General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Health Lines Pharmacy, 188 Studfall Avenue,

CORBY, Northamptonshire, NN17 1LJ

Pharmacy reference: 1035406

Type of pharmacy: Community

Date of inspection: 21/02/2022

Pharmacy context

This is a community pharmacy situated on the high street of a small town. Most of its activity is dispensing NHS prescriptions and selling medicines over the counter. The pharmacy supplies medicines in multi-compartment compliance packs to people who live in their own home. Other services that the pharmacy provides include the substance misuse service and delivering medicines to people's homes. The inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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	Overall, the pharmacy fails to adequately manage and mitigate all of the risks associated with the provision of its services.
		1.6	Standard not met	The pharmacy fails to maintain all the records required for the safe provision of pharmacy services.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's roof is not currently water-tight meaning rainwater can leak into the premises.
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy team do not always ask people who are buying over-the-counter medicines the right questions or give them advice to make sure that the medicine is appropriate or is taken safely.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

Overall, the pharmacy does not adequately manage and mitigate all of the risks associated with the provision of its services. The pharmacy does not maintain all the records required for the safe provision of pharmacy services. The pharmacy has some procedures to learn from its mistakes. It has not been recording near misses until very recently. Embedding the current approach would help ensure the pharmacy reviews and learns from its mistakes to improve its ways of working. Its team members have defined roles and accountabilities. The pharmacy manages people's personal information safely.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs). They had been read by the pharmacy team who mainly followed them. For example, the staff were observed following the SOP relating to dispensing medicines signing the 'dispensed by' and 'checked by' boxes on the dispensing labels on original packs of medicines. The SOPs seen had been written a number of years ago and didn't always reflect current practice. For example, recent changes in requirements for some controlled drugs (CD) medicines were not covered. The dispenser explained that the SOPs were being reviewed and new ones would be issued soon.

The dispenser was aware that prescriptions had a six-month validity from the date on the prescription apart from CDs which had a 28-day validity. However, she was not aware of all the CDs with a 28-day validity. She said that prescriptions waiting collection that contained a CD were highlighted but prescriptions waiting collection were seen that had not been marked. This increased the risk that they might be handed out beyond their 28-day validity. The dispenser said she would discuss the process with the team.

The pharmacy had a process for recording dispensing mistakes that were identified before reaching a person (near misses) and dispensing mistakes where they had reached the person (errors). The locum pharmacist said she would discuss near misses with the member of staff at the time and then record them in a near miss log. The pharmacy had started recording near misses again this month (February 2022) after a long gap. Staff explained that a shortage of staff, no pharmacy manager and no regular locum pharmacists were reasons that near misses had not been recorded. Staff said they had made senior managers aware of the problems.

The pharmacy adequately maintained appropriate legal records to support the safe delivery of its services. The responsible pharmacist (RP) record showed who the RP in charge of the pharmacy had been. The private prescription register complied with legal requirements and legally required entries had been made in the CD registers. When the inspector arrived the locum pharmacist had not displayed her RP notice. This meant that people visiting the pharmacy would not be able to see who the RP in charge of the pharmacy was.

There were four bags of mixed out-of-date CDs and CDs people had returned to the pharmacy in the CD cupboard. The pharmacy had not made a record of CDs that people had returned. The area manager had visited the pharmacy to destroy these CDs but due to staffing issues had not been able to do so. In a subsequent conversation the area manager said that he had given the pharmacy a book to record CDs people had returned because there wasn't one at the pharmacy. He said that he had advised the team

how to make the record but had not made any records himself.

Dispensed CDs waiting collection in the CD cupboard were clearly separated and the corresponding prescriptions were in date. When the inspector checked the methadone register there was a substantial quantity of methadone overage. The dispenser was not sure the reason for the discrepancy and said that she would investigate it. The register showed that the balance had been checked two weeks before. An audit of another CD selected at random showed that the running balance in the register and the quantity in the CD cupboard matched. An audit in January 2021 had highlighted a number of discrepancies between the running balances in the CD register and the physical stock, five discrepancies had not been resolved. The dispenser said that she hadn't been able to find the reason for these discrepancies and had reported them to the area manager. The area manager said that he had not yet had time to investigate the discrepancies and would investigate them the following week and report the outcome to the inspector. The inspector advised him that if the discrepancies were not resolved they should be reported to the Accountable Officer.

The pharmacy had appropriate professional indemnity insurance. There was a complaint procedure in place. Computer terminals were positioned so that they couldn't be seen by people visiting the pharmacy. Access to the patient medication record was password protected. Confidential paperwork was stored securely. Confidential waste was shredded. Staff had some understanding of safeguarding requirements; but had completed their training sometime ago and did not have a clear understanding of who they should report concerns too.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy's team members adequately manage the workload within the pharmacy. They are suitably trained and skilled for the roles they undertake. Team members do not feel their concerns are always responded to. But recently the area manager has increased the level of support he provides.

Inspector's evidence

During the inspection the pharmacy team adequately managed the day-to-day workload. The pharmacy team members showed a concern for the people using their service. And they were in contact with the local surgery to resolve problems around prescriptions and expressed their desire to provide a good service to their customers. There was one pharmacist and four appropriately trained members of staff. The pharmacist was a locum, and this was her first day at the pharmacy. Staff said there hadn't been a regular pharmacist for some time. Staff said that they didn't have a manager but one of the dispensers had unofficially taken on some of those responsibilities. Some staff said that they didn't feel supported by senior managers when they raised concerns.

Staff said that they had been short of staff and this had meant that some aspects of clinical governance such as regular CD balance checks and near miss recording had not been maintained. However additional staff had been recently appointed and since the end of January clinical governance activities had restarted. In a subsequent telephone conversation the superintendent pharmacist said that he had been advertising for a manager and there were problems finding locum pharmacists who would work regularly at the pharmacy. Visits by the superintendent's team to the pharmacy had stopped during the Covid-19 pandemic and this had made oversight more difficult. The area manager said that he now had daily phone calls with the branch to make sure that the pharmacy was running smoothly. New staff had been appointed who were very experienced in working in pharmacies to help the service run more smoothly.

Staff had just completed their annual personal development plan and felt that there was the opportunity for their development. Some of the team had been told that they would be able to register for a pharmacy technician qualification when the pharmacy was running smoothly. There was on-line training available, but the team said that because of staffing pressures they were behind in their regular training. The team had weekly meetings. Team members had informal training from some of the locum pharmacists to update their skills and knowledge.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy's roof is not currently water-tight meaning rainwater can leak into the premises. The pharmacy makes some changes to help keep staff and people using the pharmacy safe during the pandemic. The pharmacy keeps its premises secure.

Inspector's evidence

The pharmacy had a push-pull door which made it a little more difficult for people with a disability or with a pushchair to get into the pharmacy. There was adequate lighting and hot and cold running water was available. Heating was limited with a few electric heaters around. The dispensary was a little small for the services provided. After the recent heavy rain the pharmacy had a water leak through the roof into the dispensary. This had left a hole in the dispensary ceiling at the door between the dispensary and the public counter. The roof had not yet been repaired. Although there had been a puddle on the floor this had been cleared up and no medicines had been damaged.

The pharmacy had some processes in place to support safe working during the Covid-19 pandemic. The pharmacy had a sign on the door which restricted access into the pharmacy. There was a one-way system in the public area. There was plastic screening at the pharmacy counter. But there was a large gap in the middle where people stood and spoke through which meant that the screen was not effective. There was hand sanitiser available. The pharmacy was dusty in places. The dispenser said that they hadn't had the opportunity to regularly clean the pharmacy but were aiming to do so. There were boxes on the floor which created a trip hazard. Unauthorised access to the pharmacy was prevented during working hours and when closed.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy offers healthcare services which are mainly adequately managed and are accessible to people. But the team do not always ask people who are buying over-the-counter medicines the right questions or give them advice to make sure that the medicine is appropriate or is taken safely. The pharmacy has changed the way it provides services during the Covid-19 pandemic to keep its staff and the people who use its services safe. But further action such as regular cleaning and improving the dispensary counter screen could be taken. The pharmacy gets its medicines and medical devices from reputable sources. It mainly stores them safely. It takes the right actions if medicines or devices are not safe to use to protect people's health and wellbeing. But the pharmacy doesn't make a record of the action it has taken which could make it harder for them to show what action has been taken in response to an alert.

Inspector's evidence

The pharmacy team understood the signposting process and used local knowledge to direct people to other local health services when needed. The pharmacy delivered medicines to some people. The person delivering the prescription maintained appropriate distance due to the pandemic. The dispensing team knew the advice about pregnancy prevention that should be given to people in the atrisk group who took sodium valproate. The dispenser asked had some understanding of how to sell medicines safely. But she did not always ask the right questions when selling a medicine over the counter and didn't give advice about how to take the medicine. This might mean that some medicines were inappropriate for the person buying them.

The pharmacy used a dispensing audit trail for original packs which included use of 'dispensed by' and 'checked by' boxes on the medicine label. This helped identify who had completed each task. The pharmacy also used baskets during the dispensing process to keep medicines and prescriptions separated to reduce the risk of a mistake being made. However, the multi-compartment compliance pack checked didn't have any identifiers, such as initials, to show who had dispensed and checked the pack. The member of staff said they were aware they needed to do so and said she would make sure it was signed. There was a process to make sure that each person who received their medicines in a multi-compartment compliance pack got them in a timely manner. The compliance packs recorded the colour and shape of medicines on the packs to make the medicines easily identifiable. Patient information leaflets were sent to people every month.

Medicines were mainly stored on shelves tidily and in original containers. But some original packs contained blisters from different packs. Some of these blisters didn't have batch numbers or expiry dates. This increased the risk that out-of-date or recalled medicines might be supplied by mistake. The dispenser said that she would make sure medicines were kept in their original packs or in a white box with the expiry and batch number recorded. Some bottles were seen that had a shorter expiry date once opened but didn't have the opening date recorded. This increased the risk of a less effective medicine being supplied. The dispenser said she would make sure all bottles had the date of opening recorded. Staff explained that date checking had been carried out that week, but that they were not making a record when date checking. But a sample of medicines checked were in date. The pharmacy only used recognised wholesalers to supply them with medicines. The pharmacy team could explain the procedure for managing drug alerts appropriately but there were no records to provide an audit trail.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has access to the appropriate equipment and facilities to provide the services it offers safely. But the current storage capacity of the pharmacy fridges may not be sufficient to ensure medicines are always stored at the correct temperature.

Inspector's evidence

The pharmacy used suitable measures for measuring liquids. It had up-to-date reference sources. The pharmacy had two fridges which didn't always keep medicines that required refrigeration at the right temperatures. The records showed the fridge temperatures were often higher than the required range of between 2 and 8 Celsius. Staff had adjusted the fridge and made the head office aware. One cause may have been because the second fridge was overfull which also meant that some items were pushed to the back and risked freezing, The area manager said he would investigate the issue and order a bigger fridge if it was required. Records showed that portable electrical equipment hadn't been safety tested since 2016. Some of the cabling was covered in dust which could create a fire hazard.

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.	