General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Fresenius Medical Care, C/O Polar Speed Distribution Ltd, Nunn Brook Road, Huthwaite, SUTTON-IN-ASHFIELD, Nottinghamshire, NG17 2HU

Pharmacy reference: 1087869

Type of pharmacy: Homecare Medicine Service

Date of inspection: 16/07/2024

Pharmacy context

The pharmacy provides a homecare medicines service which involves delivering ongoing medicine supplies directly to people's homes. All of the treatments are initially prescribed by prescribers working in hospitals. Some aspects of the service, for example nursing care and the manufacture and wholesale of medicines, are not regulated by the GPhC. Therefore, we have only reported on the registerable services delivered by the pharmacy. The pharmacy is located in a large industrial unit which it shares with another company that provides its warehouse and logistics services.

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 identifies and manages the risks associated with the services it provides. It keeps its records in good order, and it protects people's confidential information. The pharmacy is receptive to feedback, and uses it to improve its services. Its team records its mistakes so it can learn from them. And it takes action to help prevent mistakes from being repeated.

Inspector's evidence

The pharmacy was owned by a global company that specialised in dialysis care and renal services. The company was also regulated by Medicines and Healthcare products Regulatory Authority (MHRA) and Care Quality Commission (CQC).

The pharmacy had service level agreements (SLAs) with a number of NHS trusts across Great Britain. It supplied medicines against prescriptions issued by the Trusts and delivered them directly to people's homes. The pharmacy service had two distinct parts. The 'home delivery' workflow focussed on the supply of smaller packages such as cold chain medicines including injections and was similar to a traditional dispensing model. The 'product' workflow focussed on the supply of haemodialysis (HD) and peritoneal dialysis (PD) products, including all the ancillary items people required to support their treatment. This workflow involved products being dispensed on large pallets from the pharmacy's warehouse. The pharmacy team worked closely with a customer care team, which liaised directly with the patients, and with a regulation team that dealt with contract monitoring and risk management. A warehouse and logistics provider (WLP), owned by a different company, was used to complete warehouse tasks and for the delivery service.

The pharmacy had a business continuity plan in place. And risk registers were available that clearly identified risks associated with the prescription journey and the individual products it supplied, and the controls in place to mitigate these risks. Each risk was given a severity scoring which determined the review frequency. All the current risks had been assessed as low severity, to be reviewed every three years. A new HD treatment had recently been introduced, which required a standalone prescription management platform. The team had received training about the therapy, the dialysis machine and the new software before the service was implemented.

The pharmacy had an information database that contained information about its specialist products, including product characteristics, patient information leaflets and any correspondence with manufacturers. Pharmacists used this information to support them in clinically assessing prescriptions and answering queries.

The pharmacy had standard operating procedures (SOPs) to support its safe and effective operation. The SOPs were held electronically and an automatic alert was generated when a SOP was due for review. Some were currently being reviewed so the pharmacy had adopted short-term 'work instructions' to support the team during the review period. Pharmacy team members could readily access the SOPs on their computers and completed training records to confirm they had read and understood them. All team members contributed to the contents of new SOPs and were able to submit a request if they thought any changes needed to be made to a SOP. Team members were passionate when speaking about their roles and demonstrated a good understanding of the pharmacy's processes,

the homecare model and the treatments and the ancillary products they dispensed.

The pharmacy monitored specific performance data and reported on its performance against national key performance indicators (KPIs). The data collection processes were manual and took a lot of time due to the considerable number of spreadsheets containing data requiring analysis. Performance data was discussed in regular meetings with the WLP to review the reasons for any delivery issues so that action could be taken to improve the service. For example, missing items on pallets had been identified as a common theme. So all warehouse operatives had been given bespoke induction training explaining the nature of the business and care needed when picking, including the need for items to be presented for dispensing on pallets in a specific way and wrapping of the pallets to be completed after all dispensing tasks were complete. The pharmacy had carried out some audits of its services. But it had not carried out a formal pharmacy specific audit for several years. This meant there may be missed opportunities to identify potential weaknesses in its systems to be able to improve them.

The pharmacy kept records of mistakes it identified at every stage of the prescription journey, known as near misses. The records were reviewed each month and a report was produced to identify trends. These reports were shared with the teams and also discussed during a clinical governance session at the company's quarterly board meetings. The data was used to identify actions that could be taken to reduce the risk of errors, and to measure the effectiveness of actions previously taken. For example, the team had identified regular mistakes involving the maximum number of deliveries a person could receive before a new prescription was required. The review process identified these were often prescriptions received from two particular NHS trusts that did not use a consistent maximum delivery when prescribing. So it had introduced extra steps when processing these prescriptions to ensure maximum delivery quantities were accurate. Another trend in near misses had identified that quantities of medicines assembled within the dispensary did not always match with people's delivery cycles, meaning they may run out before their next delivery was due. To reduce this risk, the team had introduced additional checks into the dispensing process to ensure the quantity supplied matched with the person's delivery cycle.

Mistakes identified following delivery to a person were known as dispensing incidents. The pharmacy informed NHS trusts of all reported incidents. The customer care team received specific training to help them support patients involved in dispensing incidents, and incidents were referred to the pharmacy team for investigation. The team demonstrated some actions it had taken to reduce risk following incidents. For example, a stock box of medicine had accidentally been sent to a person with their delivery. So the team had introduced a requirement for accuracy checkers to personally check the contents of shipping boxes before they were sealed.

The pharmacy had a complaints procedure to deal with any concerns it received, including feedback from homecare and renal teams working in hospitals. It had regular meetings with some NHS Trusts to review performance issues. But some Trusts did not engage. People contacted the pharmacy through its customer care line and patients had a named care coordinator within the customer care team. Records of contact were made on the patient records so the team was able to see any ongoing queries and interaction history. Concerns were investigated to identify contributory factors and the impact on people's health and wellbeing, such as missed doses. The pharmacy provided examples of feedback being used to inform change. For example, following a concern about a failed delivery, the customer care team had been reminded about the importance of confirming delivery address details when booking deliveries.

The pharmacy's telephone system did not track call waiting times or abandoned calls so it could not measure whether people had difficulty getting through. People had the option to leave a voicemail if

their query was not urgent. The customer care team explained that a concern with the telephone line a few months earlier had led to an increase in unanswered calls and feedback about excessive waiting times. The customer care manager had oversight of the tasks advisors were completing through a live dashboard. This had helped to identify that calls were not being answered and the issue was rectified quickly by the telephone service provider.

The superintendent pharmacist (SI) was the pharmacy's safeguarding lead and had completed enhanced training. All other team members completed safeguarding training relevant to their roles so that they knew how to recognise safeguarding concerns and how to report them.

The pharmacy had current professional indemnity insurance. The responsible pharmacist (RP) notice was appropriately displayed. And the RP record was completed as required. All team members used password protected computers with individual sign in. NHS secure email was used for correspondence with Trusts. The customer care team completed security checks when they spoke to people, to confirm who they were. And confidential paperwork was stored securely.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team has the appropriate knowledge and skills to safely deliver its services. And learning and development needs are continuously reviewed to help make sure that the team can work effectively. Team members work well together. They work enthusiastically within defined roles, and can demonstrate how their feedback is used to inform the way that the pharmacy operates.

Inspector's evidence

The pharmacy team consisted of the SI, the pharmacy service manager (a pharmacist), three homecare pharmacists, three pharmacy technicians working in accuracy checking roles (ACPTs), a locum ACPT, three pharmacy assistants, a trainee pharmacy assistant, and a trainee pharmacy technician. The customer care team was led by an operations manager with a customer care manager overseeing a team of 12 advisors. Teams worked on rota to provide out-of-hours cover. One pharmacist was on long-term leave and the pharmacy had a current vacancy for a pharmacy assistant. Workload was continuously reviewed throughout the day to identify if extra support was needed to complete specific tasks. For example, ACPTs working in the warehouse requested support with accuracy checks to ensure all items were checked and packed ready for handover to the WLP.

All team members completed appropriate training for their roles, and competency assessments. Annual training included topics such as health and safety, manual handling, and information governance. The team also completed annual refresher training to help understand the implication of missed doses, adverse side effects and product management. The pharmacy had a robust induction programme for all of its new starters, including locums. This included bespoke training including pharmacovigilance and training on the dialysis equipment the company used. A customer care advisor demonstrated how they applied their product knowledge to help a patient check the ancillary items they required. In addition to mandatory learning pharmacy team members completed competency assessments for each process they were proficient in. Team members received regular support, protected learning time and one-to-ones with their managers. The pharmacy used a skills and knowledge framework to ensure it had enough people with the required skills to undertake all operational activities at any given time. And it reviewed training records as part of its monthly patient safety review.

The company had a whistleblowing policy. Team members felt able to raise concerns and provide feedback. And they understood how to escalate concerns if needed. They provided examples of how their feedback had been listened to. For example, feedback from the team had prompted a review of staffing levels and skill mix, and led to the employment of the locum pharmacy technician. Team members communicated well with each other. They held weekly team meetings and and used a liaison log to record patient specific queries. All teams engaged in monthly patient safety meetings which provided opportunities to share learning following near misses and incidents.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises provide a clean, secure, and professional environment for delivering pharmacy services. They are spacious and maintained to a good standard.

Inspector's evidence

The premises consisted of a large warehouse which was shared with the WLP, the whole warehouse was registered as a pharmacy. The building included offices, staff facilities and meeting rooms as well as the warehouse floor and a dispensary. Lighting throughout the premises was appropriate. Stock holding and dispensary areas were temperature controlled and monitored. Maintenance issues were reported to the WLP who owned the building. All areas were clean and organised. The customer care team worked in an office that was a short walk away from the pharmacy in a separate building. Some of the advisors worked from home but had specific requirements, including the need to work in a space where conversations could not be overheard, and where information could not be seen by others.

The dispensary was an appropriate size for the level of activity taking place, workflow in this area was managed well. Team members undertook some dispensing and accuracy checking tasks in the warehouse area. The dispensing area was clearly mapped on the warehouse floor and health and safety risks had been assessed so they could be managed. Pharmacy team members undertaking prescription management tasks sat at computer desks within the prescription management office.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has safe and effective processes for managing its services. It has specific teams to complete key functions to help ensure people receive their treatments on time. It obtains its medicines from appropriate suppliers, and it makes continual checks to ensure its medicines and ancillary items are kept in good condition and are safe to supply to people.

Inspector's evidence

The pharmacy premises was closed to the public as it provided all of its services at a distance. People could contact the pharmacy by telephone to speak with the customer care team. New patients were sent a welcome pack which provided information about how the service worked and included details of how the pharmacy processed and shared their personal information. The pharmacy used translation services when this information was required in another language. Each person had a unique patient reference number which they used when contacting the pharmacy. People could nominate someone else to speak with the pharmacy on their behalf, and these were recorded on their personal record as authorised contacts.

Prescribing was by instalment prescriptions that authorised the pharmacy to make a maximum number of supplies before a new prescription needed to be issued.The pharmacy received around 5% of its prescriptions electronically through a prescription management platform which was used solely for one type of dialysis. It received most of its other prescriptions by tracked post. This meant there was the potential of delays occurring. The team explained that they sometimes received scanned copies of prescriptions so they could start the prescription management process whilst awaiting the original.

The pharmacy received notification of new patients from the hospitals through either email or post. The hospital sent new patient registration forms with the person's first prescription or order. Pharmacy team members checked new registration forms for key details, such as the required start dates for treatment. Then they entered information from prescriptions into the prescription management system, including the prescription reference, items required, prescription date and end date, and maximum supplies. There was a series of safety measures to support team members in entering data. For example, doses were selected from a pre-selected list for each therapy and could not be typed freely. Any dose adjustments required the authorisation of a pharmacist. Pharmacists clinically checked the prescription and data accuracy checked the information added to the prescription management system. They had access to historic prescriptions and intervention history when completing clinical checks. And they contacted prescribers if they had any concerns about a prescription. The prescription management systems recorded who had completed each task.

Team members involved with the 'product' workflow worked directly with specialist hospital renal teams rather than a hospital's homecare provider. The renal team raised an order with the pharmacy and pharmacy team members transcribed this order onto a prescription template. The templates were screened by a pharmacist prior to being sent back to the renal team for signing. Once the pharmacy received the signed copy it followed the prescription management workflow.

The customer care team contacted people to introduce themselves, arrange first deliveries and answer

any questions they had. They used the registration form to identify any specific requirements such as whether a nurse visit was required. The customer care team and the pharmacy team used a liaison log to track any queries and record specific information to support the teams in managing tasks and to inform feedback to trusts about prescription compliance. Following the first supply, the customer care team contacted people by telephone around two weeks before their next delivery was due. They routinely checked people's stock levels of all items the pharmacy supplied to ensure they had enough stock prior to their next delivery arriving. Prescriptions were only released on the system for dispensing when all prescription management tasks and customer care tasks had been completed. Any mid-cycle dose changes were clearly flagged, and these flags prompted a series of checks including the urgency of the change, and to identify if a returns collection was required when delivering any new items.

The pharmacy organised its workload by the due date of deliveries. This meant it had an overview of upcoming workload and could plan accordingly. Team members rotated tasks they were competent in completing, and those in learning roles were shadowed. Dispensing workload was split between the warehouse and the dispensary. Team members used handheld mobile devices to scan barcodes which showed them individual prescription data. The devices linked to labelling machines which produced dispensing labels. Audit trails were visible showing who had completed each activity.

In the dispensary, the team member picked and assembled medicines and used baskets throughout the dispensing process to help keep each person's medicine separate. The dispensing workflow was carefully managed to ensure the medicines requiring cold storage were out of the fridges for the minimum amount of time possible. The warehouse dispensing process saw warehouse operatives pick stock against specific stock orders which were laid out on pallets and marked with a barcode. Pharmacy team members scanned the barcode to access the prescription and completed the dispensing process. Once the accuracy check was completed the pallets were clearly marked to inform warehouse staff that they had been checked and could be wrapped to secure the contents ready for dispatch. Accuracy checkers also checked the accuracy of information on delivery labels.

The pharmacy had a buying team that took responsibility for procuring all medicines and ancillary supplies. The pharmacy team reported that it had no recent concerns about medicine and product availability. It had an escalation process for informing NHS trusts of supply concerns in good time to ensure an alternative product could be prescribed and sourced and patients contacted. And there was evidence of this process being tested.

The pharmacy kept records of the batch number and expiry dates of its products to support it in making checks to ensure its products were safe to supply. And the team completed regular checks of the warehouse and dispensary environment to ensure medicines were stored safely. Medicines kept in the dispensary were stored neatly. And items in the warehouse were stored in a temperature controlled environment. The pharmacy had two large walk-in refrigerated units with 24/7 temperature mapping and warning alerts sent to key personnel if a temperature anomaly occurred. The pharmacy used a range of packaging for its cold chain medicines with specific cold boxes used to store supplies being sent if a person was not able to store their medicines in a fridge straight away. For example, if they had their supplies delivered to their place of work.

The WLP managed the majority of the pharmacy's deliveries. A small number of deliveries to remote areas of Great Britain were completed by another company or by tracked post. Different delivery vehicles were used, dependent upon a number of factors such as, whether a cold-store van was required, the size of the delivery, the location and access into the property.

People were given a delivery window the evening prior to deliveries taking place. The customer care team tracked deliveries and liaised directly with the logistics provider. And the pharmacy had been

given assurances that the logistics provider had contingency arrangements should something go wrong. For example, if a van broke down. People were notified of failed delivery attempts and failed deliveries were returned to local depots and a re-delivery attempted. The customer care team contacted people about failed deliveries to understand why they occurred. It investigated the reasons for failed deliveries and shared learning within the relevant teams to help reduce the risk of them reoccurring.

The pharmacy received product specific alerts and recalls electronically, and it kept an audit trail of the checks it made and actions it took in response. It recorded the batch number and expiry date of all the items it supplied so it would be able to contact people about an alert or recall if needed. The pharmacy encouraged people to report adverse effects of medicines through the MHRA yellow card scheme. And it had an established system for submitting any reports of adverse effects it received with manufacturers and the MHRA.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. It has appropriate maintenance and backup arrangements to ensure its equipment remains available for use and fit for purpose.

Inspector's evidence

Pharmacy team members had access to a range of digital reference sources, including the British National Formulary. They also contacted manufacturer's own medicine information teams to support with specific treatment related queries. They had access to computers with multiple monitors to be able to view several screens at once when working between two systems. The equipment used in the pharmacy's warehouse was maintained by the WLP, this equipment was extensive and included fork-lift trucks.

The pharmacy computers were password protected. And its team members were required to logon to a virtual private network when working from home. Pharmacy team members had access to IT support should they require it. The pharmacy ran overnight backup processes to ensure any data on its systems was not lost. The pharmacy had backup generators and could use switch to an alternative internet connection in the event it suffered from connectivity issues. Its electrical equipment was subject to regular safety checks.

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.