General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Lloyds Clinical Limited, Unit 3&4 Spire Green Centre, Flex Meadow, The Pinnacles, HARLOW, Essex, CM19 5TR

Pharmacy reference: 1117146

Type of pharmacy: Closed

Date of inspection: 13/09/2024

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. Therefore, we have only reported on the registerable services provided by the pharmacy. The pharmacy is located in a purpose-built industrial unit and the premises is not open to the public. The Company is registered with the MHRA and holds a Wholesale Dealers Authorisation.

The 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 the pharmacies we inspected. Homecare pharmacies provide specialised services that differ from the typical services provided by community pharmacies. Therefore, we have made our judgements by comparing performance between 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

Overall, the pharmacy manages it's risks safely and effectively. It has a set of written procedures which team members follow to ensure they work safely. The pharmacy records and reviews mistakes so that it can learn from them and takes action to prevent similar mistakes happening again. People can provide feedback to the pharmacy about its service, which the pharmacy uses to help it improve. And the pharmacy keeps the records it needs to by law.

Inspector's evidence

The pharmacy was one of four registered pharmacies owned by the company which specialised in homecare services. It had service level agreements (SLAs) with several NHS trusts across the UK. People were signed up to access the pharmacy's services by their trust. This pharmacy mainly supplied home parental nutrition (HPN) and chemotherapy through infusions. And prescriptions for these were screened and clinically checked by the pharmacy team based at the premises. The medicines were compounded on-site for individual patients under an MHRA license. The infusions mostly required additional nursing support, and this was provided by the company's nursing service, which was regulated by CQC. The pharmacy's customer service team (CST) was based at one of the other branches, in Harlow.

The pharmacy had a comprehensive set of standard operating procedures (SOPs) which covered it's activities. The SOPs were available for all team members to view on an intranet platform. The SOPs were reviewed every two years by the superintendent pharmacist (SI). Team members were required to read the SOPs relevant to their roles. And a training record was kept showing which SOPs they had read. When SOPs were updated, team members were sent an email alert and given time to read them. When questioned, team members were able to clearly describe their roles and responsibilities.

The pharmacy had a business continuity plan in case of service disruption. It covered issues such as critical staffing levels and IT failures, as well as full power outages. Risk assessments had been completed for the individual services and products it supplied. These identified any risks with the service and how they could be managed. The pharmacy had a drugs and therapeutics committee who would oversee the introduction of any new therapies. This involved risk assessments being completed before a new therapy was approved. The team shared an example of a new product that had been introduced which had a higher risk of infusion reactions. The team had worked with the Trust to ensure people on this therapy should have six cycles of medication in the hospital without a hypersensitivity reaction before being moved to the homecare service.

The pharmacy completed two audits each year. The most recent was done in July 2024 to review the process of handling dispensing unit queries within the pharmacy team. The aim was to understand how the team could reduce delays and improve the speed at which queries were resolved. It was identified that the pharmacy team generally responded to queries within thirty minutes and that most queries related to patients wanting to know where their delivery was. One outcome of the audit was to develop a centralised document to track deliveries. This had helped reduce the number of calls the CST needed to make and therefore they were able to resolve queries more efficiently.

The pharmacy made electronic records of near misses (mistakes that were made and corrected during the dispensing process). These were reviewed monthly, and key learnings were shared with the wider team. For example, the team had identified a number of mistakes in the quantity of infusion bags being dispensed, so it had introduced a process where a pre-check was carried out and team members circled the quantity on the packing slips to highlight it. This helped reduce the incidence of quantity mistakes. Near miss trends for each of the areas (QA, the dispensing unit and the central pharmacy team) were highlighted on a patient safety board in the office. The SI explained that the pharmacy had recently implemented a new incident and quality management system which had improved the reporting of near misses and incidents. The system allowed incidents, near misses and complaints to be recorded in the same place. And this helped the SI identify trends and put actions in place to try and prevent similar mistakes happening again. The SI was also the quality and governance director for the pharmacy and was part of the company's Quality, Patient Safety & Risk Management Committee. The committee held meetings monthly and discussed complaints and incidences so they could share learnings from them across all four pharmacies. The pharmacy also held meetings with the Trusts to discuss any concerns or any changes in ways of working.

When people were registered with the pharmacy, they were sent a welcome letter which included information about the service, including contact details. The pharmacy had a complaints procedure. And this was detailed in the welcome letter and on the pharmacy's website. The pharmacy had a dedicated patient experience team who managed complaints. People could provide feedback over the phone or by email. The pharmacy reviewed complaints monthly. The pharmacy also carried out a patient satisfaction survey. The most common reasons for complaints were due to delivery issues and poor communication with the CST. As a result of this feedback, the quality and training team had started to monitor calls and used this to provide feedback and training to the CST. The SI explained that in order to improve the delivery service, the pharmacy was trialling a patient portal which allowed people to view their delivery dates and details to help reduce failed deliveries.

The pharmacy had current professional indemnity insurance in place. The responsible pharmacist (RP) notice was displayed prominently in the prescription screening office. And the RP record was completed as required with start and finish times.

Team members completed data protection and information governance training as part of their induction. And the pharmacy provided annual refreshers of this training. When questioned, team members understood how to protect people's personal information and explained how confidential information was managed appropriately. The pharmacy's privacy notice was available on its website.

All team members had completed safeguarding training relevant to their roles and knew how to identify and refer a safeguarding concern. Delivery drivers would refer any concerns onto their line managers who would escalate these to the pharmacy's safeguarding lead.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload safely. And there is adequate contingency to manage staff absence when required. Team members are appropriately trained to carry out their roles. And they receive ongoing training to help keep their skills up to date. They know how to raise concerns or give feedback about the pharmacy, to help it improve.

Inspector's evidence

The SI, deputy SI and head of clinical pharmacy were present during the inspection. The pharmacy had fifteen pharmacists and four pharmacy technicians who were working at the time of the inspection. The pharmacy had a team of 132 delivery drivers across all the pharmacies who delivered medication to people's homes. Pharmacists and Pharmacy technicians were involved in processing the prescriptions and clinical screening. The compounding and labelling of medicines were completed under the pharmacy's MHRA license but the RP was required to be present for the release of medicines from the pharmacy. Team members were observed to be working well together. The RP explained they tried to work a week in advance which allowed the workload to be managed in case of unexpected absence. The SI explained if needed, the pharmacy could bring in team members from other pharmacies in the organisation for support. Locum pharmacists were occasionally used. But only after they had been trained on the pharmacy's services.

Team members received comprehensive training during their induction. This included mandatory training on information governance and health and safety. The pharmacy team received a structured programme of training. Pharmacists worked through various training modules on the different therapy areas and each had to be signed off before they moved onto the next. Team members only worked in the areas they had completed training for. Most training was in-house, but the pharmacy also encouraged pharmacists to complete some training provided by the British Oncology for Pharmacy Association. Team members were provided with dedicated training time during their working hours. And training records were kept electronically.

Delivery drivers received a two-week induction which included mandatory e-Learning, SOP reading and on-road shadowing. At the end of the 2 weeks, they were assessed and either further training was provided, or they were signed off with their training completed.

Team members were invited to complete an annual staff survey. The most recent results had found that team members felt valued, and they found the pharmacy supportive and inclusive. Team members felt that senior leaders could be more visible. Following this feedback, the CEO had organised 'coffee and cake' meetings to allow team members to have more direct communication with the leadership team.

Team members had 6-monthly performance reviews. And they felt comfortable about raising concerns or giving feedback to their managers. The pharmacy had a whistleblowing policy in place to allow team members to raise concerns outside of the organisation.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean and well maintained. They provide a suitable environment for healthcare services. And they are kept secure from unauthorised access.

Inspector's evidence

The premises consisted of 2 large industrial units which were connected. They were well maintained and kept clean. One unit comprised of compounding units and aseptic areas where MHRA activity took place. And there was large warehouse to store the raw materials used for manufacturing the infusions. Pharmacists and technicians were located across two main offices in the other unit. This area was used for formulating and clinically screening prescriptions. There were meeting rooms and several WCs located across the units. And the lighting and temperature were adequate throughout the premises for working and storing medicines.

The pharmacy was closed to the public and kept secure. Visitors were required to sign in and sign out. And they were provided with temporary passes during their visit. 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 generally manages its services well. It communicates effectively with people to help them manage their medicines. And it reviews its processes to try and make them more efficient. The pharmacy ensures compounded medicines are stored appropriately. And it carries out checks to make sure they are suitable for use.

Inspector's evidence

The pharmacy premises was not open to the public. There was signage on the warehouse units displaying the pharmacy's logo. There was limited parking on site. People could contact the pharmacy via phone or via the 'contact us' form on the pharmacy's website. Phone calls to the pharmacy were received by the CST located at the premises in Harlow.

Access to the pharmacy's services was via referral from NHS trusts. The Trust identified patients who were suitable for the service and completed registration forms, which were sent to the pharmacy. The registration form contained contact details for the person and confirmed what information the Trust had provided to the patient about the homecare service. The pharmacy would then complete a welcome call to the person to complete the onboarding process. The pharmacy would receive a new prescription by post and would input the patient's details into the system. The prescription was then be processed. Once this had been clinically screened by the pharmacist, a phone call was made to the patient to arrange their delivery.

The pharmacy had a process for automatically ordering prescriptions six week in advance of people needing their medicine. Prescriptions were generally sent to the pharmacy by post; however, a few were collected from the Trusts. The SI explained they were trying to encourage trusts to take up electronic prescribing to improve efficiency but that it was proving difficult to do and very few currently sent prescriptions electronically. If a prescription wasn't received in within four weeks of the medicine being due, the pharmacy contacted the hospital to chase the request up to three times. A significant number of prescriptions were not received from the Trust on time. This was one of the main reasons for delays in delivery or missed doses. Often the delay issuing a prescription was because the Trust was waiting for blood test results, or the person needed to be seen in the hospital. The pharmacy had recently implemented a risk management process to try and reduce delays, where any prescriptions which were due in the next five days were flagged and a final call made to the hospital.

Most patients on the homecare service would have 'buffer' stock in case of any delays to their delivery. The CST would confirm the buffer stock levels each time they contacted people to arrange deliveries. In the case of HPN and infusions, buffer stock was usually a maximum of two bags due to the stability of the product. If a person did not have enough buffer stock, the pharmacy would liaise with the Trust to manage this.

Once a prescription was received, it was scanned into the system using the pharmacy's optimal character recognition software. This enabled a large volume of prescriptions to be scanned in and stored under the correct patient record. However, some prescriptions still had to be entered manually. This was because the software could not always clearly read the prescription details, for example due to the prescriber's handwriting. Prescriptions for HPN and infusions were formulated onto a template by

pharmacy technicians and then sent to the pharmacist for a clinical check. Pharmacists were given responsibility for a specific therapy each day. The template was sent to the Trust for a prescriber to sign and then it would come back for a final clinical screen by the pharmacist. The prescription was then released for the compounding team to prepare the product. A 'framework' form was attached to each prescription and used to track each stage of the process to map the workload. This helped maintain an audit trail and allowed pharmacists to prioritise prescriptions according to due dates.

Once the products had been compounded, they were released to the quality team under the RP. The team would check the product and labels against the respective prescriptions and complete a final accuracy check. The products were then packed and prepared for delivery. Oncology treatments were sent out within 24 hours.

Deliveries were booked for people once prescriptions had been clinically screened and released for compounding. People would receive a message one week before their delivery to let them know their delivery date. The day before, they would receive a two-hour window for when to expect their delivery. If there were any unexpected delays, the CST would contact the person to inform them. If there was a failed delivery, a note was left, and the medicine returned to the undelivered goods area until they could be re-delivered. The pharmacy was also able to make urgent same-day deliveries if required. If the pharmacy could not contact the patient, it would inform the Trust.

The pharmacy's procurement team ordered stock from licensed wholesalers and direct from manufacturers and forecasted the volume of stock needed in advance. This helped manage the stock levels. The team would liaise with the Trusts if products were in short supply and there was a dedicated switch team if medicines had to be changed due to stock shortages. The team received a daily email detailing what stock was due to expire in the next 28 days and there was a check on the system to identify any stock that would be expiring within three months. Affected stock was then removed. This information, including batch numbers was entered into the system on receipt of stock into the warehouse. Products requiring cold-storage were stored in temperature controlled cold rooms. Drug alerts and recalls were managed by the central quality team. They liaised with the supply chain teams who were able to track products by batches. Any affected stock would be quarantined. If needed, products could be recalled from individual patients and replacements supplied.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy had the equipment it needed to provide its services safely. All equipment was maintained appropriately so it was fit for purpose.

Inspector's evidence

Team members had access to any online resources they needed. These included the British National Formulary (BNF) and summaries of product characteristics (SPCs). There were a number of computers for team members to use. These were password protected to prevent unauthorised access. Team members had headsets to take calls.

There pharmacy had five cold-storage rooms. And the temperature in these were continuously monitored. If the temperature went out of range, an alarm would sound, and senior team members were alerted. The pharmacy also had temperature-controlled vans to deliver medicine to people's homes. The temperatures in these were also monitored, and the pharmacy was alerted if the temperatures went out of range. This allowed the pharmacist to make sure medicines remained suitable for use.

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.