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27 September 2023

REF: SHA/25871

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM SEATON HEALTHCARE LIMITED t/a BLYTH HEALTHCARE PHARMACY ("THE APPELLANT")

1 Outcome:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £183,648.

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:

Gordons Partnership Solicitors on behalf of Seaton Healthcare Limited
NHS BSA on behalf of NHS England

8th Floor
10 South Colonnade
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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM SEATON HEALTHCARE LIMITED t/a BLYTH HEALTHCARE PHARMACY ("THE APPELLANT")

1 INTRODUCTION

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

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

2 DECISION

The NHS Business Services Authority ("NHS BSA"), acting on behalf of NHS England, sent a decision to the Appellant on 1 February 2023 in respect of Seaton Healthcare Limited t/a Blyth Healthcare Pharmacy (ODS code FLW99). The decision stated:

"Medicines Delivery Service - Post Payment Verification

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

2.2 This service was originally commissioned across the country from 8th April 2020 and ran until 31st July 2020. The Medicines Delivery Service was limited to those patients classed as Clinically Extremely Vulnerable (CEV) to Covid, who could be identified on the Summary Care Record as 'Shielded Patients'.

2.3 The service was extended between August and October 2020, but only for deliveries made to patients in areas of the country subject to local lockdown restrictions. Only pharmacies providing delivery services to patients affected by these local lockdowns were eligible to continue to claim for the delivery service.

2.4 As part of the verification exercise, your pharmacy has been contacted by the Provider Assurance Team to request that you review all of your Medicine Delivery Service records between April 2020 and October 2020.

2.5 To date your pharmacy has provided evidence, however this did not demonstrate that the claims made between April 2020 and October 2020 were for deliveries made to patients on the Shielded Patient List and did not meet the criteria set out in the service specifications.

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

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

2.7.1 FLW99 – SEATON HEALTHCARE LIMITED claimed 19,968 deliveries for the Medicines Delivery Service between April 2020 and July 2020.

2.7.2 The NHSBSA Provider Assurance Team did receive evidence from SEATON HEALTHCARE LIMITED for claims made between April and July 2020. However, this did not demonstrate that they were to patients classed as Shielded only, and therefore could not verify that these claims met the requirements set out in the service specification.

2.7.3 FLW99 – SEATON HEALTHCARE LIMITED also claimed for 13,554 deliveries for the Medicines Delivery Service between August 2020 and October 2020.

2.7.4 The NHSBSA Provider Assurance Team has been unable to verify that during August 2020 and October 2020, SEATON HEALTHCARE LIMITED was providing the Medicines Delivery Service to patients resident in areas affected by local lockdown restrictions only and thus able to continue to claim a fee for the service provision.

2.7.5 SEATON HEALTHCARE LIMITED was contacted on 11 separate occasions by the NHSBSA Provider Assurance Team to request evidence to demonstrate that that the Medicine Delivery Service claims made during this time met the requirements set out in the service specification.

2.8 Having reviewed the information provided by the NHSBSA Provider Assurance Team, the NHS England Pharmaceutical Services Regulatory Committee has decided that an overpayment in relation to your April 2020 to October 2020 Medicines Delivery Service claims has occurred and has instructed recovery of this overpayment to be progressed in accordance with Regulation 94 (1) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.9 The table below outlines the monthly Medicine Delivery Service claims reimbursed to your pharmacy – FLW99 – SEATON HEALTHCARE LIMITED between April 2020 – July 2020 and also the maximum number of deliveries your pharmacy may have claimed for the service during this period, along with the associated recovery value.

	April 2020	May 2020	June 2020	July 2020	Total
Pharmacy delivery claims	5,720	4,820	4,218	5,210	19,968
Max potential deliveries	653	770	809	682	2,914

2.10 Total recovery for April to July 2020:

19,968 deliveries claimed – 2,914 maximum deliveries = 17,054 deliveries

17,054 deliveries x £6.00 = £102,324.00 deduction

2.11 The table below outlines the monthly Medicine Delivery Service claims reimbursed to your pharmacy – FLW99 – SEATON HEALTHCARE LIMITED during August 2020 to October 2020 along with the associated recovery value:

August 20	September 20	October 20	Total Claimed
4,215	4,215	5,124	13,554

2.12 Total recovery for August to October 2020:

13,554 claims x £6.00 = £81,324.00 deduction

2.13 Total recovery value

- April to July 2020: 17,054 x £6.00 = £102,324.00 deduction
- August to October 2020: 13,554 claims x £6 = £81,324.00 deduction
- Overall value to be recovered: £183,648.00 deduction

2.14 Action Required

2.14.1 Please respond to this correspondence at nhsbsa.pharmacysupport@nhs.net 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 3rd March 2023.

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

2.14.3 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the money, please contact us by 3rd March 2023.

2.14.4 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.

2.14.5 Please be aware that failing to contact us by 3rd March 2023 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: NHS Resolution, Primary Care Appeals, 10 South Colonnade, Canary Wharf, London, E14 4PU.

2.14.6 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.

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

2.14.8 A record of this process will be kept on your NHS England contractor file. For more information or for clarification of any of the details in the letter, please contact by email at nhsbsa.pharmacysupport@nhs.net.

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

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

2.14.11 Your co-operation is very much appreciated."

3 THE DISPUTE

In a letter dated 2 March 2023 addressed to NHS Resolution, Gordons Partnership Solicitors on behalf of the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "We act for Seaton Healthcare Limited ("Seaton") trading as Blyth Healthcare Pharmacy. Our client wishes to appeal against the decision by NHS England to recover an overpayment relating to the Medicines Delivery Service ("MDS").

The decision

3.2 The NHS Business Services Authority ("NHSBSA"), acting on behalf of NHS England, sent their decision to our client on 1 February 2023.

3.3 The decision covered two periods and stated that:-

"FLW99 – SEATON HEALTHCARE LIMITED claimed 19,968 deliveries for the Medicines Delivery Service between April 2020 and July 2020.The decision in relation to these claims is that the evidence provided did not demonstrate that they were to patients classed as Shielded only, and therefore could not verify that these claims met the requirements set out in the service specification.

FLW99 – SEATON HEALTHCARE LIMITED also claimed for 13,554 deliveries for the Medicines Delivery Service between August 2020 and October 2020.The decision in relation to these claims was that the NHSBSA Provider Assurance Team was unable to verify that during August 2020 and October 2020, SEATON HEALTHCARE LIMITED was providing the Medicines Delivery Service to patients resident in areas affected by local lockdown restrictions only and thus able to continue to claim a fee for the service provision."

3.4 The total recovery for April to July 2020 was calculated as follows:

"19,968 deliveries claimed – 2,914 maximum deliveries = 17,054 deliveries

17,054 deliveries x £6.00 = £102,324.00 deduction"

3.5 In response to a request for clarification from our client, NHS BSA stated:

"We explained how we came up with our data figures, which was from the shielded patient data request provided by NHS Digital. From which we reviewed how many were deliveries were dispensed to shielded patients and then from that we removed multiple deliveries on the same day to the same patient and potential care home deliveries to arrive at our totals."

3.6 No adequate reasons have been given for the decision made. In particular, the reasons do not identify which of the claims are accepted. Our client cannot tell whether there is an overlap in the claims he now considers to be accurate and NHSBSA's own verification. He cannot tell which shielded patient list ("SPL") periods were checked by NHSBSA to verify the claims and whether NHSBSA accounted for any possible lag in data entry on to the SPL. In addition, given that NHS England has access to data regarding each patient's underlying condition and our client does not, NHS England could have sought detailed verification from individual patients records, and there is no indication that they did so.

The appeal

3.7 It is accepted by our client that the claims made between August 2020 and October 2020 should be recovered. Our client had not appreciated the service became limited to a geographical area from August 2020 and accepts the claims were not properly made.

3.8 Our client wishes to appeal against the determination made in relation to the claims between April 2020 and July 2020. The remainder of this letter of appeals relates to those claims.

Background

3.9 Our client runs a busy pharmacy in Blyth in Northumberland; the average number of prescription items per month dispensed by the pharmacy is approximately 25,000. Of these our client estimates that 7,000 to 8,000 items are delivered to patients' homes. (This figure is based on a current average of 300 deliveries per day). Our client currently employs 14 staff. During the height of the pandemic the pharmacy used five delivery drivers although the number employed in 2019 and currently is three.

3.10 Seaton was the only pharmacy in the area with a delivery model of that scale. The pharmacy therefore became a useful resource for local GPs when they needed to get medicines urgently to patients in circumstances where the patient could not collect them from the pharmacy or arrange collection through family and friends. Seaton worked principally with the Railway Medical Group which dispenses over 60,000 items per month. The procedure for referral for delivery was that the prescribing team at the surgery would contact the pharmacy and let them know that a patient was shielding and required delivery. A letter from the Railway Medical Group providing evidence about this is attached.

Entitlement to payment

3.11 The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (the "Advanced and Enhanced Services Directions") were amended on 27 March 2020 to require NHS England to commission a home delivery service from a pharmacy contractor who is to make a delivery of a prescription as mentioned in paragraph 22A(3)(a) of Schedule 4 to the Regulations.

"(3) Where paragraph (2) does not apply, if P's pharmacy premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from P's pharmacy, the home delivery option that P must provide must comprise—

> *(a) P delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);"*

3.12 Paragraph 22A(3)(a) relates to deliveries to eligible patients in an area specified in an announcement made by NHS England with the agreement of the Secretary of State. The announcement must be to the effect that in order to assist in the management of

the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from pharmacy premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

3.13 It is common ground that the service was commissioned across the country from 8 April 2020 to 31 July 2020 and consequently reference to the area specified is not relevant when considering this appeal.

3.14 No issues have been raised regarding compliance with the service specification other than the determination of eligible patients.

3.15 The criteria for an eligible patient is set out in the service specification.

3.16 The service specification states:

"2. Service description

2.1. The Community Pharmacy Home Delivery Service During the COVID-19 outbreak ("the service") is an Advanced Service commissioned under the NHS Community Pharmacy Contractual Framework.

2.2. In line with the shielding policy, patient eligibility is defined by those patients who are deemed to be clinically extremely vulnerable should they become infected with the COVID-19 virus. The full list of eligible patient groups is set out at Annex A.

2.3. Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed clinically extremely vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains eligible for this service."

3.17 Patients who were deemed clinically extremely vulnerable were added to the SPL. NHS Digital generated an updated SPL weekly incorporating additional patient data provided by acute trusts, GP practices and other data sources. Below is a part graph extracted from the NHS Digital site showing the incremental additions to the SPL - https://digital.nhs.uk/dashboards/shielded-patient-list-open-data-set

3.18 GRAPH

3.19 NHS Digital

"Additional information about the SPL - how did the SPL work?

A set of clinical conditions and a supporting methodology were used to determine whether a patient was at high, moderate or low risk of complications from COVID-19 infection. …

Each week, individuals were: ….

added to or removed from the high-risk category by their general practice or hospital consultant depending on their changing health circumstances …"

3.20 Our client received information directly from the prescriber team at Railway Medical Practice indicating that the patient was "shielding". In reliance on that information our client made deliveries to the patients.

3.21 The service specification says that the pharmacy contractor should make "appropriate checks" on eligibility in the context where GPs could be adding patients to the list. Our client's case is that an adequate check was to rely on information received from the GP

surgery about patient eligibility. The information our client received from the surgery was that the SPL and therefore summary care records ("SCR") were not necessarily up to date and the doctors' information was accurate.

3.22 The methodology above from NHS Digital indicates that some of the information that determined whether a patient was put on the SPL was received from GP surgeries. This suggests that the GP surgery would have been correct when suggesting the information that they had was more current than the SPL. Accordingly, the claims below were made.

3.23 The figures

	April 2020	May 2020	June 2020	July 2020	Total
Original Claim	5720	4820	4218	5210	19,968
Adjusted Claim	2491	2192	2393	2194	9,270
Readjusted claim to remove the majority of care home deliveries	2291	1912	2193	1914	8,310
NHSBSA allowed	653	770	809	682	2,914

3.24 Our client checked all the claims made for April, May, June and July against the Summary Care Records in April 2021. He removed all claims where patients did not display a flag indicating that they were clinically extremely vulnerable at that date. He sent spreadsheets setting out the revised claim to NHSBSA.

3.25 He has further removed all claims for care home deliveries except one per month for each care home as he now accepts that delivery to care homes where the patient was a permanent resident was not appropriate. The one delivery a month claimed for is to account for the fact he was delivering to some temporary residents at the care home.

3.26 Our client has not removed claims where more than one delivery was made in the course of one day. As our client had five drivers making deliveries to patients each day and eight wholesale medicines deliveries per day, it was possible that an item would be out of stock in the morning but could be in stock by the afternoon. At that time obtaining medication from wholesalers was unpredictable and the pharmacy often received only part of an order. Because of this, pharmacy policy during the pandemic was to supply what medicine ordered on a prescription immediately if it was in stock and to supply the balance when it was available. In that context, it was good practice to send the medication in stock to the patient without delay and our client should not be penalised for offering a prompt service. NHSBSA appears to have applied an arbitrary limitation on claims made in one day which is not set out in the service specification.

3.27 An adjusted spreadsheet for April has been created and this is attached. Adjusted spreadsheets for May, June and July are in progress which represent the detail of the figures in the table above. In the meantime, our client encloses the spreadsheets that were sent to NHSBSA.

3.28 Our client wishes to appeal against the decision to recover payments by NHSBSA on the following basis:

3.28.1 No detailed reasoning about the NHSBSA decision has been received. Our client cannot tell whether there is an overlap in the claims he now considers to be accurate and NHSBSA's own verification. He cannot tell which SPL periods were checked by NHSBSA to verify the claims and whether they accounted for any possible lag in data entry on to the SPL. There is no indication whether the post verification exercise included checks of the medical history of patients, or

a sample of patients, which would clearly determine whether they were in fact clinically extremely vulnerable.

3.28.2 An incorrect assessment was made by NHSBSA conducting the post verification exercise as it appears they considered the SCR and SPL entry for the month of the claim and disregarded our client's exchanges with the surgery and the pharmacy's own post verification checks. A check should have been made that took account of the possibility of a time lag in data entry.

3.28.3 An incorrect assessment was made in refusing to allow multiple deliveries on one day or for one prescription form.

3.28.4 An incorrect assessment was made in refusing to allow deliveries to care home where temporary patients were resident.

Oral hearing

3.29 Direction 6 of The National Health Service Litigation Authority (Pharmaceutical Remuneration – Payment Disputes) (England) Directions 2022 allows the appellant to ask to make oral representations.

3.30 Our client wishes to reserve his right to make representations at an oral hearing until he has had an opportunity to consider the response from NHSBSA.

Summary

3.31 In summary, our client asks that NHS Resolution allows this appeal and substitutes a decision that reduces the recovery of claims by NHSBSA and reflects the validity of the claims set out in the table above, in total 8,310."

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 8th of March 2023 and the opportunity to provide representations on the appeal.

Background

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

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

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

4.1.5 To allow these patients to receive their prescriptions, an Advanced service known as the Medicine Delivery Service (MDS) was commissioned to provide funding for deliveries of prescriptions to CEV patients. The service was limited to CEV patients when the service was initially commissioned. CEV patients could be identified on their Summary Care Record (SCR) as 'Shielded Patients.' Pharmacies should have also first established whether a friend, relative, carer or volunteer was available to collect the prescription on the patient's behalf before making and claiming for the delivery. As well as protecting the public purse, these arrangements, especially using friend and family to pick up prescriptions, were required to help minimise the risk of COVID infection in this vulnerable group by reducing their contact with others outside of their friends and family.

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

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

4.1.8 In its letter of 30 June 2020 – attached - NHSE announced that the service would be extended so that both pharmacies and dispensing doctors across England will be required to ensure shielded patients can receive a home delivery of their medicines until 31 July 2020. The letter went on to explain that "The provision of this service throughout July will enable patients who are shielding time to make alternative arrangements for access to their prescription medications, after which both the essential and advanced pharmaceutical service, and both elements of the dispensing doctor COVID-19 home delivery service cease to be commissioned."

4.1.9 This and subsequent letters were published by NHSE on its website at: https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-forcommunity-pharmacy/.

4.1.10 Following the publication of each of these letters on the NHSE Website the Pharmaceutical Services Negotiating Committee – the representative body for the community pharmacy sector - also sent an update to its members highlighting the change to the service specification. A summary of the updates that were provided by the PSNC can be found at https://psnc.org.uk/national-pharmacy-services/advancedservices/pandemic-delivery-service/pandemic-delivery-service-archive/

April 2020 to July 2020 claims

4.1.11 In its letter from the 10th of April 2020, NHSE announced the commissioning of the Medicines Delivery Advanced Service, stating that patients who met the shielding criteria who were asked to stay at home and not attend community pharmacies, must be offered a home delivery option for their prescription items.

4.1.12 The letter clearly stated that the MDS was limited to those patients classed as Clinically Extremely Vulnerable (CEV) to Covid. Contractors were required to

make appropriate checks to ensure that patients who received the MDS were on the CEV list e.g., patients could be identified on the SCR as 'Shielded Patients.' The letter also made clear that claims should only be made in the event that no friend, carer, relative, or volunteer is available to collect the prescription on the patient's behalf.

4.1.13 Appendix 1: Section 5. "*The service is restricted to those patients who are covered by the shielding policy1, as set out in Annex A, and will apply across the whole of England. Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed most vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains eligible for this service. The pharmacist can check this on the Summary Care Record.*"

4.1.14 Appendix 1: Section 6. *"Patients who meet the eligible patient criteria, should be encouraged in the first instance to arrange for their medicines to be collected from the pharmacy and then delivered by family, friends or a carer."*

4.1.15 NHSBSA Pharmaceutical Provider Assurance (NHSBSA PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification exercise to ensure that pharmacy contractors claimed correctly for the MDS between the months of April and July 2020 by only claiming for those patients classed as CEV.

4.1.16 The NHSBSA PAT looked at the claims for those contractors who were considered as outliers between the months of April to July 2020 and collated the NHS numbers of all patients who had a prescription dispensed by these pharmacies during this time.

4.1.17 These NHS numbers were then provided to NHS Digital, who cross referenced them against the shielded patient list (SPL) and provided the NHSBSA PAT with the total number of patients who had a prescription dispensed at the pharmacy and who were identified as appearing on the SPL at any time.

4.1.18 The results enabled the NHSBSA PAT to then identify the total amount of prescription forms dispensed by the pharmacy between April and July 2020 to patients classed as 'Shielded'.

4.1.19 The PPV process first started in April 2021. The NHSBSA PAT contacted FLW99 – Seaton Healthcare Limited to request that they review their MDS claims made between April and July 2020. This contact was then paused between the end of June 2021 and June 2022 while additional data from NHS Digital was gathered and to allow time for the NHSBSA PAT to conduct further analysis to model the likely maximum potential number of deliveries. FLW99 - Seaton Healthcare Limited was a contractor the NHSBSA PAT were already aware of in relation to MDS claims as it was the highest claimer nationwide and had almost double the amount of MDS claims as the next highest claimer.

4.1.20 NHS Digital created and maintained the SPL which contained patients in England who were identified as being CEV, including patients identified by their GP or hospital specialist. The list was updated weekly from March 2020 to September 2021. The MDS was only commissioned for CEV patients on the SPL up until the end of March 2021.

4.1.21 The NHSBSA PAT provided the NHS numbers of all patients who had a prescription dispensed between April and July 2020 for those pharmacies that it had identified as outliers and these NHS Numbers were subsequently cross checked by NHS Digital against the SPL in November 2021.

4.1.22 This means that the data obtained by the NHSBSA PAT includes any patient who was ever identified as being on the SPL throughout the course of the MDS being commissioned for CEV patients.

4.1.23 The intention has been for this list of prescription forms dispensed by the pharmacy for its CEV patients obtained from NHSBSA PAT dispensing data and NHS Digital CEV data to be compared against the pharmacy data for its MDS claims. However, for FLW99 - Seaton Healthcare Limited, and other pharmacies identified as outliers this comparison was not possible, despite repeated requests for evidence were made to the pharmacy.

NHSBSA Modelling

4.1.24 For cases where there may be an absence of verifiable data, the NHSBSA PAT had also modelled the likely maximum number of potential deliveries to shielded patients, that the contractor could have made between April and July 2020. This potential number of deliveries has been determined based on the number of prescription forms dispensed to patients identified as being on the shielded patient list at any time, and:

4.1.24.1 For EPS (Electronic Prescription Service) prescriptions - where the patient is identified as living in a care home then all prescriptions for shielded patients to that address on that day, regardless of the NHS number, are considered to be a single delivery. Where prior to the Covid pandemic, it was understood that pharmacies had already been delivering to care homes using any existing business models that they had in place, the NHSBSA PAT has still allowed a MDS fee for the first prescription to that address for each day.

4.1.24.2 For EPS prescriptions - where the patient address cannot be identified as being a care home, then all prescriptions for shielded patients to that NHS number on that day are considered to be a single delivery.

4.1.24.3 For Paper prescriptions – each prescription form for a shielded patient is considered to be a single delivery.

4.1.25 EPS prescriptions allow the NHSBSA PAT to see the dispensed date of a prescription, which enabled the modelling to count all prescriptions from a specific day as single delivery. Paper prescriptions however do not provide a dispensed date, only the month for which the prescription was submitted, therefore a MDS fee has been allowed for each paper prescription to a shielded patient, even though most patients will receive their monthly prescription forms as a single batch.

4.1.26 The NHSBSA PAT have applied a business logic to the modelling by only counting one MDS fee per day for EPS prescriptions to a shielded NHS number, as it would be expected that even if several separate prescription forms were dispensed to the same patient on a given day, these would still be delivered as part of the same journey in most cases.

4.1.27 These maximum potential figures should still be considered as an over-estimate, as it includes:

4.1.27.1 all CEV patients who ever appeared on the SPL so if a patient was removed from the list during the lockdown all prescriptions to the removed patient would still be included,

4.1.27.2 it does not account for any deliveries that would have been made by friends, family, carers or volunteers, as per the requirement in the service specification,

4.1.27.3 It allows a claim for all paper prescription forms dispensed each month even though for many of these patients the forms will have been received as a single batch, dispensed together and delivered to the patient all at once.

4.1.27.4 The NHSBSA PAT allowing a fee each day for deliveries made to a care home, even where these would have already been covered by the pharmacy's usual business model.

4.1.28 This overestimate was accepted by NHSE as giving a fair margin, to enable a reasonable estimate of the deliveries that could be expected given that there may be operational difficulties in managing the deliveries e.g., out of stocks, missed deliveries, replacement of missing items etc.

4.1.29 The NHSBSA PAT model has been used when reviewing the claims of contractors in the absence of data from a pharmacy to show who their CEV patients were and the number of deliveries that were made to those patients during the claim periods investigated.

4.1.30 If the appellant had provided verifiable data of their CEV patients, then that could have been used to compare directly against the SPL.

4.1.31 Table 1 below shows the results of this modelling for FLW99 – Seaton Healthcare Limited.

Table 1

FLW99	April 2020	May 2020	June 2020	July 2020	Total
Pharmacy delivery claims	5720	4820	4218	5210	19,968
Max potential deliveries	653	770	809	682	2914

August 2020 to October 2020 claims

4.1.32 In its letter of 31 July 2020 – attached – NHSE reminded contractors that the Government had published plans on 22 June 2020 for a phased easing of the shielding advice to people who are CEV from 6 July 2020. In specific local outbreak areas, some patients may be advised to continue to follow previous shielding advice after 1 August 2020 (or advised to return to shielding if the pause has previously gone ahead in the area where they live). The NHS will continue to maintain the shielded patient list.

4.1.33 As a result, this letter announced that the Community Pharmacy Home Delivery Service and the Dispensing Doctor Home Delivery Service was commissioned from 1 August until 31 August 2020 for shielded patients who lived in the following local outbreak areas:

4.1.33.1 Leicester lockdown area announced on 29 June 2020.

4.1.33.2 Blackburn with Darwen.

4.1.33.3 Luton.

4.1.34 The letter included links to the post codes where the service was commissioned.

4.1.35 The need for CEV patients to be supported in these lockdown areas varied over the ensuing weeks to 5 October and NHSE issued a series of letters that updated the service specification and the patients eligible for the service. Attached are the letters that updated the service specification from:

4.1.35.1 1 September – 7 September 2020

4.1.35.2 8 September – 23 September 2020

4.1.35.3 24 September – 5 October 2020

4.1.36 The MDS dependant, in terms of eligibility of patients and the geographical areas in which it applies, on the contents of announcements made by NHSE. Pharmacies providing delivery services to those patients affected by these local lockdowns were able to claim a fee for the service under the MDS. This eligibility ceased during this period for pharmacies located and providing delivery services to patients in the rest of the country.

4.1.37 NHSBSA PAT, on behalf of NHSE, were requested to conduct a Post Payment Verification exercise to ensure that pharmacy contractors claimed correctly for the MDS between the months of August 2020 and October 2020 and ensure that any claims made were to patients' resident in an affected area.

4.1.38 The affected postcodes covered by these local restrictions were communicated via service announcements, published by NHSE, ahead of the date that the service was due to be re-commissioned in these areas as outlined above.

4.1.39 As stated in these service announcements:

"Only patients on the Government's shielded list within the areas published in this announcement are eligible for this service. Pharmacies and dispensing doctors should familiarise themselves with the details of the service before making a claim. Evidence of delivery to shielded patients within the areas notified in this announcement, should be retained for post payment verification purposes. We strongly advise that this evidence includes the postcode of the patient's place of residence."

PPV

4.1.40 In the Post Payment verification exercise undertaken by the NHSBSA PAT, FLW99 – Seaton Healthcare Limited, were identified as an outlier when comparing the number of MDS claims made between April and July 2020 with the maximum potential number of deliveries that may have been claimed for CEV patients during this time.

4.1.41 Additionally, the pharmacy continued to claim between the months of August and October 2020, when only pharmacies covered by the NHSE service announcements were able to continue to provide the service.

4.1.42 FLW99 - Seaton Healthcare Limited was the highest claiming pharmacy for the MDS in England during this time, claiming a total of 19,968 MDS claims between April and July, and a further 13,554 MDS claims between August and October.

4.1.43 The pharmacy was contacted on a total of 11 occasions to request evidence to demonstrate that the MDS claims made between April 2020 to July 2020 were claimed for CEV patients only, as specified within the service specification; and also to request evidence that the claims made between August 2020 and 5th October 2020 were for deliveries made to eligible

patients' resident in an area covered by local lockdown restrictions, as specified in the NHSE service announcements.

4.1.44 Emails were sent to the pharmacy shared NHS mail address pharmacy.flw99@nhs.net as required by NHSE. All listed pharmacies must have a valid shared NHSmail account that should be regularly monitored by the pharmacy team as part of their terms of service.

4.1.45 Phone calls were also made to the pharmacy during the PPV process, to confirm receipt of these emails.

4.1.46 The pharmacy did engage with the NHSBSA PAT; however, it did not provide sufficient evidence to demonstrate that the MDS claims made between April 2020 to July 2020 were claimed correctly for eligible patients.

4.1.47 In an email dated from 15/05/21, as well as in a phone call with the NHSBSA PAT on 26/07/21, the pharmacy did acknowledge that an overclaim had been made for the period of August to October 2020, however no response in writing was received from the contractor to confirm that the associated overpayment of £81,324.00 could be recovered.

4.1.48 As such the NHSBSA PAT were then unable to verify that the deliveries claimed met the requirements set out in the service specification; or had the written consent from the pharmacy that it could recover the overclaims admitted by the pharmacy above.

4.1.49 As the NHSBSA PAT had been unable to validate the deliveries claimed by the pharmacy during this time, the details of the case were passed to the NHSE regional team for their Pharmacy Services Regulation Committees (PSRC) to review. A decision was sought as to whether the deliveries made by the contractor were eligible for a payment under the terms of the MDS at the time that the deliveries were made; and if they were not eligible, for the delivery fees that have been paid to be recovered under Regulation 94 (1) (a) as an overpayment.

The PSRC decision

4.1.50 To assist with their review, the PSRC was provided with the service specifications relevant for the April 2020 to July 2020 period which outlined the details of this advanced service. The NHSE service announcements for the August 2020 to October 2020 period were also provided, which highlight the areas of the country that the MDS was still in place, the dates which the service was extended between and the eligible postcodes which deliveries could be made to.

4.1.51 The timeline of correspondence showing all the contacts the NHSBSA PAT had, and attempted to have, with the pharmacy was also provided to the PSRC for review. This timeline has been provided to you in addition to this representation.

4.1.52 This illustrated that FLW99 - Seaton Healthcare Limited was unable to provide sufficient evidence to demonstrate that the deliveries claimed for between April-July 2020 were to shielded patients only and thus eligible for a MDS fee.

4.1.53 The timeline also clearly shows that the premises postcode (NE24 1BD) of FLW99 - Seaton Healthcare Limited did not fall into an area covered by the service announcements during the months of August to October 2020, nor did the pharmacy provide any evidence that the deliveries claimed were made to patient's resident in one of these postcodes.

4.1.54 This was despite the repeated requests made by the NHSBSA PAT to the contractor to provide such evidence.

4.1.55 The timeline also shows that in emails dated from 15/05/21 as well as in a subsequent phone call, that the pharmacy acknowledged that the claims made between August to October 2020 were made in error and agreed that these claims should be recovered.

4.1.56 Consequently, the PSRC concluded that:

4.1.57 As the pharmacy had been unable to demonstrate that it's MDS claims between April to July 2020 were for shielded patients only, and most of the evidence that was provided could not be verified, it accepted the expected maximum which was considered reasonable by the NHSBSA PAT modelling as the level of claims that should have been paid for that period as there was no other information in the timeline to suggest otherwise.

4.1.58 Following this conclusion, the PSRC determined that the pharmacy was not entitled to the payment for which it had received.

4.1.59 Having made this decision, the PSRC then directed that as FLW99 – Seaton Healthcare Limited was not entitled to the payment that the overpayment should be reclaimed pursuant to Regulation 94 (1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.60 In making this decision the PSRC relied on the information that it had before it, following the extensive investigation undertaken by the NHSBSA PAT and the repeated requests to the contractor for evidence of how the MDS claims made for both periods of April 2020 to July 2020 and August 2020 to October 2020 met the requirements set out in the service specification.

4.1.61 In response to the points made in the pharmacy's appeal:

4.1.62 The appeal has been provided by Gordons Partnership Solicitors, who are acting on behalf of the Appellant, Seaton Healthcare Limited ("Seaton") trading as Blyth Healthcare Pharmacy.

4.1.63 They begin the appeal by stating that "*It is accepted by our client that the claims made between August 2020 and October 2020 should be recovered. Our client had not appreciated the service became limited to a geographical area from August 2020 and accepts the claims were not properly made*". They make clear that their client wishes to appeal the decision of NHSE for the period of April to July 2020 and that the remainder of the letter relates to these claims. NHSE therefore understands that that the recovery for payments made between August 2020 and October are not subject to this appeal and as a consequence, the remainder of this representation focuses on the period of April to July 2020.

4.1.64 The appellant asserts that their client runs a busy pharmacy in Blyth, stating that "*the average number of prescription items per month dispensed by the pharmacy is approximately 25,000. Of these our client estimates that 7,000 to 8,000 items are delivered to patients' homes. (This figure is based on a current average of 300 deliveries per day). Our client currently employs 14 staff. During the height of the pandemic the pharmacy used five delivery drivers although the number employed in 2019 and currently is three*."

4.1.65 NHSE appreciate it was a very busy and challenging time for pharmacy contractors serving their patients while at the same time rising to meet the challenge of the Pandemic and the new services commissioned. NHSE are

grateful for the work undertaken to protect patients and other users of the pharmacy, particularly the vulnerable, at this time.

4.1.66 However, NHSE has a duty to ensure that the taxpayer money it has to fund commissioned pharmaceutical services are only used to fund the services directly commissioned. It must be made clear that the MDS was only commissioned to support those patients identified by the Government as CEV as outlined in the MDS service specification. The PPV exercise has then tried to establish that pharmacies have been paid correctly for the provision of this commissioned service.

4.1.67 The appellant goes on to state that "*Seaton was the only pharmacy in the area with a delivery model of that scale. The pharmacy therefore became a useful resource for local GPs when they needed to get medicines urgently to patients in circumstances where the patient could not collect them from the pharmacy or arrange collection through family and friends*."

4.1.68 In the NHSE letter of 10th April 2020 that commissioned the MDS (Appendix 1: Point 11) states, '*This service does not replace any existing delivery services that a pharmacy contractor provides under normal circumstances*.'

4.1.69 The MDS was set up as a temporary service to ensure delivery of medicines to eligible patients who should not present in the pharmacy due to being assessed as CEV. It was not intended to replace any existing delivery service that the pharmacy already had in place prior to the pandemic.

4.1.70 For the avoidance of doubt, NHSE do not dispute the fact that the deliveries have been made, however the NHSBSA PAT have been requested to carry out this work on behalf of NHSE, to ensure that pharmacy contractors have claimed for the service correctly, by only claiming for deliveries made to patients classed as CEV as decided by the Government and outlined in Appendix 1: Annex A of the NHS England letter of 10 April 2020, and therefore eligible for a MDS fee.

4.1.71 The appellant may still have chosen to deliver to other patients; however, this would have been outside of the MDS and should have been carried out using any usual or new delivery methods that the pharmacy would have chosen to put in place. This would then be a private service offered by the pharmacy for which they could include the costs being passed on to the patient or absorbed as part of the overall business costs of the pharmacy.

4.1.72 The appellant has suggested that: "*The methodology above from NHS Digital indicates that some of the information that determined whether a patient was put on the SPL was received from GP surgeries. This suggests that the GP surgery would have been correct when suggesting the information that they had was more current than the SPL*." It should be noted that the SPL was collated from data provided from both primary and secondary care; and NHSBSA PAT reiterates the point that the SPL used to identify CEV patients that used the pharmacy during this period contained the details of all the patients that ever appeared on the SPL during its existence.

4.1.73 The appellant states that the pharmacy worked with Railway Medical group, which "*dispenses over 60,000 items per month*". They state that "*The procedure for referral for delivery was that the prescribing team at the surgery would contact the pharmacy and let them know that a patient was shielding and required delivery*."

4.1.74 Where the appellant has stated that Railway Medical group 'dispenses' 60,000 items per month, NHSE assume this should have been stated as 'prescribed',

as there is nothing to indicate that Railway Medical group dispenses medication themselves.

4.1.75 It is not clear whether each and every delivery request made by the GP surgery to the pharmacy were only for patients classed as CEV only, as per the government's shielding policy, or if the surgery continued to request deliveries using the pre-existing non-commissioned delivery service for patients who were outside the scope of the MDS. The NHSBSA PAT respectively suggest that during such a busy time for both the pharmacy and the practice that requests for deliveries for both CEV patients eligible for the MDS, and non CEV patients who would have been ineligible for the MDS but who would have benefitted from the private delivery service are highly likely to have occurred. It would have been incumbent on the pharmacy to then differentiate between the two request groups to then ensure that only deliveries to the CEV patients were claimed for under the MDS. There has been no evidence provided by the appellant to show how the deliveries for CEV patients were separated from those made under their private service to ensure the accuracy of the MDS claims.

4.1.76 In the letter provided by Railway Medical Group, Dr Peter McEvedy states that "*we have relied heavily on this pharmacy to deliver medicines to our elderly and vulnerable patients during this time*". This suggests that the patients the surgery requested deliveries for was extended to patients other than those identified by the Governments as being CEV, and therefore on the shielded patient list (i.e., as identified by Appendix 1: Annex A.) A number of patients may have requested deliveries or may have had deliveries requested on their behalf by the surgery, who were elderly or considered vulnerable but that does not then mean that they will be classed as CEV and then included on the SPL.

4.1.77 The letter goes on to state that "*They had provided a rapid service which unfortunately was not forthcoming from all the pharmacies in this area and hence they have been used considerably more than might possibly be expected*". As part of their terms of service all pharmacies were required to ensure that CEV patients were able to have their medicines delivered either via patient representatives (friends, family or NHS Volunteers) or via a delivery service organised by the pharmacy. NHSE is not aware of any concerns raised about the pharmacies in the area not fulfilling this requirement.

4.1.78 In contradiction of the point raised above the NHSBSA PAT found that most of the pharmacies within a relative short distance of 2 miles of FLW99 – Seaton Healthcare Limited were performing and claiming for MDS. During the period of April to July 2020, these nearby pharmacies claimed a combined total of almost 1,000 MDS deliveries. These figures are much less than those claimed by the appellant and none of these contractors appeared in our data as having potentially over-claimed for the service. It therefore contradicts the point raised in the letter from Railway Medical Group that "*They had provided a rapid service which unfortunately was not forthcoming from all the pharmacies in this area and hence they have been used considerably more than might possibly be expected*" and suggests that the pharmacy was not required to perform MDS for additional patients, as there were still many pharmacies nearby who were also providing the service to their own patients classed as CEV.

4.1.79 This suggests that FLW99 – Seaton Healthcare Limited was not following the instructions outlined in the service specification and instead was delivering to a wider range of patients than those officially classed as CEV.

4.1.80 The letter also states that "*the patients we have asked to have medication delivered will have all been in the shielded group and have been unable to attend the surgery or the pharmacy*". This part of the letter is confusing. Dr McEvedy has already stated that the practice has "*relied heavily on this*

pharmacy to deliver medicines to our elderly and vulnerable patients during this time" and yet not all elderly and vulnerable patients will meet the definition of CEV as set out by the government, and so be eligible for the MDS. It is also unclear whether Dr McEvedy was aware of the volume of MDS claims submitted by the appellant when the letter was written on 29 July 2021; and therefore, whether he was suggesting that all the 19,968 MDS claims submitted by the pharmacy for April to July 2020 were for delivery to CEV patients on the SPL. There is no mention of specific volumes of delivery requests made by the surgery within the letter which could then support the large number of MDS claims made by the appellant.

4.1.81 It should also be noted that despite including this letter in their appeal, the appellant has accepted that most of the claims made during this time period were incorrect and should be treated as an overclaim and the payments recovered.

4.1.82 The appeal states "*Our client received information directly from the prescriber team at Railway Medical Practice indicating that the patient was "shielding". In reliance on that information our client made deliveries to the patients. The service specification says that the pharmacy contractor should make "appropriate checks" on eligibility in the context where GPs could be adding patients to the list. Our client's case is that an adequate check was to rely on information received from the GP surgery about patient eligibility*."

4.1.83 In the service specification dated 10th April 2020 it clearly states that *"The service is restricted to those patients who are covered by the shielding policy1, as set out in Annex A, and will apply across the whole of England. Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed most vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains eligible for this service. The pharmacist can check this on the Summary Care Record.*"

4.1.84 NHSE accept that the appellant had been requested by the GP surgery to make deliveries to patients, however the service specification makes clear that there is an onus on the pharmacy to carry out appropriate checks to ensure the patient is eligible for the service. NHSE would argue that the responsibility remains with the pharmacy to carry out these checks before claiming an MDS fee and that a reliance on the delivery request from GP surgery in itself does not constitute an appropriate check to confirm that the patient was eligible for the service.

4.1.85 The appellant adds "*The information our client received from the surgery was that the SPL and therefore summary care records ("SCR") were not necessarily up to date, and the doctors' information was accurate*" and "*This suggests that the GP surgery would have been correct when suggesting the information that they had was more current than the SPL*". They also provide a graph showing the incremental additions to the SPL.

4.1.86 The definition of CEV patients was made by the Government and included in the service specification. Considerable work was then undertaken by a number of agencies to ensure this list was robust and contained all of those patients who met the Government's definition of CEV. Each of the patients who were assessed as being CEV were sent a letter confirming their status; as well as their details being stored on the GP record and the SCR.

4.1.87 The potential number of deliveries has been modelled by the NHSBSA PAT based on the number of prescription forms dispensed to patients using the pharmacy identified as being on the shielded patient list at any time. Therefore, the data request takes into account any patient that was assessed as being

CEV throughout the course of the service being commissioned, even if these patients were not identified and recorded on GP systems or the SCR at the start.

4.1.88 The appellant states that "*No issues have been raised regarding compliance with the service specification other than the determination of eligible patients*" and quotes the patient eligibility criteria set out in the service specification.

4.1.89 This assertion is not correct. The service specification dated 10th April 2020 also states that "*Patients who meet the eligible patient criteria, should be encouraged in the first instance to arrange for their medicines to be collected from the pharmacy and then delivered by family, friends or a carer*" and also that "*Where there is no family, friend, neighbour or carer, the pharmacy team must advise the patient of the potential for a local volunteer to act on their behalf who can collect the patient's prescription and deliver it to them*." Appendix 1: Annex B of the service specification gives further information on volunteer support for the delivery of medicines by use of the NHS volunteer responders.

4.1.90 In emails to the pharmacy dated 16/06/22 and 14/10/22, the NHSBSA PAT state that "*Between April and July 2020, the Medicines Delivery Service was limited to those patients classed as Clinically Extremely Vulnerable (CEV) to Covid, who could be identified on the Summary Care Record as 'Shielded Patients'.* ***The service specification also states that claims should only be made in the event that no friend, carer, relative, or volunteer is available to collect the prescription on the patient's behalf***." [emphasis added]

4.1.91 Throughout the PPV process or within the appeal, the appellant has not addressed this requirement of the service specification. It has not given any information on what processes were in place to determine whether a friend, career, relative or volunteer was available to collect the prescription before going on to claim a MDS fee. No information has been provided to demonstrate that any level of conversation took place or what signposting was provided to patients before deciding that a delivery needed to be made under the MDS.

4.1.92 The maximum number of deliveries modelled by the NHSBSA PAT, shows the maximum number of deliveries that may have been claimed based on how many prescriptions were dispensed by the pharmacy to patients classed as CEV, however, NHSE would still expect that a good proportion of these deliveries would have been covered by friends, family, volunteers without the need for a MDS fee to be claimed as was outlined in the service specification.

4.1.93 The appeal explains that the appellant has since reviewed the claims made for April, May, June and July 2020 against the SCR, removing patients who did not display a flag on their SCR to indicate they were CEV, and states that spreadsheets setting out these revised figures had been provided to the NHSBSA PAT previously.

4.1.94 In emails dated 24/06/21 and also on 16/06/22, the pharmacy did provide spreadsheets to the NHSBSA PAT for April, May and June 2020.

4.1.95 These spreadsheets consist of lists of patient names, some with NHS numbers, the date that the delivery was carried out and the number of deliveries claimed. There are also 'weekly' and 'monthly' lists as well as a list for care homes, however no delivery dates, patient NHS numbers or other patient information to enable their verification had been provided for these additional lists.

4.1.96 The pharmacy also provided figures for the total number of 'Shielding' deliveries and the number of 'non-shielding' deliveries for April to June 2020.

No evidence had been provided for the month of July 2020 as the pharmacy stated they were still in the process of gathering the figures.

4.1.97 The pharmacy gave their totals for 'Number of deliveries (shielding)' as April – 2491, May -2192, June – 2393.

4.1.98 When adding up all of 'No of Del' columns in these spreadsheets (including the weekly, monthly and care home lists, which provide no NHS numbers or delivery dates) the figures match the above 'Number of deliveries (shielding)' figures given by the pharmacy. However, at this stage in the PPV process, the pharmacy did not indicate that these were their revised claim figures and in their email from 24/06/21 the pharmacy advised that "*All of the deliveries of non-Shielding patients were made at the request of the GP Surgeries. Predominately Railway Medical, we are waiting for documentation from surgeries to support*".

4.1.99 The appeal then goes on to explain that "*He has further removed all claims for care home deliveries except one per month for each care home as he now accepts that delivery to care homes where the patient was a permanent resident was not appropriate. The one delivery a month claimed for is to account for the fact he was delivering to some temporary residents at the care home*".

4.1.100 The NHSBSA PAT have then interpreted the appellant's adjusted claim figures to be, April – 2291, May – 1912, June – 2193, July – 1914, giving a total of 8310 deliveries.

4.1.101 The appellant advises that an 'Adjusted' spreadsheet has been created for April 2020, however, the adjusted spreadsheets for May, June and July 2020 are still in progress. Therefore, the NHSBSA PAT can only assume that the evidence provided in the appeal for May, June and July is incomplete.

4.1.102 NHSE appreciate the appellant taking the time to review their delivery records and do recognise that in giving their revised claim figures, the appellant has acknowledged that an overclaim of 11,658 deliveries has been made for April to July 2020, which amounts to an overpayment of £69,948.00.

4.1.103 NHSE would highlight that this is the second occasion where the appellant has revised their claim figures, which confirms that the pharmacy was not carrying out the service correctly when making their original claims and that the checks carried out by Railway Medical group did not then result in accurate MDS claims being made by the pharmacy.

4.1.104 The NHSBSA PAT have also reviewed the spreadsheets provided during the investigation and during the appeal and have a number of concerns remain.

4.1.105 The appeal states that "*Our client checked all the claims made for April, May, June and July against the Summary Care Records in April 2021. He removed all claims where patients did not display a flag indicating that they were clinically extremely vulnerable at that date. He sent spreadsheets setting out the revised claim to NHSBSA*."

4.1.106 This is incorrect. The appellant has not sent verifiable evidence of the patients that it has checked against the SCR to the NHSBSA PAT. If they had done so, then the NHSBSA PAT could have then checked this directly against the data it received from NHS Digital in November 2021. Even in the data provided in the appeal, the appellant has still not been able to provide verifiable data of the CEV patients that were eligible for the MDS delivery payments that it claimed for. It is now 22 months since the PPV investigation was instigated with the

pharmacy and still they are unable to provide the data on the CEV patients so that the NHSBSA PAT can verify the deliveries made were appropriate.

4.1.107 Appendix 1 of this representation shows the review conducted by the NHSBSA PAT of the evidence provided by the pharmacy for April 2020, as this is the only month which the appellant has confirmed as complete. The review of this evidence was only able to be carried out for those entries where an NHS number has been provided.

4.1.108 When reviewing the spreadsheet for April 2020, which is the only spreadsheet the appellant has stated is complete, NHS numbers have only been provided for a proportion of patients. The parts of the spreadsheet highlighting 'weekly list' and 'monthly list' do not contain these NHS numbers.

4.1.109 For example, on the April spreadsheet, which the appellant provided to reflect their revised figure of 2291, only 623 NHS numbers have been provided. Where an NHS number, or other patient verifiable data, is not available, the NHSBSA PAT would be unable to accept this as valid evidence, as otherwise there is no way to confirm how many deliveries were then claimed for each individual patient.

4.1.110 The same is true for the spreadsheets provided for the months of May, June and July, however it is not clear what other information needs to be included by the appellant in order for these spreadsheets to be fully completed. It should be remembered that the service specification requires pharmacies to keep evidence of service delivery for post payment verification purposes.

4.1.111 In the evidence provided in the appeal for the month of April 2020, even when totalling up all of the number of deliveries, whether or not an NHS number has been provided, this comes to 2280 which still falls short of the appellant's revised figure of 2291. Therefore, it cannot be said that the evidence the appellant has provided in the appeal is entirely reliable and does not demonstrate how it was confirmed that all of the deliveries claimed for were to CEV patients only.

4.1.112 The appeal also states that "*Our client has not removed claims where more than one delivery was made in the course of one day. As our client had five drivers making deliveries to patients each day and eight wholesale medicines deliveries per day, it was possible that an item would be out of stock in the morning but could be in stock by the afternoon. At that time obtaining medication from wholesalers was unpredictable and the pharmacy often received only part of an order. Because of this, pharmacy policy during the pandemic was to supply what medicine ordered on a prescription immediately if it was in stock and to supply the balance when it was available. In that context, it was good practice to send the medication in stock to the patient without delay and our client should not be penalised for offering a prompt service. NHSBSA appears to have applied an arbitrary limitation on claims made in one day which is not set out in the service specification*."

4.1.113 NHSE accepts there will be occasions where a pharmacy will not have all of the items in stock to fulfil a prescription; and that there will be occasions when patients may get prescription forms at different times of the month. However, these would be the exception and not the normal. It would not be expected that this would be the case for many occasions, considering it was only those patients classed as CEV who were eligible for a MDS fee, and as they were shielding that they would have expected to have limited contact with people outside of their household. This is one of the reasons why pharmacies should have first established whether a friend, family member, carer or volunteer was available to collect the medication on the patient's behalf in the first instance.

4.1.114 It should be noted that the pharmacy policy described is, presumably, the policy for FLW99 – Seaton Healthcare Limited. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 requires pharmacists to make the supply within a reasonable timescale - Schedule 4 paragraph 22(a) 5. As such NHSE does not accept that it was "good practice" to "send the medication in stock to the patient without delay" if that then resulted in multiple deliveries to the same patient over the course of a few days.

4.1.115 The evidence provided by the appellant for April 2020 indicates that some NHS numbers have had multiple deliveries, some on the same date, examples of which can be seen in Appendix 2 of these representations. This does suggest that incorrect record keeping may have led to overclaiming in error as different staff members may have logged the same deliveries under different names.

4.1.116 In the example for patient 1, there have been 10 claims made for the same NHS number, however this is only over 5 days.

4.1.117 The examples for patient 2 and patient 3, show that 8 deliveries have been claimed per NHS number, however only 4 separate delivery dates have been provided for each NHS number.

4.1.118 In the example for patient 4, there have been a total of 19 claims made for this NHS number, however this is only over 10 days.

4.1.119 In all of these examples the patient's name appears to have been entered into the appellant's spreadsheet in different ways. For example, one entry for an NHS number may have the patient's forename recorded and the other entries for that NHS number may be under a surname. This suggests that there may have been further duplication when recording this information, leading to additional overclaims.

4.1.120 There are also instances where there are multiple delivery claims for the same NHS number, however the number of claims exceed the number of delivery dates provided in the evidence. For example, in patient 5 found in Appendix 2 of this representation, there are a total of 12 deliveries claimed for this NHS number, however the appellant has only provided 6 delivery dates in the evidence. Also, in the example for patient 6, there are a total of 3 deliveries claimed for this NHS number, however only 1 delivery date has been provided in the evidence.

4.1.121 Looking at the April spreadsheet alone, there is a total of 1090 claims given by the appellant for those patients where an NHS number has been provided. However, when removing examples such as the above, this gives a total of 919. This is still in excess, but far closer, to the figure provided by the NHSBSA PAT modelling.

4.1.122 The multiple issues highlighted with the evidence provided in the appeal, combined with the fact that the evidence for the months of May, June and July 2020 is incomplete, demonstrates that the revised figures provided by the appellant cannot be considered as reliable and therefore cannot be used to verify that all the delivery claims made met the requirements of the service specification.

4.1.123 The data provided by NHS Digital shows that the total amount of prescription forms dispensed to patients classed as 'Shielded' at the pharmacy during this time was significantly lower than the number of MDS deliveries claimed. This significant difference in claims made against the number of forms dispensed to CEV patients is the concern that NHSE asked the NHSBSA PAT to investigate and verify.

4.1.124 The table 2 below shows the number of patients identified by NHS Digital as being shielded, along with the number of prescription forms dispensed to these patients. It also shows the subsequent maximum potential deliveries that may have been made to these patients as modelled by the NHSBSA PAT and the revised claim figures given by the appellant.

Table 2

	Total prescription forms dispensed	Number of shielded prescription forms	Number of patients identified as shielded	Max potential deliveries to shielded patients	Pharmacy's revised claim figures
April 20	6330	1709	322	653	2291
May 20	5763	1550	303	770	1912
June 20	6132	1687	318	809	2193
July 20	6768	1807	314	682	1914

4.1.125 When comparing the appellant's revised claim figures to the total number of prescription forms dispensed to patients identified as shielded, the appellant's claims are considerably higher in each month. This would mean that even if every prescription form dispensed to a shielded patient, then had a MDS claim against it, the revised figures provided by the appellant would still exceed one delivery per form.

4.1.126 The appellant is suggesting that it was reasonable to have made a claim for each and every prescription they dispensed to a CEV patient between April and July 2020, and that it was necessary to make an average of 7 (April), 6.3 (May), 6.9 (June) and 6 (July) deliveries per month to each of these patients.

4.1.127 Even when taking into account occasions where the pharmacy may have delivered to a patient multiple times a day, this is still a far higher figure than NHSE would expect. The NHSBSA PAT modelling makes assumptions that not all of the medication required to be delivered under the MDS would be delivered in a single delivery to all of the CEV patients. NHSE understand that there will be some operational constraints that will lead to duplication of deliveries in some cases, but not to the extent suggested by the appellant.

4.1.128 Although the appellant has provided revised claim figures within their appeal which shows a significant reduction of their initial claims, which NHSE recognise amounts to a substantial recovery of overpayment, the evidence provided in the appeal does not demonstrate that all of the deliveries claimed were made to CEV patients only, that multiple deliveries to the same patient on the same day were required or that friends, family or volunteers were approached in the first instance to establish whether they could have collected the medication on the patient's behalf.

4.1.129 Even if the NHSBSA PAT was accepting of all the revised evidence provided for the month of April which the appellant has confirmed is correct, they have been unable to actually see how the contractor came up with the revised total of 2291. Accepting evidence on the weekly and monthly lists with only a forename or surname we still only come to the total of 2280, and the NHSBSA PAT therefore consider most of the evidence to be invalid. The NHSBSA PAT are therefore unsure how the appellant was able to come up with this revised total as their evidence does not support the final amount.

4.1.130 The NHSBSA PAT modelling which shows the maximum number of patients which may have received a delivery under MDS is based on the number of prescriptions dispensed to patients on the SPL and the revised claim figures provided in the appeal exceed this considerably. The maximum number of

deliveries modelled by the NHSBSA PAT should really be seen as an over-estimate, as it includes CEV patients if they ever appeared on the SPL. Therefore, even patients who had not been included on the list at the time the deliveries were made, they were still included in the data to produce the "maximum" numbers for the NHSBSA PAT modelling. The modelling also does not account for the proportion of deliveries which NHSE would have expected to have been made by friends, family, carers or volunteers, which allows a considerable margin when calculating the numbers of deliveries that a pharmacy could have reasonably been expected to make to support the MDS.

4.1.131 For these reasons NHSE would respectfully suggest that the maximum figures provided by the NHSBSA PAT are a more realistic figure than the revised claims provided by the appellant in their appeal.

4.1.132 The need for a pharmacy to make appropriate checks to ensure patients are eligible for the service was set out in the service specification. The appellant has not provided any detail in the appeal as to what checks the pharmacy undertook to ensure patient eligibility for the service, other than having a reliance on the delivery requests from the GP surgery, that would then challenge the maximum number of deliveries that the modeling [sic] undertaken by the NHSBSA PAT suggests.

4.1.133 As stated earlier, NHSE appreciate that it has been an extremely busy time for pharmacies and are grateful for the work undertaken to protect vulnerable patients. However, the NHSBSA PAT have been requested to carry out this work on behalf of NHSE, to ensure that pharmacy contractors have claimed for the service correctly by only claiming for deliveries made to patients classed as CEV and therefore eligible for a MDS fee.

4.1.134 In their appeal the appellant has not demonstrated that the deliveries made to the patients that it has claimed for under the MDS meet the eligibility criteria for the service as specified during the time period between the months of April 2020 and July 2020.

4.1.135 Therefore, NHSE maintains that FLW99 – Seaton Healthcare Limited was not compliant with the requirements set out in the service specification in providing adequate records for the purposes.

4.1.136 The claims made by the pharmacy during April to July 2020 were in excess of the maximum potential that could have been claimed, when only patients classed as 'shielding' were eligible. As a consequence of having then been paid for these deliveries to ineligible patients an overpayment had been made. The decision to then recover the overpayment of £102,324.00 for April to July 2020 was then in accordance with the regulations.

Key points for consideration

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

4.1.137.1 The NHSE service specification clearly states that the MDS was restricted to CEV patients covered by the governments shielding policy between the months of April and July 2020. Appropriate checks should have been made by the pharmacy to confirm patient eligibility, which included checking the SCR.

4.1.137.2 The number of MDS claims made by the contractor between the months of April and July 2020 exceeds the maximum potential deliveries figure, which is based on the number of prescriptions dispensed to patients flagged as CEV on the SPL.

4.1.137.3 The appellant attests that the pharmacy relied on the Railway Medical Group making the appropriate checks on whether a patient was shielding or not. It is clear from the service specification that these checks were to be undertaken by the pharmacy delivering the service and claiming the delivery. This suggests the pharmacy did not undertake such checks.

4.1.137.4 The appellant has undertaken two reviews of its delivery logs and has then made two subsequent revisions of the claims that it made for the period of April to July 2020. Both revisions have identified that the pharmacy made a number of MDS that did not meet the service specification and has agreed that the claims need to be significantly reduced. This is confirmation by the appellant that it had not undertaken the appropriate checking when making the original claims; and that any checks undertaken by Railway Medical Group did not result in the accurate claims for the MDS service made by the pharmacy.

4.1.137.5 The latest revision of the pharmacy's MDS claims is only partially supported by data that can be verified by the NHSBSA PAT. However, much of the data supplied cannot be verified and so the NHSBSA PAT respectfully asks that NHS Resolution bases its decision on data that can be verified.

4.1.137.6 When reviewing the verifiable data, the NHSBSA PAT has identified concerns with that data. The NHSBSA PAT does not accept that it is reasonable for a MDS delivery fee to be claimed multiple times for deliveries to the same patients over the course of a few days.

4.1.137.7 The appellant has made an assumption that the SPL used to determine the CEV patients that the pharmacy dispensed to and then subsequently claimed MDS fees for, is the list as it was for the month being investigated. This is not the case. The SPL used contained the details of all the CEV patients that were ever recorded as being CEV. Therefore, even patients who had not been included in the list at the time the deliveries were made, were still included to produce the "maximum" numbers for the NHSBSA PAT modelling.

4.1.137.8 The service specification required the pharmacy to have first established whether a friend, relative, carer or volunteer was available to collect the prescription on the patient's behalf before making a delivery and claiming for a MDS fee. It would be reasonable to assume that a proportion of the CEV patients that were identified as having prescriptions dispensed by the pharmacy would then have had their medicines delivered by a friend, relative, carer or volunteer. In the modelling undertaken by the NHSBSA PAT, these deliveries have not been removed from the "maximum" number of deliveries expected. This is to allow a considerable margin when calculating the numbers of deliveries that a pharmacy could have reasonably been expected to make to support the MDS.

4.1.137.9 The NHSBSA PAT modelling was carefully considered to give an overestimate of the maximum deliveries expected for a pharmacy as it was not able to use pharmacy data for a direct comparison against the Shielded patient's data it held at pharmacy level at that time. The margin of the overestimate in the modelling data was agreed with NHSE to allow for the operational difficulties that a pharmacy would be expected to incur in providing the MDS service.

4.1.138 When applying the NHSBSA PAT modelling to the number of prescription forms dispensed by FLW99 – Seaton Healthcare Limited for their CEV patients then the latest revision of claims made by the appellant is still well in excess of what NHSE expected. NHSE respectfully request that NHS Resolution accept the figures produced from the NHSBSA PAT modelling, in the absence of any meaningful verifiable evidence from the appellant. The appellant has had 22 months since the start of the PPV exercise to the appeal to collate such evidence and has failed to do so."

5 OBSERVATIONS

5.1 GORDONS PARTNERSHIP SOLICITORS ON BEHALF OF THE APPELLANT

5.1.1 "Thank you for your letter of 13 April 2023 enclosing representations from the NHSBSA Pharmacy Provider Assurance Team (NHSBSA PAT). As much of the information contained within the letter was new to my client there are a number of comments rebutting the NHSBSA PAT representation that my client needs to raise.

5.1.2 The background to the MDS service is common ground and we make no comments on that. We note that a number of pages of the representations deal with the August 2020 -October 2020 claims. These comments are irrelevant as it has been accepted in correspondence between the parties and in this appeal that the claims were made on a misunderstanding of the extent of the service at that time and it is accepted that a recovery should be made.

5.1.3 One point arises though:

5.1.4 The post verification exercise was first communicated to our client on 23 April 2021. By 15 May 2021 our client said by email:

"Regarding, the deliveries for August-October 2020:

Would it be possible to arrange the overpayment recovery, for the 3 months above? The pharmacy should not have claimed for these months as we were unaware that this service was prioritised to specified local outbreak areas in which we apologise for the inconvenience and misinformation."

5.1.5 Therefore, although it is acknowledged there was some delay in some of the responses, it is apparent that our client accepted that recovery on these claims was due at a very early stage.

Points raised on letter of appeal.

Scale of delivery service

5.1.6 In response to the appellant's comment that it was the only delivery service of the scale in the area it has been suggested that the claims replaced an existing delivery service. However the delivery service offered by the pharmacy was scaled up to deal with pandemic related deliveries. It was known as an outlier in this respect in the local area and the recognition of the work that the pharmacy carried out resulted in a visit from the local MP.

5.1.7 On receiving the post verification information, the pharmacy individually checked every patient number against the SPL and only included the patients flagged as CEV.

Accuracy of the checks by NHSBSA

5.1.8 Part of the appeal relates to the information lag between to the GP surgery and the SPL. The reason for this is that that NHS BSA said in their email of 20 May (PDF page 221) "*In regards to [sic] the GP practice not updating the SCR to show the 'Shielded Patient' information we can confirm our approach to the data was that any patient who was on the shielded patient list at any point during the months of April to July, their prescription forms will be classed as those required for the vulnerable patients."*

5.1.9 However we note that the NHS BSA now states that

"*the SPL used to identify CEV patients that used the pharmacy during this period contained the details of all the patients that ever appeared on the SPL during its existence*."

5.1.10 This is not the information that was originally communicated to our client. Given that our client checked CEV status in early 2021, the figures for CEV patients from NHS BSA PAT should be the same as our clients. The issue is then about whether modelling is relied on or whether our client is paid for actual deliveries made.

Availability of other services.

5.1.11 NHS BSA PAT has challenged the contention that our client provided a service that was not being provided by other local pharmacies. There are seven pharmacies within 2 miles of Blythe [sic] pharmacy.

5.1.12 Data from the NHS England website lists them as follows:

5.1.12.1 LloydsPharmacy is 0 miles away
Delaval Terrace, Blyth, Northumberland, NE24 1DJ

5.1.12.2 Boots is 0.1 miles away
31-35 Waterloo Road, Blyth, Northumberland, NE24 1BW

5.1.12.3 Boots is 0.1 miles away
60-62 Maddison Street, Blyth, Northumberland, NE24 1EY

5.1.12.4 Boots is 0.2 miles away
Community Hosp & Hlth Ctr, Thoroton Street, Blyth, Northumberland, NE24 1DX

5.1.12.5 Eden Pharmacy & Healthcare Limited is 1.2 miles away
21E Briardale Road, Cowpen, Blyth, Northumberland, NE24 5LB

5.1.12.6 Boots is 1.4 miles away
514 Plessey Road, Newsham, Blyth, Northumberland, NE24 4AA

5.1.12.7 Asda Pharmacy is 1.7 miles away
Cowpen Road, Blyth, Northumberland, NE24 4LZ

5.1.13 The majority of these are large chain pharmacies and our client's recollection is that they used the flexibility in the regulations that allowed temporary closures during the pandemic period to close more frequently than usual. In contrast, our client remained open for its contracted hours for the duration of the pandemic.

5.1.14 It is said by NHS BSA PAT that the surrounding pharmacies claimed 1,000 deliveries between them over the four-month period. This only equates to 71 deliveries per month per pharmacy and suggests that these pharmacies were not delivering to their own CEV patients. It can therefore be seen why the GP

surgery regarded our client's pharmacy as a valuable resource. Accordingly It is refuted that the delivery data from other local pharmacies undermines Dr McEverdy's comment that "*They had provided a rapid service which unfortunately was not forthcoming from all the pharmacies in this area and hence they have been used considerably more than might possibly be expected*."

Onus on pharmacy to carry out checks

5.1.15 It is accepted by our client that the pharmacy needed to be sure that the patient required the delivery. However, as stated in the appeal letter the source of the information was the GP surgery itself. The check with the Summary Care Record was not mandatory; the service specification says "*The pharmacist **can** check this on the Summary Care Record*" (emphasis added), not that the pharmacist **must** check the Summary Care Record. In relation to the checks with the patient as to whether a friend, family or carer could collect the prescription, we are instructed that the pharmacy would make a check with the patient. However this would be a one-time check, once the patient had indicated they needed delivery they would not phone for every delivery. We are instructed the vast majority of patients would not have or want anyone to come to the pharmacy for them. It is felt that the NHS BSA PAT has not taken into consideration the social attitudes during April to July 2020 when there was extreme reluctance to mix with others and support structures were just being developed.

Sending medicines to patients without delay

5.1.16 It is said in the NHS BSA PAT representations that "NHSE does not accept that it was "good practice" to "send the medication in stock to the patient without delay" if that then resulted in multiple deliveries to the same patient over the course of a few days."

5.1.17 This is a surprising statement for two reasons: firstly the representations misquote the obligation on pharmacists under the terms of service – schedule 4, paragraph 5 (2) states that "*P must, with reasonable promptness, provide drugs so ordered*…". The obligation is not about a reasonable timescale, there is a specific obligation to be prompt. Secondly, in the context of the pandemic when there was no confidence about regular delivery of pharmacy stocks from wholesalers, it would not have been reasonable to wait for the all the drugs ordered on a prescription to arrive before delivering as there was often no indication about how long the wait would be.

Concerns remaining regarding errors in data entry

5.1.18 Our client has checked the entries in schedule 2 of the representations and accepts these are errors. They have gone on to check whether there are any other similar errors and have found further errors. The appellant apologises for this and attaches revised figures discussed below.

Methodology and conclusions

5.1.19 We are grateful for the detailed representations received from NHS BSA PAT. It would have been extremely helpful to have this level of information prior to notification of the decision to recover monies so that our client could have understood exactly what was required and why.

5.1.20 It is unfortunate that the respondent has relied on modelling data when initial figures were delivered in June 202, and NHS BSA PAT was given an invitation to visit the pharmacy to inspect all material on 15 May 2021 and 4 August 2021.

5.1.21 Table 2 from the NHS BSA PAT's representations is helpful. We have inserted the appellant's revised figures so that it can be seen that the "real world" figures for number of shielded patients are now extremely close but there is a discrepancy between the actual and modelled number of deliveries.

Table 2 from PDF page 19 with appellant's detailed figures

	Total prescription forms dispensed	Number of shielded prescription forms	Number of patients identified as shielded	Max potential deliveries to shielded patients	Pharmacy's revised claim figures (figures with disputed elements removed)
April 20	6330	1709	322 (341)	653	2,291 (1061)
May 20	5763	1550	303 (352)	770	1912 (557)
June 20	6132	1687	318 (380)	809	2193 (521)
July 20	3768	1807	314 (333)	382	1914 (960)
Totals				2,914	8,310 (3,099)

Method used for appellant's revision to the table:

5.1.22 The suggestion is that the modelling disregards deliveries where more than one delivery is made on the same day. It is our client's recollection and experience that, as stated above, stock deliveries were delayed so medicines for a prescription form could often not be delivered in one batch. It would also be very rare to get the prescriptions for a patient sent from the GP surgery in one or two batches.

5.1.23 On the figures given above it appears that in real terms the NHS BSA PAT has verified, for April 2020, 322 shielded patients who received 1709 prescriptions. That is an average of 5.3 prescriptions per patient per month. The modelling data suggests that there were only 653 deliveries to those patients.

5.1.24 This means that is estimated by NHS BSA PAT that only 2 deliveries per month were required for patients that received 5.3 prescription forms. The appellant considers this to be an underestimate of the deliveries required.

5.1.25 However the appellant has now calculated a figure excluding deliveries made on the same day, any duplication errors and the Monitored Dosage System (MDS) deliveries, and our client's figures are given above in red. The revised spreadsheets documenting these figures with disputed areas removed are attached. Our client's position is that 3,099 is the absolute minimum number of deliveries that should be regarded as verified.

5.1.26 In relation to the weekly and monthly MDS figures that were previously included on the spreadsheets without delivery dates or NHS numbers it is the appellants position that these are shielded patients as they were verified by our client against the SPL in 2021. There were 340 monthly MDS trays for April, May and June and 339 for July. There are also approximately 200 weekly MDS trays - these patients were checked against the SPL. These deliveries account for approximately 800 claims per month. Time constraints have not permitted completion of this data and a second internal check against records held.

Summary

5.1.27 It can be seen that the figures given by NHS BSA PAT and the appellant for shielded patients are very close. The main disagreement relates to the number of deliveries actually carried out. Our client is relying on his actual data and the NHS BSA PAT are relying on modelling. We suggest that the numbers that rely

on actual data should be preferred. The appellant's position is the recovery should be, at the very least, on the basis that deliveries between April and July 2020 totalling 3,099 are verified and accepted. However, our client has provided evidence to suggest that he also delivered monitored dosage systems to many CEV patients and provided an extremely prompt service in the face of supply issues which meant that on some occasions he made multiple deliveries on the same day to some patients. These deliveries are currently not accounted for in the reclaim figures requested by NHS BSA PAT.

5.1.28 The calculation for recovery based on 3,099 claims accepted would be:

19,968 deliveries claimed – 3,099 deliveries accepted = 16,869 deliveries

16,869 claims x £6 = £101,214 deduction.

5.1.29 However it is contented this represents a small proportion of the actual deliveries properly made by the appellant to CEV patients and claimed under the Medicines Delivery Service.

Oral hearing

5.1.30 Although Direction 6 of The National Health Service Litigation Authority (Pharmaceutical Remuneration – Payment Disputes) (England) Directions 2022 allows the appellant to ask to make oral representations our client is content for the appeal to be decided on the papers.

5.1.31 In conclusion, our client asks that NHS Resolution allows this appeal and substitutes a decision that reduces the recovery of claims by NHSBSA and reflects the actual delivery activity carried out by our client."

6 FURTHER COMMENTS

6.1 NHS BSA

6.1.1 "Thank you for your letter of the 9th May 2023 and the opportunity to provide any comments on the observations received from the appellant.

6.1.2 The NHSBSA Provider Assurance Team (PAT) have tried to respond to each of those below in the order that they appear in the response from the appellant.

Scale of delivery service

6.1.3 The appellant stated that "On receiving the post verification information, the pharmacy individually checked every patient number against the SPL and only included the patients flagged as CEV."

6.1.4 It should be noted that the service specification required each pharmacy delivering the service to confirm the eligibility of those patients that the pharmacy claimed the delivery for. However, the appellant appears to be saying that the check against the Shielded Patient List (SPL) was not carried out at the time of the delivery but only after the post verification information was provided.

6.1.5 The NHSBSA PAT are unclear when the appellant is suggesting that this check against the Shielded Patient List (SPL) was completed, and questions the veracity of this check.

6.1.6 The NHSBSA PAT would again like it noted that the total number of CEV patients that it has identified for Blyth pharmacy was found by comparing the

list of all of the patients that Blyth Pharmacy dispensed a prescription for within the sample period of April to July 2020, checked against the SPL that was held by NHS Digital in 2021. This then included every patient that appeared on the SPL at any time.

6.1.7 This then means that the number of CEV patients that the pharmacy could have identified from a check against the SCR for their delivery patients could not have exceeded the number identified by the NHSBSA PAT comparison, unless the pharmacy had made deliveries to patients that it did not dispense to. This is allowed under the service specification, if the pharmacy making the deliveries, was making these deliveries to patients who had their prescriptions dispensed by another pharmacy, or dispensing doctor, and was doing so on their behalf. There has been no suggestion by the appellant that this is the case.

Accuracy of the checks by NHSBSA

6.1.8 The appellant restated that part of the appeal relates to the information lag between the GP surgery and the SPL. Having noted from the NHS BSA representation that the NHSBSA evidence was taken from the full SPL the appellant states,

"This is not the information that was originally communicated to our client. Given that our client checked CEV status in early 2021, the figures for CEV patients from the NHSBSA Provider Assurance Team (PAT) should be the same as our clients. The issue is then about whether modelling is relied on or whether our client is paid for actual deliveries made."

6.1.9 During the post payment verification exercise the appellant was advised that the list of all of the patients that Blyth Pharmacy dispensed within the sample period of April to July 2020 were checked against the SPL that was held by NHS Digital. This then included every patient that appeared on the SPL at any time. The NHSBSA PAT agree that if the pharmacy had checked the patients that they had claimed for against the SCR in 2021 then they would have had the same figures as the those identified by NHSBSA PAT and NHS Digital. If there had been any difference, then the pharmacy figures would have been likely to be lower as that would have been based on those patients that were on the SPL at that point in time. The NHSBSA PAT and NHS Digital figures may have included extra patients who have since been added, and included those that were removed from the list available to contractors to view on the Summary Care Record at any one time. The NHSBSA data encompasses all patients who ever appeared on the list, so is therefore more generous.

6.1.10 Since that comparison was completed, the SPL has not been available to review since 30 June 2022 – see Shielded Patient List - NHS Digital.

6.1.11 Unfortunately, at the expiry of the COPI notice (on 30 June 2022) organisations who received the NHS SPL needed to securely delete the information held except where it formed part of the patient's medical record. As a result, the NHBSA have not been able to use the SPL data since June 2022 to do a direct comparison of the list of the patients that the appellant has provided against the list of CEV patients that the NHSBSA had identified had been dispensed to by Blyth. The NHSBA PAT has had to rely on the modelling of the deliveries based on the total number of CEV patients that it has verified as having prescription dispensed by the appellant during April to July 2020.

Availability of other services

6.1.12 In the response it was stated that the NHSBSA PAT were challenging the contention that the appellant was providing a service that was not available from other local pharmacies.

6.1.13 This is correct, NHSBSA PAT maintain that the other pharmacies in the area provided the MDS. There is claim evidence to demonstrate this, and there were no complaints received by NHS England for this area. So, there is no evidence to suggest that this service was not offered by other pharmacies in the area.

6.1.14 The average claims for the other pharmacies in the area for this service were lower than the national average over the time period of April to July 2020, however they were far closer to the average than the claims submitted by Blyth pharmacy.

6.1.15 This shows that although the pharmacies close to Blyth pharmacy were not claiming for high levels of MDS deliveries, the majority of them were providing and claiming for the service. The NHSBSA PAT therefore strongly refutes the argument suggested by the appellant that the service was not available amongst nearby pharmacies.

6.1.16 This lower-than-average claiming could, quite rightly, suggest that these pharmacies were not making deliveries to all of their CEV patients themselves. They could have been following the service specification and checking with their patients to see if the medication could be collected by family, friends, or NHS Volunteers. This would appear to be the more likely scenario given the absence of any complaints from any CEV patients about a lack of delivery services available.

Onus on pharmacy to carry out checks

6.1.17 The appellant states that they accept the pharmacy needs to be sure the patient required the delivery however, the check with the Summary Care Record (SCR) was not mandatory.

6.1.18 Although the check on the SCR was not mandatory the appellant appears to have missed the point that this was not to confirm if a patient would require a delivery but whether any such delivery was eligible for the MDS. The NHSBSA PAT has repeatedly made it clear that there is no dispute as to whether a patient needed a delivery this is not part of its remit. The service specification is clear that the pharmacy needs to carry out an appropriate check on a patient's CEV status to confirm eligibility for the MDS.

6.1.19 In the service specification dated 10th April 2020 it clearly states that "*The service is restricted to those patients who are covered by the shielding policy, as set out in Annex A, and will apply across the whole of England. Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed most vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains eligible for this service. The pharmacist can check this on the Summary Care Record*."

6.1.20 NHSE accept that a check against the Summary Care Record is not the only check that a pharmacy could have completed, and other checks could also have been undertaken e.g., checking if the patient had an NHS letter to confirm their CEV status. However, it maintains that a reliance on a GP referral is not in itself sufficient. It is not the GP Practice responsibility to be aware of the service specification, and to advise the pharmacy of which deliveries are eligible for MDS and which are not.

6.1.21 In relation to the checks as to whether family, friends or a carer could collect the prescription on the patient's behalf the appellant stated that checks would be made with the patient however this would be a one-time check only, therefore no further checks would be made before any subsequent deliveries. It should be noted that this was an operational decision by the pharmacy, and not an approach suggested in the service specification.

6.1.22 The service specification states in Appendix 1: Section 6 that '*Patients who meet the eligible patient criteria, should be encouraged in the first instance to arrange for their medicines to be collected from the pharmacy and then delivered by family, friends or a carer*.' And in Appendix 1: Section 8 it states, '*Where there is no family, friend, neighbour or carer, the pharmacy team must advise the patient of the potential for a local volunteer to act on their behalf who can collect the patient's prescription and deliver it to them*.'

6.1.23 It is the view of NHSE that it is difficult to believe that there were no occasions at all where patients would not have had family, friends, or a carer able to collect medications on their behalf considering the volume of deliveries made. It must be noted that the volunteer service was also available to deliver any medication if no-one else was available to collect the patients' prescriptions. Again, NHS England find it difficult to believe that if the pharmacy was following the service specification that there would not have been any instances when family, friends, a carer, or an NHS Volunteer would not have been available to support the pharmacy to deliver medicines when needed.

Sending medicines to patients without delay

6.1.24 The appellant states that "*in the NHSBSA PAT representations it is said that NHSE does not accept that it was 'good practice' to "send the medication in stock to the patient without delay" if that then resulted in multiple deliveries to the same patient over the course of a few days*."

6.1.25 The NHSBSA modelling does have excess deliveries built-in to account for occasions where a repeated delivery for out of stocks may be necessary. However, for this to then lead to the repeated deliveries stretches incredulity and cannot be considered reasonable. There are several examples of this in the evidence provided.

6.1.26 For example, one patient in the evidence in the month of April 2020 has 11 separate MDS deliveries with some of these on consecutive days, which were claimed for the dates of 1st, 2nd, 3rd, 6th, 8th the 9th and further. Another example of this, also from April 2020, is a second patient with 10 MDS deliveries claimed for the dates of 1st, 2nd, 3rd, 4th, 6th, 7th, 8th and further, again showing repeated deliveries with some on consecutive days.

6.1.27 This was a time of acute concern for patients generally, and for CEV patients particularly, so it would appear obvious to anyone, but especially for those in a clinical setting, that keeping the number of visits to a CEV patient to a minimum would be essential to reduce the risk of spreading infection at this time.

Concerns remaining regarding errors in data entry

6.1.28 It is stated that "*the client has checked the entries in schedule 2 of the representations and accepts these are errors and has subsequently gone to check whether there are any other similar errors. They have found further errors and provided revised figures*".

6.1.29 The NHSBSA PAT is grateful that the appellant has gone back and checked their figures again, however it should be noted that this is now the third revision of these figures. Each revision has then identified errors and the total number

of claims has been reduced accordingly. Whilst these figures provided by the appellant now are far closer to the figures that the NHSBSA PAT have modelled there is still no evidence provided by the appellant that demonstrates why these figures should be any more accurate than those provided earlier.

6.1.30 The appellant provided revised figures however when these revised figures were reviewed it was apparent that they were still incorrect. The table below shows the outcome after the review of the latest revised figures undertaken by the NHSBSA PAT.

Month	Revised figures with disputed elements removed	Actual figures from data provided by FLW99	Duplicates found in the data provided	Total corrected figures with duplicates removed
April 2020	1,061	977	49	928
May 2020	557	557	16	541
June 2020	521	521	9	512
July 2020	960	960	7	953
Totals	3,099	3,015	81	2,934

6.1.31 The appellant originally claimed for 19,968 MDS deliveries for the period April to July 2020.

6.1.32 On 16th June 2022, the pharmacy provided its evidence to support these claims. However, this only included evidence for the months of April, May, and June 2020; no evidence was provided for July 2020.

6.1.33 The appellant has since revised their claims to 8,310 on 8th March 2023. They stated that they had reviewed that evidence, and this was now correct and included all four months from April 2020 to July 2020.

6.1.34 The appellant then revised their claims again on 9th May 2023, advising these revised figures are correct, and the number of MDS claims being 3,099. Again, evidence was provided; however, this evidence still does not support the revised number of claims.

6.1.35 It should be noted that in this final representation the appellant has referred to the “evidence” that it has provided. This is the copies of their delivery logs provided in pages 6 to 49 of their submission. As stated in our representation the NHSBSA PAT does not dispute that these deliveries were made. However, the NHSBA PAT does challenge the validity of this evidence. It is still not clear how the pharmacy has determined that the patients were CEV and so were on the shielded patient list. The appellant has stated in previous representations that it has completed the necessary checks and that they can confirm that these patients were all on the shielded patient list. It has not however, provided details of how these checks against the SPL were carried out, noting that the SPL has not been accessible since June 2022. If the checks were carried out before June 2022, then surely the appellant would not have provided different figures in their submissions of 16 June 2022 and the 8 March 2023.

6.1.36 Consequently, the NHSBSA PAT respectfully ask that NHS Resolution will treat these latest figures with caution, and that the figures provided by the NHSBSA PAT are used as these are based on the total number of the CEV patients that were ever on the CEV list, is based on the number of forms that these patients had dispensed by the pharmacy. The modelling does not discount the number of deliveries that should have been collected by family, a friend or carer and so there is an "overage" that has been included to allow for repeat deliveries or a "reasonable" number of out-of-stock items.

Methodology and conclusions

6.1.37 The appellant states they are grateful for the detailed representation received from NHSBSA PAT and it would have been helpful to have this level of information prior to notification of the decision to recover monies.

6.1.38 The timeline provided shows the numerous occasions that the NHSBSA PAT tried to engage with the appellant to try and verify the payments for the claims that they had submitted. The NHSBSA PAT made it clear on each of these occasions that the PAT was available to discuss how that verification evidence could have been provided. There is nothing in the representations made by the NHSBSA that would not have been shared with the appellant where necessary during the PPV investigation.

"The appellant has now calculated a figure that excludes deliveries made on the same day, any duplication errors, and the Monitored Dosage System deliveries. The revised figures are that 3,099 is the absolute minimum that should be regarded as verified."

6.1.39 It is helpful that the appellant has revised the figures again for the third time however, they have not provided any objective reasoning or evidence to support this further revision of their claim figures. As such the NHSBSA appreciates this further revision but would stress that there is no further evidence or reasons to explain why NHSR should accept these revised figures as being accurate either.

6.1.40 Unfortunately, the NHSBSA PAT is not able to provide the definitive evidence it had access to in 2021, i.e., the list of the CEV patients that Blyth pharmacy had dispensed to in this period. However, the NHSBSA PAT has provided its modelled figures based on the number of CEV patients which it has been able to retain and would urge NHSR to accept the figures provided by this modelling.

6.1.41 The NHSBSA PAT modelling was carefully considered to give an overestimate of the maximum deliveries expected for a pharmacy as it was not able to use pharmacy data for a direct comparison against the Shielded patient's data it held at pharmacy level at that time. The margin of the overestimate in the modelling data was agreed with NHSE to allow for the operational difficulties that a pharmacy would be expected to incur in providing the MDS service.

6.1.42 It is the appellants position that the weekly and monthly MDS figures previously included on the spreadsheets without delivery dates or NHS numbers are shielded patients that were verified against the SPL in 2021:

"In relation to the weekly and monthly MDS figures that were previously included on the spreadsheets without delivery dates or NHS numbers it is the appellants position that these are shielded patients as they were verified by our client against the SPL in 2021. There were 340 monthly MDS trays for April, May, and June and 339 for July. There are also approximately 200 weekly MDS trays - these patients were checked against the SPL. These deliveries account for approximately 800 claims per month."

6.1.43 NHSE notes that the appellant has stated that they did not check the patient's status on the Shielded Patient List. Instead, it chose to confirm with the GP surgery that the patient needed a delivery. The NHSBSA does not dispute that a delivery was made, or that the pharmacy may have understood from the GP practice that a delivery to a patient was deemed as necessary. However, that is not the same as confirming that a patient was CEV and was therefore on the SPL. The appellant has still not demonstrated how its revised delivery claims meet the MDS eligibility criteria as set out in the service specification.

6.1.44 The appellant also states that approximately 800 claims per month were for patients on the Monitored Dosage System, which were checked against the SPL in 2021. This is confusing and the NHSBSA PAT are unclear why this check was made in 2021, when the claims were submitted in 2020 for deliveries made in 2020. The NHSBSA PAT are also curious as to why these checks have come to light now and were not included in the evidence provide in their revised figures of 16th June 2022 or 8 March 2023. The NHSBSA PAT question whether these figures can now be accepted as “evidence”.

6.1.45 It should be noted that the provision of monitored dosage systems is not a service commissioned nationally by NHS England. However, Community Pharmacies are required to provide “reasonable adjustments” to support patients accessing services provided by the pharmacy under the Equality Act 2010. Part IIIA of The Drug Tariff describes how the single activity fee includes a contribution for provision of auxiliary aids for people eligible under the Equality Act 2010.

6.1.46 The Monitored Dosage System is provided to patients to help them take their medications. Whilst it is indeed possible that some of the patients that have been provided monitored dosage systems services by this pharmacy may be CEV, the provision of monitored dosage systems in itself does not mean the patient is eligible for the Medicines Delivery Service. It appears from the revised figures that the appellant is relying on the number of deliveries of the Monitored Dosage System as their reasoning for their revised MDS claims. This suggests two things: that the appellant is not able to rely on their checks that they state the pharmacy had undertaken at the time of the delivery; and that as a result the revised figures cannot be considered accurate as they are not based on reliable relevant information.

6.1.47 DHSC made the decision of which patients were assessed as CEV and so were eligible for the support that was put in place for this cohort of patients including the provision of the MDS. The groups of patients that were identified as CEV were included in the service specification in Annex B: Eligible patients during COVID–19 outbreak.

6.1.48 The appellant also states that ‘time constraints have not permitted completion of this data and a second internal check against the records held’.

6.1.49 It should be noted that the appellant was required to keep records to support any PPV investigation as stated in the service specification; Section 8.1: The pharmacy contractor must maintain appropriate records to ensure effective ongoing service provision and to support post-payment verification. This should include, as a minimum, details of the eligible patients to whom a delivery was made under this service and the date of the delivery.

6.1.50 The NHSBSA PAT provided the summary timeline to the appellant on 4th October 2022 and again on 1st February 2023 in order that they could provide evidence to verify their claims before the case was referred to the PSRC. Therefore, they have had several months to review, collate, and provide evidence to verify their claims.

Summary

6.1.51 It is noted that the figures given by the NHSBSA, and the appellant are very close, and the appellant states that the main disagreement relates to the number of deliveries carried out.

6.1.52 The NHSBSA do not dispute that the deliveries have been made however, the disagreement is in regard to the number of eligible deliveries that were made under this service.

6.1.53 The appellant states that they are relying on their actual data and the NHSBSA are relying on modelling, and they suggest the numbers that rely on actual data should be preferred.

6.1.54 However, the appellant appears to be relying on data for deliveries made and is now trying to find ways of proving eligibility for MDS payments which are two fundamentally different things. What seems patently obvious throughout the PPV investigation, and the appeal is that the appellant did not have the correct records of CEV eligibility to identify which deliveries were eligible for the MDS and which were not. It also appears to have paid little regard to the need to check for whether deliveries could be made by family, friends, or a carer before making the delivery and then claiming under the MDS.

6.1.55 The NHSBSA has not seen any evidence that the "actual data" claimed by the appellant is data supporting delivery eligibility. The NHSBSA PAT respectively submit that it should be the NHSBSA modelling figure that is used to determine the number of eligible deliveries that this pharmacy should be paid for.

6.1.56 The appellant stated they have provided evidence to suggest they also delivered monitored dosage systems to many CEV patients and provided an extremely prompt service in the face of supply issues which meant that on some occasions he made multiple deliveries on the same day to some patients.

6.1.57 As stated earlier the Monitored Dosage System is not evidence of CEV. An extremely prompt service was not required in the service specification or in the Terms of Service and therefore was inappropriate for a service that was designed to protect CEV patients from the risk of infection.

6.1.58 In conclusion, NHSE respectfully request that NHS Resolution accept the figures produced from the NHSBSA PAT modelling, in the absence of any meaningful verifiable evidence from the appellant.

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

7 ADDITIONAL COMMENTS

7.1 GORDONS ON BEHALF OF THE APPELLANT

7.1.1 "Thank you for your letter of 23 May 2023 enclosing further representations from the NHSBSA Pharmacy Provider Assurance Team (NHSBSA PAT).

7.1.2 Our client believes it has set out its case fully in the appeal and the further representations and accordingly the majority of the representations made by NHSBSA PAT have been addressed in previous correspondence.

7.1.3 However, our client would like to clarify that in respect of the points raised in "onus on pharmacy to carry out checks" it acted in reliance on information from the Railway Surgery that a patient was CEV and required delivery as set out in the original appeal. It was not the case that all delivery patients regardless of CEV status were referred by the GP.

7.1.4 Some comments made by NHSBSA PAT appear to be speculation and not based on evidence. We would ask NHS Resolution to disregard these; examples include the suggestion that the low numbers of claims from the surrounding pharmacies were a result of those pharmacies arranging more collections through family and friends, and the suggestion that there were no supply issues during the pandemic that led to a need for repeated deliveries. Speculation such as this is absolutely refuted by our client.

7.1.5 It is noted that the NHSBSA PAT have no access to their database. Our client has provided patient NHS numbers and dates of delivery so a difficulty for NHSBSA PAT in verifying our client's claim should not result in loss to our client. In addition, access to patient records is still available and it is possible that NHSBSA PAT could have directly checked these. As we have repeatedly said, our client made its own checks against all the patient numbers in early 2021 and verified those listed in the final claim.

7.1.6 In conclusion, our client asks that NHS Resolution allows this appeal and substitutes a decision that reduces the recovery of claims by NHSBSA and reflects the actual delivery activity carried out by our client."

8 ADDITIONAL QUESTIONS

8.1 On 28 June 2023 I wrote to both parties requesting answers to a set of additional questions which I felt were necessary in order to properly understand the circumstances and facts of the Appeal.

8.2 In its answers, Gordons Partnership Solicitors on behalf of the Appellant stated:

8.2.1 "Thank you for your letter of 28 June 2023 raising queries to be answered by our client. Our client's response is as follows:

8.2.2 **When receiving delivery instructions from the GP surgery, as indicated in your submissions, how was the assurance that the patient in question met the necessary CEV requirements provided?**

8.2.3 The delivery instructions our client received from the GP surgery were initiated by Dr McEvedy, who it is understood gave instructions to surgery colleagues Russell Tong and Liam Riddell to contact the pharmacy to see if the pharmacy could make the deliveries. This was done via a telephone call to the pharmacy dispensing team. When the arrangement first arose, the pharmacy would check the Summary Care Record, but would often find that the person the surgery was indicating was shielding was not listed in the SCR. The pharmacy team would check with the surgery that this individual should be treated as shielding or clinically extremely vulnerable. Confirmation was received that it was appropriate to deliver. The explanation given was usually that there was a backlog in registering people as shielding and the pharmacy was told that the surgery would make sure that the person was recorded as CEV in the future. It later emerged that the surgery could not directly change the record.

8.2.4 The pharmacy also raised the issue of inconsistency between surgery instructions and SCR with the GPhC (an individual named Faiyaz referred to at p89 of the bundle) and was told to make the delivery and claim for it in reliance on the surgery's instructions. This was raised with NHS BSA in May 2021.

8.2.5 **Was there confirmation from the GP for every single delivery made that has been claimed for?**

8.2.6 Subject to any inadvertent data entry errors, our client believes that there was confirmation from the GP surgery for each delivery made and claimed for.

8.2.7 **Can you provide explicit confirmation from the GP practice that each delivery they requested met the requirements for clinically extreme vulnerability, if so please provide the GP's written confirmation?**

8.2.8 Our client has contacted the surgery to obtain written confirmation, but Dr McEvedy has retired from his role as senior partner and our client has not yet received a response from the practice manager. It should be noted that Dr

McEvedy has already confirmed that "*The patients that we have asked to have had medication delivered will have been in the shielded group and have been unable to attend surgery or the* pharmacy."

8.2.9 You have indicated that checks were carried out regarding clinical vulnerability using the Summary Care Records in 2021:

8.2.9.1 **Was this carried out for every single delivery claimed?**

8.2.9.2 Yes

8.2.9.3 **How was this carried out?**

8.2.9.4 Harpreet Kullar and some of the pharmacy team came in on several weekends to check every name on the delivery sheet against the Summary Care Record. The pharmacy team put the results on spreadsheets that were sent to NHS BSA.

8.2.9.5 **Why was this not carried out before the delivery was made?**

8.2.9.6 Summary Care Records were checked on occasions prior to the delivery being made but inconsistencies arose and, as discussed above, instructions by the doctor were relied on.

8.2.9.7 **Did you send the updated spreadsheets amended after the SCR check to NHS BSA and if so, did they contain patient identifiable information such as NHS numbers for each patient? If not, why not?**

8.2.9.8 The initial spreadsheets were created after the SCR check. These covered the months of April, May and June. These were sent to NHSBSA and did contain patient identifiable information such as first name, surname, and NHS number for the majority of patients. It was thought that this information was sufficient and NHSBSA would have access to databases where they could verify the claims on the basis of the information provided.

8.2.9.9 **Can you explain why no patient verifiable data has been submitted at any point regarding the monitored dosage system deliveries? Was any other patient verifiable data for these deliveries provided to NHS BSA or NHS England to enable them to check eligibility?**

8.2.9.10 Spreadsheets in relation to MDS deliveries have been submitted to NHS BSA - the MDS deliveries are on the initial spreadsheets marked weekly and monthly. These contained first name and surname.

8.2.9.11 It was a hugely labour-intensive exercise to produce more information as the pharmacy had to open up PMR record for the patient and extract further data. The pharmacy was extremely busy with limited resources.

8.2.10 We hope this satisfactorily answers the queries raised but if there is anything further our client is happy to assist."

8.3 In its answers, the NHSBSA stated:

8.3.1 "Thank you for your letter of the 28th June 2023 which requested further clarification regarding a few specific issues.

8.3.2 **Please see our response below to the questions raised**: -

8.3.3 "**Your records indicate that the appellant provided delivery records in 2021 that contained NHS Numbers.**"

8.3.3.1 "**Can you confirm that this is the case?**" – Yes, that is correct, the contractor provided evidence on 24/06/21 (and same again on 16/06/22 and both these dates are already referenced in our representation and included on the timeline of contact held with the pharmacy).

8.3.3.2 However, this evidence was incomplete. It only covered the period of Apr-June 2020, despite repeated requests, evidence to support the claims for July were not provided. Where records were provided not all entries included an NHS number:

- the April data only showed 699 NHS numbers for the 5720 MDS claims made.
- May had 695 for the 4820 MDS claims made.
- June had 588 for the 4218 MDS claims made.
- July has no records but 5210 MDS claims were made.

8.3.3.3 The records provided also did not include the date of delivery in many cases.

8.3.3.4 No NHS numbers or delivery dates were provided for the 'weekly' or 'monthly' lists, nor were they given for the care home lists.

8.3.3.5 "Were these records ever compared to the SPL for verification? If not, why not?" – The NHS numbers that were provided in 2021 were not compared against the SPL. This is because at that time the PAT were engaging with the contractor and had been informed that the contractor would provide the PAT with a more complete set of records that would enable a full comparison. At this point, the PAT had no reason to doubt that this information would be forthcoming. An email was received from the contractor on 27/05/2021 which stated they require more time to compile their lists for June and July, and a further email was received on 24/06/2021 which included the June review figures. However, they also stated they were still compiling their figures for July. Despite the best efforts of the PAT, it did not receive the full amount of evidence to cover the full time-period of Apr-Jul. The timeline provided shows that repeated requests were made to the contractor for this data set but regrettably no further evidence was ever received from the contractor. The PPV process first started in April 2021. The NHSBSA PAT contacted FLW99 – Seaton Healthcare Limited to request that they review their MDS claims made between April and July 2020. This contact was then paused between the end of June 2021 and June 2022 while additional data from NHS Digital was gathered and to allow time for the NHSBSA PAT to conduct further analysis to model the likely maximum potential number of deliveries.

8.3.3.6 NHS Digital held the shielded patient list and had made it clear that this list could not be shared with the NHSBSA. However, NHS Digital would run data provided by the NHSBA against the shielded patient but only when necessary. The NHSBSA, acting in good faith, waited on the contractor to provide the full data set before seeking to run the comparison against the NHS Digital data. The NHSBSA understood that it had less than 10% of the NHS numbers of the patients that has been claimed for over this time period, and that the outstanding data was being collated by the pharmacy to support the verification process.

At the time it seemed right to get a fuller data set before doing the comparison.

8.3.3.7 "**Was any form of direct comparison verification carried out, or is there only the modelled figures?**" – No direct comparison was made using the NHS numbers provided in the contractor's evidence as this was an incomplete data set. The PAT had hoped that a complete data set would have been provided so that a direct comparison verification could have been made. However, access to the SPL was then restricted by the (Control of Patient Information) Regulations 2002 (COPI) expiring from 30th of June 2022. This meant that the legal basis for processing personal data related to the national policy for shielding patient purposes had ceased, and therefore the legal basis for NHS Digital to be able to share details of the shielded patient list was no longer applicable. If the contractor had responded during the initial engagement, we could have made a direct comparison of the data. The NHSBSA had requested several extensions to access the shielded patient list data prior to the expiration of the COPI notice but these were not granted. Access to the data is now only available to the Covid Enquiry.

8.3.3.8 A direct comparison was made against the NHS numbers of all patients who had a prescription dispensed by the pharmacy between Apr-Jul 2020 and this was then used to model the maximum likely number of deliveries.

8.3.3.9 Our process was to obtain the shielded patient data from NHS Digital and compare that against MDS claims made by the pharmacy. This process would have highlighted any patient who was on the shielded patient list at any time as any prescription dispensed to them would have been classed as an acceptable claim.

8.3.3.10 This means even if patients were removed from the shielded patient list during that four-month time period we would have continued to accept claims for those patients as acceptable in our data.

8.3.3.11 Even looking at the total number of prescriptions that were dispensed in this time period to patients identified as being on the shielded patient list, this only comes to 6753 prescriptions (for the 1257 patient's identified as being on the SPL), which is far short of the figures given by the contractor in their revised claim.

8.3.3.12 **"With the Appellant having now submitted detailed records, is there any way for you to now confirm the CEV status of the patients for the deliveries claimed?"** – No

8.3.3.13 "**If not, why not?**" –

- The PAT has not been able to cross check the evidence provided as part of the appeal against the SPL due to COPI notice expiring. Despite the best efforts by the PAT, it has not been possible to gain permission from NHS Digital to run this comparison. As a result, the PAT has used the NHSBSA modelling as it best attempt to estimate a maximum total of deliveries that would reasonably be expected to be claimed by this contractor as explained in earlier representations.

- It should be noted that the appellant has not provided any detail as to how they have confirmed the patient's CEV status; and that that they have revised the number of patients they believe were

CEV on three occasions. For each of these revisions the appellant has provided no new evidence or reasoning as to why the updated list of CEV patients is any more accurate than the previous one; or provided any evidence or reasoning as to why the modelling provided by the NHSBSA should not be accepted.

8.3.3.14 Further, the appellant has made no attempt to show how they have worked with friends, family, volunteers etc, as a first option to provide deliveries to CEV patients before claiming for a MDS fee."

9 FURTHER OBERSERVATIONS

9.1 Both parties were provided with the opportunity to provide further observations in relation to the statements made by either party.

9.2 In its further observations, Gordons Partnership Solicitors on behalf of the Appellant stated:

9.2.1 “Thank you for your letter of 21 July 2023 enclosing the response received from NHSBSA.

9.2.2 In summary it appears that for almost a year (from 24 June 2021 (see page 76 of initial bundle)) NHSBSA had our client’s patient identifiable data for April, May and June but did nothing to verify it. The email of 24 June 2021 was the point at which our client set out the numbers of shielding patients for which claims were made and provided supporting spreadsheets.

9.2.3 When, in 2022, it became apparent that there was limited time to verify this information against the SPL, at the very least, a sample should have been checked by NHSBSA. Alternatively, our client should have been notified of the position. In the circumstances, the appeal should be upheld in relation to the claims that were confirmed by our client in 2021 but not checked by NHSBSA although they were able to do so between 24 June 2021 and 30 June 2022. Our client additionally relies on the grounds of appeal set out in previous correspondence.

9.2.4 We repeat our client’s request that NHS Resolution allows the appeal and substitutes a decision that reduces the recovery of claims by NHSBSA and reflects the actual delivery activity carried out by our client over the period April to July 2020.”

9.3 In its further observations, the NHS BSA stated:

9.3.1 “Thank you for your letter of the 21st July 2023 which provided a copy of the appellants response to the questions raised with them. Our comments on this are as follows:

9.3.2 **When receiving delivery instructions from the GP surgery, as indicated in your submissions, how was the assurance that the patient in question met the necessary CEV requirements provided?**

9.3.3 It appears from the response given to this question that the pharmacy was stating they were following the lead of the GP Surgery for meeting the requirement of who was eligible for the service rather than confirming the eligibility themselves e.g., by checking the information on the Summary Care Record (SCR), or the patient letter confirming their CEV status at the time of delivery.

9.3.4 The pharmacy also responded stating: -

9.3.4.1 "*The pharmacy team would check with the surgery that this individual should be treated as shielding or clinically extremely vulnerable. Confirmation was received that it was appropriate to deliver.*"

9.3.5 From PAT's perspective and as outlined in the service specification for the service the appropriateness to deliver is not confirmation that the patient is clinically extremely vulnerable as defined by the Govt guidance and so eligible for the service. This point also fails explain how the pharmacy goes about preparing the delivery to the patient and checking whether friends, family or the volunteer service were available to perform the delivery as outlined in the service specification. It is clear these steps should be performed alongside any confirmation that a patient is classed as CEV and therefore qualifies as a potential MDS delivery.

9.3.6 The pharmacy also suggests in answer to the questions that: -

9.3.6.1 *"It later emerged that the surgery could not directly change the record".*

9.3.7 It is the understanding of PAT and NHS England that clinicians could add any patient to the shielding patient list providing they met the Govt criteria for CEV. If these patients were not added to the shielding patient list it suggests that these patients did not meet the CEV criteria, and hence not eligible for a MDS delivery.

9.3.8 **Was there confirmation from the GP for every single delivery made that has been claimed for?**

9.3.9 The pharmacy have not produced any evidence to show this so no further comment from PAT.

9.3.10 **Can you provide explicit confirmation from the GP practice that each delivery they requested met the requirements for clinically extreme vulnerability, if so please provide the GP's written confirmation?**

9.3.11 In response to this question the pharmacy stated: -

9.3.11.1"*Our client has contacted the surgery to obtain written confirmation, but Dr McEvedy has retired from his role as senior partner and our client has not yet received a response from the practice manager. It should be noted that Dr McEvedy has already confirmed that." "The patients that we have asked to have had medication delivered will have been in the shielded group and have been unable to attend surgery or the pharmacy."*

9.3.12 Whilst it is significant that the pharmacy has not been able to provide explicit confirmation from the GP practice that each delivery they requested met the requirements for clinically extreme vulnerability the NHSBSA PAT would still maintain that the responsibility for confirming the eligibility for the deliveries was with the pharmacy not the GP surgery. We have already addressed this re the surgery is not responsible for confirming eligibility and this was raised in our original representation on page 12 [paragraph 4.1.83 above]:

9.3.12.1In the service specification dated 10th April 2020 it clearly states that "*The service is restricted to those patients who are covered by the shielding policy1, as set out in Annex A, and will apply across the whole of England. Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed most vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains*

eligible for this service. The pharmacist can check this on the Summary Care Record."

9.3.13 NHSE accept that the appellant had been requested by the GP surgery to make deliveries to patients, however the service specification makes clear that there is an onus on the pharmacy to carry out appropriate checks to ensure the patient is eligible for the service. NHSE would argue that the responsibility remains with the pharmacy to carry out these checks before claiming an MDS fee and that a reliance on the delivery request from GP surgery in itself does not constitute an appropriate check to confirm that the patient was eligible for the service.

9.3.14 **You have indicated that checks were carried out regarding clinical vulnerability using the Summary Care Records in 2021:**

9.3.15 **Was this carried out for every single delivery claimed?**

9.3.16 The pharmacy responded yes to this question however this is contradicted in the contractors original appeal information and information provided by Gordon's solicitors –

9.3.16.1"*Between this period of April 2020 and July 2020, we were inundated with phone calls from Railway medical Practice, Blyth to deliver medication. We asked Railway Medical are these patients deemed clinically extremely vulnerable (CEV) to covid and the answer received was YES, please deliver. At this time, as you can imagine pharmacies were extremely busy and our pharmacy relied on Railway Medical to instruct which patient is CEV or not. At this period, we had no method of checking up to date Summary Care Records. We were informed SCR, we are not up to date and had to rely information from Railway Medical, Blyth."*

9.3.16.2"*It is accepted by our client that the pharmacy needed to be sure that the patient required the delivery. However, as stated in the appeal letter the source of the information was the GP surgery itself. The check with the Summary Care Record was not mandatory; the service specification says "The pharmacist can check this on the Summary Care Record" (emphasis added), not that the pharmacist must check the Summary Care Record."*

9.3.17 **How was this carried out?**

9.3.17.1"*Harpreet Kullar and some of the pharmacy team came in on several weekends to check every name on the delivery sheet against the Summary Care Record. The pharmacy team put the results on spreadsheets that were sent to NHS BSA.*"

9.3.18 In response the PAT must ask what spreadsheets are these?

9.3.19 If these were the original spreadsheets the pharmacy provided as evidence to support their claims, we are unclear why the appellant has then three times revised the number of claims that it says it made that were eligible for the service. The evidence is inconsistent at best and therefore a main reason why we felt unable to trust the contractor's evidence to support the number of claims and instead believe the data highlighted by PAT is a fair reflection of the true number of CEV patients and forms dispensed to those patients.

9.3.20 **Why was this not carried out before the delivery was made?**

9.3.21 No comment from PAT on the contractors response again it goes against the previous answer confirming they checked the SCR for every delivery.

9.3.22 **Did you send the updated spreadsheets amended after the SCR check to NHS BSA and if so, did they contain patient identifiable information such as NHS numbers for each patient? If not, why not?**

9.3.23 In response to the question above the pharmacy stated: -

9.3.23.1"*It was thought that this information was sufficient and NHSBSA would have access to databases where they could verify the claims on the basis of the information provided."*

9.3.24 The NHSBSA was assured by the pharmacy that further evidence would be forthcoming and so waited for this before conducting a direct comparison, we would not do any direct comparison without receiving the full amount of evidence requested by the contractor. A full month of evidence (July 2020) was not provided even after further prompting by PAT. That evidence was only received by PAT during the appeal representation window. Because of this the time it became clear that no more evidence would be forthcoming the window for a direct comparison was closed – due to the COPI notice – and so we had to rely on the NHSBSA modelling.

9.3.25 **Can you explain why no patient verifiable data has been submitted at any point regarding the monitored dosage system deliveries? Was any other patient verifiable data for these deliveries provided to NHS BSA or NHS England to enable them to check eligibility?**

9.3.26 The pharmacy responded to this query stating that: -

9.3.26.1"*Spreadsheets in relation to MDS deliveries have been submitted to NHS BSA – the MDS deliveries are on the initial spreadsheets marked weekly and monthly. These contained first name and surname. It was a hugely labour-intensive exercise to produce more information as the pharmacy had to open up PMR record for the patient and extract further data. The pharmacy was extremely busy with limited resources."*

9.3.27 Again, we re-iterate that supply of Monitored Dosage System does not then mean a patient is CEV and therefore was eligible for the service. The PAT is not disputing that the deliveries actually took place but instead whether they were eligible for a service that was clearly defined. In this case the evidence provided by the contractor does not show that patients on monitored dosage systems were classed as CEV. Alongside that as previously mentioned even if a patient requiring regular deliveries was CEV, PAT would still expect the contractor to check if friends/family or the volunteer service was available before claiming the delivery as MDS.

9.3.28 If you require anything further to help in these deliberations please let me know."

10 CONSIDERATION

10.1 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.

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

10.2.1 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

10.2.2 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).

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

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

10.3.2 the grounds of the appeal are valid.

10.4 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:

10.4.1 a hearing is unnecessary; or

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

10.5 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.

10.6 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.

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

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

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

10.10 It is clear to me that the home delivery service is dependant in terms of eligibility of patients and the geographical areas in which it applies on the contents of announcements made by NHS England. The NHS BSA has provided copies of these announcements.

10.11 I note that this Appeal can be divided into two main elements:

10.11.1 the 19,968 deliveries claimed for that occurred between April 2020 and July 2020, to the value of £119,808.00; and

10.11.2 the 13,554 deliveries claimed for that occurred between August 2020 and October 2020, to the value of £81,324.00.

10.12 In relation to the latter claims, I note that there is no dispute between the parties that the deliveries did not take place in an area affected by local lockdown restrictions. Therefore, these deliveries were outside of the scope of the home delivery service. I consequently determine that the amount of £81,324.00 should be recovered from the Appellant in relation to these deliveries if it has not already been recovered.

10.13 I will next consider those deliveries that occurred between April 2020 and July 2020. I note that there is no dispute that at the time the deliveries took place in an area affected by lockdown restrictions – as the entire country was in lockdown. Therefore, this Appeal relates purely to matters of eligibility.

10.14 I note that the service specification has been provided by the NHS BSA, it states:

10.14.1 2.2."2.2 *In line with the shielding policy[4], patient eligibility is defined by those patients who are deemed to be clinically extremely vulnerable should they become infected with the COVID-19 virus. The full list of eligible patient groups is set out at Annex A.*

10.14.2 2.3. 2.3 *Pharmacy contractors should be aware that GPs have the ability to remove or add patients to the list of those deemed clinically extremely vulnerable as their clinical condition changes. Appropriate checks should therefore be made to ensure that the patient remains eligible for this service."*

10.15 Annex A provides:

10.15.1 *"Patients should have been notified via a letter, sent out by NHS England and NHS Improvement or their general practice or hospital consultant, and will be asked to contact their pharmacy if they need to have their prescriptions delivered.*

10.15.2 *The delivery service must only be provided to the following groups of patients:*

10.15.3 *Solid organ transplant recipients*

10.15.4 *People with specific cancers:*

10.15.4.1*People with cancer who are undergoing active chemotherapy or radical radiotherapy for lung cancer*

10.15.4.2 *People with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment*

10.15.4.3*People having immunotherapy or other continuing antibody treatments for cancer*

10.15.4.4*People having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors.*

10.15.4.5*People who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs.*

10.15.5 *People with severe respiratory conditions including all cystic fibrosis, severe asthma and severe COPD*

10.15.6 *People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as SCID, homozygous sickle cell)*

10.15.7 *People on immunosuppression therapies sufficient to significantly increase risk of infection*

10.15.8 *People who are pregnant with significant congenital heart disease*

10.15.9 *People who have been added to the list by their GP because of the very high risk (in line with the risk of those above) to them associated with COVID-19"*

10.16 I will therefore consider how the above specification has been complied with in regard to the deliveries in question. However, as an initial point I consider it important to set out exactly how many deliveries are in dispute. This is because, having considered all of the correspondence between the parties and the submissions as part of this Appeal, I note the number of deliveries eligible under the home delivery service has been revised several times. The initial claim was for 19,968 deliveries, this was then reduced to 8,310 in the letter of Appeal due to removing "*the majority of care home deliveries*". In observations, however, this figure was further reduced to 3,099. The reasons given for this is that it removes errors and "*deliveries made on the same day, any duplication errors and the Monitored Dosage System (MDS) deliveries*". Nevertheless, I note that the Appellant continued to state that both the monitored dosage system and multiple same day deliveries should properly be considered eligible for payment under the service.

10.17 I note that the NHS BSA has calculated a maximum of 2,914 eligible deliveries based on its modelled figures; I will consider the specifics of this modelling later in this determination. Therefore, the difference between the Appellant's lowest figure and the NHS BSA modelled figure is 185 deliveries, not taking into account the monitored dosage system. I note that the NHS BSA has not sought recovery of the entirety of the amount paid to the Appellant, despite the fact that several of its statements contend that there was a lack of compliance by the Appellant to the specification. Therefore, I will only consider these statements in light of how they impact the accuracy and reliability of the Appellant's figures, and make no determination as to whether the specification was or was not complied with on the whole.

10.18 I will start by considering the monitored dosage system and same day deliveries, as they relate directly to the total figure claimed by the Appellant. I note that the Appellant initially provided the NHS BSA with tables setting out "MDS Deliveries". I consider that this is somewhat confusing as the acronym for the home delivery service as used by the NHS BSA in its comments is the MDS (Medicine Delivery Service). I will therefore continue to refer to the monitored dosage system in its full form to avoid confusion.

10.19 I note that there are four tables provided by the Appellant, one for each month, the monitored dosage system deliveries appear at the end of each of these. The first two, April and June are divided into weekly and monthly and labelled MDS (presumably monitored dosage system), the second two are the same but are not labelled. I will therefore assume that all four relate to the monitored dosage system deliveries. I note that the first three tables were provided to the NHS BSA by way of an email on 24 June 2021. The month of July was only provided as part of the Appeal.

10.20 I have considered the information in the tables, and note that in the original versions only the patients first and last name was provided. When they were provided as part of the Appeal, the first or last name of the patient was redacted, which means that for the month of July only one name has been provided (it is unclear which). The table provides for the columns: surname, firstname [sic], NHS Number, Address, Address, Address, Post code, No of Del and Covid Del. I note that only surname, No of Del and Covid Del has been completed for the monitored dosage system deliveries, leaving the rest of the table blank.

10.21 The reason that I consider this important is that the specification for the service sets out what data needs to be recorded as a minimum to allow for post-payment verification. These are:

10.21.1 Details of the eligible patients to whom a delivery was made;

10.21.2 Postcode of the address; and

10.21.3 Date of delivery.

10.22 It is unclear what exactly "*details of the eligible patients*" may entail, but I would expect this to be at the very least the patient's name, and most likely the NHS number. The wording of the specification is clear that it must be appropriate to allow post-payment verification; I would consider that the minimum information would be that which would allow for an individual patient to be identified.

10.23 The Appellant has stated that it was unable to provide further information in relation to these monitored dosage deliveries because of limited resources. Given the specification's record keeping requirements, the provision of this information should not have required any additional work as the records should have been kept for each of these deliveries and readily available. I consider that a first and/or last name, in isolation, is not suitable to enable post-payment verification by the NHS BSA as it would be difficult to know if the correct patient was being reviewed (due to the likelihood of other persons within England having the same name) and which deliveries or prescriptions were being claimed. Therefore, I determine, in support of the NHS BSA's decision, that the monitored dosage system deliveries are not suitable for reimbursement, due to a lack of evidence supporting that the deliveries were suitable for repayment.

10.24 The Appellant has stated that it frequently delivered medication in multiple deliveries in order to expedite the receipt of the prescription by the patient. Its original tables of deliveries showed these deliveries, with the NHS BSA noting multiple instances of this. The NHS BSA has disputed the necessity of these deliveries and in its observations the Appellant has subsequently removed these duplicate same day deliveries to calculate its revised figure. However, while the Appellant has provided a reduced figure it still states that these multiple deliveries should be accounted for, and that the 3,099 represents a minimum possible amount. I will therefore consider these multiple same day deliveries.

10.25 I note that the service specification states:

10.25.1 "*7.3 The pharmacist should use their clinical judgement, based on the information presented to them, to take into account the clinical need of the patient and the urgency with which the prescription item(s) should be delivered.*"

10.26 This provides the pharmacist with discretion to determine the way in which each delivery is carried out. However, I note that the Appellant has stated that the pharmacy policy was to send out whatever it had as soon as it had it, and it appears to have had no regard to the individual need of each patient or the urgency warranted by the medication. I also note the provided extract from schedule 4, paragraph 5 (2) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations"). Whilst I agree that there is a requirement to be prompt, rather than "*within a reasonable timescale*", as stated by the NHS BSA, I note that this is still caveated with the requirement of reasonableness. Therefore, I consider that there are two considerations that should have been made when deciding the timescales for deliveries, the needs of the patient and the requirement of reasonableness in the Regulations.

10.27 I consider it likely that some of the deliveries that occurred within consecutive days might meet these requirements. However, I note the statements provided by the NHS BSA regarding occasions where there were 10 deliveries across 5 days, or 8 deliveries across 4 days. I find it hard to accept that in every one of these cases it was reasonable and necessary to provide the medication so quickly. I also note the NHS BSA's arguments regarding the potential impact of having multiple deliveries to shielding patients where contact, at that time, should have been as minimal as possible. When considering the clinical needs of the patient, this should not only have involved speed but also consideration of the amount of contact being made. The Appellant has not suggested that any such considerations were carried out and instead only considered immediacy. Accordingly, I consider it likely that most of the occasions where more than one delivery was made in the course of one day were not carried out in accordance with the specification. Given this reasoning I do not consider it appropriate to accept the entirety of the duplicates as eligible.

10.28 I note that, due to the Appellant removing both errors and repeat deliveries in the same table, it is difficult to ascertain the actual scope of valid repeat deliveries and to make a determination as to which of these were indeed eligible. Therefore, I determine that the highest figure that I might consider as eligible is the Appellant's reduced figure of 3,099 deliveries although I go on to consider other matters relating to this figure below. Consequently, I consider that at least £101,214 is suitable for recovery by the NHS BSA, which is the 19,968 original deliveries claimed, minus the 3,099 revised deliveries claimed by the Appellant (which results in 16,869), and then multiplied by £6.

10.29 I will now consider those 3,099 claimed deliveries which the Appellant states it has verified. I note that this figure was provided by the Appellant in its observations, by way of amendments to the table provided by the NHS BSA in its representations, replicated above at paragraph 5.1.21. I note that there are still significant disparities each month between the maximum potential deliveries provided by the NHS BSA and the Appellant's figures, even if the total figures are fairly close.

10.30 The maximum potential deliveries, as stated by the NHS BSA, have been arrived at through a process of modelling. This was explained to the Appellant in an email dated 16 June 2022, and further detailed in its decision and representations. To summarise, this figure was based on an analysis of the prescriptions issued by the pharmacy and comparing those to a list of all patients who were classified as clinically extremely vulnerable at any point, in order to establish the number of prescriptions issued to vulnerable people. The complete explanation is provided above at paragraph 4.1.24 onwards. I note that the NHS BSA considers these figures an overestimate, and has explained its reasons for believing this to be so.

10.31 The Appellant's revised figures were based on its delivery records cross checked with the SPL at a later date. I note that the only table for which there is confirmation of SPL status is the month of April, where there is a column marked "shiedling [sic]". The original grounds upon which the Appellant based its Appeal are provided at paragraph 3.28 above, I will consider these first.

10.32 Regarding the lack of detailed reasoning provided by the NHS BSA. I note that an email was sent to the Appellant on 16 June 2022 which clearly set out that the reason for the issue was due to the number of deliveries claimed being significantly lower than the number of prescription forms dispensed to shielded patients.

10.33 As noted above, an explanation of the calculation process was provided which sets out that it was for patients who were on the shielded patient list at "*any time*" and that it allowed for 1 delivery to a care home per day. I consider that this suitably explains the reasoning to the Appellant. The remaining issue in the Appeal is in regard to the modelled data only reflecting 1 delivery per patient per day, which I have already addressed.

10.34 As a consequence of the above, the remaining issue is whether the modelled figures should be favoured over the Appellant's own records. I therefore consider the question of accuracy. I note that in the aforementioned updated claim table the Appellant has disputed both the maximum potential deliveries and the number of patients identified as shielded. Given the significant increase for each of the number of patients identified as shielded, if correct, this would explain the disparity between the NHS BSA's modelled figures and the Appellant's records.

10.35 I consider that, since the NHS BSA's number of shielded patients is based on the pharmacy's own prescription dispensing records there should be no discrepancies between the two sets of figures. However, the NHS BSA has stated that the only situation in which its figures will be incorrect is where the Appellant has delivered medications dispensed somewhere else. In the correspondence prior to the NHS BSA's decision this was explained to the Appellant and it was requested to consider where it made deliveries that had been dispensed elsewhere. I note that no commentary on this has been provided by the Appellant, and it has never confirmed whether this occurred and whether there is any evidence to support such a claim. Given that the Appellant has stated that the delivery requests came from GP Surgeries, and that this is how the eligibility checks were met, I can see no suggestion that a different dispensing pharmacy requested that items were delivered on its behalf.

10.36 I consider, therefore, that it is difficult to understand for what reason and on what basis the Appellant is seeking to dispute the "*number of patients identified as shielded*". As the NHS BSA's figures include patients who were shielding at any time, and the Appellant's checks were carried out in 2021, the NHS BSA's figures should be the higher of the two.

10.37 Regarding the general nature of the figures provided by the Appellant, I note that when it sought its own confirmation of the status of the patients on its delivery record it found that 16,768 of its claimed delivered were for non-shielding patients. It has stated that it relied on confirmation from the GP Surgery who issued the prescription to confirm the status of the patients. Having regard to the specification, as provided the NHS BSA, it states that checks should be carried out to ensure that patients are eligible. As I have referred to, I am not determining whether the specification was or was not adhered to. However, the lack of checks beyond this confirmation has clearly resulted in claims for those that were not shielding, as illustrated by the Appellant's change in its initial figures. I therefore consider that there is or at the very least was some level of unreliability in the Appellant's records, and it is difficult to understand how this has been remedied.

10.38 Further to this there was additional revision from the Appellant's claim figures to its observation figures. The Appellant has stated that this was due to errors, but it has not provided any specific information regarding what these errors were or how they occurred or how they were subsequently resolved. I consider that this adds difficulty in verifying the Appellant's claims that the figures are now error free.

10.39 The final dispute regarding the modelling is why the spreadsheets provided by the Appellant in 2021 were not compared to the SPL and hence directly verified, instead of the modelling approach being taken. I note that the Appellant has stated that the NHS BSA had the patient identifiable data for April, May and June for over a year. However, I do not consider this statement to be entirely accurate. I note that a key reason for the NHS BSA's not carrying out the direct verification was due to a lack of information provided by the Appellant including a lack of NHS Numbers, post codes, and delivery dates. Having considered the tables provided, and my other comments in this determination, I do not believe that the information provided by the Appellant for those months could correctly be said to be wholly "*patient identifiable data*". There were some instances where enough information was provided but this was not the case for every entry.

10.40 As I have alluded to, the specification required that the Appellant keep records of this information, and so it should have been readily available. I also note that the entire month of July had been omitted until the Appeal stage, therefore validation of this information would have not been possible.

10.41 Further to this, upon consideration of the Appellant's correspondence with the NHS BSA, I note that it missed several deadlines set with regard to providing information and also asked for extensions that it did not meet. I consider it likely that had it provided the full patient identifiable information it should have had, in line with the deadlines provided, then a full verification would have been possible. However, this was not the case. I do consider that the NHS BSA should have sought to notify the Appellant that the opportunity for validation was only available until a certain date, though I note that the COPI notice expiration was public knowledge. Nevertheless, noting that some of the information has still not been provided by the Appellant and the missed deadlines, I am not convinced that this would have changed the outcome.

10.42 I also note the Appellant's suggestion that a sample, or the incomplete data could have been verified. Whilst this is possible, I do not see how a sample would be any better than the modelled data as the sample would have then been extrapolated, creating an equally artificial figure. Further to this, as I have noted, the month of July was not provided until the Appeal, this accounts for 278 of the disputed deliveries (the difference between the modelled figures and the pharmacy's revised claim). Even if all the data that had been provided was validated (accounting for the errors and duplicates), and the Appellant's revised claim figures (2,139) proven, the NHS BSA would still have had to model the data for July. This would have resulted in a total figure of 2,821 deliveries – which is less than either the total modelled figure or the Appellant's figure. Therefore, I do not consider that this line of reasoning aids the Appellant. Accordingly, I do not consider that the NHS BSA should have verified what information it had or that the fact that it did not supports the use of the Appellant's figures over the modelled data.

10.43 To summarise, the main argument put forward by the Appellant, that its data should be relied on, is that it is a contemporaneous record rather than a modelled one. I do consider this argument to be compelling. However, the NHS BSA has stated that there have been multiple revisions to these figures, and there is still an outstanding lack of information regarding their nature. This leaves me in the untenable position, that whilst neither figure is likely to be a factual representation of the eligible deliveries, I must choose one over the other.

10.44 For all of the reasons set out above, I consider that the NHS BSA's figure is the more likely of the two to be accurate. The key reason for this is the fact that the Appellant's figure relies upon disputing the number of patients identified as shielding. The Appellant has not provided sufficient reasoning to suggest that the NHS BSA's figure should be disregarded. The original statement by the Appellant was that these were incorrect due to possible lag in the amending of the patient status. However, as the NHS BSA stated and I have set out above, this figure was based on all patients who were ever classified as shielding. This should therefore be an overestimate, rather than an underestimate. To disprove this figure the Appellant needed to indicate where it took on deliveries dispensed by other pharmacies, and I have determined that there is no evidence or suggestion that this is the case. Therefore, I cannot understand how the higher number of patients identified as shielding has been arrived at.

10.45 Extrapolating from this, it is likely that some patients for whom delivery is being claimed must not have been on the shielded patient list. This would render a number of deliveries ineligible, which combined with the overall lack of information provided by the Appellant's records, does not provide the requisite confidence in either the validity or accuracy of the data provided. I do not consider that any of the reasons stated by the Appellant persuades me that its figures are the more accurate of the two. The NHS BSA's figures whilst modelled are based on dispensed prescriptions to verified shielded patients, this provides me with a higher level of certainty that these deliveries were eligible under the specification, even accounting for the elements of over estimation.

For these reasons, I agree with the NHS BSA that the decision to recover the overpayment is appropriate.

10.46 The overpayment amount able to be recovered is £183,648 which is the value of the amount for the originally claimed number of deliveries (19,968 multiplied by £6 = £119,808) plus the amount for the August to October claims (13,554 multiplied by £6 = £81,324) minus the amount for the modelled total (2,914 multiplied by £6 = £17,484).

11 DECISION

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

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

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

11.1.3 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.

11.2 I dismiss the Appeal and confirm the decision of NHS England to recover the overpayment of £183,648.

11.3 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