General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Baxter Healthcare Ltd, Units 11/12, Lawnhurst Trading Estate, Ashurst Drive, Stockport, Greater Manchester, SK3 0SD

Pharmacy reference: 9010745

Type of pharmacy: Closed

Date of inspection: 03/09/2024

Pharmacy context

The pharmacy provides a homecare medicines service which involves delivering ongoing medicine supplies direct to people's homes. Hospital prescribers initiate all the supplied treatments. Some aspects of the service, for example nursing care, are not GPhC regulated. Therefore, this report focusses solely on the registerable services that the pharmacy provides. The pharmacy is in a purpose-built industrial estate unit, which is not open to the public. The company that owns the pharmacy holds MHRA manufacturer and wholesale dealer authorisations.

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 carries out regular risk assessments and takes steps to manage the risks it identifies. Team members follow standard operating procedures to help them work effectively. They review things that go wrong so they can learn from them. And they know how to handle sensitive information to protect people's privacy.

Inspector's evidence

The pharmacy was part of a company that provided homecare services. Its main activity involved the supply of parenteral nutrition (PN) feed bags, Outpatient Parenteral Antimicrobial Therapy (OPAT), and desferrioxamine against prescriptions from NHS hospital Trusts (the Trusts). And it delivered them to people across England and Wales. The pharmacy also supplied infusion devices and any ancillary equipment that the people needed.

The pharmacy team worked with other teams across the company to provide the homecare service, which included the manufacturing and patient services teams. The manufacturing and quality assurance (QA) teams were based at other sites in the UK. The patient services team was based on the same site as the pharmacy and it was the service user's main point of contact and co-ordinated their supplies. The pharmacy partnered with external national courier, and nursing services to deliver and administer people's treatments and associated products. The nursing service was CQC registered. The pharmacy also worked with a homecare equipment provider who supplied refrigerators and pump devices to patients.

The pharmacy had written procedures for the services it provided. The procedures had been recently reviewed, and there were online records demonstrating the team had read and accepted them. When questioned, a pharmacy team member was able to clearly describe their duties.

The pharmacy had audited some of its written procedures in June 2022, to assess compliance with them and identified the actions to be undertaken. It had addressed some of these identified improvements such as updating the written procedures. But there were some issues that remained outstanding. The pharmacy had recently carried out an audit to assess whether its services met the expected standards, and had found good compliance.

The pharmacy risk assessed its activities and maintained risk registers that included a description of the risk, the possible impact on pharmacy service users, existing controls to mitigate the risk, and recommended actions to reduce the risk. An example of an OPAT service related issue that had been reviewed included provision of advice and training to patients about the correct storage of their products. This led to a one page pictorial refrigerator storage document being sent to patients, and the pharmacy now discussed storage arrangements with the pateint during an introductory telephone call to the service. The risk registers were reviewed every two years or if an incident occurred.

The superintendent pharmacist, the company's clinical therapy leads and commercial manager attended an internal clinical governance meeting each week. During the meeting they reviewed any reported concerns, and any relevant details were subsequently shared with the pharmacy team for reflection and learning.

The company's clinical therapy leads held monthly and quarterly meetings with the Trusts and nursing service to review the homecare service performance. The therapy leads also had weekly meetings with the nursing service to discuss any relevant incidents. Any matters considered to be relevant to the pharmacy were forwarded to the superintendent pharmacist.

The superintendent and homecare commercial manager met the courier's representatives each month to review the delivery service performance and discuss any complaints people had raised about the delivery service. The courier provided a regular audit and, if necessary, implemented corrective actions to address the concerns. The courier confirmed the remedial action it had taken regarding delayed deliveries that had led to patients missing their feed. For example the courier implemented processes to help make sure delivery drivers did not forget to obtain the keys from the depot for patients on the keyholding service.

A pharmacist from the pharmacy team and the commercial manager held monthly meetings with the homecare equipment provider to review pump and refrigerator supply performance. This included reviewing the number of reserve pumps and refrigerators available if needed, and any that had to be exchanged or returned to the manufacturer.

The pharmacy kept a dispensing audit trail identifying which team members had prepared and checked each prescription item it had supplied, which assisted with investigating and managing mistakes. Pharmacy team members discussed near miss mistakes they had made at the time they were identified. The team made records of near misses and reviewed them weekly, to learn from what had happened. And they took action to mitigate against risks in the dispensing process that they identified. For example there were mistakes picking the incorrect bactericidal and fungicidal syringe product used to protect against catheter-related infections and occlusion. So, the team implemented a process and patient record to reduce the frequency of these events. The superintendent explained that some near miss incidents had been due to the patient services team incorrectly entering prescription information on a shared electronic data system, but admitted that these were not always recorded. This meant the patient services team may not always be aware of their mistakes so may miss opportunities to improve.

When new patients registered with the service, they were sent a welcome pack, which included details of how they could provide feedback or raise a concern. Patients, Trusts and nursing services were able to provide general feedback or raise concerns via the patient services team, who recorded this information on a shared electronic incident reporting system. The pharmacy reviewed this information, which created opportunities for it to learn from incidents. Patient services team members received regular training so they could help patients with basic problems, and they could forward more difficult queries to a pharmacist, if necessary.

An incident report was completed for any dispensing errors or patient safety incidents, and copies were sent to the patient and the relevant Trust. The pharmacy team documented any learning points against the concerns that were recorded on the shared system. For example, it had identified that the incorrect expiry date had been applied to a product that had been dispensed. So, to help avoid this happening in future, the product stability procedure had been changed to include an additional check by the pharmacy. The senior management met quarterly to identify any trends in concerns and review the remedial action taken.

The pharmacy maintained appropriate RP records, and the RP notice was displayed. It initially received a scanned version of the prescription via email, and it subsequently received the original via the post within seven days. A form that accompanied the prescription was completed at each stage of the PN formulation, prescribing and dispensing processes, which provided an audit trail. The pharmacy retained the certificate of conformity for each unlicensed medicine that it supplied, which was

annotated with the prescriber's details and a duplicate of the medicine dispensing label was attached.

Pharmacy team members securely stored people's information and they disposed of confidential waste appropriately. The pharmacy used passwords to protect access to people's electronic data. A privacy notice displayed on the pharmacy's website explained how the pharmacy handled people's personal information. Patient services team members had completed General Data Protection Regulation (GDPR) and level two safeguarding for adults and children training. Pharmacy professionals had level two safeguarding accreditation. The pharmacy had safeguarding leads and there were details of safeguarding contacts for reporting concerns.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to effectively manage its workload. Team members have defined roles and understand what is expected of them. They are appropriately trained for the work that they do, and they receive regular ongoing training to help keep their knowledge and skills up to date.

Inspector's evidence

Most pharmacy team members worked full-time. The pharmacy team was divided into office and warehousing and dispensary teams. The office team consisted of six pharmacists, with a minimum of four pharmacists working when the pharmacy operated. The dispensary team consisted of one pharmacist, seven dispensers and two trainee dispensers. One of the dispensers supervised the dispensary team. The warehousing team consisted of dispensers. The pharmacy also retained a locum pharmacist to cover leave.

The pharmacy had enough staff to comfortably manage its workload. It consistently dispensed all the products in time for their scheduled dispatch. Time and motion studies were used to model the staff numbers required each day, and there was a business continuity plan if an incident significantly disrupted services. Each team member had a defined role and set of responsibilities, which was reviewed twice each year, and detailed the tasks they needed to complete each day. One of the office team pharmacists supported the dispensary team each afternoon when it received supplies from the manufacturing team. The staffing resource was regularly reviewed against projected service demand.

The pharmacy team held daily meetings. The pharmacy and patient services management met weekly to discuss operational issues, near misses, and process improvement. The superintendent and patient services manager worked together to coordinate the pharmacy and patient service teams operations.

The patient services team, all of whom were all dispensers or trainee dispensers, entered prescription information into patient's records that the dispensary team relied on for preparing supplies to people. However, the management structure meant this team did not report to the superintendent pharmacist. So, they did not have any control over part of the dispensing process for which they were accountable.

Both trainee dispensers were completing training for an appropriate dispenser qualification. One of the pharmacists in the office team tutored the trainees. For the first three months another dispenser closely supervised each trainee dispenser while they worked. The dispenser completed a checklist to confirm that the trainee had achieved the required competency. After three months, each trainee's performance was reviewed more broadly to make sure they continued to develop their skills and knowledge. New pharmacists working in the pharmacy team were closely supervised until they had completed a series of competency checks.

Following the superintendent's review in 2022, the pharmacy team's skill mix and knowledge had been significantly updated. The compliance and governance team monitored training and sent regular emails to the pharmacy team outlining the outstanding training that needed to be completed. Line managers held regular performance reviews individually with each pharmacy team member when they also discussed their development.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean, secure and spacious enough for the pharmacy’s services. It provides a professional environment for healthcare services and keeps people's information secure.

Inspector's evidence

The premises were clean and tidy. The dispensary and distribution areas, which was a large warehouse-style part of the premises, had the space and lighting that the dispensary team needed to prepare and supply prescription products safely. It was organised and tidy. The pharmacy office and patient services teams occupied separate open-plan spaces adjacent to the dispensary. The design of all three teams’ areas facilitated collaborative working that supported providing a safe service to patients. The premises were access controlled, which meant unauthorised people could not enter or view confidential information.

Principle 4 - Services ✔ Standards met

Summary findings

Overall, the pharmacy's working practices are effective, which helps make sure people receive safe services. It gets its medicines from licensed manufacturers and suppliers and manages them effectively to make sure they are in good condition and suitable to supply.

Inspector's evidence

The pharmacy operated Monday to Friday 8am to 6pm. An on-call pharmacist was available outside of normal operating times to handle any urgent queries. The patient services team provided an information pack to new patients which explained all aspects of the pharmacy's service. The pack was available in Welsh if requested, and it could be translated into other languages or provided in a pictorial version if needed.

The pharmacy was required to supply new PN patients within five working days of agreeing to provide them the service, The Trusts completed a registration form for each new patient that it sent to the pharmacy along with the suggested PN formulation.

The pharmacy needed to supply OPATs and desferrioxamine urgently, usually within one or two days after it received the prescription from the Trust. The Trusts submitted a registration form and prescription for each new patient. The pharmacy immediately forwarded the prescription to the off-site manufacturing team who supplied the OPAT to the pharmacy. The pharmacy could arrange Saturday delivery if needed.

The delays in supplying products to new patients were usually beyond the pharmacy's control. For example, the Trust's prescriber may not have fully completed their details on an OPAT prescription. If this happened, the pharmacy promptly contacted the Trust to resolve the issue. If the pharmacy had a query about a desferroxamine prescription, there could be a delay in the Trust responding if there was a lack of expertise within the Trust's staff for this treatment. These delays were rare due to the small proportion of treatments that these prescriptions represented.

The pharmacy had written procedures for formulating and prescribing PN products. The pharmacy's office team used specialist software to check the Trust's proposed formulation, which the offsite manufacturing unit verified. A Trust pharmacist then clinically screened the pharmacy's suggested PN formulation and prescription before approving them. The Trust sent the signed prescription via email to the pharmacy, and the pharmacy received the original prescription five to seven days later. The pharmacy's office team completed a compounding formulation clinical screening check. The dispensary team supplied all PN products and ancillary equipment against the signed prescription.

The Trusts issued desferrioxamine and PN prescriptions that covered six and twelve months' supply respectively, which the pharmacy then supplied to the patients in instalments when needed. The pharmacy's office team requested desferrioxamine and PN prescriptions via email one and two months respectively before they were due. It used a paper-based audit trail to track each repeat prescription request. These prescriptions were usually issued in a reasonable time for the pharmacy to arrange supplies.

Trusts sometimes did not issue repeat desferroxamine prescriptions by the due date. On these

occasions the pharmacy asked patients to contact their hospital to expedite the situation. These delays were occasionally due to the Trust not using the latest prescription format, or patients switching from a paediatric to adult dose. These patients rarely missed their medication because it was not a daily treatment. The superintendent explained that it was often difficult to discuss these issues with the Trusts because they could not identify a specific person who had responsibility for the treatment.

The Trusts completed an NHS England needs assessment to determine if a patient needed nursing support at home to administer their treatment. Patients who did not need nursing support were trained on how to administer their treatment when they were in hospital or post discharge by the nursing team.

A patient services team member demonstrated how patient's details and their prescription information were added to the electronic patient record shared with the dispensary team. They used a checklist that also acted as an audit trail of each completed task. The lead pharmacist and superintendent explained the HPN, OPAT and desferrioxamine dispensing processes. A pharmacist completed the final accuracy check of each prepared product and the corresponding certificate of conformity.

Patient services contacted patients via telephone and email and kept details of their next of kin if the patient was unavailable. They routinely called people to confirm that they had enough medicines and ancillary stock at home. A 'queries' pharmacist in the office team responded to emails from patients within one hour of receipt. All communications with people were recorded on their patient records.

The dispensary team only ordered treatments when it received a prescription and supplied feeds shortly after they had been manufactured. So, a stock expiry date check programme was unnecessary. The pharmacy replenished its ancillary stock every two weeks. As a contingency the pharmacy contacted other suppliers and liaised with Trusts when there was a stock shortage. The dispensary team stored stock in an organised manner. It separated people's medicines during the dispensing process, which helped to organise its workload. All temperature sensitive products were stored in temperature monitored refrigerators. Most feeds had a thirty-day shelf life, which helped to reduce the number of times people had to order them. When the prescription products had been dispensed and checked, the dispensary team packaged and transferred them to a dispatch area for the external couriers to collect.

Patient services communicated with patients and the courier to co-ordinate deliveries. PN feeds were scheduled for delivery every two or four weeks from when patients registered for the service. OPAT patients were contacted to arrange supply immediately after the pharmacy received their prescription. The delivery schedule was mutually agreed with desferrioxamine patients when they started using the service.

The pharmacy provided people with a 'buffer reserve' of their treatments to keep in case of delayed deliveries, supply-chain issues or faulty items. Patient services checked how much extra stock people had each time they arranged a delivery. If the pharmacy did not have enough to supply the full amount it communicated this on the delivery receipt, with the reason why some was owed. For example, if there had been a faulty PN feed. Patient services then contacted that patient to arrange the owed product delivery.

The pharmacy used insulation and ice packs to package temperature sensitive products and it used a specialist cold-chain courier that had vehicles with ambient and cold chain temperature monitoring installed. It dispatched products at 5.30pm on weekdays that the couriers delivered the next day as standard. This helped to supply urgently required OPAT and desferrioxamine promptly, due to the short notice the pharmacy had to provide these medications. There were limited standard delivery dates to remote post codes. But there were contingency arrangements to deliver urgent treatments to these

locations if necessary, which included using an alternative courier. The couriers also delivered on Saturday and could deliver on the same day if necessary.

The courier notified the pharmacy of any cold-chain temperature excursions during transit. The delivery driver quarantined the affected packages until the pharmacy team had reviewed the vehicle refrigerator temperature data and consulted guidance on maintaining a cold chain. The pharmacy then either approved the supply of the products already in transit or arranged for replacement products to be supplied the same or next day depending on the patient's reserve feed stock.

When there was a failed delivery the patient services team contacted the patient to re-arrange delivery up to three times. After forty-eight hours packages were returned to the pharmacy, and the Trust was informed. The courier kept temperature sensitive products under refrigerated conditions throughout this period. The pharmacy had access to the courier's electronic delivery records when needed.

The superintendent and QA team received product alerts and recalls via email. The QA team would check to see if the alerts affected any products the pharmacy supplied and take appropriate action. All alerts were archived electronically after being actioned.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services effectively. It properly maintains its equipment and it has the facilities to secure people's information.

Inspector's evidence

The team had the facilities it needed to dispense prescription items. Staff could report equipment issues to the contracted maintenance company, which helped to sustain service continuity. IT issues were reported to a global internal team that attempted to resolve them remotely, and a local subcontractor was used if necessary. The pharmacy had a contingency plan for unresolved IT issues. The Trusts were informed of any reduced service level, and the options would be discussed regarding OPAT supplies, and preparing and supplying products during weekends.

The pharmacy had the facilities needed to secure people's written and electronic information. It regularly backed up its people's data on its patient medication record (PMR) system, so it secured patients' electronic information and could retrieve their data if the PMR system failed.

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.