NHS Resolution

1 May 2025

REF: SHA/26509

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM APEX PHARMACY (FHD65) ("THE APPELLANT")

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

Tel: 020 3928 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 £3,006.52.

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:

Apex Pharmacy
NHS BSA on behalf of NHS England

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

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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM APEX PHARMACY (FHD65) ("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").

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 29 January 2025 in respect of Apex Pharmacy (ODS code FHD65). 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 2019 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 2019 and January 2021.

2.4 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 74 OOPE claims totaling [sic] £3,006.52 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 FHD65 were passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary. Due to size limitations, you will also receive a link to access the second timeline via Egress.

2.6 To access the second timeline, which covers the 2023-2024 period, please follow the link within the email which will originate from workspace@egresscloud.com. Please use pharmacy.fhd65@nhs.net account to log into Egress. The password will be the same password used to access the NHS.net email address. You will then have the option to download a copy of the timeline for your reference. Please also check any

'Junk' folders. If you have any issues accessing the timeline, please contact us at pharmacysupport@nhsbsa.nhs.uk.

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

2.7.1 FHD65 – Apex Pharmacy submitted 567 Out of Pocket Expense claims, totalling £22,876.00 between February 2019 and January 2021.

2.7.2 FHD65 – Apex 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.

2.8 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 2019 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.

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

Number of claims	Total Recovery Value
74	£3,006.52 deduction

2.10 **Action Required**

2.11 1.Please respond to this correspondence at pharmacysupport@nhsbsa.nhs.uk to confirm your agreement for the overpayment to be recovered pursuant to Regulation94(1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. **Please send this confirmation by 28th of February 2025.**

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 **28th of February 2025.**

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 2. **Please be aware that failing to contact us by 28th of February 2025 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. A record of this process will be kept on your NHS England contractor file.**

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

2.20 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

2.21 Your co-operation is very much appreciated."

3 THE DISPUTE

In a letter dated 8 February 2025 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "We do not agree with the Pharmacy Provider Assurance Team (PAT) or NHS England local Pharmaceutical Services Regulations Committee (PSRC) view that there has been an overpayment and that some money should be deducted because we have claimed Out of Pocket (OOP) inadvertently or not according to the Rules and Regulations laid down in the Drug Tariff.

3.2 We have revisited all of the claims and confirm that they were all claimed correctly and met all 3 conditions outlined in the Drug Tariff, Part II Clause 12; and that we have the invoices which clearly show that we were charged the OOP that we are claiming.

3.3 Furthermore all OOPE claims were within the rules and regulations as stipulated in the word document they sent attached to the email of November 2021, which is attached here for ease of reference.

3.4 They were all claimed correctly and met all 3 conditions outlined in the Drug Tariff, Part II Clause 12 because of the following explanations:

3.5 Over recent years our pharmacies have experienced a huge increase in the prescribing of nutritional / borderline supplements. Whilst these places [sic] challenges on storage, deliveries due their weight [sic] and size but much more importantly they come in different flavours and are often short expiry dated and have reimbursement issues.

3.6 From most suppliers, we do not receive any discount on most if not all of these products but have a discount clawback applied to them by the NHSBSA which is roughly 10% of their cost price. This means that we would be reimbursed at 10% less than its list price (our cost price). Since we dispense a lot of these products it would put a huge financial pressure on us at a time when remuneration is already being cut.

3.7 So we have sought to find suppliers that give discounts on these products since according to the drug tariff a discount clawback will be applied on most products and we could not find any other than some that charge OOP. They are charging OOP only on the products that they are allowed to in the relevant section of the drug tariff. There were other suppliers who were charging a lot more OOP but we took all reasonable care to choose the supplier(s) that charged the least OOP. So these are both exceptional cases and we have taken reasonable steps to avoid claiming OOP.

3.8 We cannot order any particular supplement in bulk due to the multiple flavours available and patient choice being different, short expiry date and thus it may expire before the next prescription, and size and weight since it would occupy a lot of space. Also, even if the same person is prescribed the same flavour supplement in multiple prescriptions over intervals it is not possible to order in advance because a) there is no guarantee that they will remain on that item next time, b) according to the rules of the drug tariff and OOP, the OOP claim cannot be split over multiple prescriptions but attributed to one only. The OOP must be for a specific product and specific prescription. So even if it looks like we ordered the same supplements over and over again during a period these may have been different flavours. There is also the prospect of a penalty being charged, 'ordered in error' surcharge, by all mainline suppliers in case we return anything e.g. if we returned because flavour was wrong.

3.9 The example that they have mentioned in one of their emails, Ensure Plus Milkshake style liquid (9 flavours), is not strictly correct. Each of those were not for all 9 flavours dispensed. Each flavour in itself is a different product and so each different product was not dispensed as frequently as they have mentioned. On each occasion one or two flavours may have been dispensed and as mentioned above this would be patient choice as to which flavour(s) and impossible to order as bulk due to all the reasons outlined above.

3.10 We are not allowed by the rules of the drug tariff to bulk order and split the OOP over several prescriptions as they seem to suggest we should have done. The OOP must be for a specific prescription and hence we cannot bulk order for same month or future months.

3.11 Also, there is no way of predicting if we are going to get a prescription for the same item later on in the month or following months. It is of course easy to see that with hindsight that for a particular product we received X number of prescriptions in a given month but at the time it is impossible to predict if another prescription would come later on.

3.12 If the product is only dispensed for the same patient either within the month or the next month then also we cannot bulk order due to additional factors such as the item may be short dated e.g. Juvela bread etc, or if the patient moves on (different pharmacy or dies) then we would be left with wasted stock and a loss.

3.13 If the product is dispensed to different patients within the month then the issues about different flavours, short dated and storage space come into consideration. We cannot give Patient A Ensure Plus Strawberry just because we have excess stock from when we ordered for Patient B if Patient A wants a different flavour. So therefore different flavours of what may be the same product is actually a different product regardless if it has the same prescriber code. Also, just because more than one person is prescribed the product does not mean that there will always be a demand. Either the GP can change its prescribing habits or those patients can move on and hence we would be left with wasted stock and loss.

3.14 So above are the arguments for what may appear to be frequently supplied to either the same patient or different patients either in the same month or different months but are not actually frequently supplied and cannot be ordered in bulk and claim OOP split over all the prescriptions.

3.15 'Not required to be frequently supplied' is an arbitrary clause e.g. we dispense Amlodipine hundreds of times a month so an item dispensed 2 to 3 times a month would definitely comply with that clause that it is not frequently supplied.

3.16 When an item is dispensed less than 5 times a month, this indicates that there are not many patients to whom it is dispensed therefore if we were to order in bulk and those few patients move to a different pharmacy, change or stop their medication, that item would become 'dead stock' and therefore a big financial loss to the pharmacy.

3.17 As mentioned previously, the steps we took to avoid claiming OOP was that we sought to find suppliers that give discounts on these products or give them at a reduced price since according to the drug tariff a discount clawback will be applied on most products and we could not find any other than some that charge OOP. Others were charging more OOP and giving bigger discounts but we chose the one who charged the least OOP albeit the product price was higher.

3.18 Having gone through the email and attachment by the PPV team in June 2024 and all our past correspondence we have the following points to make:

3.19 As far as other pharmacies who were able to dispense these products without claiming OOP, we would not know their reasons but could speculate that maybe they were able and willing to dispense at a loss or maybe they were happy to risk the stock becoming 'dead stock' or maybe they were multiples who were able to negotiate discounts with their buying power.

3.20 We must disagree with them regarding different flavours being the same product. When we order, we have to specify the flavour. Also if we tried to dispense a vanilla flavoured supplement to a patient who requested strawberry flavoured and attempted to explain the difference by saying 'it has the same prescriber code', we hope you can appreciate the response the patient would give. Therefore if we order vanilla one week and then strawberry a week later, that cannot be considered as the same product being ordered.

3.21 Furthermore, the guidance sheet that was sent to us at the outset of this PPV process, attached here, clearly states that OOP CAN BE claimed for readily available products so just because other pharmacies were not claiming is not reason enough that we should also be denied. The guidance clearly states that it can be claimed for READILY AVAILABLE products including ACBS and that is what we have done. We have merely followed the guidance. [Appellant's emphasis]

3.22 So whilst the exact thought process for each individual prescription dispensed over 5 years ago is impossible to recollect precisely, and that there is no definitive quantifiable guidance or instructions in the drug tariff as to what is exceptional circumstances, or what is frequent or what constitutes reasonable steps, we would say that we DID meet ALL 3 conditions of the drug tariff as well as having invoices for all the OOP claims: [Appellant's emphasis]

3.23 1 – These were exceptional circumstances whereby we were being asked to dispense at a loss (if this was not an exceptional circumstance and a significant proportion of our prescriptions were dispensed at a loss, then our business would not have been viable many years ago).

3.24 2 – The items were not required to be dispensed more than a very few times in a month, if that, and to a very few number of patients. So they were not required to be dispensed frequently.

3.25 3 – We sought to find alternative suppliers who would give us a discount to limit our losses without charging us OOP but were not able to do so. Therefore we did take reasonable steps to avoid claiming and chose the supplier that was charging the least OOP.

3.26 It is very unreasonable to expect us to remember each and every event which is now 5 and half years ago and therefore we have no option but to give a general reply and explanation. Had we been asked the month after the event we could have given a specific reason for each event but it is unreasonable to expect that now.

3.27 Nowhere on the guidance sheet or the drug tariff does it say for the OOP claims to be valid X number of pharmacies also need to be claiming for our claim to be considered acceptable. As explained in earlier correspondence different pharmacies may have different deals and different buying power and hence may not need to claim OOP for those products and as such cannot be used as comparison.

3.28 It was correctly noted that some of the reasons we have outlined that proved that all the conditions of the drug tariff were met including but not limited to:

3.28.1 Increase in prescribing of these products and storage and deliveries challenges

3.28.2 Different flavours and short expiry dates

3.28.3 Financial pressures around discount deductions

3.28.4 Lack of suppliers giving discounts without charging OOP

3.29 Regarding the attachment they sent and the table therein we have the following comments:

3.29.1 Number of pharmacies seems wrong as we believe there are only around 10,000 but in the first case shows 15,600 pharmacies. And for two it shows 17,700. So those figures seem to indicate that it could be wrong for the whole table.

3.29.2 For the 4 items highlighted in yellow and the 2 items in orange- they may have been different patients, diff flavours etc. etc. as mentioned many times before in previous correspondence.

3.29.3 Whilst it is not as per the rules or regulations to compare with other pharmacies the comparison of % of national claims made by FHD65 throws up incorrectly a higher figure when compared to FHD65 as a % of pharmacies that made the claim- so 4.38% becomes -1/64=1.5%, 22.83% becomes 1/21=4.7%, 45.16% becomes 1/8=12.5% and finally 8.44% becomes 1/61=1.6%. So as you can see we do not represent a large /significant % of pharmacies that made a claim for those items contrary to what they have decided to focus on.

3.29.4 Furthermore the 2 items highlighted in Orange – they were not dispensed more than once in a given month except possibly on one occasion which they earlier indicated in their previous emails would generally mean not dispensed frequently and therefore complies with the requirement and as such are valid

expenses and should not be deducted even though we may have been the only pharmacy to make the claim.

3.29.5 We have been very transparent and have fully cooperated at every stage of this enquiry which they have kindly acknowledged.

3.30 In summary we claimed as per the regulations and rules in the drug tariff and have invoices to prove the costs incurred which we have sent previously and they have also acknowledged. We have done absolutely nothing wrong. We have maintained and continue to maintain that we did not claim inadvertently. We abided by the rules and regulations at all times."

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 12/02/2025 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 were not to be frequently supplied, and the pharmacy has taken all reasonable step 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.

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 Only certain products are eligible for a OOPE claim and are as follows:

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 to January 2021 OOPE PPV**

4.1.11 NHSBSA Pharmaceutical Provider Assurance Team (PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification (PPV) exercise to ensure that pharmacy contractors were claiming correctly for OOPE. The assurance activity was initiated in response to cases raised by various Integrated Care Boards (ICB's) that resulted in contractors having money recovered for over-claiming for the OOPE service following decisions made by NHS Resolution.

4.1.12 The Counter Fraud Authority (CFA) raised concerns around how the allowance was being claimed by a small number of pharmacy contractors following these high profiles cases, and in response PAT was asked to perform a small-scale pilot engaging with a small number of the highest claimers for OOPE. 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 the engagement, PAT included contractors in the sample that had claimed more than £10,000 for 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:

4.1.13.1 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)

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

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

4.1.14 Apex Pharmacy was included in Sample One which covered February 2019 to January 2021 as their total OOPE claims for the period totaled [sic] £22,876.00.

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:-

4.1.15.1 Claims were made only in 'exceptional circumstances'

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

4.1.15.3 The contractor took all reasonable steps to avoid claiming OOPE

4.1.16 NHSE and 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 recognised that the 3 conditions were not quantified and were therefore subject to individual circumstances for each pharmacy. This therefore required 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 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 re-engagement, 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 recommended recovery value were any claims the pharmacy had highlighted as having been claimed incorrectly in their initial self-review. The PAT provided Apex Pharmacy with an overview, containing all the pharmacy's claiming data alongside national claim data.

4.1.20 Once this was agreed upon, it was decided to initiate a further phase of engagement, which explains why two separate timelines are provided for these cases, as well as the gap between engagements. The first phase of engagement began in November 2021 and ended in November 2022, and the second phase lasting from July 2023 to September 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 the overpayments from the contractor.

4.1.21 **Apex 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's shared NHS mail address (pharmacy.fhd65@nhs.net) as required by NHSE.

4.1.23 During the first phase of the PAT's PPV engagement, FHD65 – Apex Pharmacy was contacted on November 10th, 2021, and were asked to complete a self-review appendix of the items they claimed OOPE on from February 2019 to January 2021, demonstrating how they met the Drug Tariff's requirements.

4.1.24 Apex Pharmacy responded on the 26th January 2022 with their completed OOPE self-review appendix highlighting that all the OOPE claims met the 3 OOPE obligations set out in the Drug Tariff, as well as a letter detailing the reasoning for their conclusions. Apex Pharmacy outlined that they have experienced a huge increase in prescribing of nutritional/borderline supplements that come with challenges around storage, deliveries due to weight and size, variations of flavours and with short expiry dates also reimbursement issues. PAT contacted the pharmacy to inform them that the findings of PAT's assurance activity will be shared with NHSE before deciding upon next steps.

4.1.25 During the second phase of engagement, Apex Pharmacy was contacted on seven occasions to request further evidence and allow them to detail the circumstances that existed within the pharmacy to demonstrate that their OOPE claims met the cumulative conditions outlined in the Drug Tariff.

4.1.26 On August 28, 2023, Apex Pharmacy responded in the form of a letter with their reasonings, stating that they had reviewed the OOPE claims in question again and believed they were all correctly claimed, meeting all three conditions outlined in the Drug Tariff. Apex Pharmacy restated prior remarks about nutritional/borderline supplements, which come with the difficulty of storage, deliveries due to weight and size, variations of flavours and short expiry dates, and reimbursement issues.

4.1.27 They go on to state that most of the products have a discount clawback applied to them, which is *"roughly 10% of its cost price",* and that they will be reimbursed at 10% less than the list price. They claim that, because they distribute a large amount of these products, it would put them under a lot of financial stress, especially because their remuneration is already being reduced. Due to these circumstances they sought to find suppliers that gave discounts on these products, and they couldn't find any other than some that charged OOPE. Apex Pharmacy explains that there were other suppliers who were charging a lot more for OOPE, but they feel they took all reasonable care to identify suppliers that charged the least amount for OOPE.

4.1.28 Apex Pharmacy states that they are unable to order any specific supplement products in bulk due to the variety of flavour's available and the patients' diverse tastes, as well as the products' short expiry dates, size, and weight, which would all present storage concerns. They go on to explain that under the Drug Tariff, OOPE claims cannot be spread over multiple prescriptions but must be ascribed to only one, so they believe that it looks like they have ordered the same supplement products over and over during a period however, these may have been different flavours. At the end of their letter, they state that they are constantly monitoring their OOPE claims and that they have reduced OOPE claims to nearly zero since February 2021. Along with this letter, Apex Pharmacy produced invoices for the claims.

4.1.29 PAT responded on September 11, 2023, explaining that there is no disputing the fact that these items were provided to patients and a cost was incurred, but rather the individual circumstances that the claims met the requirements outlined for OOPE in the Drug Tariff, so the invoice evidence, while appreciated, is not the type of evidence required for this PPV exercise. PAT goes on to dispute Apex Pharmacy's rationale for the nutritional/borderline supplements, citing data that demonstrates most pharmacies could dispense these items without resorting to OOPE claims in the period in question. PAT goes onto refute the explanation given by Apex Pharmacy in relation to the different flavours of the nutritional supplements being technically different items. PAT state that this is not the case; all different flavours of Ensure Plus Milkshake still have the same prescriber code in terms of OOPE, and NHS England have confirmed that just because a different flavour is dispensed, that would have no impact on how the item is seen in regards of the three conditions in the Drug Tariff. PAT reiterated the evidence required would need to demonstrate how all OOPE claims made against every item met the 3 conditions set out in the Drug Tariff.

4.1.30 On September 25, 2023, Apex Pharmacy responded by reaffirming previous points and contesting PAT's conclusions. Stating that it's "virtually impossible" to remember every situation relating to the claims due to it being 3-4 years after the claims were submitted, so therefore can only give general arguments which they believe are accurate and apply to each of the claims. They go on to say that under the Drug Tariff, they are not permitted to bulk order and split OOPE across multiple prescriptions; the OOPE must be for a specific prescription and

go on to argue that while it is easy to observe trends in prescribing behaviour in retrospect, predicting future prescriptions is impossible at the moment. The contractor is correct in that one OOPE claim should not be split across multiple prescriptions. However, if they had a patient who repeatedly required an item or specific flavour each month, which could only be obtained by incurring additional fees, it is reasonable to expect the pharmacy to order additional items to supply in the near future in that one order and only incur the additional fees once, as a result. This would then be claimed via the OOPE endorsement for that specific prescription and be within the requirements of the Drug Tariff.

4.1.31 Apex Pharmacy attached a NHSBSA Out of Pocket Expenses Claims guidance document for Pharmacy Contractors, pointing out that the guidance indicates that OOPE can be claimed for widely available items, which they insist is exactly what they did. They find that these were unique circumstances since they were asked to dispense at a loss, and the items that had to be dispensed were not required *"more than a few times in a month, if that, and to a very small number of patients"* therefore, they believe were not dispensed frequently. They restate that they attempted to identify alternative suppliers who would give them discounts to limit their own losses without charging OOPE, but were unable to do so, thus they chose the provider with the cheapest OOPE. This statement confirms that the pharmacy may have been able to obtain the item without incurring additional fees, however, they chose to only use suppliers who sold the items at a discount to reduce any potential loss the pharmacy may incur after reimbursement. However, these suppliers charged additional fees which the pharmacy then passed on to the NHS through the OOPE endorsement. This does not support that the pharmacy took reasonable steps to avoid claiming for OOPE as required in the Drug Tariff.

4.1.32 After reviewing all the information provided, PAT issued confirmation of the review's outcome on June 27th, 2024, that the case would be referred to PSRC, with the recommendation that PAT were unable to identify how 6 items (74 claims) met the three conditions for claiming OOPE therefore it was judged that an overpayment of £3,006.52 has been received and should be recovered. Although Apex Pharmacy had provided some general information about the circumstances that led to the pharmacy claiming OOPE during the sample period, there had been insufficient evidence that claims matched the three conditions outlined in the Drug Tariff. PAT gave a deadline of July 25th, 2024, to respond with any further information and evidence the pharmacy would like to be considered by PSRC or an agreement to the recommended recovery figure.

4.1.33 Apex Pharmacy's [RG] replied on June 28, 2024, requesting an extension of the deadline to September 30, 2024, due to him and his business partner's annual leave commitments. [RG] goes on to state in summary they do not believe they have claimed inadvertently and proposed *“if we offered as way of settlement 50% (of the recommended recovery figure) - i.e. £1500 in total then will you be able to conclude the matter and close the case?”.* PAT responded to grant Apex Pharmacy’s request for a deadline extension to September 30, 2024, however confirmed that the NHSBSA were not permitted to negotiate settlements (although this information would be communicated to the relevant PSRC as part of the decision making on this case).

4.1.34 Apex Pharmacy responded on September 16, 2024, repeating previously given statements and again offering as a *"goodwill gesture"* to pay 50% of the recommended recovery figure *"without any acceptance of liability or claiming inadvertently."* PAT responded, thanking Apex Pharmacy for their response

and ongoing engagement, and outlined that PAT will compile all correspondence and recommendations from this process and share it with the PSRC so they can make a decision.

4.1.35 To avoid confusion, NHSE and PAT acknowledge that OOPE claims are difficult to quantify and are dependent on the unique circumstances of each pharmacy, but the information provided by Apex Pharmacy was based on general statements rather than specific evidence for the claims in question and did not demonstrate how the claims met the cumulative conditions required before an OOPE claim should be considered.

4.1.36 After reviewing the data and information Apex Pharmacy had provided alongside the National data, the PAT found that four items had been claimed on more than 24 occasions over the 24 months reviewed. The PAT had received no evidence of information from the contractor to support that these claims were not required to be frequently supplied, nor that these were exceptional circumstances. Therefore, after allowing the first 24 occasions of these claims for each item, PAT concluded that the contractor had received an overpayment of £2,571.52 for these items (64 claims).

4.1.37 The data also highlighted that Apex Pharmacy were the only pharmacy nationally to submit OOPE claims for the following items:

4.1.37.1 Infatrini liquid

4.1.37.2 Calogen Extra Shots emulsion (2 flavours)

4.1.38 Apex pharmacy claimed OOPE on these items despite them being dispensed by a minimum of 1,000 other pharmacies on a minimum of 12,000 occasions without the need for an OOPE claim. Without evidence or information to identify what steps the pharmacy took to avoid incurring additional expenses when obtaining these items, it was determined that the ten claims for these items were also unnecessary, and that the pharmacy had received an overpayment of £435.00 for these claims.

4.1.39 PAT concluded that a total recommended recovery figure of £3,006.52 should be reclaimed for OOPE claims (74 claims) not meeting the three cumulative conditions of the Drug Tariff and therefore should be recovered under regulation 94-(1)-(a) as an overpayment. Apex Pharmacy did not accept the proposed full recommended recovery therefore the details of the case were passed to the NHS regional team for their PSRC review. A decision was sought as whether the claims made by the contractor were eligible for a payment under the conditions of the Drug Tariff or whether they felt the 6 identified items did not meet the cumulative conditions and therefore should be recovered under regulation 94-(1)-(a) as an overpayment.

4.1.40 **The PSRC decision**

4.1.41 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 Apex Pharmacy. These timelines have been provided to you in addition to this response.

4.1.42 The engagement showed that despite repeated requests by the PAT, Apex Pharmacy was still unable to provide sufficient 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.

4.1.43 Consequently, the PSRC concluded that the PAT had been unable to find any evidence to demonstrate that the 6 items (74 claims) claimed by Apex Pharmacy between February 2019 and January 2021 met the requirements set out in the Drug Tariff for claiming OOPE.

4.1.44 Following the conclusion, the PSRC determined that Apex Pharmacy was not entitled to the payment made for which it had received for these claims.

4.1.45 Having made this decision, the PSRC then directed that as Apex 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.

4.1.46 In making this decision the PSRC relied on the information that they had before them following the investigation undertaken by the PAT and the repeated requests to Apex Pharmacy for evidence of how the Out of Pocket Expense claims made between February 2019 and January 2021 met the requirements set out in the Drug Tariff.

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

4.1.48 The Drug Tariff requirements for an eligible claim is detailed in the background section of this representation.

4.1.49 Each of the points in bold are prerequisites that must be met for a claim to be considered before OOPE submission. For the 6 items (74 claims) highlighted in PAT's recommended recovery, Apex Pharmacy have not provided sufficient evidence to support that these conditions were met prior to submitting the claims.

4.1.50 In their appeal, Apex Pharmacy outline the reasonings behind the OOPE claiming as follows: *"we do not receive any discount on most if not all of these products but have a discount clawback applied to them by NHSBSA which is roughly 10% of their cost price. This means that we would be reimbursed at 10% less than its list price. Since we dispense a lot of these products it would put a huge financial pressure on us at a time when remuneration is already being cut. So we have sought to find suppliers that give discounts on these products since according to the drug tariff a discount clawback will be applied on most products and we could not find any other than some that charge OOP. There were other suppliers who were charging a lot more OOP but we took all reasonable care to choose the supplier(s) that charged the least OOP. So these are both exceptional cases and we have taken reasonable steps to avoid claiming OOP."*

4.1.51 Apex Pharmacy outlines financial challenges in relation to reimbursement on *"these products"* and they believe this is exceptional circumstances and justification for them to then source items with a discount, but also incur additional fees as a result, therefore mitigate any financial loss to the pharmacy at the expense of the NHS. PAT contests this logic on several grounds as, although we appreciate the Drug Tariff is open to interpretation, the definition of 'exceptional circumstances' refers to extremely uncommon situations that pharmacy contractors rarely encounter. First, the reimbursement concerns raised by Apex Pharmacy are more general remarks in relation to the

reimbursement process which would affect every pharmacy contractor nationally, citing a *"discount clawback"* is *"roughly 10%"* implying that they would be reimbursed at 10% less than *"it's list price".* Apex Pharmacy does not elaborate or specify these points in relation to the individual items to corroborate the circumstances they are describing, and how this is an issue specific to their pharmacy. Drug reimbursement is applied at the same value for each item to all pharmacy contractors nationally, the reimbursement cost of an item is reviewed monthly to reflect market trends. Although this may present as an underpayment on some items, other items may receive an overpayment. This does not mean that contractors should look for lower priced items which then result in additional charges, at the expense of the NHS through the OOPE endorsement. As can be seen in the PAT's Data Overview **Table 1** (below), the *National Dispensed Occasions* are vast which shows that all four items were frequently dispensed nationally under the same reimbursement conditions without the majority of other pharmacies needing to claim for the OOPE endorsement in the same period. As an example, 15,657 pharmacies dispensed Ensure Plus milkshake style liquid (9 flavours) on a total of 628,489 occasions within the same 24 month period. Only 64 of these contractors then claimed OOPE for this item.

4.1.52 **Table 1** *(Excerpt from PAT 2019-21 Data Overview for Apex Pharmacy)*

Product (FHD65 – Made at least one OOPE claim within the 24 month period)	FHD65 Dispensed Occasion Total (19-21)	FHD65 Claim Occasion Total (19-21)	Nation Claim Occasion Total	Number of pharmacies claimed for item	Percentage of National claims made by FHD65	National Dispensed Occasion Total	Number of pharmacies dispensed item	Months Claimed in by FHD65
Ensure Plus milkshake style liquid (9 flavours)	77	63	1439	64	4.38%	628489	15657	21
Nutriprem 2 powder	42	42	184	21	22.83%	91184	8543	14
Complan Shake oral powder 57g sachets strawberry	33	28	62	8	45.16%	53574	8317	16
Juvela gluten free fibre	32	27	320	61	8.44%	46205	Data not available	20

loaf sliced								

4.1.53 The data also highlighted (Highlighted orange on the Data Overview) that Apex Pharmacy were the only pharmacy to submit OOPE claims for Infatrini Liquid and Calogen Extra shots emulsion (2 flavours) nationally. Despite Infatrini Liquid being dispensed by 5,235 other pharmacies on 46,747 occasions, Calogen Extra shots emulsion (2 flavours) being dispensed by 9,116 pharmacies on 114,385 occasions without the need for an OOPE claim. Without evidence or information to identify what steps the pharmacy took to avoid incurring additional expenses when obtaining these items, it was determined that the six claims for Infatrini and the four claims for Calogen Extra shots Emulsion (2 flavours) were also unnecessary, and the pharmacy had received an overpayment of £435.00 for these claims.

4.1.54 Furthermore, Apex Pharmacy have looked to utilise suppliers that give discounts and in doing so some have charged OOPE. This demonstrates the pharmacy's prescribing activity was driven by financial considerations, and while PAT appreciates the financial demands of running a pharmacy, the rationale for selecting a supplier based on discounts offered and seeking suppliers charging the lowest amount of OOPE does not constitute for "*the contractor has taken all reasonable steps to avoid claiming"* as the pharmacy has implied, or in fact meeting all three cumulative OOPE conditions set out in the Drug Tariff. Apex Pharmacy has offered no specific evidence or material demonstrating the method and steps they employed to review their OOPE claims on a regular basis.

4.1.55 Apex Pharmacy explains in their appeal *"Over recent years our pharmacies have experienced a huge increase in the prescribing of nutritional/borderline supplements."* and *"dispense a lot of these products"*; these statements suggest that Apex Pharmacy has identified the six items listed in the recommended recovery as items that the pharmacy frequently supplies. This observation also implies there was a significant amount of time that had passed for Apex Pharmacy to consider this prescribing pattern and adjust, for the claiming to not be exceptional and be able to put in place reasonable steps to avoid claiming.

4.1.56 Apex Pharmacy also state in their appeal that "*We cannot order any particular supplement in bulk due to the multiple flavours available and patient choice being different, short expiry date and thus it may expire before the next prescription, and size and weight since it would occupy a lot of space."* PAT appreciate the point being made by the appellant however the same conditions will exist in the majority of pharmacy contractors. With this in mind, the overall claim data shows clearly that the majority of pharmacies were not claiming OOPE on these items and for the ones who have, it is not with the same longevity and consistency as Apex Pharmacy. PAT tried to obtain the individual circumstances that would explain the need for these OOPE claims, unfortunately this was not provided by Apex Pharmacy who instead outlined they sought suppliers out in regard to discounts offered.

4.1.57 Apex Pharmacy then go on to state "A*s far as other pharmacies who were able to dispense these products without claiming OOP, we would not know their reasons but could speculate that maybe they were able and willing to dispense at a loss or maybe they were happy to risk the stock becoming 'dead stock' or*

maybe they were multiples who were able to negotiate discounts with their buying power." PAT appreciate Apex Pharmacy will not be aware of the individual circumstances in other pharmacies nationwide but believe it is disingenuous to suggest that every other pharmacy is happy losing money and there is no better approach to ordering items required for their patients than that which is taken by Apex Pharmacy while still following the guidance on claiming in the Drug Tariff.

4.1.58 The PAT's Data Overview (***Table 1***) for Apex Pharmacy also confirms that the four items (highlighted yellow in Data Overview) were frequently required over the 24-month sample period with Ensure Plus milkshake style liquid being claimed in 21 of the 24 months, Nutriprem 2 powder claimed for in 14 of the 24 months, Complan Shake oral powder 57g sachets strawberry 16 out of the 24 months and Juvela Gluten free fibre loaf sliced 20 out of the 24 months. Apex Pharmacy goes onto challenge the percentages used in the PAT's Data Overview *"your comparison of % national claims made by FHD65 throws up incorrectly a higher figure when compared to FHD65 as a % of pharmacies that made the claim".* The contractor is considering two different conditions in this statement. The Data Overview shows the percentage of the total national OOPE claims that FHD65 submitted for an item. For example, there were 1439 OOPE claims submitted nationally for Ensure Plus milkshake style liquid (9 flavours), FHD65 submitted 63 of these claims, therefore they were responsible for 4.38% of the national claims for that item. In comparison, the contractor is only considering the percentage FHD65 made up in relation to the number of pharmacies claiming for the item. They were one of the 64 pharmacies claiming for the same item; therefore, they make up 1.56% of the ***pharmacies*** claiming for the item. The percentage of national claims highlighted by the PAT shows a clearer picture of how this pharmacy is an outlier. When considering the Ensure Plus milkshake again and removing the claims submitted by FHD65 for this item, it shows that 63 pharmacies submitted 1,376 OOPE claims for the item. On average, each of those additional 63 pharmacies only submitted 22 claims for the item; this is far less occasions than the 63 FHD65 claimed for the same period.

4.1.59 When considering how many OOPE claims were submitted nationally in comparison to how many times the item was dispensed, it shows that only 0.23% of Ensure Plus milkshake style liquid, 0.20% of Nutriprem 2 powder, 0.12% of Complan Shake oral powder 57g sachets strawberry and 0.69% of Juvela gluten free fibre loaf sliced were dispensed on 99% of occasions without the necessity for an OOPE claim.

4.1.60 It can be seen from the data provided that the pharmacy required stocks of Ensure Plus milkshake style liquid, Nutriprem 2 powder, Complan Shake oral powder 57g sachets strawberry and Juvela Gluten free fibre loaf sliced on a regular basis and could have avoided extra charges from the suppliers by ordering larger amounts, at less frequent intervals. Apex Pharmacy go on to state "*challenges on storage, deliveries due their weight and size but much more importantly they come in different flavours and are often short expiry dated"* in relation to the items recommended for recovery. PAT acknowledges the storage challenges the pharmacy may face, but they have not provided any explanations around the challenges and what the pharmacy did or changed to accommodate any potential storage solutions or avoid claiming OOPE for these items.

4.1.61 The product characteristics for Nutriprem 2 powder shows that it has Shelf life of 18 months from date of manufacture and no flavour variations. Complan

Shake oral powder 57g sachets strawberry has a Shelf life of 15 months [link not accessible] also comes in different flavour variations. Ensure Plus milkshake style liquid (9 flavours) has shelf life of 3 months and comes in different variations of flavours. Although the shelf life is shorter than Nutriprem 2 powder and Complan shake oral powder 57g sachets strawberry it's still a reasonable length to be able to stock especially as Apex Pharmacy supplied this regularly throughout the sample. Therefore, it is entirely reasonable that PAT would then expect the contractor to take reasonable steps to limit the costs of obtaining this item and to limit the costs it passed onto the NHS. Although Juvela gluten free fibre loaf sliced has a much shorter shelf life, the pharmacy was required to dispense the item in 20 of the 24 months sampled. As this item was required frequently, the pharmacy has not provided any information into the steps they took to avoid claiming for this item when it was required on an almost monthly basis. The pharmacy has previously stated that they sought out suppliers with discounts, if they had selected alternative suppliers who did not offer the discounts, could they have avoided incurring the additional fees which they then passed onto the NHS via the OOPE endorsement?

4.1.62 The variety of flavours adds an additional challenge to the pharmacy; however, PAT believes that it is reasonable to expect the pharmacy to manage stock and to be able to analyse market trends and identify popular flavours, and or explore options on the market for assorted flavour packs to help avoid *"dead stock".* Apex Pharmacy's ordering process to identify suppliers with discounts may have limited their alternatives, but it is important to note that the justification for ordering in this manner in fact, defies the conditions outlined in the Drug Tariff for the OOPE endorsement. In reference to Apex Pharmacy's argument that the different flavours of the nutritional supplements are technically different items; although it may be possible for contractors to order specific flavours, they are reimbursed under the same code by NHSBSA. However, the Data Overview highlights that the pharmacy was able to dispense Ensure Plus milkshake on 14 occasions without also submitting an OOPE claim. If the contractor only had issues with specific flavours, it is likely that the majority of the claims the pharmacy did submit for this item were for the same flavour. The same pattern in claiming would also show all pharmacies dispensing the item nationally, and as the evidence suggests, this is not the case for large majority of pharmacies.

4.1.63 Apex Pharmacy have not provided specific evidence or information directly related to the items highlighted for recovery other than generalisations and challenges to the interpretations of the Drug Tariff. Apex Pharmacy state, *"It is very unreasonable to expect us to remember each and every event which is now 5 and half years ago".* PAT would contest this, as evidenced by the timelines which demonstrates that the first engagement with the pharmacy regarding the disputed OOPE claims began in November 2021. PAT appreciate that Apex Pharmacy did engage with the PPV request, however, that took the form of them stating all of the claims raised were correct and followed the instructions in the Drug Tariff no further explanation was provided around individual circumstances for the items raised. After that, Apex Pharmacy had numerous opportunities to provide responses with the requested evidence and information at multiple stages as PAT wanted to give contractors additional opportunities to engage with this request. Therefore, PAT would disagree with this point by Apex Pharmacy that its unreasonable to expect this level of information from them, as from November 2021 they were made aware of this ongoing PPV activity.

4.1.64 Apex Pharmacy have included supporting information in its appeal submission, in the shape of the NHSBSA OOPE guidance document, which was distributed to pharmacists as an educational piece on 31st July 2020 by the NHSBSA. The pharmacy highlights that the guidance allows *"OOPE can be claimed for readily available products"* and that they *"have merely followed the guidance."* PAT are not disputing the fact that readily available items can be claimed under the OOPE endorsement, but rather the individual circumstances that the claims met the cumulative conditions outlined for OOPE in the Drug Tariff, and in the guidance document the pharmacy are referencing. It is also key that pharmacies should take reasonable steps to avoid claiming for the item, whereas Apex Pharmacy have specifically identified that they sought items for their discounts to limit personal losses, regardless of if the item then incurred an additional cost that could be passed on to the NHS through the OOPE endorsement. PAT acknowledges that there may be times when the pharmacy did need to claim for these items. However, due to the frequency of the claims, the pharmacy should have looked for other solutions to obtain the item without incurring additional expenses on a monthly basis, PAT feel the reasoning provided by Apex Pharmacy does help to view the situation from their point of view however, have seen no evidence that any 'reasonable' steps were taken to avoid claiming OOPE on the highlighted items (highlighted in yellow on the Data Overview) and the issues raised by the pharmacy would certainly exist in the majority of other pharmacy contractors who have not claimed OOPE on these items to the same extent or consistency.

4.1.65 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 Apex Pharmacy's OOPE claims discussed did not meet the cumulative condition listed in the Drug Tariff. The final recovery figure is made up from items which were identified by PAT as failing to meet the conditions within the Drug Tariff.

Product	Recommended Recovery Total
Ensure Plus milkshake liquid (9 flavours)	£1,571.76
Nutriprem 2 powder	£720.00
Complan Shake oral powder 57g sachets strawberry	£158.93
Juvela gluten free fibre loaf sliced	£120.83
Infatrini liquid	£275.00
Calogen Extra Shots emulsion (2 flavours)	£160.00
Total of PSRC Recovery	£3,006.52

4.1.66 NHSE and PAT maintain that Apex Pharmacy did not demonstrate that they had complied with the Drug Tariff's conditions, and that the claims made for the OOPE endorsement for the three items highlighted did not meet the cumulative conditions that are prerequisites for the endorsements. As a result of receiving payment for these excess claims, an overpayment was made. NHSE and PAT believe the contractor has not provided sufficient evidence to support that the claims for the three highlighted items met the conditions

outlined in the Drug Tariff, so the decision to recover £3,006.52 correct and was also upheld by PSRC.

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 OOPE

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 for their ICB. Apex Pharmacy did not provide any evidence to show how the three conditions were met. Consequently, the PAT were unable to assure NHS England that the claims identified as overclaims met the Drug Tariff requirements.

4.1.68.3 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.

4.1.68.4 The PSRC considered all the information provided about the case by the PAT when determining the overpayment under regulation 94.

4.1.68.5 The initial engagement for the OOPE PPV exercise began the same year of the sample period under consideration. The contractors' assertion about challenges to respond in detail due to the vast amount of time that had passed since the sample are not accurate.

4.1.68.6 The pharmacy's ordering process was driven by personal financial considerations rather than necessity, and while PAT appreciates the financial demands of running a pharmacy, the rationale for selecting a supplier based on discounts offered does not constitute that the contractor has taken all reasonable steps to avoid claiming.

4.1.68.7 The contractors' 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 PAT and NHSE England respectfully suggests that NHS Resolution conclude that the decision made by the PSRC

in respect of the £3,006.52 overpayment and its subsequent recovery from Apex Pharmacy was fair and in accordance with the regulations.

4.1.70 Please let me know if you require any further information to help with these deliberations."

5 OBSERVATIONS

5.1 The Appellant stated:

5.1.1 "Having read the arguments put forward in response to our Appeal by the Pharmacy Provider Assurance Team (PAT) or NHS England local Pharmaceutical Services Regulations Committee (PSRC) we have the following comments to make.

5.1.1.1 Timeline- We were being asked on numerous occasions to provide specific details for each OOP claim as to why we had to make an OOP claim, the first of which occasion was November 2021. In one of our replies we wrote that it was over many years ago and hence we can only give general answers because we cannot remember since it is too far back. They have, in their response argued that it was not over 5 years ago. We accept that from their first occasion it was not over 5 years ago, however since we were being asked to provide details from Feb 2019 to Jan 2021 and since their first request was in November 2021 it is plainly obvious that at best it was 10 months ago and at worse it was 2 years and 10 months ago. I am sure you can appreciate that in a busy pharmacy dispensing on average in excess of 5000 prescription items per month it is difficult to remember even a month ago and impossible to remember the further back you go especially more than 3 months. If there was a requirement in the Drug Tariff to endorse each OOP claim with the exact reasons for claiming and ordering an OOP claim we could have done so but it is not in the Drug Tariff. So the summary is that we have no option but to give general answers.

5.1.1.2 Shelf- Life- Whilst it is easy to quote the manufacturer's standard product shelf life but in practice it does not work that way. For example for Ensure, which is most disputed product, even if the manufacturer quotes as having 3 months from date of manufacture, since we are not ordering direct from them and directly as it comes off the production line we do not get products with those expiry dates. One needs to factor in the elapsed time that the manufacturer has before dispatch, then the length of time the wholesaler has in its warehouse before dispatch and whether they have effective stock rotation or else why would even the wholesaler have products going out of date. So all in all with specialist foods we have to assume very short expiry dates even more so with specific products like Juvela bread / loaf which is also disputed which only have days as with the regular bread we find on supermarket shelves.

5.1.1.3 We have argued against most of their points in the first letter we sent in the Appeal but we would still just like to emphasise 2 main points. Firstly, the 3 requirements in the Drug Tariff are not quantifiable which even they have accepted and thus it is within the grounds of reasonableness we have interpreted those 3 criteria. Secondly, even if different flavours of the same product have the same code- it simply

is not the same product. So ordering different flavours as OOP cannot count as ordering the same product multiple times. That we believe is plainly obvious.

5.1.2 In summary we claimed as per the regulations and rules in the drug tariff and have invoices to prove the costs incurred which we have sent previously and they have also acknowledged. We have done absolutely nothing wrong. We have maintained and continue to maintain that we did not claim inadvertently. We abided by the rules and regulations at all times."

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 note the NHS BSA's reference to the Drug Tariff and that it has provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff from December 2019 through to the current Drug Tariff in place (January 2025) could be found. I further note that the Drug Tariff has not been disputed by the Appellant.

6.8 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 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 were 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."

6.9 The NHS BSA was requested to conduct a Post Payment Verification exercise (PPV) for OOPE following a request from various ICBs. 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.

6.10 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*".

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

6.11.1 *"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)*

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

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

6.12 The NHSA BSA states that the Appellant falls into sample one "*Contractors with claims over £10,000 in both years … February 2019 to January 2021*" as the total OOPE for the Appellant for this period totalled £22,876.00.

6.13 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:

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

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

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

6.14 I note 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:

6.14.1 ***"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.*

6.14.2 ***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.*

6.14.3 ***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."*

6.15 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.

6.16 It is not disputed that between November 2021 and July 2024 the pharmacy was contacted by the NHS BSA a total of 11 times. I note that the Appellant appears to have engaged with the process by responding to the NHS BSA's requests at both stages, albeit after a number of contacts in the second stage.

6.17 It is noted that the Appellant's pharmacy submitted 567 OOPE claims totalling £22.876.00 between February 2019 and January 2021, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the overpayment to be recovered was for 74 claims totalling £3,006.52. 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 £3,006.52.

6.18 I note that the period in question is from February 2019 to January 2021. I am therefore of the view that the relevant Drug Tariffs are dated February 2019 and February 2020 as these are the Drug Tariffs that were in force at the beginning of each period to which the OOPE claims relate.

6.19 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."

6.20 I next consider the OOPE claims for the 6 items identified by the NHS BSA (Ensure Plus Milkshake style liquid (9 flavours), Nutriprem 2 powder, Complan Shake oral powder 57g sachets strawberry, Juvela gluten free fibre loaf sliced, Infatrini liquid and Calogen Extra Shots emulsion (2 flavours)). 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:

6.20.1 That there are exceptional circumstances;

6.20.2 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;

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

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

6.21 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.

6.22 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. I note that 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.

6.23 I first consider exceptional circumstances.

6.24 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 simply 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.

6.25 I note the Appellant's comments that "*Over recent years our pharmacies have experienced a huge increase in the prescribing of nutritional / borderline supplements*" and that they "*were being asked to dispense at a loss*". The Appellant explains that they do not receive a discount on the majority of the products in question from most suppliers, but that there is a discount clawback applied by the NHS BSA which is roughly 10% of the cost price and therefore it puts the Appellant under financial pressure at what is already a difficult time. I note that the Appellant has therefore sought out suppliers that offer a discount, but states that it could not find any that did not charge OOP.

6.26 In response the NHS BSA states "*Apex Pharmacy does not elaborate or specify these points in relation to the individual items to corroborate the circumstances they are*

describing, and how this is an issue specific to their pharmacy. Drug reimbursement is applied at the same value for each item to all pharmacy contractors nationally, the reimbursement cost of an item is reviewed monthly to reflect market trends. Although this may present as an underpayment on some items, other items may receive an overpayment. This does not mean that contractors should look for lower priced items which then result in additional charges, at the expense of the NHS through the OOPE endorsement."

6.27 The NHS BSA highlights that its Data Overview spreadsheet "*shows that all four items were frequently dispensed nationally under the same reimbursement conditions without the majority of other pharmacies needing to claim for the OOPE endorsement in the same period. As an example, 15,657 pharmacies dispensed Ensure Plus milkshake style liquid (9 flavours) on a total of 628,489 occasions within the same 24 month period. Only 64 of these contractors then claimed OOPE for this item.*" Additionally, the Data Overview indicates that "*Apex Pharmacy were the only pharmacy to submit OOPE claims for Infatrini Liquid and Calogen Extra shots emulsion (2 flavours) nationally. Despite Infatrini Liquid being dispensed by 5,235 other pharmacies on 46,747 occasions, Calogen Extra shots emulsion (2 flavours) being dispensed by 9,116 pharmacies on 114,385 occasions without the need for an OOPE claim.*"

6.28 Whilst I sympathise with the Appellant regarding the circumstances it has described and the financial pressure that it is under, I note that no information has been provided to indicate that the Appellant is alone in experiencing this. I am mindful that it is likely to be a situation which all pharmacies are subject to and deal with accordingly.

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

6.30 I note the Appellant's comment that "'*Not required to be frequently supplied' is an arbitrary clause e.g. we dispense Amlodipine hundreds of times a month so an item dispensed 2 to 3 times a month would definitely comply with that clause that it is not frequently supplied.*" The NHS BSA has had regard to the criteria above at paragraph 6.14.1 and I consider that it is reasonable to set a benchmark in this regard.

6.31 The NHS BSA has provided information confirming the frequency of supply. Table 1 shows that four of the items were dispensed on more than 24 occasions each over the 24 months reviewed (Ensure Plus Milkshake style liquid - 77, Nutriprem 2 powder - 42, Complan Shake oral powder 57g sachets strawberry - 33, Juvela gluten free fibre loaf sliced - 32). Given this pattern, across the 2 years, I consider it reasonable to conclude that they were being frequently supplied.

6.32 With regard to Infatrini Liquid and Calogen Extra Shots Emulsion, I note that these were dispensed in total on 6 and 4 occasions respectively, over the 24 month period. This does not appear excessive and I therefore consider it reasonable to conclude that these two products were not required to be frequently supplied.

6.33 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.

6.34 I am mindful again of the arguments put forward by the Appellant regarding exceptional circumstances above and note the Appellant's comments that:

6.34.1 "*…the steps we took to avoid claiming OOP was that we sought to find suppliers that give discounts on these products or give them at a reduced price since according to the drug tariff a discount clawback will be applied on most products and we could not find any other than some that charge OOP. Others were charging more OOP and giving bigger discounts but we chose the one who charged the least OOP albeit the product price was higher.*"

6.34.2 "*We sought to find alternative suppliers who would give us a discount to limit our losses without charging us OOP but were not able to do so. Therefore we did take reasonable steps to avoid claiming and chose the supplier that was charging the least OOP.*"

6.35 In response, the NHS BSA states "*…the rationale for selecting a supplier based on discounts offered and seeking suppliers charging the lowest amount of OOPE does not constitute for "the contractor has taken all reasonable steps to avoid claiming" as the pharmacy has implied...*".

6.36 I have also had regard to the NHS BSA's data regarding other pharmacies. I consider that if there were a need financially, to seek out suppliers offering discounts as the Appellant has done, then this pattern would show for other pharmacies as well. Looking at each item in turn, the NHS BSA indicates that during the period in question 64 pharmacies nationally claimed for Ensure Plus milkshake style liquid, 21 for Nutriprem 2 Powder, 8 for Complan Shake oral powder 57g sachets strawberry and 61 for Juvela gluten free fibre loaf sliced. However, the Appellant made up 4.38%, 22.83%, 45.16%, and 8.44% of the OOPE claims respectively. I further note that the Appellant was the only pharmacy nationally to claim for Infatrini Liquid and Calogen Extra Shots Emulsion. Whilst it is possible that the Appellant had a noteworthy number of patients requiring these items, these numbers suggest that it was a significant outlier. This would either suggest that the discount clawbacks being applied were less impactful than the Appellant suggests, or that, if they were, then other pharmacies found solutions. 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 a substantial proportion of other pharmacies were able to resolve the issues and make less claims.

6.37 I note the Appellant's comments that it is unable to order any supplement in bulk due to the multiple flavours available, the uncertainty as to which flavour will be required and the short expiry dates. The NHS BSA comments that the data shows that the Appellant required stocks of Ensure Plus milkshake style liquid, Nutriprem 2 powder, Complan Shake oral powder 57g sachets strawberry and Juvela gluten free fibre loaf sliced on a regular basis and therefore it could have avoided extra charges from suppliers by ordering larger amounts less frequently. It states further that Nutriprem 2 powder has a shelf life of 18 months with no flavour variations, Complan Shake oral powder 57g sachets strawberry has a shelf life of 15 months (and also comes in different flavour variations) and Ensure Plus milkshake style liquid (9 flavours) has a shelf life of 3 months. I note it is accepted that Juvela gluten free fibre loaf sliced has a much shorter shelf life. I consider that it would have been prudent for the Appellant to order additional stock for those products with a longer shelf life. Whilst I accept that there will be challenges for the pharmacy in managing stock levels and the demand for different flavours, I note that this trend is not reflected nationally and therefore other pharmacies are finding ways around the challenges. Whilst I note the comment from the Appellant with regard to storage space, I am mindful that no information has been provided to expand on this issue and how they have taken reasonable steps in this regard.

6.38 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.

6.39 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.

6.40 I also note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2019 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 provide the initial information as requested by the NHS BSA at this time. Given that the Appellant was first contacted in November 2021, I am of the view that they were aware from this date that they were subject to a PPV and records should therefore have been retained along with any further information that they had with regard to OOPE for those medications.

6.41 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 £3,006.52.

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