General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Lloyds Pharmacy Clinical Homecare Ltd, Unit 3/5, Stoney Gate Road, Station Road Spondon, DERBY, Derbyshire, DE21 7RX

Pharmacy reference: 1087393

Type of pharmacy: Closed

Date of inspection: 20/08/2024

Pharmacy context

The pharmacy provides a homecare medicines service which involves delivering ongoing medicine supplies direct to people's homes. All of the treatments are initially prescribed by hospital prescribers. Some aspects of the service, for example nursing care, are not regulated by GPhC or are carried out at a different pharmacy. Therefore, we have only reported on the registerable services provided by the pharmacy. The pharmacy is located in industrial units and the premises are not open to the public. The Company is registered with the MHRA and holds a Wholesale Dealers Authorisation. This inspection is one of a series of inspections we have carried out as part of a thematic review of homecare services in pharmacy. We will also publish a thematic report of our overall findings across all of the pharmacies we inspected. Homecare pharmacies provide specialised services that differ from the typical services provided by traditional community pharmacies. Therefore, we have made our judgements by comparing performance between the homecare pharmacies we have looked at. This means that, in some instances, systems and procedures that may have been identified as good in other settings have not been identified as such because they are standard practice within the homecare sector. However, general good practice we have identified will be highlighted in our thematic report.

Overall inspection outcome

✔ **Standards met**

Required Action: None

Follow this link to [find out what the inspections possible outcomes mean](#)

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy effectively manages the risks associated with its services. It carries out regular audits and risk assessments and encourages people to give feedback so that it can take action to improve the service it provides. Members of the pharmacy team work to professional standards, and they are clear about their roles and responsibilities. They record their mistakes so that they can learn from them, and they act to help stop the same sort of mistakes from happening again. The team members keep people's private information safe. And they know how to help protect children and vulnerable adults.

Inspector's evidence

The pharmacy had service level agreements in place with a large number of NHS Trusts to provide homecare services to patients in the community. The pharmacy was one of four registered pharmacies owned by the company, which provided homecare services.

The pharmacy's main activity was compounding Home Parenteral Nutrition (HPN). It also compounded some desferrioxamine (Desferal) infusions and some antibiotic infusions. The HPN and infusions were aseptically compounded against prescriptions for named patients under a Medicines and Healthcare products Regulatory Agency (MHRA) Specials license. There was a separate compounding team, and a quality assurance (QA) team. The HPN and infusion therapies generally required nurse support. There was a nursing team at the pharmacy and the nursing service was registered with the Care Quality Commission (CQC). The responsible pharmacist (RP) needed to be present for the 'release' of products from the compounding unit into the logistics chain. The compounded products were labelled and checked and then supplied to people's homes by the pharmacy's delivery and transport team. The pharmacy also supplied ancillary items such as giving sets, alcohol wipes, dressings, and needles, but prescriptions were not required for these.

A customer service team (CST) and a prescription management team operated from the company's pharmacy in Harlow. All of the prescriptions which the pharmacy dispensed were received by the Harlow branch, usually by post. Pharmacists in Harlow clinically screened the prescriptions and the teams there transcribed all the required information onto the system and scanned in copies of the prescriptions. This process was known as 'building.' The company had recently introduced a new software system that could recognise a patient when a prescription was scanned onto the system, and added the treatment details onto the patient's record, instead of it having to be added manually. This had gone live for most therapies and the full transition was due to be completed within a month. This was predicted to support faster matching of patients to their records to reduce administrative burden. The time taken to add the information to the system had recently been reduced from five days to within 24 hours of receipt to help to avoid delays. Each prescription was given a unique number and it could be tracked throughout the process, including its delivery to the patient's home. Once the information had been added to the system the pharmacy could access it in order to dispense the prescriptions.

The pharmacy had up-to-date electronic standard operating procedures (SOPs) for the services it provided. These were also available as hard copies. There were individual records showing that members of the pharmacy team had read and accepted the SOPs. An RP notice was appropriately displayed. And because the pharmacy was large, an email was sent to team members to inform them

when there was a changeover of RP.

A business continuity plan was in place which gave guidance and emergency contact numbers to use in the case of systems failures and disruption to services. It focused on identifying and prioritising the recovery of critical activities and resources.

The company kept a risk register and had a Quality, Patient Safety and Risk Management Committee chaired by the superintendent pharmacist (SI) that met monthly to review company-wide risks. There was a separate monthly review of pharmacy issues that fed into this committee meeting. The SI attended the statutory board meetings to report back on the identification and management of risks within the company.

All new services, medicines or prescribers went through an approval process prior to being progressed. Risk assessments were required for all submissions covering the specific risks to providing the service and how these would be mitigated. For example, for a nursed service how would the infusion related reactions be managed.

Audits were carried out at least twice a year. A recent audit had been completed to evaluate and improve the process of handling clinical screening queries within the pharmacy team. This aimed to better understand the current workflow, assess the effectiveness of communication between departments, and determine the impact of these queries on overall capacity. It was found that same day deliveries (SDD) were the second most frequent query type. The agreed actions were to improve the communication processes and initiate a centralised and live document, which all departments could use to track progress of SDDs, so the queries could be resolved more quickly.

Near miss incidents were reported electronically. The pharmacy team reviewed the records monthly and generated a report which was used to identify learning points to be actioned and shared within the teams. A monthly Safer Care bulletin was sent out with learning points from any patient safety incidents. For example, the most significant errors were incorrect quantities being dispensed due to confusion between packs and their individual components. This had been addressed by the introduction of a standard unit which was to be used by the building team when inputting the prescription details. There was a quarterly review to ensure that learning points had been actioned and taken forward.

The pharmacy had a Complaints and Incidents Management SOP which outlined the steps to be followed to manage any complaints or incident reports received from Trusts, patients, and other stakeholders. Complaints ranged from long call waiting times with the CST, to more serious incidents such as a patient missing a dose, which could potentially lead to hospitalisation. The pharmacy had identified that the most common reason for missed doses was late prescription receipt from a Trust, which was generally outside the control of the pharmacy. Prescriptions getting lost or delayed in the post, and postal strikes, was one reason that prescriptions were not received in time. Because of this, there was a drive within the homecare pharmacy sector for electronic prescriptions, and there was a pilot of electronically transmission of prescriptions taking place which involved a small number of hospitals. The pharmacy had taken steps to address issues they had identified that were within their control, for example they had changed the staff resourcing model and were training more staff, so that they were able to answer phone calls and queries more quickly. And the pharmacy had introduced a new incident reporting and management tool, which enabled all complaints and incidents to be tracked on one system rather than several different systems.

Every patient was asked to complete a full satisfaction survey on an annual basis. In previous years, the

survey had been posted out to patients, but this year a link had been sent by text, which had received a better response rate. The pharmacy also contacted a sample of patients every month and asked three questions in order to obtain feedback on how likely people were to recommend the pharmacy's service to others. The pharmacy team was able to describe improvements that had been made in response to feedback that had been received. For example, following reports that a number of patients did not have positive call experiences when contacting CST, the team had introduced a new quality assurance framework to upskill call handlers, monitor the quality of calls and manage the performance of the call handlers more effectively.

The pharmacy team held regular performance meetings with the Trusts where they discussed a variety of issues including the responses from patient satisfaction surveys, complaints, delays in receiving prescriptions, stock and supply issues and changing to new suppliers, as well as reviewing performance against specific targets. They also invited the Trust to complete a satisfaction survey annually and asked them three questions about the delivery service, the patient interaction, and the nursing service. Professional indemnity insurance was in place and the SI confirmed that it covered all the activities carried out at the pharmacy. The RP record was appropriately maintained.

All members of the pharmacy team had read and signed a confidentiality procedures SOP and a data protection policy. The warehouse and transport manager knew the difference between general and confidential waste and understood what it meant to maintain patient confidentiality. He explained that confidential waste was stored in designated bags until it was collected by a waste disposal company. Individual passwords were required to sign onto the software system containing prescriptions and patient records, to help maintain confidentiality.

There were SOPs on safeguarding children and vulnerable adults. Pharmacists and nurses had completed advanced level training on safeguarding. Other staff had completed training at a level relevant to their role, including people who interacted directly with patients such as the CST team. The warehouse and transport manager confirmed that all delivery drivers had completed training on safeguarding and would report any concerns to the pharmacy. All concerns were shared with the nursing team within two hours.

Principle 2 - Staffing   ✔ Standards met

Summary findings

The pharmacy has enough suitably trained and qualified team members to manage its workload. It encourages team members to keep their skills up to date and supports their development. Team members are comfortable providing feedback to their managers and they receive feedback about their own performance to help them improve.

Inspector's evidence

The SI, deputy SI and head of clinical pharmacy were present at the inspection. The SI was the director of quality governance and director of quality assurance. There were three other pharmacists present. One pharmacist was working remotely from home, answering clinical queries. The four pharmacists were part of a team of seven regular pharmacists who clinically screened prescriptions for two of the other pharmacies. The staffing level was adequate for the volume of work during the inspection and the team members were observed working collaboratively with each other. If the team found it difficult to manage the workload at any time, other staff could be called in, or other sites could be asked to take over some of the work.

The SI and deputy SI each visited the pharmacy around two days every month and the head of clinical pharmacy worked at the pharmacy two or three days each month, and occasionally worked as the RP. The pharmacists who clinically screened prescriptions received training on the types of medicines that the pharmacy supplied, such as parenteral nutrition. This training was reinforced by short assessments. The team at Harlow could be contacted to help with any specific queries about compounding. The pharmacy team carried out ongoing training through an online learning platform and this included annual mandatory training on information governance and health and safety. New team members had performance reviews at one, three and six months, with six-monthly appraisals thereafter. They were also able to speak to their line managers informally on an ad-hoc basis.

All team members received an induction when they first started working at the pharmacy. They were required to read and sign SOPs relevant to their role and received specific on-the-job training. All the training was in-house with no formal qualifications. The pharmacy employed a team of 21 delivery drivers. The drivers received a two-week induction and in-house training specific to their roles, which included reading SOPs and 'on the road' shadowing and training. At the end of the two-week induction the drivers were assessed and either signed off as competent or given further training. Agency drivers from a separate company were sometime used. These drivers underwent the same training as the employed drivers. The daily performance was monitored for delivering on time and for any failed deliveries. Appropriate action was taken to address any issues identified.

The pharmacists confirmed that they were comfortable making suggestions and raising concerns with their line managers and senior management. They were aware that the company had a whistleblowing policy and understood that they could contact the GPhC if they wished to raise concerns outside the organisation. 'Speak Up!' notices were on display throughout the premises which allowed people to report concerns anonymously via an external confidential helpline. All team members had 6-monthly performance management reviews during which they were given feedback to help them improve.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and well maintained. It is secure and safeguarded from unauthorised access. And it provides an appropriate environment for healthcare services.

Inspector's evidence

The premises consisted of three large industrial units which were clean, spacious and in a good state of repair. One unit contained the compounding suite, associated warehouse, and QA area where the 'release' took place. The other two units contained large warehouses, a clinical screening office, and meeting rooms. The clinical screening office was also used by the nursing team. A maintenance person worked in the pharmacy two or three days each week for minor repairs. Cleaning was contracted out to a team who worked under supervision. Swipe cards with different levels of access were used by all staff working on the site. When a staff member left the business, their swipe card was immediately cancelled. The list of staff members using swipe cards to access different parts of the premises was checked and reviewed three times each day, to help ensure that only authorised people had access to restricted areas, such as the clinical screening office and the QA area. The temperature and lighting were adequately controlled. Staff facilities included two staff tea rooms with kitchen areas, and several WCs with wash hand basin and antibacterial hand wash. The pharmacy had a website (www.lpclinicalhomecare.co.uk) which contained information about the company and the clinical homecare service.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are generally well managed and easy for people to access. The pharmacy has introduced new initiatives to improve its efficiency and support patient safety. It gets its medicines from licensed suppliers, and it carries out checks to ensure medicines are in good condition and supplied safely.

Inspector's evidence

The pharmacy premises were closed to the public. People could communicate with the pharmacist and staff via the CST. When people used the pharmacy's service for the first time, they completed a registration process with the team at the Harlow branch. The registration process provided the pharmacy with the person's contact details and a section confirming that the hospital team had discussed the homecare service with them. The CST's telephone system had a call-back option for people to choose when the line was busy, and the CST were required to complete all call-back calls by the end of the working day.

The CST arranged a delivery date with people when their first, and subsequent prescriptions, were received. People received a text message the night before the delivery, with an expected two-hour slot. Six weeks before the patients next prescription was due the prescription management team would send an email message to the hospital. The pharmacy then expected the prescriptions to be received at the Harlow branch at least four weeks before the supply was due. But the team reported that this timeframe often slipped and said this was one of the major causes of delay. There were also sometimes delays because of issues with the prescriptions they received. For example, if they were incomplete or had not been signed. Prescription requests were chased up three times if the prescription was not received. Often the pharmacy then found out that treatment had been stopped and the patient did not require the prescription. But sometimes this was not the case, and the patient would call to book a delivery only to find that their prescription had not been received. The pharmacy would then have to contact the Trust urgently to resolve this issue. This constituted a patient safety risk, with delayed deliveries or even missed doses as a result. The pharmacy had just started trialling a new process whereby the patient was added onto an 'at risk' report if their prescription had not been received five days before the supply was due. The relevant hospitals were then called to chase the outstanding prescriptions. The team felt the new process had been more effective and helped avoid further delays.

Another common reason for delays to people receiving their medication was problems obtaining stock and ingredients from the supply chain. It wasn't a straightforward process to switch from one brand to another or even to change generic brands, as the pharmacy had to go back to the prescriber at the Trust to obtain permission. This was because the NHS Trusts and manufacturers liaise to agree a treatment plan for each specific medicine, and the manufacturer might give discount to a Trust for specific regimes. The contract with the pharmacy usually specified these details. Changing to a different brand or formulation usually had cost implications. The SI confirmed that in an emergency, to avoid a patient going without medication, the financial implications would be ignored.

Most patients using the homecare service received two weeks' worth of buffer (safety) stock by the pharmacy delivering their second order two weeks early. This 'extra' stock was to tide them over in an emergency if they did not receive a delivery for any reason. However, this was not possible for HPN and

infusions because generally they only had an expiry date of around eight-days and the usual supply interval for them was one week. So, adults typically had one week of buffer stock and children might only have two to three days because paediatric HPN had an even shorter stability time. Whenever a delivery was booked in, the CST team always checked with the patient to see how much buffer stock they had left.

Patients were educated by the hospital to understand which ancillaries they needed, and people could call at any time and order any they required. The pharmacy supplied ancillary items and charged the Trust accordingly. The pharmacy sent ancillary items out at any time if urgent, and in any quantity.

The pharmacist responsible for the 'release' of the HPN and infusions carried out an accuracy check against the prescription and the prescription transcription sheet. They added their initials to the Good Manufacturing Practice (GMP) sheet to show they had carried out the final QA check.

The pharmacy maintained an electronic audit trail for the delivery service. The delivery driver used an electronic handheld device to record each delivery, and a signature was obtained from the recipient, along with their name and relationship to the patient. A note was left if nobody was available to receive the delivery and the medicine was returned to the pharmacy. The CST normally called people the same day to see when they would like their items to be redelivered. Redelivery attempts were made until the delivery was successful. The electronic system was geo-tagged so the driver and the organisation could see exactly where they were, and there had not been any known incidents of a delivery to the wrong address. Four of the delivery drivers were designated to carry out emergency deliveries and they had the capacity to carry out up to 100 emergency deliveries each day. In a typical day around 30 emergency deliveries would be necessary. People had access to the delivery schedule so they could check when their delivery would arrive. This helped to reduce the risk that a patient was not at home to receive the delivery. A patient portal where people could book their own delivery slots was being developed and was due to go live at the end of the year.

Recognised licensed wholesalers were used to obtain stock medicines and ingredients. These all had to be authorised by the Trusts because of the cost implications. The pharmacy carried out date checking of all ingredients used for compounding and this was inspected by the MHRA.

Alerts and recalls were received via the QA team and shared with warehouse teams. The relevant stock would be quarantined if there was any in the warehouse and returned to the manufacturer if required. Batch numbers were always logged onto the pharmacy's software system, so people could be contacted via the CST if they had received an affected batch, and a replacement would be organised. A record of the action taken was kept by the QA team, so the team were able to respond to queries and provide assurance that the appropriate action had been taken. Any pharmacovigilance reports regarding adverse effects were sent direct to manufacturers and Yellow Card reports were also completed.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has access to the equipment and facilities it requires to provide its services safely. It appropriately maintains and monitors the equipment to help make sure it is fit for purpose and safe to use.

Inspector's evidence

The pharmacists could access the internet for the most up-to-date reference sources. For example, the electronic British National Formulary (BNF), BNF for children and electronic medicines compendium (eMC). Summaries of Product Characteristics (SPCs) were generally viewed on the eMC website. The MHRA website was used for SPCs which were not available on the eMC website. The pharmacists used the General Medical Council (GMC) website to check the prescribers' registration numbers and verify their registration, if they weren't familiar to them.

The pharmacy had 19 temperature-controlled vans to transport medicines to patients' homes. HPN and infusions were prioritised for delivery as they had very short expiry dates and minimising temperature fluctuations was critical to maintain their stability. The vans' temperatures were monitored by a temperature monitoring team. An alert was sent to the warehouse and logistics team if the temperature fluctuated outside the required temperature range, known as an 'excursion'. There was a cold chain custody SOP. The pharmacy used the NHS Excursion tool for checking temperature fluctuations that occurred during the delivery process and contacted manufacturers for advice if necessary. A pharmacist used their professional discretion as to any action that needed to be taken following an excursion, depending on the temperature reached and the time it was out of range.

A back-up internet connection was available for use if the main connection failed. The SI explained that this switched over automatically, so there was negligible downtime on the rare occasions that it needed to be used. The pharmacy software systems were protected with passwords.

What do the summary findings for each principle mean?

Finding	Meaning
✔ **Excellent practice**	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ **Good practice**	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ **Standards met**	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.