General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pines Pharmacy, Unit 1 The Pines, 5 Fleming Court, DENNY, Stirlingshire, FK6 5HB

Pharmacy reference: 1121888

Type of pharmacy: Community

Date of inspection: 13/12/2023

Pharmacy context

This is a community pharmacy in Denny. It dispenses NHS prescriptions including supplying medicines in multi-compartment compliance packs. The pharmacy provides substance misuse services and dispenses private prescriptions. Pharmacy team members advise on minor ailments and medicines use. And they supply over-the-counter medicines and prescription only medicines via patient group directions (PGDs).

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 not all met	1.1	Standard not met	The pharmacy does not identify and manage key risks with the dispensing and management of some of its higher-risk medicines. This includes the team's failure to carry out ongoing checks on the stock levels of these medicines.
		1.6	Standard not met	The pharmacy does not keep all its records complete and accurate. This includes for some of its higher-risk medicines. And it does not have its private prescription records available.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy does not always enrol its team members on qualification training appropriate for their role in a timely manner.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy keeps some of its medicines in a way that creates a risk of unauthorised access.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't adequately identify and manage all the risks associated with its services. And pharmacy team members do not always follow the written procedures. They do not accurately keep all the records required to by law. And they do not adequately investigate concerns with the records to identify safety risks. They keep records of the errors they make during dispensing and make some changes to reduce the risk of similar errors. Team members suitably manage people's confidentiality. And they generally understand how to protect vulnerable adults and children.

Inspector's evidence

The pharmacist had taken up their post in April 2023 and the pharmacy had undergone a refurbishment around November 2023. This included the installation of an automated dispensing machine for original pack dispensing. The pharmacist had not been informed by the owner about the new machine until a week before the installation works were due to commence. This meant they had limited time to identify and manage any service risks or make staffing arrangements to ensure continuity of services. The pharmacy used standard operating procedures (SOPs) to define its working processes. The previous superintendent pharmacist (SI) had reviewed and updated the SOPs in October 2021. This included SOPs for the safe management of controlled drugs (CDs). But there was no evidence to show that team members had read or undertaken to follow them. Team members had been trained to operate the new automated dispensing machine. But the pharmacy had not defined the operating procedures in documented SOPs for them to refer to. On taking up their new role, the pharmacist had identified gaps in the pharmacy's working practices. This included a failure to complete fridge temperature checks and expiry date checks. And they had re-introduced the checks and associated records to show that medicines were being safely managed and were fit for purpose.

Team members signed medicine labels to show who had dispensed and who had checked prescriptions. This provided the RP with the opportunity to help individuals learn from their dispensing mistakes. The pharmacist documented the near miss errors that team members made at the time of dispensing and assembling medicines. They monitored the records on an ongoing basis to identify concerns. But they did not carry out a regular documented review. This meant they may miss opportunities to identify patterns and trends to mitigate any new and emerging risks in the pharmacy. Team members had made some improvements to dispensing practices such as taking extra care to manage the risk of tablets moving between compartments when handling multi-compartment compliance packs. They also maintained the usual accuracy checks on items they dispensed using the automated dispensing machine. This was due to an anomaly that they identified with the bar-code technology and a subsequent mix-up with atenolol 25mg and 50 mg tablets.

The pharmacy did not have a notice or provide information to people about how to give feedback about the services they received. Team members knew how to manage complaints. And they knew to refer dispensing mistakes that people reported after they left the pharmacy. The pharmacist used a template report which was designed to include information about the root cause and any safety improvements they had introduced.

Team members maintained some of the records they needed to by law. And the pharmacy had public

liability and professional indemnity insurances in place which were valid until 2 March 2024. The pharmacist displayed a responsible pharmacist (RP) notice that showed the name and registration details of the pharmacist in charge. The RP record showed the time the pharmacist assumed their duties. But it did not always show the time their duties ended. The RP maintained the controlled drug (CD) registers but they did not carry out regular balance checks to confirm the accuracy of stock. Not all balances were correct and the registers had not been updated. People returned CDs they no longer needed for safe disposal. And team members used a CD destruction register to record unwanted CDs returned by people. The pharmacist signed the register to confirm destructions had taken place. At the time of the inspection there were several CDs in need of destruction.

Team members filed prescriptions so they could easily retrieve them if needed. They kept records of supplies of unlicensed medicines ('specials') that were up to date. But the pharmacist was unable to produce the legal register they used to record supplies against the private prescriptions they had dispensed. The pharmacy did not provide people with information about its general data protection regulation UK (GDPR UK) arrangements. But team members demonstrated they knew how to protect people's privacy. For example, they used designated containers to dispose of confidential waste that an approved provider collected for off-site destruction. Team members knew how to manage safeguarding concerns effectively and team members referred individuals when they had cause for concern. They also informed the NHS about concerns, for example when some people who were registered with supervised consumption schemes failed to collect their medication.

Principle 2 - Staffing **Standards not all met**

Summary findings

Overall, the pharmacy has a fairly large team with the experience and skills for the services provided. But the pharmacy does not enrol all its team members on the necessary qualification training for their roles. so, they may not have the knowledge they need to complete tasks safely. Team members sometimes discuss improvements to keep services safe and they work together well to manage the workload.

Inspector's evidence

The pharmacy had appointed a new pharmacist in April 2023. And they also acted as the company's operational manager. This involved visiting the other four branches, observing the practices that were being followed and providing feedback to the pharmacy owner. The pharmacist was responsible for the recruitment of staff. Preferred candidates were interviewed by the pharmacy owner who made the final decision. The pharmacist had conducted a staffing review when they took up their new role. They identified team members that were enrolled on qualification training but had not progressed with their coursework due to a lack of oversight. They had also identified long-serving team members who had not been enrolled on the necessary qualification training. This included four delivery drivers and two team members that worked at the medicines counter. At the time of the inspection team members were still not enrolled on relevant qualification courses.

The pharmacy's prescription workload had increased significantly since the new pharmacist had taken up their post. And there had been staffing changes with team members leaving and new team members recruited to replace them. The pharmacy had introduced an automated dispensing machine in November 2023 which team members used for original pack dispensing. This had helped the pharmacy team to manage the pharmacy's large prescription workload and to manage the risk of dispensing mistakes. The systems manufacturer had delivered on-site training to small groups of staff after the engineers had installed and calibrated the machine for use. A newly appointed dispenser who had experience of automated dispensing machines in a previous role had been supporting the other team members in its use and when there were operational problems. At the time of the inspection the dispenser had been able to resolve a problem when the machine had rejected certain packs at the time of loading them for dispensing. A second pharmacist worked two days each week to support the regular pharmacist whilst they provided flu vaccinations in the consultation room. The regular pharmacist had identified the need for an accuracy checking dispenser (ACD) or accuracy checking pharmacy technician (ACPT) to help with final accuracy checks.

The new RP had reviewed each pharmacy team member's performance to identify the strengths and weaknesses within the team. They had subsequently delegated tasks to those who had demonstrated competence in a particular area. For example, one of the experienced dispensers was responsible for overseeing the dispensing of multi-compartment compliance packs. And the pharmacy supervisor supported new team members at the time of their induction. They discussed topics such as the need for confidentially and provided examples such as not discussing medication regimes between family members.

There was a mixture of long-serving and recently appointed team members. This included one full-time pharmacist, one part-time pharmacist providing double cover, five full-time dispensers, four part-time

dispensers, one full-time medicines counter assistant (MCA), two part-time MCAs, and four part-time delivery drivers. One dispenser and one MCA worked alongside the pharmacist on a Saturday. And the pharmacist had arranged for an extra dispenser to work over the festive period. The pharmacist briefed the pharmacy team about some dispensing risks when they reviewed near miss errors so that team members knew to take greater care, such as when assembling and checking multi-compartmental compliance packs. They also kept team members up to date with changes to the formulary for the NHS pharmacy first service and changes when prescription only medicines (POMs) were switched to pharmacy only (P) classification. The dispenser that managed multi-compartment compliance pack dispensing knew about propantheline shortages after discussing supply problems with the pharmacist. Team members understood their obligations to raise whistleblowing concerns if necessary. And they knew to refer concerns to the pharmacist.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises support the safe delivery of services. And the team effectively manages the space for the storage of medicines. The pharmacy has suitable arrangements for people to have private conversations with the team.

Inspector's evidence

The premises provided a large, modern, purpose-built environment from which to safely provide services. A sound-proofed consultation room was available for use. And it provided a confidential environment for people to speak freely with the pharmacist and other team members during private consultations. It also provided a clinical environment for the provision of vaccination services. A separate booth provided a private area for the supervised consumption of some medicines. Team members regularly cleaned and sanitised the consultation room and the pharmacy. This ensured they remained hygienic for its services. Lighting provided good visibility throughout, and the ambient temperature provided a suitable environment from which to provide services. A separate room provided an area for team members to have comfort breaks.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy mostly stores and manages its medicines as it should. But it does not adequately protect all its medicines from unauthorised access. The pharmacy provides services which are easily accessible. And overall it provides its services in accordance with safe working practices.

Inspector's evidence

A ramped entrance provided access to the pharmacy which helped people with mobility difficulties. It provided some information leaflets including those for the NHS Pharmacy First service for people to self-select. The pharmacy purchased medicines and medical devices from recognised suppliers. It had a systematic approach to date checking which managed the risk of supplying short-dated stock in error. This included the items it kept in its automated dispensing machine which team members checked once a month. The pharmacy used a large fridge to keep medicines at the manufacturers' recommended temperature. The fridge was organised with items safely segregated which helped to manage the risk of selection errors. An audit trail evidenced the fridge had remained with the accepted temperature range of between two and eight degrees Celsius. Team members used three secure cabinets for some of its items. Medicines were well-organised, for example, a separate cabinet was used for multi-compartment compliance packs. The pharmacy used a prescription collection point that provided a secure way for people to collect their medicines, 24 hours a day, 7 days a week without having to go into the pharmacy premises. Some medications were not placed in the machine, such as controlled drugs and fridge items due to storage requirements.

Four drivers delivered a substantial number of prescriptions to people in their homes. And new drivers used a digital platform to help them with deliveries until they were deemed competent in their role. For example, it linked to the pharmacy's patient medication record (PMR) system and this meant that pharmacy team members could track deliveries. The pharmacy benches were arranged around a large, automated dispensing machine which was positioned in the middle of the dispensary. Team members used dedicated workstations for the different dispensing activities it carried out. And they used baskets to keep medicines and prescriptions together during the dispensing process. This helped them manage the risk of items becoming mixed-up. Designated shelves were used for items that had been dispensed and awaited a final accuracy check before being placed in another area for collection or delivery.

Team members received notifications of drug alerts and recalls. They kept an audit trail which evidenced that they had removed affected stock. For example, they had checked for Evorel Sequi in September 2023. The pharmacy had medical waste bins and CD denaturing kits available to support the team in managing pharmaceutical waste. Some medicines were at risk of unauthorised access and this was not being managed adequately.

At the time of the inspection the pharmacist was unable to provide assurance that team members knew about the risks for people who were prescribed valproate-containing medication. And they did not know about the warnings on the pack or the need to provide information leaflets. Following the inspection, the pharmacist confirmed they had delivered training to most of the pharmacy team so they understood the risks and the dispensing arrangements so that people received the necessary information. The pharmacist confirmed they supplied valproate medication to around three or four people within the at-risk group. But they had not carried out any checks to confirm they had a plan in place in line with the Pregnancy Prevention Programme. Following the inspection the pharmacist

explained their reflection and plan of contact with the relevant GP to confirm arrangements were in place. At the time of the inspection the pharmacist had not completed risk assessments when supplying valproate-containing medication outside of the manufacturer's original pack for people receiving these medicines in compliance packs. This was for around six or seven people. The pharmacist confirmed following completion of a risk assessment people received valproate medication in original packs.

A separate area was used for the large number of multi-compartment compliance packs the pharmacy dispensed to help people with their medicines. The pharmacy continued to register people with the pharmacy's multi-compartment compliance pack dispensing service. And the pharmacist had not placed a limit on the number of people it could provide the service to. Team members were around a week and a half ahead with dispensing and this had helped to manage the workload, for example, at the time the automated dispensing machine had been installed. Supplementary records helped team members manage dispensing to ensure people received their medication at the right time. They referred to records that provided a list of people's current medication and the time of the day it was due. And they checked new prescriptions for accuracy and kept records up to date. For example, following changes which were communicated by GPs they used an agreed template form which was retained in each person's folder. Team members retained part of the packaging for the pharmacist to carry out final accuracy checks. But the packaging did not always provide the batch number, or the expiry date for the checks to be safely carried out. Team members provided descriptions of medicines on the medicines administration record (MAR) chart they attached to each pack with the first pack of the four-week cycle. And they supplied a patient information leaflet (PIL) at the same time. Some people arranged collection of their packs either by themselves or by a representative. And team members monitored the collections to confirm they had collected them on time. This helped them to identify when they needed to contact the relevant authorities to raise concerns.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide safe services. And it uses its facilities to suitably protect people's private information.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources, including the British National Formulary (BNF). Team members used crown-stamped measuring cylinders, and they used separate measures for methadone. They had highlighted the measures, so they were used exclusively for this purpose. The pharmacy stored prescriptions for collection out of view of the public waiting area. And it positioned the dispensary computers in a way to prevent disclosure of confidential information. Team members could conduct conversations in private if needed, using portable telephone handsets. The pharmacy used a prescription collection point and team members knew to contact the manufacturer's service line when they needed help to resolve problems. The pharmacy used an automated dispensing machine, and a service contract was in place to minimise the risk of breakdowns and to ensure service continuity. Team members had been trained to use the system and they knew how to retrieve medications in the event of a breakdown. A list of cleaning tasks was displayed on the machine which included a weekly vacuum of the carpet.

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.