General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Lloydspharmacy, 52 High Street, Princes Risborough, AYLESBURY, Buckinghamshire, HP27 0AX

Pharmacy reference: 1029075

Type of pharmacy: Community

Date of inspection: 12/05/2022

Pharmacy context

This is a community pharmacy located in the centre of the market town of Princes Risborough, in Buckinghamshire. The pharmacy dispenses NHS and private prescriptions. It sells over-the-counter medicines and offers a local delivery service. The pharmacy also supplies several people with their medicines inside multi-compartment compliance packs if they find it difficult to take them.

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 is not identifying and managing several risks associated with its services as indicated under the relevant failed standards and Principles below. The pharmacy team could not locate the company's standard operating procedures (SOPs) at the point of inspection. There is no evidence that all of the current team has read the pharmacy's SOPs. The staff are not routinely working in line with all of the pharmacy's SOPs. And there is evidence that things have gone wrong because of this.
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. Staff are not routinely recording details about incidents, complaints or near misses, they are not completing their company's internal Safer Care processes and there is no evidence of remedial activity or learning occurring in response to mistakes.
		1.6	Standard not met	The pharmacy has not been keeping and maintaining all the necessary records for the safe provision of pharmacy services.
		1.8	Standard not met	The pharmacy has evidently failed to appropriately safeguard the welfare of vulnerable people. They have not always ensured that people receive the correct medicine(s) in a timely manner or within multi-compliance packs. And there is evidence that mistakes have happened because of the lack of staff, inadequate staff training and due to the chaotic manner in which the team is having to work.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough suitably qualified and skilled staff to provide its services safely and effectively. The current staffing arrangements are insufficient to cope with the workload, the team is significantly behind and routine tasks are not being completed or undertaken in a timely manner.
		2.5	Standard	The pharmacy’s management has not taken

Principle	Principle finding	Exception standard reference	Notable practice	Why
			not met	appropriate action when the pharmacy team members raise legitimate concerns about their working environment and training needs. And any action they did take was inadequate. So members of the pharmacy team remain inadequately supported, and under-resourced. This means that they cannot effectively manage the safe operation of the pharmacy.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's services are not currently being provided in an environment that is appropriate for the provision of healthcare. The dispensary is cluttered, untidy and disorganized, the pharmacy's workspaces are not kept clear enough to safely work on, and parts of the premises have significant piles of rubbish or returned medicines which have not been cleared effectively. In addition, there are health and safety risks such as the risk of tripping on poorly maintained stairs, which have not been addressed, fixed or highlighted appropriately.
		3.3	Standard not met	The pharmacy's premises are not maintained to a level of hygiene appropriate for the services it provides. Some parts of the pharmacy are dirty. The pharmacy is not being cleaned regularly. This includes the toilets.
4. Services, including medicines management	Standards not all met	4.1	Standard not met	The pharmacy's services are currently insufficiently accessible to patients and the public. The pharmacy is not routinely allowing people freely into its premises and closing every afternoon. It is not providing its usual repeat prescription service or the delivery service on time for people who have signed up for them because it does not have enough staff. This means that people are unable to easily access their medicines.
		4.2	Standard not met	The pharmacy's services are not managed or delivered safely and effectively. There are risks associated with the preparation and assembly of multi-compartment compliance packs and there is evidence that mistakes

Principle	Principle finding	Exception standard reference	Notable practice	Why
				have subsequently happened.
		4.3	Standard not met	The pharmacy has compromised the safety of medicines and medical devices due to inadequate management of its medicines. The team has not consistently been checking medicines for expiry. The pharmacy has large quantities of date-expired medicines in amongst its stock, short-dated medicines are not identified and the staff cannot show that they have been storing medicines requiring refrigeration at the appropriate temperatures.
		4.4	Standard not met	The pharmacy cannot demonstrate that it has appropriate procedures in place to raise concerns when medicines or medical devices are not fit for purpose. The pharmacy team has not been dealing with and appropriately acting upon the drug alerts issued by the Medicines and Healthcare products Regulatory Agency.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy is not operating safely. It doesn't effectively identify and manage the risks associated with its services. And it's working environment is extremely unsafe. The company has set procedures to help manage risks. But they are not present in the pharmacy to help guide the staff. And members of the pharmacy team are not working in line with them. The pharmacy does not effectively safeguard vulnerable people. It is unable to demonstrate that it records all its mistakes or learns from them. And, it has not maintained its records, in accordance with the law or best practice.

Inspector's evidence

The GPhC received some concerns relating to mistakes, routine closures, poor internal standards, the lack of support staff and people being left without their medicines or not being able to access their medicines on time. An inspection was subsequently carried out to assess the situation. The inspector arrived just before the pharmacy's scheduled opening time, several people were already queuing and waiting outside but the team did not open the doors on time, despite two pharmacists being inside and present. The inspector had to intervene to get the staff to open the pharmacy. People who had been queuing told the inspector that this was common, the pharmacy had staff shortages and they were often left without their medicines or received them late. A notice was on display on the front door advising that only three people at a time could be allowed inside and that the pharmacy closed after lunchtime. This meant that there was constantly a long queue of people outside, the service was slow and often inaccessible (see Principle 4).

Throughout the inspection, it was clear that the pharmacy was not operating in a safe and effective manner. There were no systems in place to identify or monitor the safety of the services being provided. The pharmacy did not have enough staff to manage the workload effectively (see Principle 2). Team members were severely behind with the workload. Staff were seen to check the pharmacy system, download prescriptions or search to locate every single person's prescription. No-one's prescription was ready on time for them to collect. And each person was seen to wait for a considerable amount of time despite the inspector being told that this was a 'good' day by the team. It was also observed that some people, after giving their details in, left and came back only to have to wait again.

The team had been unable to complete routine tasks. The pharmacy needed cleaning, there were health and safety concerns with the premises which had not been appropriately identified or managed and all the workspaces were cluttered with stock that had not been put away (see Principle 3). Several date-expired medicines were present in the pharmacy's stock and multi-compartment compliance packs that required a final accuracy-check had been left in the dispensary upstairs, unsealed from the night before (see Principle 4).

During the inspection, people using the pharmacy's services informed the inspector about the issues and concerns they had experienced or seen. This included mistakes that had happened with vulnerable people. Staff, including one of the pharmacists and the manager did not know how to handle these situations appropriately or in accordance with the company's procedures (see below and Principle 2). They said that they had not been shown, taught how to do this or how to access the company's system. They also said that most of the complaints were about waiting times and that people usually complained direct to the company's head office. The responsible pharmacist (RP) said that he had not

dealt with any incidents but his process to manage complaints or incidents was appropriate. There were no recorded details located of previous incidents despite the inspector knowing of and being made aware of specific incidents that had happened here. In addition, the inspector had highlighted these concerns with senior members of the company, including the superintendent pharmacist with little evidence of any appropriate action being subsequently taken to rectify the situation.

There was no evidence that the pharmacy was identifying its mistakes or learning from them. The pharmacy team had last recorded their near miss mistakes in July 2021. There had been no details recorded to verify that they had been reviewed, about the contributory factors, or the learning and action taken. The company's 'Safer Care' procedures were not being adhered to. There was only out-of-date information in the 'Safer Care' folder at the point of inspection to verify this, booklets and case studies had also not been completed since June 2021. The inspector was told by staff that there had been no team meetings or briefings about 'Safer Care'. And there were no details on the noticeboard. This meant that there was no evidence that the near misses or incidents had been formally reviewed, any trends or patterns identified, or that any remedial action had been taken in response.

The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The inspector was aware that the company had a range of standard operating procedures (SOPs) to provide its team with guidance on how to complete tasks appropriately. However, there were no SOPs seen and staff could not locate them. Only one member of staff said that she had seen, read, and signed them but this could not be verified. Newer members of the team had not accessed, read, or signed the relevant procedures for their role. This meant that the majority of the team did not know how to complete most tasks appropriately (see Principle 2).

The pharmacy had no details present to verify its professional indemnity insurance, but the inspector knew that this was through the National Pharmacy Association and due for renewal after 30 June 2022. None of the pharmacy's records were compliant with statutory and best practice requirements. This included the RP record, a sample of registers seen for controlled drugs (CDs), and records of CDs that had been returned by people and destroyed at the pharmacy. There were several gaps in the RP register. Staff said that people had returned CDs this year to be destroyed but the last records seen were from mid 2021. On randomly selecting CDs held in the cabinet, their quantities did not match the stock balances recorded in the corresponding registers. The pharmacists said that the relevant details may not have been entered into the CD registers when supplies had been made against prescriptions by other pharmacists. This could not be verified at the time. The team also confirmed that records of private prescriptions and unlicensed medicines had not been maintained. Private prescriptions were being filed with other processed prescriptions without documenting or entering any of the required information. Records verifying that fridge temperatures had remained within the required range had also not been regularly completed (see Principle 4).

The pharmacy team routinely ensured people's confidential information was protected. The pharmacy's confidential waste was separated and removed for disposal. There was no sensitive information visible from or left in the retail space and the pharmacy's computer systems were password protected. Staff used their own NHS smart cards to access electronic prescriptions. The pharmacy had the company's information governance process in place, but this did not have recent sign-off sheets and had not been read and signed by all the current members of the team.

The inspector was aware that the company had procedures in place to safeguard the welfare of vulnerable people. However, this policy could also not be located at the inspection. And there were no contact details seen for the relevant agencies. This meant that the team may not know how to respond to concerns appropriately. Experienced staff members had however, been trained on this, they

described reading this information and knew who to refer to in the event of a concern. Both pharmacists were trained to level 3 to safeguard the welfare of vulnerable people. New members of the team however, had not read, seen or signed this policy. There was evidence that mistakes had happened with vulnerable people's medicines. And that vulnerable people had been left without their medicines for long periods or had to access emergency prescriptions because of the ongoing issues at this pharmacy.

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

Summary findings

The pharmacy does not have enough staff to manage the workload safely. Its current staffing levels means that the team is significantly struggling with the workload. Members of the pharmacy team are therefore under considerable pressure and stress. They are unable to effectively keep up to date with routine tasks. And new members of staff are not being trained properly. This situation is unsafe.

Inspector's evidence

The pharmacy dispensed a large volume of prescriptions and supplied many people with their medicines inside compliance packs. There was no regular pharmacist and the pharmacy was currently being run on locums. Staff present during the inspection included two locum pharmacists, a newly employed pharmacy technician who was the pharmacy manager and a full-time, trained, medicines counter assistant (MCA). There was also a very newly employed part-time, trainee dispensing assistant who had been enrolled on accredited training. The latter was observed initially standing around, watching the MCA until the inspector intervened (see below). This member of staff and the manager confirmed that neither had read the company's SOPs. There was no contingency cover in place.

It was evident that the pharmacy did not have enough staff to support the pharmacy’s current volume of work. The team confirmed that they were four weeks behind with dispensing prescriptions. People who arrived to collect their prescriptions were seen to wait for long periods as described in Principle 1. The manager needed to prepare compliance packs upstairs, one pharmacist was seen to move between upstairs and downstairs, the other was seen to work alone for periods, dispensing and completing accuracy-checks on his own work (self checking) because there were no other staff available to help. Prescriptions were therefore being prepared one at a time. After noticing the new member of staff standing around, not doing much, the inspector intervened, asked her to go outside and 'queue bust'. She was instructed to obtain names and addresses of people, taking care to protect their personal data and then asked to bring this list inside so that their prescriptions could be batch printed and prepared in advance of people entering the pharmacy.

The inspector was told that several members of staff had left the pharmacy in February 2022, the complaints, delays and concerns seen had resulted since then. Some staff had experienced abuse from people in the street which had reduced them to tears. Others cried during the inspection when dispensing mistakes that had been reported by members of the public were brought to the team's attention. It was clear that this was a highly stressful, pressurised and unsafe environment to work in. The inspector contacted the new regional manager to obtain more staff as the situation in-house was unacceptable. An assurance was given that more staff including another pharmacist would come, but as the inspection finished, only one, trained dispensing assistant arrived from another of the company's pharmacies in the surrounding area.

Members of the pharmacy team were struggling to use the company's new pharmacy system. They said that they had not been trained on this or shown how to use it and this was adding to the delayed service. The inspector was told by new members of the team, that they had not had enough training, support or been shown how to complete most tasks because of the lack of staff and despite them repeatedly asking for assistance. Even experienced staff said that they felt that they weren't being listened to. The team had raised these concerns to their regional managers and to two people from

head office who staff thought were divisional managers. The manager had only received two days of training in another pharmacy as some members of staff were then off sick, which had meant that for the remainder of the time, she was then required to work as a dispenser. The pharmacy manager was new to the company and had previously worked in a completely different pharmacy setting before. There were no team meetings being held, no formal appraisals undertaken, and no time provided to complete ongoing training. This included appropriate initial training for new starters.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy's premises are currently unsuitable to deliver healthcare services. The pharmacy does not adequately maintain parts of its premises, leaving them insufficiently safe and clean. And the pharmacy's workspaces are extremely untidy. This increases the risk of mistakes happening.

Inspector's evidence

The pharmacy was situated in the centre of the town, on the High Street, in a building, with two floors. The retail space, main dispensary, a small office, and another room which contained medicines returned by people for disposal were based on the ground floor. A second dispensary was upstairs where compliance packs were assembled and stored. The staff WC, kitchen/rest room and two stock rooms were also on this first floor, accessible by stairs. The pharmacy had modified its premises to help limit the spread of infection from COVID-19. This included a clear barrier in front of the medicines counter and markers on the floor to help with social distancing. The pharmacy also had a signposted consultation room present in its retail space. This was small but of an adequate size for its intended purpose. It contained appropriate equipment as well as lockable cabinets. The ambient temperature inside the premises was suitable for the storage of medicines and the pharmacy was appropriately lit and ventilated.

Both dispensaries generally had enough space to assemble, prepare and accuracy-check prescriptions. However, most of the workspaces in the main dispensary on the ground floor were extremely untidy and cluttered with stock. This meant that staff could not easily work safely and effectively. The rear section of this dispensary had several boxes of stock that needed putting away. This included CDs that had been delivered on the day. Staff were seen to be unable to complete this task because they were dealing with the queue of people and prescriptions that needed dispensing. Medicines that had been delivered on previous days had also not been put away and were left on workspaces. In addition, the room used to store returned medicines was completely full (see Principle 4) and inaccessible because of the boxes of stock in the way. One of the stock rooms upstairs, contained consumables such as dispensing bottles. However, some of them had been left without lids, meaning that there was a risk of contamination from dust and insects. This room was also very cluttered.

Some parts of the pharmacy needed cleaning and were dirty. This included the staff WC. Team members confirmed that they had not been regularly cleaning the pharmacy and wiping down surfaces. The manager had been trying to clean the WC every week but due to the staffing shortages, it was not possible for her to maintain this alone. There was a very large, mountainous pile of rubbish including cardboard boxes and other general refuse on the first floor opposite the staff kitchen which had not been removed. According to the manager, this was worse previously and had been cleared before but had accumulated again.

Additional health and safety risks were seen when accessing the first floor as some of the pharmacy’s fixtures and fittings had not been appropriately maintained. Three of the steps up to this floor were broken, they had not been repaired. Parcel tape had been placed along them, but they were not adequately or clearly identifiable and no hazard warning tape had been placed here or any warning signs to highlight this risk. The inspector was advised to descend carefully, but only after accessing this area a few times. This meant that there was a risk of trips and falls.

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

Summary findings

The pharmacy doesn't always provide its services, prepare, or store its medicines in a safe and effective way. People are not always able to easily access the pharmacy's services. The pharmacy is assembling its compliance packs in a potentially unsafe manner. Although the pharmacy makes some checks to ensure that medicines are not supplied beyond their expiry date, they are inadequate, and the records are unsatisfactory. The pharmacy cannot show that temperature sensitive medicines are stored appropriately. It cannot demonstrate that it has been taking the appropriate action in response to safety alerts. This risks people receiving medicines and devices that are not safe to use. And the pharmacy's team members are not making any checks to help people with higher-risk medicines take their medicines safely. But, the pharmacy obtains its medicines from reputable sources.

Inspector's evidence

The pharmacy had some on-street, car parking spaces available in its vicinity and a local car park available nearby. People could enter the pharmacy through wide doors at street level and the retail area was made up of some clear, open space. This assisted people with restricted mobility or using wheelchairs to easily enter and generally access the pharmacy's services. There were also a few seats available for people to use if required. However, access to the pharmacy's services was limited. This had been mentioned in the concerns received at the GPhC. Very few services were currently being provided. In addition to limiting the number of people coming inside the premises, the pharmacy had routinely been closing its doors to members of the public because of the lack of staff available. Staff confirmed that this included the afternoons. The pharmacy's repeat prescription collection service which people had signed up to had been suspended. Staff confirmed that the pharmacy was unable to offer a routine delivery service. This was a service that people had paid an annual fee for (up to £60 for 12 months). Team members explained that they had been unable to prepare people's prescriptions ahead of time, so prescriptions were not ready for delivery. The inspector had been informed on several occasions that the pharmacy had left people without their medicines for considerable periods of time. This situation meant that people were not able to easily access the pharmacy's services either in person, or via any paid or additional services usually provided by the company.

The pharmacy prepared and supplied many people with their medicines inside compliance packs. Staff explained that they had been initially obtained from three of the company's surrounding pharmacies (such as Chinnor) and they were sent back to those pharmacies for collection or delivered from these pharmacies to people once assembled. The pharmacy ordered prescriptions on behalf of people for this service and specific records were kept for this purpose. Any queries were checked with the prescriber and the records were updated accordingly. Unstable medicines, 'when required' items and higher-risk medicines were supplied separately. All the medicines were de-blistered into the packs with none supplied within their outer packaging. Records to verify when and where compliance packs had been delivered had also been kept. Staff said that they had mostly caught up with this service and the pharmacy was only a few days behind with preparing compliance packs for people.

However, several prepared compliance packs had been left unsealed overnight. The compliance packs had generated descriptions of the medicines included in them but the member of staff responsible for preparing them did not know how to change the details on the system (because she had not been shown or trained on how to do this). This meant that descriptions of the medicines were potentially

inaccurate. One of the concerns mentioned to the inspector on the day of the inspection described people being confused with which medicines had been placed inside their compliance packs. Details about medicines 'not in the cassette' or compliance pack were also sometimes inaccurate. This had led to a mistake happening. Patient information leaflets were supplied every other month. This was discussed at the time. People prescribed higher-risk medicines were not routinely identified, asked relevant questions or details about their treatment recorded.

The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. CDs were generally stored under safe custody and keys to the cabinet were maintained in a manner that prevented unauthorised access during the day as well as overnight. But a CD key log to help verify this was not seen or located. And the pharmacists confirmed that this had not been completed. The pharmacy used licensed wholesalers such as AAH and Alliance Healthcare to obtain medicines and medical devices.

Medicines returned for disposal, had been accepted by staff, except for sharps which were referred appropriately. Counter staff could identify returned medicines which were hazardous or cytotoxic and the designated containers that they needed to be stored in as there was a list available to help guide them. However, the team had run out of designated containers to store returned medicines and they were now being stockpiled. The inspector was told that these medicines had not been collected for the past four weeks. This increases risk and is affecting the pharmacy's storage capacity.

The team had not date-checked medicines for expiry regularly or for several months. The last records of when this was done were from April 2021. Short-dated medicines had not been identified. And the inspector found several date-expired medicines in a sample of drawers checked. Staff were also aware of this situation. The team confirmed that they did not have time to complete this task but said that they had been incorporating a date-check of each medicine into their final accuracy checks. As mentioned in Principle 1, records to verify that the temperature of the fridges had remained within the required range had also not been maintained. There were several and sustained gaps seen in the records with the last recorded details made in March 2022.

Drug alerts and product recalls were usually received through the company, however, staff confirmed that the stock had not been regularly checked or appropriate action taken in response. The company's system could not be accessed by the team present, as they said they had not been taught how to do this. There was no up-to-date audit trail to verify that this process had taken place as records seen were from 2021. The pharmacy therefore could not show that it had taken the appropriate action in response to affected batches of medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the appropriate equipment and facilities it needs to provide its services safely. And its equipment is used in a way to maintain people's privacy.

Inspector's evidence

The pharmacy generally had the necessary equipment and facilities it needed to operate appropriately. The pharmacy's equipment included current versions of reference sources, counting trays, pharmacy fridges, a few standardised conical measures for liquid medicines and the dispensary sink that was used to reconstitute medicines. The latter could have been cleaner. The pharmacy had hot and cold running water available. Cordless phones were available for private conversations to take place if required and the pharmacy's computer terminals were positioned in a way that prevented unauthorised access.

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.