacy also state: '*This is a very busy Pharmacy, operating under extremely challenging conditions during the worst months of the COVID pandemic, when the supply chain was under extreme breaking point, and we are located in a very rural location.'* NHSE and PAT do not dispute that the Pandemic was a difficult time for community pharmacies alongside the other points raised of being busy and located in a rural location. However, that does not change the fact that there are certain prerequisite conditions that need to be met before an item can be claimed under OOPE. The overall national data shows that claims for OOPE were less for the first 6 months of the Pandemic than the previous year. PAT also question this statement as the data shows that the year before the pandemic, North Walsham Pharmacy had dispensed Metoject Pen 20mg 88 times and claimed OOPE for the item 64 times. For this one item alone in their ICB area they were responsible for 17.30% of the claims, and a similar pattern occurs for the other highlighted items.

4.1.48 North Walsham Pharmacy go on to state: '*It should also be noted that it is very hard for us to provide detailed replies as the period in question starts almost five years ago.'* PAT would dispute this as clearly shown in the timelines. The first engagement with the pharmacy around these disputed OOPE claims actually occurred within the same year the claims were submitted as PAT began its assurance activity in November 2021. North Walsham Pharmacy had numerous opportunities to provide detailed responses with the requested evidence at multiple stages, as PAT wanted to give contractors additional opportunities to engage with this complex request. Ultimately the detailed information was not provided by North Walsham Pharmacy. PAT would re-iterate that we appreciate the engagement which did take place but that the detail was not set out, but rather a general statement regarding how the Covid Pandemic affected supplies and therefore their claiming for OOPE.

4.1.49 North Walsham Pharmacy base the bulk of their OOPE appeal information on two key themes one of which is that: *'The vast majority of the claims (nearly all) are for Metoject and Methotrexate Injections. Kindly note, it is commonly known that during this period (the worst months of the pandemic) the supply chain was unreliable and at sometimes broken - and this affected most suppliers - including mainline wholesalers during this period. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.'*

4.1.50 PAT's data overview of the case shows that of the six items recommended for recovery five of these items are Metoject Pen pre-filled pens of varying strengths and Methotrexate devices of varying strengths. The additional item is the claim North Walsham Pharmacy identified themselves on their self-review that had been claimed in error for OOPE. The argument from North Walsham Pharmacy that the claims were mainly in response to the Pandemic is simply not supported by the data. The item with the largest amount of OOPE claims submitted by North Walsham Pharmacy is Metoject Pen 20mg/0.4ml pre-filled pen. Overall North Walsham pharmacy claimed OOPE on this item over the 12 months reviewed on 125 occasions which was over 95.42% of the times this item was dispensed. This demonstrates that the pharmacy was able to obtain the item without resorting to OOPE on some occasions but also that the pharmacy had a consistent claiming behaviour resorting to claiming OOPE on the item. No information provided by North Walsham Pharmacy allowed PAT (and therefore NHSE) to understand the conditions behind these OOPE claims. PAT would also question what the pharmacy is doing to avoid claiming OOPE on the item as outlined in the Drug Tariff if they continue to claim OOPE on it every month? PAT would also ask how those claims meet the other cumulative conditions of not being frequently supplied and being claimed only in exceptional circumstances as, again, nothing in the response from North Walsham Pharmacy allows the PAT to understand the reasoning behind those claims and how they were following the Drug Tariff instructions.

4.1.51 The below table refutes the Pandemic reasoning given by North Walsham Pharmacy as it shows the pharmacy were claiming OOPE for Metoject pen 20mg, for example, on almost every occasion on a monthly basis, in the year previous to the sample (Feb 19- Jan 20) and also in the year following the sample (Feb 21-Jan 22). North Walsham Pharmacy was not included in our Feb 19 – Jan 20 sample, as they had claimed less than our qualifying amount of £10,000 for that year. Pat now feels after reviewing the data it would be unfair to challenge and request any additional information for these items, due to the time lapsed. PAT have not completed a review for the period Feb 21 – Jan 22 to date and these items still may be potentially recovered from North Walsham Pharmacy.

4.1.52

Metoject PEN 20mg/0.4ml inj pre-filled pen. Data for years Feb 19 - Jan 22 including percentage of OOPE claims in their ICB Area					
Year	Occasions dispensed	Occasions OOPE claimed	Months dispensed	Months OOPE claimed	% of OOPE claims in ICB area
Feb 19 – Jan 20	88	64	12	9	17.30%
Feb 20 – Jan 21	131	125	12	12	20.49%
Feb 21 – Jan 22	39	39	12	12	4.62%

4.1.53 Metoject Pen 20mg/0.4ml pre-filled pen is the item with the most claims submitted against it, however PAT argue the same points for the other strengths of Metoject Pen and Methotrexate devices with OOPE claims. These different strengths have OOPE claimed on less occasions but each of them has similar concerns to a lesser extent. The items have still been frequently supplied by North Walsham Pharmacy with OOPE being submitted for the majority of occasions the pharmacy had dispensed the items. Alongside this, the item is dispensed regularly by many contractors nationally, however only a small number of contractors have claimed OOPE on the item and the national percentage of OOPE claims made by North Walsham Pharmacy is high for an individual branch. When looking at the national OOPE claims for Metoject PEN 7.5mg/0.15ml inj pre-filled pens, over 48.98% of OOPE claims on this item over the 12 months reviewed were submitted by North Walsham Pharmacy. PAT would argue that the response from North Walsham Pharmacy does not provide the level of detail around individual circumstances that would support this volume of claims and outline what conditions existed within their own branch, which does not appear to be the case for the majority of pharmacy contractors.

4.1.54 PAT looked at three years of data for North Walsham Pharmacy in relation to the claims for Metoject Pen and it shows that their claiming behaviour for this item was already evident in the year prior to the Covid-19 pandemic and the year after the height of the pandemic. Therefore, the reasoning North Walsham Pharmacy provided regarding deliveries and claiming for the service is not supported by the data.

4.1.55 Within the same explanation North Walsham Pharmacy state other potential reasons for claiming for OOPE such as missed deliveries and rescheduled appointments. However, PAT would stress this line of reasoning would not explain the continued pattern of claiming OOPE for the item and how the pharmacy feels the claims were meeting the conditions outlined in the Drug Tariff. The national data shows that the item is being dispensed on a large volume of occasions over the year reviewed (50,000+) but only a small number of pharmacy contractors needed to resort to claiming OOPE on the item and even amongst them North Walsham Pharmacy alone has over 15% of the OOPE claims nationally for Metoject Pen 20mg/0.4ml pre-filled pen and PAT feel the explanation above does not show why on 125 occasions North Walsham Pharmacy felt the conditions had been met to support these claims.

4.1.56 PAT do not dispute that the Pandemic was stressful for pharmacies and some of the issues raised may have warranted claiming OOPE on an item at a point in time to cover individual circumstances. However, the consistent nature of the claims is where this claiming contradicts the instructions in the Drug Tariff - PAT and NHSE are not recommending the recovery of every claim on these items to make allowances for such circumstances but are instead allowing for occasions up to a point. The recovery figure is based on circumstances where it appears the item is required frequently over multiple months, and the contractor does not appear to be taking all reasonable steps to avoid claiming. The PAT are not disputing the fact that costs were incurred, but what changes were made within the pharmacy to avoid consistently claiming OOPE on these items, continuing to claim OOPE without any change in behavior [sic] to avoid such claims, deters from conditions set out in the Drug Tariff for the claiming of OOPE.

4.1.57 Another key theme raised by North Walsham Pharmacy in their appeal response was: - '*We have a requirement to supply stock in a timely manner. I think solus distribution models (where medicines are only available from a single primary wholesaler) are to blame for these OOP claims - if Metoject was available from more than one mainline wholesaler, there would have likely been no need to purchase this stock as a special obtain. It is a real difficulty to source stock at times, especially during an unprecedented pandemic.'* North Walsham pharmacy went on to state "*It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler".* In the following months after first having difficulties obtaining/delivery of items, North Walsham Pharmacy continued to order these items with additional fees when dispensing the item and therefore claimed OOPE on almost every occasion without changing their claiming behaviour, rather than staff exploring other options available to them. As the NHSBSA data clearly shows, North Walsham Pharmacy were already claiming OOPE regularly on these items' pre-pandemic.

4.1.58 PAT would also suggest that the situation is the same for every pharmacy contractor when sourcing items from a single primary wholesaler and we do not see consistent OOPE claims from other pharmacy contractors for this item. PAT do not believe the information provided proves that individual circumstances within the pharmacy warranted the volume of OOPE claims on these items. Instead, PAT would argue the conditions of the Drug Tariff have not been met and that the significant levels of OOPE claims on these items pre-date the Pandemic and exist long after it occurred.

4.1.59 The eligibility criteria for OOPE claims laid out in the Drug Tariff are there to support contractors who incur costs on an exceptional basis when providing medications to their patients. It also ensures to protect the NHS and ultimately the taxpayer by imposing requirements on the contractor to takes steps to avoid claiming OOPE unless unavoidable.

4.1.60 It can be seen from the data provided that the pharmacy required stocks of Metoject on a regular basis and so could have avoided the extra charges from this supplier by ordering larger amounts, at less frequent intervals. The summary of product characteristics for this product show that it has a shelf life of 30 months. It is therefore entirely reasonable that the NHS would then expect the contractor to take reasonable steps to limit the costs of obtaining the medications and to limit the costs it passed onto the NHS. Clearly, other contractors in similar situations have been able to do this. North Walsham Pharmacy provided other supporting information in their appeal paper detailing comments made by NHSE, Boris Johnson, Rishi Sunak regarding the support for NHS service providers to address the extra challenges they faced from the added COVID pressures, reiterated by Tony Dean (Joint Chief officer from Community Pharmacy Norfolk and Suffolk). However, PAT would suggest that these are more general reflections on the response to the Pandemic rather than being focused on how this affected OOPE claiming. They should not be considered as reasonable ground for a contractor to ignore the requirements of Part II, clause 12 of the Drug Tariff when submitting claims for OOPE.

4.1.61 PAT would therefore state that without specific evidence explaining individual circumstances for multiple consistent claims for OOPE rather than general explanations, the PAT have been unable to provide assurance that the North Walsham Pharmacy’s OOPE claims discussed did not meet the cumulative conditions listed in the Drug Tariff.

4.1.62 The PAT can see from the data that North Walsham Pharmacy claimed OOPE on these items every month, the items were being dispensed on a regular basis, and there was no correspondence received by PAT to understand why the pharmacy’s claiming behaviour did not change over the period under review. In fact, the pharmacy was already claiming OOPE on these items prior to the pandemic and continued after the pandemic.

4.1.63 As the data from the years surrounding 2020 show, the pharmacy was dispensing and claiming OOPE on the same items highlighted on almost every occasion. It shows the pharmacy had behaviours in place for the process of obtaining these items before the Covid 19 Pandemic which also resulted in OOPE claims. North Walsham Pharmacy stated that the vast majority of their claims were for Metoject and Methotrexate injections and that these were a “*solus distribution”* available from only one wholesaler. In the sample period, the PAT data shows Metoject Pen 20mg was dispensed 6770 times within the QMM ICB, but only 610 OOPE claims were submitted. Of the 610 OOPE claims, North Walsham Pharmacy submitted 125 of those claims, contributing to 20.49% of the OOPE claims for the item within their ICB area; the data is similar for all other highlighted items. In the year prior and post Covid there was no change in claiming behaviour, so PAT fail to see what the exceptional circumstances were, that then continued for multiple years. The data also supports that all of the highlighted items were frequently supplied.

4.1.64 NHS England maintain that North Walsham Pharmacy was not compliant with the requirements set out in the Drug Tariff and their OOPE claims for the different strengths of Metoject Pens and Methotrexate devices did not meet the cumulative conditions outlined as pre-requisites for the OOPE claim. Therefore, as a consequence of having been paid for these excess claims, NHSE consider that an overpayment had been made. NHSE and PAT consider that the contractor has not provided sufficient evidence to support that the claims for the Metoject Pens and Methotrexate Devices were meeting the conditions outlined in the Drug Tariff and therefore the decision to then recover £9,013.71 is the correct one.

4.1.65 The final recovery figure is made up of the one claim for Colecalciferol 50,000unit tablets North Walsham pharmacy had indicated OOPE was incorrectly claimed, and the other remaining items were identified by PAT as failing to meet the conditions set out within the Drug Tariff.

4.1.66

Drug Name	Recovery Value
Metoject PEN 20mg/0.4ml inj pre-filled pens	£4,824.52
Metoject PEN 15mg/0.3ml inj pre-filled pens	£2,439.75
Metoject PEN 7.5mg/0.15ml inj pre-filled pens	£1,535.67
Methotrexate 20mg/0.4ml inj pre-filled disposable devices	£129.17
Methotrexate 17.5mg/0.35ml inj pre-filled disposable devices	£42.61
Colecalciferol 50,000unit tablets	£41.99
TOTAL	**£9,013.71**

4.1.67 **Key points for consideration**

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

4.1.68.1 The requirements outlined in Part II; Clause 12 of the Drug Tariff stipulate that the following three cumulative conditions must be completed before submitting an OOPE claim:

4.1.68.1.1 Claims were made only in ‘exceptional circumstances’

4.1.68.1.2 Claims were made only where the item is not required to be frequently supplied

4.1.68.1.3 The contractor took all reasonable steps to avoid claiming for the service

4.1.68.2 The contractor had numerous opportunities to provide assurance that all OOPE claims made during the PPV sample period met the cumulative conditions set out in the Drug Tariff. Only contractors where no or insufficient evidence of meeting the requirements were referred to the regional PSRC. North Walsham Pharmacy did not provide any evidence to show how the three conditions were met PAT were unable assure NHS England that the claims identified as overclaims met the Drug tariff requirements.

4.1.68.3 The initial engagement for the OOPE PPV exercise began in the same year of the sample period under consideration. The contractor's assertion about challenges to respond in detail due to the amount of time that had passed since the sample period are not accurate. They had numerous opportunities to respond, yet engagement from the contractor was minimal.

4.1.68.4 The PAT disputes the contractor's statement that the claims were due to the issues around the Covid-19 pandemic, as the data shows the contractor was claiming OOPE for these items regularly, the year prior to COVID and also post COVID.

4.1.68.5 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in Out of Pocket claims nationally for the disputed items (different strengths of Metoject Pens and Methotrexate devices) over the sample period.

4.1.68.6 The PSRC was presented with all timelines of correspondence, showing all contact between the PAT and the pharmacy, and all the relevant data that the NHSBSA PAT has on contractors' dispensing and claiming histories nationally in relation to OOPE.

4.1.68.7 The PSRC considered all of the available information about the case when determining the overpayment under regulation 94.

4.1.68.8 The contractor's appeal provides no specific details or evidence on what measures they took to ensure that their claiming of OOPE on a regular basis over the sample period was in line with the Drug Tariff. As a result, the OOPE claims are invalid under Part II, Clause 12 of the Drug Tariff, and an overpayment has been made.

4.1.69 Having considered these matters NHS England respectfully suggests that NHS Resolution conclude that the decision made by the PSRC in respect of the £9,013.71 overpayment and its subsequent recovery from North Walsham Pharmacy was fair and in accordance with the regulations.

4.1.70 Please let me know if you need anything further to help in these deliberations."

4.1.71 [Enclosures:

4.1.72 Spreadsheet timeline FN670 – 2021-22

4.1.73 Spreadsheet timeline FN670 – 2023-24

4.1.74 FN670 – Data Overview (1)]

5 OBSERVATIONS

No observations were received by NHS Resolution in response to the representations received on appeal.

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 Before considering the substantive point, I wish to comment on a point made by the Appellant in its appeal that it *"genuinely believed Pharmacy was included in the pledge to support the NHS, particularly around the costs in supporting pharmacies to continue providing frontline services"*, as a result of statements from the former Prime Minister, Boris Johnson, in March 2020 that *"We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy"* and by the former Chancellor, Rishi Sunak, that *"I can* *say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis".*

6.8 On this point, the Appellant relies on public statements made by senior government officers at the start of the pandemic to support an argument that the Appellant had a legitimate expectation that each and every cost incurred by it during the pandemic would be repaid. In my view, the statements that the Appellant has set out in its appeal documentation are very broad and wide-ranging; they lack specifics about pharmacies and reimbursement of costs incurred by pharmacies. I note the NHS BSA's comments that these statements were general reflections, rather than specifically about OOPE claims. I consider that on this point the NHS BSA is correct, these general statements do not provide reasonable grounds for the Appellant to ignore the express requirements of the Drug Tariff.

6.9 I note that the NHS BSA refers to the Drug Tariff and provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff through to the current Drug Tariff in place (March 2025) could be found. I further note that the Drug Tariff this has not been disputed by the Appellant.

6.10 The appeal relates to payments made to the Appellant in respect of claims for Out of Pocket Expenses ("OOPE"). The NHS BSA states that *"An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.*

Out of Pocket Expenses should only be claimed in exceptional circumstances, where items are not to be frequently supplied, and the pharmacy has taken all reasonable steps to avoid claiming. If additional expenses were necessary obtaining necessary eligible drugs, appliances or chemical reagents, as per Part II, clause 12 of the Drug Tariff."

6.11 The NHS BSA were requested to conduct a Post Payment Verification exercise (PPV) for Out of Pocket Expenses (OOPE) following a request from various ICB's. In addition, the Counter Fraud Authority ("CFA") had raised concerns and after a small scale pilot where Contractors had admitted that they had not followed the Drug Tariff requirements it was considered that a review of other claims and other Contractors should be carried out. I should add that there is no suggestion from the NHS BSA that the claims subject to this dispute were fraudulent.

6.12 The NHS BSA confirms that they commenced the PPV by reviewing claims over a two year period from February 2019 to January 2021. It is noted that the NHS BSA were conscious of the number of claims and therefore concentrated on those that were the largest claimers of OOPE. It is noted that the CFA were also involved with the PPV exercise and had requested "*that a number of additional pharmacies be included too due to concerns around their claims*".

6.13 As set out above, the NHS BSA split the review into three separate samples for the OOPE PPV exercise:

6.13.1 "*Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)*

6.13.2 *Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)*

6.13.3 *Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three)."*

6.14 The NHS BSA states that the Appellant falls into sample three *"Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three)"* as the total OOPE for the Appellant for this period totalled £12,591.42.

6.15 Initially any contractor identified was asked to complete a self-review of the relevant OOPE claims and was asked to confirm that they had met three cumulative conditions:

6.15.1 *"Claims were made only in 'exceptional circumstances'*

6.15.2 *Claims were made only where the item was not required to be frequently supplied*

6.15.3 *The contractor took all reasonable steps to avoid claiming OOPE"*

6.16 I note, from the comments from the NHS BSA that not all contractors engaged with the initial process, so, following further meetings it was proposed that there would also be a recommended recovery value for any items which fell into three further categories:

6.16.1 *"**Frequently supplied items** – includes any items which were claimed by the pharmacy on more than 12 occasions in the 12 months reviewed. Any items which fell into this category would be entitled to the first 12 claims, however, it would be recommended that any claims in addition to the initial 12 would be recovered. These items appear to have been supplied frequently throughout the year.*

6.16.2 ***100% of the National claims for an item** – includes any items in which the contractor was the only pharmacy nationally to submit an OOPE claim for an item. It was also considered how many pharmacies had dispensed the item without an OOPE claim, and the number of occasions it had been dispensed nationally without an OOPE claim. Therefore, a minimum of 500 pharmacies must have dispensed the item on a minimum of 12,000 occasions nationally, before any 100% claims would be considered in a recommendation for recovery.*

6.16.3 ***Commonly dispensed items** – includes any items which NHSE considered to be extremely common items, therefore the pharmacy should not have encountered any additional fees when obtaining the item. As a minimum, these items were required to have been dispensed by 10,000 pharmacies, on a minimum of 2.5 million occasions nationally for the item to have been considered commonly dispensed."*

6.17 The NHS BSA states that this is why there were two engagement periods, the first being from November 2021 to July 2022 and the second from July 2023 to July 2024.

6.18 It is accepted by both parties that between November 2021 and July 2024 the pharmacy was contacted by the NHS BSA, a total of 11 times, however there was very little engagement from the Appellant during this time.

6.19 It is noted that the Appellant's pharmacy submitted 294 OOPE claims totalling £12,591.42 between February 2020 and January 2021, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the overpayment to be recovered was for 211 claims totalling £9,013.71. This is in line with the NHS BSA's "frequently supplied items" category in that they allowed "the first 12 occasions of these claims for each item". The NHS BSA, after taking the frequently supplied items into account is of the view that the Appellant has received a total overpayment of £9,013.71.

6.20 I note that the period in question is from February 2020 to January 2021, I am therefore of the view that the relevant Drug Tariff is dated February 2020 as this is the Drug Tariff that was in force at the beginning of the period to which the OOPE claims relates.

6.21 The Drug Tariff at Part II "Requirements enabling payments to be made for the supply of drugs, appliances and chemical reagents" Clause 12 with regard to "Out of Pocket Expenses" states:

"Where, in exceptional circumstances, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and imported products not listed and not required to be frequently supplied by the contractor, or where out-of-pocket expenses have been incurred in obtaining oxygen from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate the contractor has taken all reasonable steps to avoid claiming."

6.22 I note that the Appellant claimed for Colecalciferol on one occasion. During the first phase and the self-review of these claims, the Appellant identified the one occasion as claimed in error. This has not been disputed by any party. Therefore, included in the total recovery amount of £9,013.71 is the overpayment of £41.99 for the one claim which the Appellant identified as being claimed in error. I therefore consider that the NHS BSA should make the necessary arrangements for recovery of the monies in relation to the OOPE claims for Colecalciferol.

6.23 I have next moved on to consider the OOPE claims for Metoject pre-filled pens of varying strengths ("the Pens") and Methotrexate pre-filled disposable devices of two strengths ("the Devices"). In doing so I have considered the wording of Part II Clause 12 of the Drug Tariff and consider that the NHS BSA is correct in that it makes clear that for an OOPE claim to be successfully made, there are certain criteria that need to be met:

6.23.1 That there are exceptional circumstances;

6.23.2 That the product is a type of product for which an OOPE claim can be made, with reference to parts and categories of the Drug Tariff;

6.23.3 That the product is not required to be frequently supplied; and

6.23.4 That the contractor has taken all reasonable steps to avoid claiming OOPE.

6.24 I also concur that Part II Clause 12 makes clear that these are cumulative conditions – all must be met in order for a claim for OOPE to be successfully made.

6.25 I note that there are no definitions for 'exceptional circumstance', 'frequently supplied' or 'take all reasonable steps to avoid claiming' included in the Drug Tariff. They are therefore to be given their everyday meaning. 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. I note that the question being asked of the Appellant was to review their claims and provide evidence to support the claims made for the relevant period. Whilst it is accepted by the NHS BSA that the OOPE can be difficult to quantify due to the criteria as set out in the Drug Tariff, it is noted that the Appellant has provided very little information in response to the three relevant criteria.

6.26 I first consider exceptional circumstances.

6.27 I consider that this condition shares some similarity to the “not required to be frequently supplied” condition in that both can be read as relating to the extent to which it is usual for the drug to be supplied. I do consider, however, that “exceptional circumstances” can be read more widely than simple frequency of supply to encompass other circumstances that may make such ordering very unusual. I would consider “exceptional” to indicate that such circumstances are very unusual rather than simply unusual.

6.28 I note the comments from the Appellant that during this period (February 2020 to January 2021) it was the worst months of the Pandemic and as a result the supply chain was unreliable and this had affected suppliers. Whilst I appreciate the problems that were encountered during the Pandemic and the also appreciate the lengths that pharmacies went to in order to ensure a continuous supply of medication, I am mindful of the need to balance this against any OOPE claims which have been made alongside the application of the Drug Tariff. I further note the comparisons which the NHS BSA have carried out in respect of the Appellant’s claiming for one of the Pens before, during and after the pandemic. I note the comments from the NHS BSA regarding the analysis of the same data, as set out in the table at 4.1.52 above and note that the Appellant has not provided a response to this.

6.29 I further note that the Appellant was not included in “Sample 1” for the period February 2019 to January 2020 as they had claimed less than £10,000 for that year and so did not trigger a review.

6.30 In response to the criteria of “exceptional circumstances” it is noted that the Appellant makes reference to the Pandemic and I accept that the relevant period in question could be considered exceptional. Further, in the appeal there is reference to ongoing supply issues requiring the Pens to be sourced from one wholesaler nationwide. However, I consider that if circumstances continue for a prolonged period of time, then this would cease to be exceptional, as this would become the norm. I also note from the NHS BSA’s representations that the Pens were, and continue to be, dispensed across the UK by other contractors (sourced from the same wholesaler) without the need to claim OOPE.

6.31 I consider that at the start of the Pandemic, the circumstances would likely have been exceptional, however, I would expect that as these conditions persisted they would become simply the circumstances in which the pharmacy was operating. Therefore, the Appellant would need to evidence that there were continued changing exceptional circumstances, which necessitated the OOPE claims, which they have not done. Similarly, I consider that supply chain issues could be exceptional circumstances. However, the fact that the claims both preceded and followed the Pandemic and the alleged supply issue, I consider suggests continuing circumstances, rather than any exceptionality. As I have noted, exceptional circumstances are more than merely unusual, and I consider that any event that continues for three years would require a level of evidence to support it being *very* unusual.

6.32 I also note that the Appellant states that the OOPE process was utilised rather than *"the unreliable service of a mainline wholesaler"*. This is preceded with the explanation that there were *"missing/late deliveries".* I consider that if there was a missing or late delivery then this event could constitute exceptional circumstances, due to the delivery not materialising, provided that this was very unusual. However, I do not consider that pre-empting the possibility of a delivery being missed or late could be such, as the circumstances had not actually, and may never, have come to pass. I also consider that if this was a regular occurrence, then it would cease to be unusual.

6.33 Consequently, I consider that it is reasonable to consider that the Appellant has not met the "exceptional circumstances" condition.

6.34 I have also not been provided with any information from the Appellant to rebut the NHS BSA's assertion that the products in question was *"not required to be frequently supplied"*. The NHS BSA has provided information confirming the frequency of supply and the Appellant has not provided any response to this either on appeal or in subsequent representations. In the table at 4.1.52 above, the NHS BSA indicate that this particular Pen was claimed, at least once, every month, for 12 months. I consider that 125 claims, across 12 months, with at least one being claimed each month, must be considered frequent. This pattern, across three years, I consider must mean that it was being frequently supplied.

6.35 Finally, I note the third part of the claim for OOPE states "the contractor has taken all reasonable steps to avoid claiming". The use of "reasonable" to qualify the steps to be taken means the Appellant is not required to do everything it possibly can to avoid claiming OOPE. It does, however, mean that certain steps need to be taken. It will always be difficult to quantify exactly the extent to which a party must act to evidence taking reasonable steps. I note that apart from the statement from the Appellant to *"solus distribution models"* which has not been expanded upon, I have not been provided with any information as to the steps that the Appellant went to in order to avoid claiming.

6.36 Regarding this supply chain issue I also note the NHS BSA's data regarding other pharmacies. I consider that if there were supply chain issues then these should have been felt elsewhere as well. I also note the Appellant's statements regarding the remoteness of its location. The NHS BSA indicates in its representations that during the period in question the Appellant made up 20.49% of overall OOPE claims in the ICB area. Whilst it is possible that the Appellant had a noteworthy number of patients requiring both items, these numbers suggest that it was a significant outlier. This would either suggest that the supply chain issues were less impactful than the Appellant suggests, or that, if they were, then other pharmacies found solutions to resolving the issues. Accepting the Appellant's statements on that matter, that there were significant issues, then I must conclude that not every reasonable step was being taken, as other pharmacies were able to resolve the issues and make less claims.

6.37 Further to this, I note that the NHS BSA's data indicates that on some occasions the items were dispensed without an OOPE claim. I also note the NHS BSA's comments that the Pens have a 30 month shelf life and that it could have bulk ordered them as an OOPE claim so as to reduce costs. Given that at least one claim was made per month, I consider that this was not done, despite it being reasonable. I do not consider that either of these actions are suggestive of all reasonable steps being taken to avoid claiming.

6.38 Finally, I note the language used by the Appellant in its appeal, notably *"We gave staff the option to order this stock*" and *"colleagues in the branch chose to use the option of a special obtain"*. I do not consider that this is indicative of any steps being taken to prevent claiming, but rather that it was simply offered as an option alongside the ordinary method for ordering. Therefore, taking into account each of these factors, I do not consider that the Appellant took all reasonable steps to avoid claiming OOPE.

6.39 I consider that the Drug Tariff makes clear that the criteria are cumulative - all of the criteria need to be fulfilled and information relating to all three parts needs to be provided in order for a claim to be successfully made. It is not sufficient to claim exceptional circumstances without also providing information regarding the frequency of the supply and how all reasonable steps have been taken to avoid claiming.

6.40 I am of the view, given that the Appellant has not provided any information to substantiate their OOPE claims in line with the information expected as set out in the Drug Tariff, that the Appellant does not qualify for OOPE payment in line with the Drug Tariff.

6.41 I note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2020 to January 2021, however I am mindful that the NHS BSA initially contacted the Appellant in November 2021. I am of the view that the Appellant should have been able to provide the initial information as requested by the NHS BSA at this time. Further, I am of the view that the Appellant was aware, from November 2021 onwards, that they were subject to a PPV and therefore the Appellant should have retained any further information that it had with regard to the OOPE for those drugs.

6.42 I agree with the NHS BSA that the decision to recover the overpayment is appropriate.

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 £9,013.71.

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