Registered pharmacy inspection report

Pharmacy Name:One Stop Pharmacy, Unit G, Key Industrial Park, Fernside Road, Willenhall, West Midlands, WV13 3YA

Pharmacy reference: 9011139

Type of pharmacy: Internet / distance selling

Date of inspection: 16/07/2024

Pharmacy context

The pharmacy provides a homecare medicines service which involves delivering ongoing medicine supplies to NHS Trusts. All of the treatments are initially prescribed by hospital prescribers. 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.

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 its services to make sure people receive appropriate care. It uses regular audits and risk assessments to help make changes or improvements to the services and the way the pharmacy operates. It is responsive to feedback, and it uses this to make improvements. Members of the pharmacy team follow written procedures to make sure they work safely. They record their mistakes so that they can learn from them. And they make changes to stop the same sort of mistakes from happening again. There are safeguarding procedures in place and the team knows its responsibilities in keeping vulnerable people safe.

Inspector's evidence

The pharmacy specialised in dispensing and delivering medication for mental health conditions. Medicines were dispensed for named patients then delivered to NHS Trusts across the United Kingdom for onward supply. The pharmacy and the Trusts had service level agreements (SLAs) which covered how the arrangement worked and the individual accountabilities of the pharmacy and of the Trust. The pharmacy also had an NHS distance selling contract and dispensed some NHS prescriptions, which were delivered directly to people. The company directors, and the senior management team were pharmacists.

Risk assessments were carried out before any new service was introduced, if there was a change to a current service, and following an incident or complaints. Risk assessments were carried out by the head of compliance with support from other members of the team. A risk assessment template was used and followed a logical process to identify and evaluate the risks, put measures in place to control the risks and decide what level of risk was acceptable. For example, a risk assessment for managing out of stock medicines had been undertaken as the pharmacy supplied some medicines that were not commonly dispensed. The pharmacy forecasted upcoming usage of medicines and worked with suppliers to ensure sufficient stock was assigned to the local distribution warehouse to ensure there was no delay in medicines being obtained. A bespoke prescription management system (PMS) had been created to help to manage the pharmacy's workload and the associated tasks. This had been designed to automate some of the processes and to create alerts and schedule prescriptions that were dispensed at regular intervals.

Daily, weekly, monthly and annual checks took place, and they were tracked using a spreadsheet. The process had been designed to incorporate different areas of the pharmacy's operation so had HR and payroll, invoicing, record keeping, pharmacovigilance, GPhC, MHRA and NHS checks and audits to carry out. Some checks were carried out by the head of compliance, and some were carried out by the pharmacy manager. The pharmacy had partnerships with medicines manufacturers, and they audited the pharmacy. The auditors provided a written report and a list of observations which were each given a risk rating.

A range of standard operating procedures (SOPs) were in place which covered the operational activities of the pharmacy and the services provided. SOPs had been prepared by the management team and were approved by the superintendent pharmacist (SI). SOPs included any risk reduction measures that had been identified in the risk assessments. One copy of each SOP was printed onto bright yellow paper

to indicate that it was the original and only copy of that SOP, to avoid older versions being referred to. A spreadsheet was used to track SOPs that were due to be reviewed to make sure they were kept up to date. Staff signed training records to confirm they had read and signed SOPs relevant to their roles.

A near miss log was used to record any mistakes that were identified while prescriptions were being dispensed. The dispenser involved was normally asked to correct their own error to help them learn from it. Each near miss was discussed with the people involved to understand why it had happened. And the operations lead reviewed the near miss log for patterns and trends every month and produced a report. The findings of the near miss review were discussed during weekly team meeting to see if there were any further learning opportunities. There had been some mistakes with dispensing into compliance aid trays so the team had been made aware to take more care when assembling trays and the trays were not sealed until they had been checked so that any mistakes could easily be identified and rectified. Dispensing errors that left the pharmacy were recorded and thoroughly investigated. The pharmacy delivered medication directly to Trusts for administration, or onward supply so any errors were normally identified when a member of staff at the Trust carried out a final check. The pharmacy recorded error rates on the key performance indicator reports that it sent to the Trusts, and also shared details of errors and of any complaints it received. A pharmacy technician explained that one of the Trusts required the injection location to be included on the dispensing label. The technician had noticed that this was sometimes being overlooked during the labelling process. This had been addressed at the time by speaking to the teams and did not wait until the monthly review.

The pharmacy's complaints procedure was published on its website. The pharmacy sent an annual survey to the Trusts to gather feedback about the services it provided. The management team also had regular service review meetings with the Trusts to discuss performance. The pharmacy had received negative feedback about its delivery service from several Trusts in light of this it had reviewed the service, tried to work with the original logistics company to resolve the problems and then had decided to switch to another logistics company. The pharmacy managers had chosen the new company partly based on positive feedback from other homecare providers. A risk assessment, communication with the Trusts, training for team members, and ongoing service review meetings with the new delivery company had taken place to support the change. There had been some initial problems identified, but these had been addressed and the feedback from the Trusts was now positive. Deliveries were tracked by the customer services team, and feedback from the Trusts was monitored. This information allowed the operations lead to monitor and review the effectiveness of the delivery service.

The pharmacy had current professional indemnity insurance in place. The responsible pharmacist (RP) notice was clearly displayed. The RP log was appropriately maintained. Private prescription details were recorded on the PMS, and on the patient medication record. The pharmacy did not currently stock any schedule 2 controlled drugs, but registers were available if the need arose.

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 safeguarding policy and members of the team, including the delivery driver had received safeguarding training. Members of the pharmacy team did not have direct contact with patients. But the understood the principles of safeguarding and the action they should take if they had any concerns.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough team members to manage its workload. Team members are suitably trained for the jobs they do. And they complete ongoing training to help them improve. The team works flexibly so there is always enough cover to provide services effectively. And team members work well together in a supportive environment, where they can raise concerns and make suggestions.

Inspector's evidence

The pharmacy staff were separated into different teams with specific responsibilities. The management team comprised of the head of compliance and the pharmacy manager, who were both pharmacists and the operations lead who was a dispenser. The customer services team comprised of a pharmacy technician and three trained dispensing assistants. The dispensary team comprised of four trainee pharmacy technicians, and a pharmacy technician who worked as an accuracy checker (ACPT), and a dispensing assistant. The pharmacy employed a part-time delivery driver for local deliveries, and a finance manager. The teams were supported by the superintendent (SI) and the business development director, who were both pharmacists. Three of the pharmacists had completed a post-graduate qualification in psychiatric therapeutics which they found helpful with day-to-day accuracy checking and clinical screening of prescriptions and also when designing risk assessments. New members of the team completed a thorough induction period. The drivers employed by the delivery company received specific training, which included safeguarding and information governance.

The management team had assessed the staffing levels needed to manage the workload, and deliberately employed more than the minimum staffing level needed so that team would be ready to take on new business. Members of the team were up to date with the workload and clear about the tasks that they had to complete for the day, and week to ensure they remained on track. The pharmacy management constantly reviewed the upcoming workload and there was a contingency plan that freed up more pharmacist and dispenser cover if it was required.

Team members had regular discussions with their line managers about their performance and personal development. Several members of the team were training to be pharmacy technicians. And some team members also worked at two local community pharmacies while they were training, to give them a broader experience.

Team members completed annual training on topics such as pharmacovigilance, health and safety and safeguarding. Some training was provided by medicine manufacturers, and the team was encouraged to suggest training topics they thought would be useful. Then the pharmacy management team researched what was available to address their needs. And team members were allocated protected learning time to complete their training.

The team had a Monday meeting where they discussed the workload for the week and shared business information and updates. The management team used the PMS to track the progress of the workload throughout the week so they could address any issues. Holidays were booked in advance and the team did overtime or swapped shifts to provide cover. Tasks were allocated to each member of the team so that they knew what their job was for the day. These were recorded on a spreadsheet on the computer,

and there was also a white board showing the planned workload for the next month.

The management team were seen supporting the team, discussing queries from the Trusts, and coaching team members while they were working. Some targets were in place for senior team members, linked to performance against the quality standards. The pharmacy staff said they would be comfortable discussing any ideas, concerns or suggestions with the pharmacists or SI, and they knew they could contact the GPhC if they had any concerns that were not addressed.

Principle 3 - Premises Standards met

Summary findings

The pharmacy is clean, tidy and well maintained. It provides a safe, secure, and professional environment that is suitable for the healthcare services provided.

Inspector's evidence

The pharmacy had a website to promote its services, which contained the premises address and contact details, and information about the services offered. The pharmacy did not sell medicines through the website or offer any online prescribing services.

The premises were smart in appearance and well maintained. The dispensary was large, and well organised. Separate workbenches were used for dispensing and checking activities and there was ample workbench and storage space. Additional space was available to install additional workbenches and storage if the business grew. There were various management offices, a boardroom, and staff facilities. A separate area of the premises was used for MHRA wholesale activity.

All areas were clean and tidy with no slip or trip hazards. The pharmacy was cleaned by pharmacy staff on a rota. The sinks in the dispensary and staff areas had hot and cold running water, and hand towels and hand soap were available. The pharmacy lighting was adequate and ambient temperature was monitored to make sure it was appropriate. The business continuity plan was available to all team members and contained details of who should be contacted if any maintenance or repairs were needed.

Principle 4 - Services Standards met

Summary findings

The pharmacy team is well organised and delivers the pharmacy's services safely and effectively. And it supports other healthcare professionals to help make sure patients get the care they need. The pharmacy gets its medicines from licensed suppliers and stores them appropriately, so they are kept in good condition and safe to use.

Inspector's evidence

The pharmacy had contracts with the Trusts it supplied, specifying a specific formulary of medicines that the pharmacy was able to supply. Many of the medicines it supplied were specialist and could not be obtained from the usual pharmacy wholesalers. So, the pharmacy had contracts with manufacturers to obtain medicines directly.

The pharmacy dispensed prescriptions issued by the NHS Trusts. When a new Trust started to use the service for the first time, a timeline was agreed so that there would be enough time to prepare for the first delivery. There was an onboarding process in place to ensure the pharmacy had a complete list of all the patients, the medicines that they required and the frequency of the supply. The Trust obtained consent from patients for their prescriptions to be sent to the pharmacy. The pharmacy team explained that different Trusts had different views on the consent that people needed to give, so it was not always clear whether people properly understood that their prescriptions were being dispensed by a pharmacy that was not part of the Trust.

Paper prescription forms were used and they were issued as repeatable private prescriptions which authorised the pharmacy to make several supplies before a new prescription needed to be ordered. The pharmacy management team explained that they had tried to introduce electronic prescriptions, but the Trusts had not been willing to use them. When the customer services team uploaded a new prescription to the PMS, they also automated the repeat supplies. A report was generated by the system that listed when new prescriptions were due to be issued and this was forwarded to the Trust. Reminders were then sent at set intervals until the new prescriptions were received. The prescription forms were stored in folders for each individual Trust and also scanned and saved on the PMS.

The pharmacists clinically screened all prescriptions. The PMS allowed the pharmacists to see the patient's previous prescriptions and records of any interventions or queries. But the pharmacy did not have access to the patient's hospital or NHS notes, so they relied on a clinical screen being completed by a healthcare professional at the Trust to check information such as blood test results and interactions with other prescribed medicines. But some of the Trusts had not agreed to include this extra check, which could increase the risk of important information being overlooked. The pharmacists made interventions with the NHS Trusts as they felt necessary, by telephone or by emailing queries to the prescribers, and details were recorded on the pharmacy's computer system.

After a prescription had been clinically checked, the information from it was entered onto the computer system, then the medicines were assembled, accuracy checked by the ACPT or a pharmacist, and then packed and labelled for dispatch. Prescription forms had a 'four-way' stamp in the top corner that team members initialled to record which pharmacist had completed the clinical check and who had been

involved in different stages of the dispensing process.

Workload was organised by delivery date and the team could view the upcoming work due to be completed. Team members were given different tasks dependent on the workload for that day. Some of the prescriptions contained medicines that needed to be stored in the fridge, so a large walk-in fridge in the warehouse was used to store dispensed medicines that were awaiting delivery.

The cold chain was validated once a year by using temperature data loggers so that any temperature fluctuations within the dispensing and delivery process could be identified and addressed. A data logger was packaged and sent out using the logistics company and returned to the pharmacy where the results were analysed.

Most deliveries were made by a specialist delivery company. The deliveries were fully tracked, and proof of delivery was obtained. Each delivery location had specific instructions so that the driver knew where it should be taken when they arrived at the building. This was important as there were some buildings that had several clinics within the same building, and the Trust required the delivery to be taken to a specific location, rather than to a central drop off point. The customer services team tracked deliveries throughout the day and liaised with the delivery company and Trust if a delivery was showing as delayed. Some local deliveries were made by the pharmacy's own delivery driver. The pharmacy had a delivery vehicle with temperature control so that it could transport cold-chain medicines in the same way as the specialist delivery company. The routes were planned using a delivery management system and proof of delivery was obtained using a smartphone app linked to the delivery management system.

Delivery issues were discussed during the pharmacy's meetings and the pharmacy had taken steps to address issues that were within its control, for example, it had improved the specific delivery information provided to the drivers and amended delivery timings to fit in with the needs of the Trusts.

The pharmacy obtained medicines from a range of licenced wholesalers and directly from some manufacturers. Stock medicines were stored in an organised manner on the dispensary shelves. All medicines were in their original packaging. A random sample of dispensary stock was checked, and all the medicines were found to be in date. Date checking records were maintained and date checking was overseen by the operations lead. Split liquid medicines with limited stability once they were opened were marked with a date of opening. Patient returned medicines were stored separately from stock medicines in designated bins. The pharmacy received drug alerts by email from MHRA and from manufacturers. Pharmacovigilance reports were created for every reported side effect or issue, however minor, and were reported back to the manufacturers to support their safety monitoring.

There was a large walk-in fridge which was well organised and was used to hold both stock medicines and assembled medicines. Temperature records were maintained and showed that the fridge had consistently operated within the required temperature range of 2°C and 8°Celsius.

The company had started to develop their sustainability strategy and had an appointment for a carbon baseline survey so that they could quantify the value of the actions that they took. They had already taken some steps to reduce their carbon footprint. For example, they had switched to electric cars, energy efficient lighting, recyclable multi-compartment compliance packs and recyclable delivery packaging.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment it needs to provide services safely. The pharmacy team uses the equipment in a way that keeps people's information safe.

Inspector's evidence

The pharmacy had a range of up-to-date reference sources, including the British National Formulary (BNF), national guidelines and the electronic medicines compendium. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. Screens were not visible to the public as members of the public were excluded from the dispensary.

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.	