

Registered pharmacy inspection report

Pharmacy Name: B Braun Medical Ltd, Brookdale Road, Thorncliffe Park Estate Chapeltown, SHEFFIELD, South Yorkshire, S35 2PW

Pharmacy reference: 1104704

Type of pharmacy: Closed

Date of inspection: 04/09/2024

Pharmacy context

The pharmacy is one of two pharmacies on the same B Braun site. The site is in a large industrial park and is closed to the public. It provides a homecare medicines service which involves delivering ongoing medicine supplies directly to people's homes. All the treatments are initially prescribed by prescribers working in hospitals. Some aspects of the pharmacy's services, 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. 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

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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 suitably identifies the risks associated with its services. It uses regular risk assessments and audits to manage these risks and improve service provision. The pharmacy obtains feedback from people who use its services. And it uses the feedback to make changes to the way it operates so it can improve. The pharmacy's team members follow written procedures to support them in working effectively. They record things that go wrong so they can learn from them. And they take action to help prevent their mistakes from happening again.

Inspector's evidence

The pharmacy was owned by a company with specialities including dialysis care and home parenteral nutrition (HPN). The pharmacy held service level agreements (SLAs) with 38 NHS trusts across the UK. The SLAs outlined the nature of the arrangement between the trusts and the pharmacy and their individual accountabilities.

The pharmacy had a comprehensive range of digital standard operating procedures (SOPs) that covered its services. They were regularly reviewed by the superintendent pharmacist (SI) to ensure they remained up to date. Team members had access to the SOPs via the company's intranet. They were required to read SOPs when they started employment with the pharmacy and when any changes were made to an SOP. They completed training records to confirm they had read and understood those SOPs that were relevant to their role. Each SOP contained a documented version history which summarised the changes made between versions.

The pharmacy had a business continuity plan in place. It maintained a risk register for various aspects of its service. For example, the contingency arrangements when a medicine was in short supply or out of stock. The register outlined the risks that had been identified, along with actions to mitigate the risks. Each risk was given a probability and severity rating. The risk register was periodically reviewed to assess whether the agreed actions were effective.

The pharmacy had an information database that contained information about its specialist products, including product characteristics, patient information leaflets and any correspondence with manufacturers. Additionally, the pharmacy had an internal medicines information team who were available via telephone to provide support in assessing prescriptions and answering queries. The pharmacy carried out regular audits of various parts of its services to provide assurance that processes and procedures were being followed correctly. The pharmacy assessed its performance periodically against national key performance indicators (KPIs).

The pharmacy advertised its complaints handling procedure on its website, and within a welcome pack and frequently asked questions (FAQs) document that was provided to each new patient. Several members of the pharmacy's customer care team were responsible for managing complaints and dealing with feedback about the quality of its services. The team described a recent example where patients had reported they were missing a product that they were expecting to receive. The team established that patients were sometimes unable to find each product within the packaging due to the way the products had been packed for transit. To help reduce the frequency of such incidents, the team had implemented the use of 'contains multiple items' alert stickers which were attached to the packaging.

The pharmacy kept records of mistakes that were identified during dispensing, which were known as near misses. The pharmacy team discussed each near miss when they happened to help understand the cause and learn from it. The team admitted that they sometimes failed to record details of some near misses, due to team members not always having the time to do so. To help improve, the pharmacy used printed near miss template forms to allow team members to manually capture the detail of each near miss immediately. Team members then added the details recorded on the form onto the digital record. Near misses records were analysed periodically by three team members who had been appointed as patient safety champions (PSC). The PSCs discussed near misses and any identified further learning opportunities during team meetings. They had identified that the number of near misses was higher on Fridays and that this was because the team members had less time to dispense due to the late release of some products. Team members were reminded not to rush the dispensing process and take more care before sending products for a final check. Additionally, the pharmacy's on-call pharmacist was informed of any potential late releases. This gave the team the opportunity to manage the workload accordingly.

Mistakes identified following the delivery of products to a person were known as dispensing errors. All incidents were recorded, fully investigated, and shared with the associated NHS trust. The customer care team were appropriately trained to support people who reported dispensing incidents. Then the incidents were reported to the pharmacy team for investigation. A recent incident involved the incorrect strength of a magnesium product being supplied. The team agreed that the error had happened due to different strengths of the product being stored close to each other in the dispensary. To help reduce the risk of a similar incident happening again, the different strengths had been moved to different locations.

The pharmacy had current professional indemnity insurance. A responsible pharmacist notice was displayed close to the dispensary. The RP record was appropriately maintained. Private prescription details were recorded on the prescription management system, and on the patient medication record. The pharmacy did not supply any schedule 2 controlled drugs.

The pharmacy had information governance policies in place. Members of the pharmacy team had read and signed the policies and had signed confidentiality agreements. Confidential waste was stored separately and destroyed securely by a specialist company. The pharmacy was registered with the Information Commissioners Office and the privacy policy was displayed on the website.

The pharmacy had a documented safeguarding policy. Team members including delivery drivers and customer care team members had received safeguarding training. When questioned pharmacy team members understood the importance of safeguarding vulnerable adults and children and knew how to raise any concerns.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy employs a skilled and experienced team to help safely manage its workload. Team members complete ongoing training to help keep their knowledge and skills up to date. They work well together and know how to raise concerns and provide feedback if they need to.

Inspector's evidence

On the day of the inspection, the pharmacy team consisted of the SI, the pharmacy service manager (non-registrant), four pharmacists, four pharmacy technicians, five pharmacy dispensers and a trainee dispenser. The pharmacy also employed another pharmacy technician and two pharmacy dispensers who were not present during the inspection. Workload was continually assessed to ensure that the pharmacy had enough team members working to operate safely. There was a sub-team designated to manage some of the dispensing workload in the pharmacy's walk-in fridge. Due to the low temperatures, team members were restricted to working in the fridge for no more than three hours at a time.

All team members were ahead of schedule with their workload. They were observed supporting each other to complete various tasks and dispensing without any significant time pressures. The customer care team consisted of a team manager and 11 full-time team members (including team leaders). Team leaders managed a work rota to provide cover.

The pharmacy team completed a training programme including periodic training on various topics such as manual handling and health and safety. The pharmacy worked alongside an external training provider to provide an internal verification process for pharmacy technicians. Training records were kept showing the training team members had completed.

Locum pharmacists were regularly employed to cover times when the regular pharmacists were not working. Many of the locum pharmacists had little to no experience of working within a homecare pharmacy, however, they were required to complete a short induction and were asked to only complete tasks within their personal competency. Customer care team members received annual training on safeguarding, data protection and information governance. All new team members were required to complete an induction period and had regular one-to-one with their line manager, to ensure they met various core competencies. And they completed bespoke training on the use of ancillaries.

The company had a whistleblowing policy and team members could raise concerns anonymously. The policy was outlined on several notices displayed throughout the building. Team members described how they were able to raise concerns with their line manager. The teams held regular meetings to discuss work matters and were able to give feedback on ways to improve processes. The pharmacy held regular meetings with trusts and organised ad-hoc meetings following dispensing incidents, dependent on the severity level. A designated pharmacist within each trust was authorised to liaise with the pharmacy team to answer questions and queries. Each trust could contact the pharmacy team

directly via telephone, without having to liaise with the customer care team.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is hygienic, kept secure and of a highly professional standard. The premises is spacious and well maintained.

Inspector's evidence

The registered premises was within a large industrial park. The building included a large warehouse which had another small, registered pharmacy premises within it. Other nearby buildings owned by the company included offices, staff facilities and meeting rooms. There was also a large area used for the aseptic manufacture of products which was regulated by MHRA.

All areas of the pharmacy were clean and kept hygienic. There was a cleaning rota in place. Toilets and handwashing facilities were available to all team members. 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 of an appropriate size for the volume of dispensing activity. Workload was well managed with benches kept organised throughout the inspection. Team members undertaking prescription management tasks worked in a separate office space where there were several computer terminals for use.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy safely manages the services it provides. Team members work well with other organisations to ensure people's healthcare needs are appropriately managed. And they take steps to avoid any delays with treatment. The pharmacy appropriately obtains, manages, and stores its medicines and ancillary products. And the team carries out checks to ensure the medicines are kept in good condition and fit for purpose.

Inspector's evidence

The pharmacy premises was closed to the public and all its services were provided at a distance. People could contact the pharmacy by telephone and would be connected to a member of the customer care team. All new patients were provided with a Patient Charter. This gave clear information about how the service worked, what they could expect from the homecare company and their own responsibilities. The pharmacy had access to a translation service if a patient wished to communicate with the team in another language. Patients were able to nominate an authorised person to communicate with the team on their behalf, for example, a relative or a carer. Details of the authorised person were recorded on the patient's electronic record.

Each patient's details and requirements were assessed by one of the pharmacy's business development managers (BDMs). The BDM considered the compounding capacity of the unit, and capacity of the pharmacy's nursing team to manage the patient effectively. Once the BDM had made the decision that the pharmacy had the capacity to manage the patient's needs, the trust was notified, and the registration process could commence. In order to register with the pharmacy, patients had to complete a consent form which clearly outlined that their products would be dispensed by the pharmacy and included the pharmacy's contact details. Following successful registration, the pharmacy provided each patient with a welcome pack and a list of FAQs, such as 'Who do I contact in an emergency?'. Both the welcome pack and the list of FAQs could be printed in various languages if required. A customer care team member contacted each patient via telephone within 48 hours of registration. The team member discussed the various aspects of the service such as the process to order ancillaries.

Once a patient was successfully registered with the pharmacy, the trust sent the pharmacy the registration form, nursing form (if applicable) and a formulation request via secure email. The team then entered the information onto the patient's electronic record. If the pharmacy had any concerns or queries about the formulation, they raised them with the Trust. A designated 'on-call' pharmacist was the point of contact for any such queries and was always contactable via telephone. When the formulation had been agreed, the pharmacy produced a draft prescription, which was checked by a pharmacist to assess its suitability and make sure the pharmacy would be able to dispense it. The draft electronic prescription was then sent to the Trust, where it was clinically checked by a pharmacist and signed by a prescriber, before being returned to the pharmacy for dispensing. The pharmacy did not have access to the patient's hospital or NHS notes such as blood test results, so these were reviewed as a part of the Trust's clinical check.

When the pharmacy received the finalised prescriptions, they were printed and moved into the main dispensary where they were stored in a locked filing cabinet until the team was ready to dispense them. Prescriptions were issued as repeatable versions which authorised the pharmacy to make several

supplies, before a new prescription needed to be issued. The pharmacy computer systems automatically identified when a prescription needed to be renewed and sent an alert to the team. Alerts were routinely issued around 28 days before the prescription due date. Team members explained this gave them ample time for the repeat prescription to be issued, thus reducing the risk of delays in supply to patients. Some Trusts prompted the pharmacy when a prescription was due to be renewed, but the team did not rely on these prompts because they were not consistent across all Trusts.

Team members working within the dispensary organised the workload for each day. They prioritised the dispensing of prescriptions based on the respective patient's delivery due date. Team members were allocated specific tasks to complete based on the day's workload. The dispensing and the final checking processes were completed on specific benches to keep these activities separate. Team members explained that there was often a lack of bench space, but they ensured they kept the benches tidy to maximise space and reduce the risk of errors occurring. A full audit trail was kept showing which team member had completed each part of the dispensing process.

The pharmacy dispensed a significant number of products that required cold storage. It had a large walk-in refrigerator and two other refrigeration containers. The operating temperatures of each unit were continuously monitored, and alerts were sent to authorised team members if any were outside of the accepted range. The team managed the dispensing workload to ensure that cold storage products were kept outside of the fridge for the shortest possible amount of time. Once dispensed they were segregated in a dedicated part of the fridge.

Dispensed products were packed in boxes, which were sealed using parcel tape and stored in the dispensary while awaiting dispatch. Several of the boxes were seen not to be completely sealed with the tape, which meant there was a risk that some of the contents could fall out in transit. The team gave assurances that they would review the process of sealing the boxes to make sure it was effective. A sticker was placed on the packaging to alert delivery drivers when there was an additional cold chain item that needed to be added before being sent out for delivery. And if patients were unable to store their medicines in their fridges immediately, the pharmacy supplied the products with a cool box containing ice packs which could keep them at the correct temperature for up to 72 hours.

The delivery service was provided by two contracted delivery companies. One of the companies had the ability to store cold chain products at its depot should a delivery be unsuccessful. The other company did not have this ability but were contracted to complete more urgent, same-day deliveries. Drivers working for this company returned to the pharmacy any products that were not delivered successfully. All deliveries were tracked throughout the time products were in transit. The customer care team contacted patients to notify them of any failed deliveries and also notified the relevant Trust.

Delivery drivers were trained to carry out checks at the time of delivery to confirm which products patients had remaining in their homes and rotated products to ensure they were used in order of earliest expiry date. The information collected was used to inform the next supply and highlight any concerns to the pharmacy team. The routes drivers took were planned via a delivery management system and proof of delivery was obtained digitally.

Medicines and ancillary products were either obtained from licensed wholesalers or directly from the company's manufacturing unit. The pharmacy had a separate buying team responsible for all purchasing. The pharmacy team periodically checked all products to make sure they had not expired. And team members also routinely checked expiry dates during the dispensing process. Expired and patient returned medicines were kept segregated from other stock, prior to disposal to avoid them being dispensed to people in error.

The pharmacy received details of drug alerts and recalls via email from the MHRA and from manufacturers. A complete audit trail was maintained of the action the team took in response to an alert. Team members recorded the batch numbers and expiry dates of the products they supplied to patients. This helped them to efficiently contact people if a product supplied to them had been subjected to a recall.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the appropriate equipment it needs to provide pharmacy services safely. The equipment is used correctly to help keep people's confidential information secure.

Inspector's evidence

Team members had access to various references sources. These included hard copies and the electronic version of the British National Formulary (BNF), clinical guides and the electronic medicines compendium. Each computer terminal had internet access enabled.

Each computer terminal was password protected. Team members were provided with secure laptops to when they worked from home. Team members had access to IT support when required.

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.