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28 October 2024

REF: SHA/26254

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

1 **Outcome**:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £3,120.00 in respect of self-isolating claims and £3,168.00 in respect of CEV claims.

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:

Shaftesbury Pharmacy Ltd
NHS BSA on behalf of NHS England

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10 South Colonnade
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London
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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM SHAFTESBURY PHARMACY LTD ("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 17 June 2024 in respect of Shaftesbury Pharmacy Ltd (ODS code FQ718). The decision stated:

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

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

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

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

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

2.6 **Your pharmacy has been unable to provide evidence to demonstrate that the Medicines Delivery Service claims made during this time met the requirements set out in the service specification, i.e. that these claims for deliveries were to self-isolating patients. This is despite several attempts made by the NHSBSA Pharmacy Provider Assurance Team to seek further/alternative evidence of how the claims have met the scheme requirements.**

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

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

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

2.9.1 FQ718 – SHAFTESBURY PHARMACY LTD claimed 520 Self-Isolating (SI) and 528 CEV deliveries for the Medicines Delivery Service in the months of April 2021 to July 2021.

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

2.9.3 SHAFTESBURY PHARMACY LTD was contacted on seven separate occasions by the NHSBSA Provider Assurance Team to request evidence to demonstrate that that the Medicines Delivery Service claims made during this time met the requirements set out in the service specification.

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

2.11 The tables below outline the monthly Medicines Delivery Service claims reimbursed to your pharmacy – SHAFTESBURY PHARMACY LTD – FQ718 in the months of April 2021 to July 2021 for Self-isolating and CEV patients, along with the associated recovery values:

2.12 **Self-isolating claims**

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

	April 2021	May 2021	June 2021	July 2021	Total

Self-isolating claims paid	229	104	185	2	**520**

2.14 520 Self-isolating claims paid x £6.00 **= £3,120.00**

2.15 **CEV claims**

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

	April 2021	May 2021	June 2021	July 2021	Total
CEV claims paid	220	308	N/A	N/A	**528**

2.17 Subsequently this has resulted in the following overpayment:

2.18 528 CEV claims paid x £6.00 **= £3,168.00.**

2.19 **Total recovery for April 2021 – July 2021**:

2.20 520 Self-isolating claims paid x £6.00 **= £3,120.00**

2.21 528 CEV claims paid x £6.00 **= £3,168.00.**

2.22 **Total value to be recovered = £6,288.00 deduction**.

2.23 **Action Required**

2.24 1. Please respond to this correspondence at pharmacysupport@nhsbsa.nhs.uk to confirm your agreement for the overpayment to be recovered pursuant to Regulation 94(1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. **Please send this confirmation by 17th July 2024.**

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

2.26 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 17th July 2024.

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

2.28 2. **Please be aware that failing to contact us by 17th July 2024 to agree that there has been an overpayment DOES NOT mean that the overpayment cannot be recovered.** Instead, where you do not agree that an overpayment has been made you have a right of appeal to the Secretary of State against NHS England's decision. Should you choose to appeal then send a concise and reasoned statement of the grounds for your appeal **within 30 days of the date of this letter** to nhsr.appeals@nhs.net or:

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

2.30 3. 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.

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

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

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

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

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

2.36 Your co-operation is very much appreciated."

3 THE DISPUTE

In a letter dated 16 July 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "I would be grateful if the following points and statement as grounds for an appeal could be considered by the NHS Resolutions team:

3.2 1. I refer to the email of 14/12/23 and 25/06/204 [sic] from the NHSBSA Provider Assurance team:

3.3 *Concerns were raised how MYS continued to allow claims for Clinically Extremely Vulnerable (CEV) patients to be made by pharmacies in April and May 2021 if the service had ceased on 31st March 2021. We in response outlined why MYS were reluctant to remove the CEV function in-case the service changed again and these patients were once again eligible so instead put steps in place to ensure CEV claims were no longer paid for but this only came into effect after May 2021*.

3.4 The reluctance expressed in the two emails above was not made known to contractors, but an internal decision by NHSBSA. This crucial plan should have been notified to us contractors, the service providers.

3.5 2. In response to key points of discussion stated on email of 14/12/2023 from the NHSBSA Provider team:

3.6 Contractors follow the continuation of services that are available to claim on MYS, as only claimable services are active on MYS. Thus, it was assumed that the service was still active and allowed to be claimed. All other services are closed on MYS on the last day of the service.

3.7 *It was queried if any of the CEV claims made in the months of April and May 2021 could be from the previous months prior to the CEV part of the service ending. If the contractor had evidence of this we would review this evidence but we made it clear we are aware the contractor did still claim for CEV patients in earlier months and were paid for those claims.*

3.8 Payments for the previous months were authorised and valid so we were fully aware of the process of checking eligibility of CEV patients. This eligibility was confirmed but the documents were shredded as mentioned.

3.9 It needs to be acknowledged that the delivery service (reimbursement of £6 per delivery) was not a profit-making venture but a purpose to serve housebound patients during the pandemic. Every delivery was incurring a loss for us, with overheads expenses of a car, driver, insurance, fuel. We have documents to support the delivery expenses which would confirm that each delivery was simply to provide pharmaceutical services to vulnerable patients and not for financial gain.

3.10 • Record retention period and point out that the specification just says:

3.11 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, including the postcode of the patient's address, and the date of the delivery

3.12 In addition, it is unreasonable of the commissioner to think that records would be kept this long when:

3.13 · There was no stated time in the service specification for which remuneration records should be kept for

3.14 · In the absence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period, at that time, for Advanced Services, it was a retention period of two years; and therefore

3.15 · Two years is the maximum reasonable time records would be kept –

3.16 · The data protection legislation requires you to keep such data only <u>as long as necessary.</u>

3.17 · The relevant two years is from the date the service was provided to the date the first request for evidence from NHSBSA.

3.18 · The request for evidence from the NHSBSA has been received **two years and five months** after the last provision of the service and for deliveries provided in April 2021, it is **two years and seven months** after provision of the service.

3.19 3. Email of 17 June 2024 from NHSBSA Provider Assurance team:

3.20 *SHAFTESBURY PHARMACY LTD was contacted on seven separate occasions by the NHSBSA Provider Assurance Team to request evidence to demonstrate that that the Medicines Delivery Service claims made during this time met the requirements set out in the service specification.*

3.21 Most of the seven occasions mentioned in the timeline refer to attempts made to confirm details of a meeting with [AG] and [ML], and not to request evidence. The above comment is portrayed as Shaftesbury Pharmacy Limited's lack of co-operation; however, emails read by me have been responded to punctually. Emails sent to the Shared Pharmacy Account are accessed by 14 staff for patient/ prescription related communications with surgeries. Emails were marked as read by staff without bringing them to my attention, thus the lack of response. Previous history of email exchanges confirms the promptness of responses on my part. Staff not bringing emails to my notice is an oversight, an issue with generic email accounts accessed by various members of staff.

3.22 Please note the below table of key to help illustrate to the appeal's committee that my engagement with the NHSBSA Team and challenge the suggestion that I did not co-operate / engage and to appeal the PSRC decision.

3.23 Initial NHSBSA contact

3.24 6th December 2023

3.25 NHSBSA contact Contractor contact / reply to dates LPC contact

3.26 9th December 2023

3.27 11th December 2023 11th December 2023

3.28 11th December 2023

3.29 11th December 2023 11th December 2023 11th December 2023

3.30 13th December 2023 13th December 2023 13th December 2023

3.31 14th December 2023 21st December 2023

3.32 28th February 2024

3.33 Dates of the claims

3.34 April - July 2021

3.35 Dates to keep evidence until based on 2 years of retention and in the absence of supplementary guidance

3.36 May - August 2023

3.37 How long after 2 years of record retention until initial contact by NHSBSA

3.38 For April 2021 claims 7 months

3.39 For May 2021 claims 6 months

3.40 For July 2021 claims 5 months

3.41 I did engage and co-operate with the post payment verification activity duly.

3.42 5. My email of 22/12/23 to NHSBSA Provider Assurance team:

3.43 *With regards to the CEV claims, I did not recall any communication advising me that the claims for CEV patients had ceased. You will appreciate that we were overwhelmed with communications from NHSE during the most challenging times in Pharmacy history. As the MYS portal was still open to claim, I assumed that the service was ongoing. Other discontinued services are no longer available on MYS when they are stopped.*

3.44 *I confirm that our records were shredded by a recruited agency, as part of our internal policy, to facilitate space for other mandatory records to be maintained. As mentioned, there were no guidelines with regards to the period that the records were to be retained, thus our decision to shred the records. As the data controller for my pharmacy, I believed this to be a reasonable period of time.*

3.45 To support evidence that we have a shredding process in place to support the appropriate management and destruction of records no longer required, I attach an invoice from a shredding company dated 31/07/2023. Further invoices for the shredding service are also available to confirm that documents are continually shredded as part of a cycle of renewing storage space for mandatory documents and to ensure data is not retained for longer than it is required in line with data protection legislation.

3.46 *When the referral is made to PSRC, I would like to request that consideration be provided to the demanding times that the Pharmacy profession had experienced, and appreciation of the immense pressures that I personally faced with skeleton workforce during Covid illnesses, opening 14-16 hours per day, ensuring that pharmaceutical services were provided to the most vulnerable and housebound patients. The burdens we experienced to manage patient care whilst surgeries were closed were enormous, at times, taking a toll on our personal health and welfare.*

3.47 *I request that the PSRC consider the personal challenges we encountered and appreciate that some emails may have been filtered through the channels of communications, whilst coping with the Covid workload and the continual webinars that were planned. With the MYS portal still continuing for claims, whilst other ceased services' claim processes were closed, it was my assumption that the CEV services were ongoing.*

3.48 Please review the above points.

3.49 6. I express concern that the PSRC did not respond to or acknowledge the points raised in my email dated 22/12/23 to the NHSBSA Provider Assurance team; therefore, I have no means of knowing if the points I had raised were considered before a determination was made.

3.50 7. I acknowledge from the information provided that deliveries to support Clinically Extremely Vulnerable (CEV) patients, ended at the end of March 2021. Therefore, am willing to consider accepting, where CEV deliveries and service claims were made outside the commissioned period to this patient cohort, that these payments were not in line with the service specification and the pharmacy claims for these were in error.

3.51 Therefore, if despite my appeal, it is decided that the payment in relation to CEV patients needs to be recovered, I agree for the CEV elements of the claims for the highlighted months to be recovered as an overpayment and consent to this. As per the NHSBSA letter this is 528 CEV claims paid x £6.00 = **£3,168.00**.

3.52 Regarding claims for Self-Isolating patients following notification by NHS Test and Trace, my pharmacy was **contacted 2 years and 5 months after the date of the pharmacy's last service claims** (July 2021). I do not feel that it is fair that I am expected to produce records beyond a point in time that is viewed as reasonable for records to be retained, when no retention period was clearly defined by the service commissioner. **I do not agree for service fee associated with this element of the service to be recovered.**

3.53 In conclusion, please consider the following:

3.54 · Our records are maintained for the recommended periods as per the service specifications for NHS commissioned services. There was no guidance with regards to the period that records would need to be maintained, thus our decision to shred documents that were not required to be kept.

3.55 - At a point in time where healthcare providers were under immense amounts of pressure, communication about the changes to the service was and the MYS portal had continued to accept claims, which will have contribute to busy pharmacy owners

assuming that the service was still commissioned and claimable. It is therefore, unfair to punish us for trying to do the right thing to assist patients during the pandemic.

3.56 I look forward to a favourable response following deliberation of the various points addressed above."

4 SUMMARY OF REPRESENTATIONS

This is a summary of representations received on the appeal.

The NHS BSA on behalf of NHS England stated:

4.1 "Thank you for your letter of the 19th of July 2024 and the opportunity to provide representations on the appeal.

4.2 **Background**

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

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

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

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

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

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

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

4.10 **April 2021 to July 2021 March 2022 claims**

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

4.12 The guidance stated that only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it. A record of the Test and Trace Account ID reference number must be made and retained as part of the contractor's delivery record to ensure effective ongoing service provision, and for post-payment verification purposes. It also stated that pharmacies should familiarise themselves with the details of the service before making a claim.

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

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

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

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

4.17 However, MYS became aware that contractors continued to claim for deliveries to CEV patients. Once it became apparent that many contractors were still submitting claims for these ineligible patients, MYS was amended to ensure these claims were no longer automatically paid. CEV claims submitted after 05 May 2021 were not paid and only claims for deliveries to SI patients were processed for payment.

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

4.19 In the Post Payment Verification (PPV) exercise undertaken by the NHSBSA PAT, FQ718 – Shaftesbury Pharmacy Ltd were contacted on seven occasions between 6th December 2023 and 28th February 2024 to request evidence that the 520 Self-Isolating patient claims made between April 2021 and July 2021 were for deliveries made to eligible patients' self-isolating in response to a positive Covid test, as specified in the NHSE service announcements.

4.20 Alongside that, NHSBSA PAT outlined that FQ718, Shaftesbury Pharmacy Ltd also incorrectly claimed for 528 CEV patients during the months of April and May 2021 and

advised that claims for deliveries to CEV patients after 05 April 2021 were eligible for payment.

4.21 Emails were sent to the pharmacy shared NHS mail address pharmacy.fq718@nhs.net as required by NHSE. All listed pharmacies must have a valid shared NHSmail account that should be regularly monitored by the pharmacy team as part of their terms of service.

4.22 NHSBSA PAT engaged with Shaftesbury Pharmacy Ltd during the PPV process. The responses and the engagement with the pharmacy was prompt however it was made clear to PAT that no evidence was available to support the SI claims and that Shaftesbury Pharmacy Ltd also believed the CEV claims made should be allowed as the pharmacy was putting their patients first even though it was made clear that those patients were no longer eligible for the service after March 2021.

4.23 A Microsoft Teams meeting was organised between PAT, Ms. Tr (manager of Shaftesbury Pharmacy Ltd) and a member of Ms. T's local LPC. On this call it was discussed how the pharmacy recorded the evidence which they stated met the requirements outlined in the service specification and how they were unaware of the change to the service which took place after March 2021, with CEV patients no longer being eligible. PAT did challenge that if the contractor was unaware of the change to the service how did they become aware that the SI claims could now be claimed for the service. No reason was given from Shaftesbury Pharmacy Ltd as to why they did not know that CEV were no longer eligible, but SI claims were. It should be noted that the announcement of the service extension made both of these changes clear.

4.24 Despite the attempts made by the NHSBSA PAT, Shaftesbury Pharmacy Ltd did not provide any evidence to demonstrate that the 520 Medicine Delivery Service deliveries claimed for between April 2021 and July 2021 were made to self-isolating patients who had provided their Test and Trace referral number when requesting the service as specified in the service specification at this time.

4.25 During the engagement Shaftesbury Pharmacy Ltd stated, *"With regards to the CEV claims, I did not recall any communication advising me that the claims for CEV patients had ceased. You will appreciate that we were overwhelmed with communications from NHSE during the most challenging times in Pharmacy history. As the MYS portal was still open to claim, I assumed that the service was ongoing. Other discontinued services are no longer available on MYS when they are stopped."*

4.26 PAT can appreciate it was a challenging time for pharmacy contractors however it is unclear how the communication was missed around CEV patients no longer being eligible while the pharmacy was somehow aware that self-isolating patients were now the eligible patients for the service. Having the awareness that SI patients were eligible does also suggest that the pharmacy was aware that Test and Trace referral numbers was the evidence contractors must now maintain for this service.

4.27 Shaftesbury Pharmacy Ltd has stated they continued to claim for CEV patients as they were able to on MYS which does also raise the question of how the pharmacy identified the difference in claims between which patients were classed as CEV and which ones were classed as SI claims, as we also have no evidence of the deliveries claimed for the ineligible CEV patients.

4.28 Either way despite the engagement with the pharmacy, Shaftesbury Pharmacy Ltd was not able to provide records to demonstrate that the claims that were submitted for the MDS for April 2021 onwards were for patients eligible for the service at that time.

4.29 As such the NHSBSA were then unable to verify that the deliveries claimed met the requirements set out in the service specification.

4.30 To avoid any doubt there is no dispute about these deliveries having been made, the engagement with the pharmacy was to confirm that the deliveries were made to patients who had been informed by Test and Trace to self-isolate and were therefore eligible for the Medicine Delivery Service.

4.31 As the NHSBSA PAT have been unable to validate the deliveries claimed by the pharmacy during this time, the details of the case were passed to the NHS England regional team for their Pharmacy Services Regulation Committee (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 Medicine Delivery Scheme at the time that the deliveries were made; and if they were not eligible, for the delivery fees that have been paid to be recovered under regulation 94 (1) (a) as an overpayment.

4.32 **The PSRC decision**

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

4.34 The engagement showed that despite repeated requests made by the NHSBSA to the contractor over three months to provide evidence of patient eligibility for the service claims submitted, no such evidence was forthcoming.

4.35 Consequently, the PSRC concluded that the NHSBSA had been unable to find any evidence to demonstrate that the 520 deliveries claimed by the contractor between April 2021 and July 2021 for deliveries to SI patients met the requirements set out in the service specification alongside the incorrectly claimed 528 claims made for CEV patients.

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

4.37 Having made this decision, the PSRC then directed that as Shaftesbury Pharmacy Ltd 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.

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

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

4.40 The service specification/Service Announcements states:

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

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

4.43 Shaftesbury Pharmacy Ltd does not state what evidence they kept so we have no confirmation that they followed the service specification and recorded Test and Trace reference numbers. Instead, the pharmacy stated that *"I confirm that our records were shredded by a recruited agency, as part of our internal policy, to facilitate space for other mandatory records to be maintained. As mentioned, there were no guidelines with regards to the period that the records were to be retained, thus our decision to shred the records. As the data controller for my pharmacy, I believed this to be a reasonable period of time."*

4.44 Shaftesbury Pharmacy Ltd elaborates further with evidence that they shred documents in the pharmacy *"To support evidence that we have a shredding process in place to support the appropriate management and destruction of records no longer required, I attach an invoice from a shredding company dated 31/07/2023. Further invoices for the shredding service are also available to confirm that documents are continually shredded as part of a cycle of renewing storage space for mandatory documents and to ensure data is not retained for longer than it is required in line with data protection legislation."*

4.45 The NHSBSA appreciate the contractor may use an outside company to come and securely destroy patient identifiable information however the invoice for the shredding service and explanation is not evidence that the records of patient eligibility for the claims made for deliveries to SI patients for the MDS were included in those records destroyed, or whether that evidence met the requirements in the service specification i.e. included the Test and Trace referral numbers.

4.46 Throughout the investigation Shaftesbury Pharmacy Ltd did not provide any evidence as to how and when the eligibility of patients for the service were confirmed, where those records were made or by whom.

4.47 In a Teams call meeting with [LT] and [ML], CEO of Middlesex LPC, on the 13.12.24, the process when delivering to Self-Isolating (SI) patients was explained by [L] and [M] and this included obtaining their name, address and Test and Trace Account ID number and this was captured on the evidence. However, when the PAT queried how the evidence was captured i.e. digitally/paper based and who in the pharmacy performed this no response to the question was given. [L] and [M] were advised that if there was any additional information that they would like presented for review or any further information you wish to share it was recommended to be included in a response to this email. Whilst further comments were returned, none relate to how and when the eligibility of patients for the service were confirmed, where those records were made or by whom.

4.48 As such, the NHSBSA has then been unable to gain any assurance that the service was only claimed for deliveries to eligible patients as specified in the service announcement.

4.49 In the appeal Shaftesbury Pharmacy Ltd states that *"There was no stated time in the service specification for which remuneration records should be kept for · In the absence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period, at that time, for Advanced Services, it was a retention period of two years; and therefore · Two years is the maximum reasonable time records would be kept – · The data protection legislation requires you to keep such data only as long as necessary."*

4.50 NHSBSA PAT acknowledges that whilst the service specification is clear that records need to be kept for PPV purposes, it does not advise of exactly how long contractors were required to keep such evidence. However, it is also unclear how this contractor formed the opinion that records only needed to be retained for two years.

4.51 Section VIC of the Drug Tariff contains the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. Throughout the directions there are

repeated requirements for records to retained [sic] for post payment verification purposes without the reference to a time scale for retention.

4.52 For the New Medicines Service there is a time scale mentioned in paragraph 7- ongoing **conditions of arrangements**:

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

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

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

4.56 Records of other service provision are required to be kept for 3 years for other services e.g. the Blood Pressure Checking service. See Advanced service specification: NHS community pharmacy hypertension case-finding advanced service (NHS community pharmacy blood pressure check service) (england.nhs.uk)

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

4.58 FQ718 Shaftesbury Pharmacy Ltd in their appeal also state that *"Please note the below table of key to help illustrate to the appeal's committee that my engagement with the NHSBSA Team and challenge the suggestion that I did not co-operate / engage and to appeal the PSRC decision".*

4.59 The PAT acknowledge that Shaftesbury Pharmacy Ltd has engaged in communication with PAT which is clearly shown on the timeline of engagement. However, the PAT escalated the case to PSRC as we were unable to give assurance behind the validity of the claims made by the pharmacy as we were unable to review any evidence from the contractor for SI claims made. Shaftesbury Pharmacy Ltd admitted they had claimed for ineligible patients however they felt that they were still entitled to the payment already received for this. As a result, this case was escalated to the PSRC following our procedure, as the PAT had no valid evidence that enabled us to verify the SI claims.

4.60 In the appeal information, Shaftesbury Pharmacy Ltd also states *"It needs to be acknowledged that the delivery service (reimbursement of £6 per delivery) was not a profit-making venture but a purpose to serve housebound patients during the pandemic. Every delivery was incurring a loss for us, with overheads expenses of a car, driver, insurance, fuel. We have documents to support the delivery expenses which would confirm that each delivery was simply to provide pharmaceutical services to vulnerable patients and not for financial gain."*

4.61 The NHSBSA are not disputing the volume of deliveries performed or the pressure the pharmacy was under in performing prescription deliveries to patients who may have requested them. It is also unable to comment of the costs incurred by the pharmacy or the profitability of providing the service. The NHSBSA are aware that many pharmacies provide a private service to patients to deliver prescriptions to their patients and that the demand for these services significantly increased both during and after the pandemic.

4.62 However, the NHS England commissioned service, the MDS, was restricted to eligible patients as defined in the relevant service announcement for the time period that service announcement referred to. This process for updating the details of the commissioned service via the service announcement was agreed by DHSC, NHSE and the PSNC. Each of the announcements made it clear how long the service was commissioned for, which patients were eligible and the need to retain records for PPV purposes.

4.63 The explanation provided by the contractor does not provide any clarification of how the pharmacy confirmed the eligibility for the service of the claims made during this final phase of the commissioned service, or how it retained records to demonstrate this. The NHSBSA are unable to assure NHSE that claims for the service delivery from April 2021 onwards made by Shaftesbury Pharmacy Ltd were to eligible patients as outlined in the service specification.

4.64 The PAT accepts that Shaftesbury Pharmacy Ltd may have made the decision to provide delivery services to 'housebound patients' as it states. However, an assessment that a patient is house bound whether made by the patient, a representative or by the pharmacy does not mean the patient was therefore eligible for the MDS commissioned. The service was only commissioned for those patients that had been assessed as CEV patients in the early phases of the commissioned service and for SI in the latter stages of the service. The relevant service announcement for the service commissioned at the time outlined how the pharmacy should confirm the eligibility and retain records for PPV purposes.

4.65 The evidence provided by the appellant during the initial investigation and for this appeal would suggest that Shaftesbury Pharmacy Ltd were not aware of the need to keep records of eligibility for patients eligible for the service; and supports the decision of the PSRC that these claims were not for deliveries made to those patients identified as eligible under the Medicine Delivery Service from April 2021 onwards i.e. who had provided their Test and Trace SI confirmation.

4.66 To be clear NHSE do not dispute that the deliveries were made, but it is not assured that the contractor was performing the necessary steps to only claim for those deliveries to self-isolating patients who were eligible for the service. This eligibility should have been recorded including details of the patients Test and Trace referral numbers as outlined in the service specification.

4.67 In their appeal the appellant attests that *"Payments for the previous months were authorised and valid so we were fully aware of the process of checking eligibility of CEV patients. This eligibility was confirmed but the documents were shredded as mentioned."* Shaftesbury Pharmacy Ltd were not identified as significant outliers for any previous MDS PPV reviews and so were not included in any previous samples.

4.68 During the period CEV patients were eligible for MDS, NHSBSA PAT were able to perform data modelling on the maximum potential number of deliveries that could be expected from pharmacies delivering the service. This modelling was applied to pharmacies seen as being outliers for the various stages of the service.

4.69 NHS Digital created and maintained the Shielded Patient List 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.

4.70 The NHSBSA PAT provided the NHS numbers of all patients who had a prescription dispensed during the sample period being reviewed 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.

4.71 Until April 2021 Shaftesbury Pharmacy Ltd were regular substantial claimers for the MDS for deliveries to CEV claims but were not identified as significant outliers that needed to be followed up in the PPV exercises in the earlier stages of the MDS.

4.72 The NHSBSA PAT are therefore able to confirm that the previous claims for the service were authorised, but not that they were valid, as they were not investigated as part of any previous PPV exercise.

4.73 The payments system is built upon a high level of trust, and it is only when a contractor is classed as an outlier or chosen to be randomly sampled that evidence is requested to support the claims in the terms of the service as outlined in the service specification. Shaftesbury Pharmacy Ltd were not considered an outlier for the previous samples or identified for random sampling.

4.74 When reviewing the claims made by the pharmacy to respond to the appeal, the pharmacy has submitted and been paid for consistent volumes of claims from when the service was first commissioned in April 2020 until they ceased claiming for the service in October 2021.

4.75 Table 1 shows MDS deliveries claimed by Shaftesbury Pharmacy Ltd to CEV patients during the initial phase of the service, where the service was commissioned for CEV patients across England and from all community pharmacies in England.

4.76 *Table 1 – April to July 2020 MDS claims paid*

	April 2020	May 2020	June 2020	July 2020
MDS claims paid	440	457	496	491

4.77 It should be noted that between August 2020 and October 2020 the MDS was not commissioned nationally but was limited to small areas of the country where lockdown restrictions continued. During this time, Shaftesbury Pharmacy Ltd did not claim for any service delivery during that time. Suggesting that the pharmacy was aware of the change in the commissioning arrangements of the service during this time.

4.78 The service was then recommissioned nationally for the month of November only. Shaftesbury Pharmacy Ltd claimed for the service delivery during this month.

4.79 The service was again commissioned during the latter stages of December on an area-by-area basis until it was finally commissioned country wide from January 2021. Shaftesbury Pharmacy Ltd claimed for a lower level of service delivery in December presumably in accordance with the changes to the service specification.

4.80 From January 2021 until March 2021 the service was commissioned nationally from all pharmacies for deliveries to CEV patients only. During January to March 2021, Shaftesbury Pharmacy Ltd returned to its similar level of claims.

4.81 Table 2 presents the number of deliveries Shaftesbury Pharmacy Ltd claimed and was paid for each month during November 2020 to March 2021.

4.82 *Table 2 – November 2020 to March 2021 MDS claims paid*

	November 2020	December 2020	January 2021	February 2021	March 2021

MDS claims paid	533	217	461	478	533

4.83 Table 3 combines the claims that were submitted and paid for both CEV and SI claims together and this continues to show the similar pattern of claiming behaviour - similar levels of claims submitted as for those previously claimed for the CEV claims alone.

4.84 Both the claims for deliveries to CEV patients when the service was not commissioned for this cohort of patients, and the large number of claims for deliveries to SI patients in the months of April and May 2021 led to this pharmacy being classed as an outlier, and for their inclusion in the PPV exercise for the final phase of the service.

4.85 Following the amendment to the MYS portal in June 2021, claims for the provision of service to CEV patients were not paid. Shaftesbury Pharmacy Ltd appeared to be unaware of this situation as it continued to claim for the service to CEV patients, as well as claiming for deliveries to SI patients.

4.86 In the PPV exercise undertaken, the PAT only investigated the claims submitted by the contractor between April and July 2021, as the contractor was paid for both the claims for CEV and SI claims submitted.

4.87 Table 3 – April 2021 to October 2021 MDS claims submitted

	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021	Sept 2021	Oct 2021
Self-isolating claims paid	229	104	185	2	2	1	0
CEV claims paid	220	308	0	0	0	0	0
CEV claims not paid	0	0	303	487	435	445	420
Total claims submitted	449	412	488	489	437	446	420

4.88 The CEV claims submitted by Shaftesbury Pharmacy Ltd after June 2021 were not paid. The low level of SI claims submitted after June were not sufficient to make the pharmacy an outlier necessary for PPV for their subsequent claims from July 2021 onwards. Therefore, the PAT did not investigate the pharmacy further for the claims they submitted for service provision after June 2021.

4.89 Shaftesbury Pharmacy Ltd did not submit any claims for service provision after October 2021, despite the service still being commissioned for a further 5 months. During the engagement, the PAT raised questions as to the sudden end to the high volume of MDS claims. Shaftesbury Pharmacy Ltd offered no explanation and chose not to provide further explanation.

4.90 The NHSBSA were therefore unable to verify that the deliveries claimed for were eligible under the Medicine Delivery Service. The NHSBSA also did not have agreement from the pharmacy that an overpayment had been made and could be recovered, and so had no alternative but to refer the case to the PSRC.

4.91 Shaftesbury Pharmacy Ltd does state in their appeal *"I express concern that the PSRC did not respond to or acknowledge the points raised in my email dated 22/12/23 to the*

NHSBSA Provider Assurance team; therefore, I have no means of knowing if the points I had raised were considered before a determination was made."

4.92 PAT included the information provided by Shaftesbury Pharmacy Ltd as it was added to the timeline of engagement so this information would have been discussed by PSRC when reviewing the case.

4.93 In their appeal response Shaftesbury Pharmacy Ltd raised concerns about the CEV deliveries they claimed after March 2021 when this cohort of patients were no longer eligible for the service. Shaftesbury Pharmacy Ltd states *"Concerns were raised how MYS continued to allow claims for Clinically Extremely Vulnerable (CEV) patients to be made by pharmacies in April and May 2021 if the service had ceased on 31st March 2021."*

4.94 The reasoning for this has been explained earlier in this representation. NHSE made it clear to contractors in all of their announcements the length the service would be commissioned for, the areas the service was commissioned for and the cohorts of patients that would be eligible for the service. Following the announcement in March 2021 it was made clear that the eligibility would change and that CEV patients would no longer be eligible and instead it would be SI patients, as identified with a Test and Trace referral number, that would be eligible.

4.95 It was only later, after some contractors continued to claim for deliveries to CEV patients, that the change was made not to process claims submitted on MYS for these claims. All contractors who were paid for ineligible claims for deliveries to CEV patients are subject to the same PPV process.

4.96 Shaftesbury Pharmacy Ltd goes on to state *"With regards to the CEV claims, I did not recall any communication advising me that the claims for CEV patients had ceased. You will appreciate that we were overwhelmed with communications from NHSE during the most challenging times in Pharmacy history. As the MYS portal was still open to claim, I assumed that the service was ongoing. Other discontinued services are no longer available on MYS when they are stopped."*

4.97 PAT and NHSE do appreciate that the pandemic and the recovery was a busy and challenging time for pharmacy contractors, NHSE were conscious of the need to provide timeous targeted communications to the sector at this time to provide the necessary information and not bombarding contractors with information overload.

4.98 Shaftesbury Pharmacy Ltd also highlights that "*we were overwhelmed with communications from NHSE during the most challenging times in Pharmacy history".* NHSE worked with DHSC and PSNC throughout the pandemic to try and get the balance right but appreciate that they may not have got the balance right in each situation. However, following the change to the service in April 2021 the majority of pharmacy contractors stopped claiming for deliveries to CEV patients. Suggesting these pharmacies were fully aware of the change to the eligible patient group, and it was only a minority that did not.

4.99 Ultimately however the appeal around these contractors' rests on the key information that these patients were no longer eligible for the service so these claims are ineligible for payment and should be recovered as they fall outside the statutory framework for payment.

4.100 Only claims for deliveries to SI patients covered by the NHSE announcements between the months of April 2021 to March 2022 were still eligible to claim for the Medicine Delivery Service. Pharmacies choosing to deliver to non-eligible patients did so outside of the scope of the Medicine Delivery Service and therefore the costs for these deliveries would need to be met by means other than claiming under the Medicine Delivery Service.

4.101 The PSRC considered that Shaftesbury Pharmacy Ltd had not provided any evidence to demonstrate that the claims it had submitted between April and July 2021 were for deliveries to patients eligible for the MDS. As a result, the decision determined that the £3,120.00 payment for SI claims and the £3,168.00 paid for the ineligible CEV claims were over payments and should then be recovered from the contractor.

4.102 **Key points for consideration**

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

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

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

4.103.3 Throughout the investigation Shaftesbury Pharmacy Ltd were unable to provide any evidence of how the eligibility of patients for the service were confirmed, where those records were made or by whom to enable the NHSE to e [sic] assured that the service was provided to eligible patients in accordance with the service specification.

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

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

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

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

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

4.103.9 The appeal has not provided any evidence to suggest that the deliveries were made to patients eligible for the Medicines Delivery Service. The deliveries then claimed were not eligible for the Medicines Delivery Service payments resulting in an overpayment to the pharmacy.

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

4.104 Having considered these matters NHS England and Improvement respectfully suggests that NHS Resolution conclude that the decision made by the PSRC in respect

of the £6,288.00 for both CEV and SI overpayment recovery from Shaftesbury Pharmacy Ltd was fair and in accordance with the regulations.

4.105 Please let me know of [sic] you need anything further to help in these deliberations."

5 OBSERVATIONS

The Appellant stated:

5.1 "As our response, I am forwarding you the guidance below from Community Pharmacy England (CPE). I endorse and agree with the points raised and would be grateful if these would be considered as part of the appeal. I have sought the support of CPE and we have agreed on the following details addressed in the email from CPE. Please consider this as my response.

5.2 I also attach my personal response as a letter and statements from patients, as mentioned in my letter.

5.3 I trust these will be considered as part of the appeal."

5.4 The Appellant's response:

5.5 "In response to the representations from NHSBSA PAT, please consider the following:

5.6 *Throughout the investigation Shaftesbury Pharmacy Ltd did not provide any evidence as to how and when the eligibility of patients for the service were confirmed, where those records were made or by whom.*

5.7 *In a Teams call meeting with [LT] and [ML], CEO of Middlesex LPC, on the 13.12.24, the process when delivering to Self-Isolating (SI) patients was explained by [L] and [M] and this included obtaining their name, address and Test and Trace Account ID number and this was captured on the evidence. However, when the PAT queried how the evidence was captured i.e. digitally/paper based and who in the pharmacy performed this no response to the question was given.*

5.8 It was confirmed that the eligibility was confirmed by recording the details on the patients' bag labels which were on the daily pages of the delivery diary.

5.9 *However, it is also unclear how this contractor formed the opinion that records only needed to be retained for two years.*

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

5.11 Further endorsement, **in the absence of guidance**, it would be reasonable for pharmacy owners to consider a normal retention period, at that time, for Advanced Services, it was a retention period of two years; and therefore two years is the maximum **reasonable** time records would be kept.

5.12 *Shaftesbury Pharmacy Ltd admitted they had claimed for ineligible patients however they felt that they were still entitled to the payment already received for this.*

5.13 We discussed that it is likely we had claimed for CEV patients outside the allowable period, not all patients.

5.14 *The appeal has not provided any evidence to suggest that the deliveries were made to patients eligible for the Medicines Delivery Service. The deliveries then claimed were not eligible for the Medicines Delivery Service payments resulting in an overpayment to the pharmacy.*

5.15 As confirmation of deliveries made to SI patients and Track and Trace numbers provided and recorded, Shaftesbury Pharmacy has contacted 61 patients who have willingly confirmed that deliveries were made, and Track and Trace numbers were provided. See attached sample of patients who have signed statements confirming the same. **Further numerous statements are available from patients confirming that they were self-isolating and Track and Trace numbers were provided, if required.** Most of the patients in the attached statements had multiple deliveries during the period of concern, some patients receiving weekly deliveries for their monitored dosage trays.

5.16 **Request for NHS Resolution to Consider**

5.17 I would request that the NHS Resolution consider the points raised in the appeal provided, and the following:

5.18 1. As confirmed in the Appeal, the records were retained for two years, which was a **reasonable period in the absence of any guidance**. These records were:

5.18.1 Names and addresses of patients

5.18.2 Date of the delivery

5.18.3 Track and Trace number provided over the phone or to the delivery driver.

5.19 2. With non-existence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period. At that time, for Advanced Services, it was a retention period of two years; and, therefore, two years is the maximum **reasonable time** records would be kept.

5.20 3. Refer to attached sample statements from patients confirming that they were self-isolating, and Track and Trace numbers were provided. This is evident that process of checking for Track and Test eligibility was carried out, as per the guidance. More patients are willing to provide statements."

5.21 Email dated 1 September 2024 from Community Pharmacy England to the Appellant:

5.22 "We provide the following information for use in your appeal.

5.23 **Retention period**

5.24 **Prescribed retention period**

5.25 *NHSBSA PAT acknowledges that whilst the service specification is clear that records need to be kept for PPV purposes, it does not advise of exactly how long contractors were required to keep such evidence.*

5.26 *They go on to advise in their response that - However, it is also unclear how this contractor formed the opinion that records only needed to be retained for two years.*

5.27 Our response to this is:

5.28 *Section VIC of the Drug Tariff contains the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. Throughout the directions there are repeated requirements for records to retained for post payment verification purposes without the reference to a time scale for retention.*

5.29 Section VIC of the Drug Tariff requires retention, it does not advise a retention period. In practice, the retention period required for each service is stated in the service specification.

5.30 In the absence of any stated time to retain records in the service specification, the pharmacy owner must decide a reasonable retention period.

5.31 **Reasonable retention period**

5.32 NHSBSA PAT reference other services but their interpretation is not accurate. A reasonable time being 3 years is in our view incorrect. It is this that needs to be challenged. They say:

5.33 *Records of other service provision are required to be kept for 3 years for other services e.g. the Blood Pressure Checking service. see Advanced service specification: NHS community pharmacy hypertension case-finding advanced service (NHS community pharmacy blood pressure check service) (england.nhs.uk).*

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

5.35 However, the service they highlight (Blood pressure) was not commissioned until October 2021. This is after your last service provision to SI patients in September 2021. Also while it has a 3-year retention period for PPV purposes this longer retention period is a new development. At the time contractors were providing MDS, the other Advanced services that were available were:

5.35.1 NHS Flu – **No guidance in the service specification, Determination or Directions at this period**;

5.35.2 New Medicine Service – **retention for at least 2 years;**

5.35.3 Community Pharmacist Consultation Service – **retention of remuneration records for 2 years and then moved to 3 years**;

5.35.4 Medicines Use Reviews (MURs) – **retention of remuneration records for at least 2 years advised in Directions**

5.35.5 C-19 Lateral Flow Device Distribution Service – **no retention period advised**

5.36 It is from these services that you and other pharmacy owners might have been expected to consider how long to keep records. We say this period would have been 2 years, but this is subject to the next paragraph.

5.37 For the MDS service, the relevant information may have been recorded on the delivery logs for the pharmacy. These could have been retained for a short period of time, for example, 3 months. In the absence of any requirement to retain the records for a stated time, we say this would have been reasonable. Such delivery logs are not usually retained for long and at the time of the pandemic we do not consider there would have been much time to consider these issues.

5.38 Pharmacy owners will also have drawn retention guidance from other guidance sources, an example of this is below on page 4:

5.39 https://www.cpcw.org.uk/wp-content/uploads/sites/19/2016/08/CPCWRecommendations-for-the-Retention-of-Pharmacy-Records-v1.pdf

5.40 There is also an SPS guide

5.41 Additional services records in community pharmacy – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

5.42 **So, we suggest you argue with this information that a 2-year retention period was reasonable and appropriate in the absence of a stated retention period in the service specification – subject to reasonable decisions by pharmacy owners to keep the records for a shorter time.**"

6 CONSIDERATION

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

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

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

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

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

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

6.3.2 the grounds of the appeal are valid.

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

6.4.1 a hearing is unnecessary; or

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

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

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

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

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

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

6.10 I note that the NHS BSA has indicated that the deliveries that are covered by the decision on overpayment are those made in the period April 2021 to July 2021. These were split into 520 deliveries to those who were self-isolating and 528 deliveries to those who were Clinically Extremely Vulnerable (CEV).

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

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

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

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

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

6.14 I do not appear to have been provided with an announcement relating to the period 1 July 2021 to 31 July 2021. The NHS BSA has provided announcements dated 9 April 2020 and 30 June 2020 which do not appear to apply to the period 1 July 2021 to 31 July 2021. However I note that there is no dispute that the Community Pharmacy Home Delivery Service was commissioned during the period April 2021 to July 2021 inclusive and that it was only available to people during their 10-day self-isolation period who had provided their NHS Test and Trace Account ID when requesting the service.

6.15 The specifications and guidance provided state:

6.15.1 "*Pharmacy contractors should ensure that they are only delivering to eligible patients in the areas specified in the announcement in place at that time when they are acting in accordance with this service specification. Appropriate*

checks should be made to ensure that the patient remains eligible for this service, which may include checks on the summary care record."

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

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

6.18 In relation to deliveries to CEV patients, I note that the Appellant in its appeal refers to two NHS BSA emails which it considers indicate an internal decision made by the NHS BSA to not remove the function for CEV payments to be approved on the MYS system, however steps were not put in place to ensure that CEV claims were not paid until after May 2021. I note the Appellant's comment that this should have been notified to contractors.

6.19 The NHS BSA has referred to the specifications and guidance issued to contractors on 16 March 2021 and comments that "*The guidance stated that only self-isolators that have provided their Test and Trace Account ID reference number when requesting the service are eligible to receive it.*"

6.20 In its observations the Appellant states "*I acknowledge from the information provided that deliveries to support Clinically Extremely Vulnerable (CEV) patients, ended at the end of March 2021. Therefore, am willing to consider accepting, where CEV deliveries and service claims were made outside the commissioned period to this patient cohort, that these payments were not in line with the service specification and the pharmacy claims for these were in error."* I note further the Contractor's agreement to the relevant amount to be recovered if it is so decided, despite its appeal.

6.21 Given that the Appellant accepts that the deliveries to CEV patients made in April and May 2021 were claimed in error, despite its views regarding the functionality of the MYS system, I consider that the NHS BSA should now make the necessary arrangements for recovery of the monies.

6.22 I therefore limit the rest of my consideration to those payments in relation to self-isolating patients.

6.23 The NHS BSA has provided a timeline detailing its contact with the Appellant between 6 December 2023 and 28 February 2024, in order to request evidence that the 520 self-isolating claims made between April 2021 and July 2021 were for deliveries made to eligible patients as details in the service specification.

6.24 I note that the service specifications state:

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

6.25 I note in its appeal the Appellant states:

6.25.1 "*… it is unreasonable of the commissioner to think that records would be kept this long when:*

- There was no stated time in the service specification for which remuneration records should be kept for

- In the absence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period, at that time, for Advanced Services, it was a retention period of two years; and therefore

- Two years is the maximum reasonable time records would be kept –

- The data protection legislation requires you to keep such data only as long as necessary.

- The relevant two years is from the date the service was provided to the date the first request for evidence from NHSBSA.

- The request for evidence from the NHSBSA has been received ***two years and five months*** *after the last provision of the service and for deliveries provided in April 2021, it is* ***two years and seven months*** *after provision of the service.*" [emphasis added]

6.26 The Appellant further states that for claims made in the period April to July 2021, based on a two year retention period "*…and in the absence of supplementary guidance…*" the relevant dates until which to retain evidence would be May to August 2023.

6.27 The Appellant notes that the initial contact regarding this matter was made by the NHS BSA 7 months, 6 months and 5 months after a two year retention period for April, May and July 2021 respectively.

6.28 In response the NHS BSA has acknowledged that the service specification does not specify for how long contractors should keep records of the deliveries made but relies on the caveat that records must be retained for post payment verification. The NHS BSA states that "*Contractors were advised to retain evidence of deliveries made to Self-isolating patients as highlighted in the service announcements for post payment verification purposes*." The NHS BSA goes on to state that "*Throughout the investigation Shaftesbury Pharmacy Ltd were unable able to provide any evidence of how the eligibility of patients for the service were confirmed, where those records were made or by whom to enable the NHSE to e* [sic] *assured that the service was provided to eligible patients in accordance with the service specification."*

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

6.30 However the question being asked of the Appellant, was to review their claims and provide evidence to support the claims made for the relevant time period. Simply because the records have been destroyed does not mean that the Appellant did not collect the relevant information in relation to these claims. That being said, if the records were not retained in line with the service specification, then I do not consider that the lack of records should result in the benefit of the Appellant.

6.31 I note the NHS BSA's comment that in a Teams meeting call with the Appellant "*the process when delivering to Self-Isolating (SI) patients was explained by [L] and [M] and this included obtaining their name, address and Test and Trace Account ID number*

and this was captured on the evidence. However, when the PAT queried how the evidence was captured i.e. digitally/paper based and who in the pharmacy performed this no response to the question was given."

6.32 I note the Appellant's response that "*It was confirmed that the eligibility was confirmed by recording the details on the patients' bag labels which were on the daily pages of the delivery diary*." The Appellant has provided a number of signed statements from patients to whom deliveries were made confirming that their Track and Trace numbers were provided at the time. Whilst this provides a form of evidence that the correct details were recorded, I do not consider that this satisfies the requirements for the purpose of post-payment verification.

6.33 The NHS BSA states that "*It is unclear how this contractor formed the opinion that records only needed to be retained for two years*." I note the Appellant's response in its observations that "*With non-existence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period. At that time, for Advanced Services, it was a retention period of two years; and, therefore, two years is the maximum* ***reasonable time*** *records would be kept*."

6.34 The Appellant has also provided an email dated 1 September 2024 from Community Pharmacy England (CPE) containing guidance regarding the retention period. I note CPE's view that "*a 2-year retention period was reasonable and appropriate in the absence of a stated retention period in the service specification – subject to reasonable decisions by pharmacy owners to keep the records for a shorter time.*"

6.35 It is unhelpful that the service specification did not identify a requirement for the records to be retained for a set period. I also sympathise with the challenges faced by pharmacies as referred to by the Appellant in the appeal. I note that the Appellant has stated that "*Our records are maintained for the recommended periods as per the service specifications for NHS commissioned services. There was no guidance with regards to the period that records would need to be maintained, thus our decision to shred documents that were not required to be kept.*" I note that whilst the NHS BSA acknowledges that the New Medicine Service, for example, has a minimum 2 year retention date for records, it states that "*Records of other service provision are required to be kept for 3 years for other services e.g. the Blood Pressure Checking service.*" There are two matters arising from the NHS BSA relying of the above specification. Firstly, unlike in the Community Pharmacy Home Delivery Service, there is a clearly defined retention period. Secondly, the above specification post dates the verification exercise.

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

6.37 As I have noted, other similar services had retention periods of both 2 and 3 years. I note the Appellant's comment that "*With non-existence of guidance, it would be reasonable for pharmacy owners to consider a normal retention period. At that time, for Advanced Services, it was a retention period of two years; and, therefore, two years is the maximum* ***reasonable time*** *records would be kept.*" I do not consider it reasonable that, where a service specification expressly requires records to be maintained to support post payment verification, a pharmacy should be entitled to apply

a particular retention period without confirmation that there will be no post payment verification, and especially in circumstances where there are similar services which require a longer period.

6.38 With regard to the Appellant's comment on data protection legislation, whilst there is a requirement that data is kept for no longer than is necessary, there are also obligations on data controllers to ensure that retention periods are reflected in their privacy notice including any changes to data retention periods.

6.39 I have not been provided with any evidence to suggest that, at the time of the records destruction, there was any representation made to the Appellant that a 2 year retention period was appropriate or should apply to the Community Pharmacy Home Delivery Service. In circumstances where it was in its best interest to retain the records and it was aware of the consequences of not doing so, I must conclude that a 2 year retention period was not reasonable.

6.40 I consider that had any evidence, at all, relating to these months been provided then this might have enabled the Appellant to evidence that claims were made in accordance with the service specification. However, the Appellant has stated that they made a decision "*to shred documents that were not required to be kept*". I do not consider that this destruction was in accordance with the service specification as the Appellant has not set out a reasonable basis for applying a 2 year retention period. I consider that the Appellant should have been able to provide the necessary information for post payment verification by the NHS BSA. As it has not done so, I consider that the NHS BSA's decision to recover the overpayment is the only appropriate outcome.

7 DECISION

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

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

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

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

7.2 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £3,120.00 in respect of Self-isolating claims and £3,168.00 in respect of CEV claims.

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

Head of Appeals
NHS Resolution