General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Adelaide Pharmacy Ltd, The Adelaide Health Centre, Western Community Hospital, William Macleod Way, SOUTHAMPTON, Hampshire, SO16 4XE

Pharmacy reference: 1104564

Type of pharmacy: Community

Date of inspection: 31/12/2019

Pharmacy context

This is a community pharmacy located inside a purpose-built health centre in Southampton, Hampshire. The pharmacy dispenses NHS and private prescriptions. It sells a range of over-the-counter medicines, delivers medicines, offers Medicines Use Reviews (MURs), the New Medicine Service (NMS) and seasonal flu vaccinations. The pharmacy also provides multi-compartment compliance aids to people if they find it difficult to manage their medicines.

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. There is also no evidence that the team has read the pharmacy's standard operating procedures and the staff are not always working in accordance with them
		1.6	Standard not met	The pharmacy's records are not always maintained in line with legal requirements. This includes the RP record, records of unlicensed medicines and private prescriptions. The pharmacy has not verified that a discrepancy identified in the registers for a controlled drug has since been rectified
		1.7	Standard not met	There is evidence that confidential waste is not being appropriately stored and destroyed. The pharmacy has significant amounts of confidential waste accumulating in different areas of the pharmacy that has not been routinely disposed of. This includes constantly storing sensitive information in an unlocked consultation room and at the home of a member of staff. In addition, the pharmacy does not inform people about how their private information is maintained, and people's sensitive information can be seen from the way signatures are obtained during the delivery service
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy is not meeting the GPhC's minimum training requirements for the team as some members of the pharmacy team are undertaking tasks without being enrolled on accredited training appropriate for this and have been working at the pharmacy for longer than three months
3. Premises	Standards not all met	3.1	Standard not met	Pharmacy services are not provided from an environment that is appropriate for the provision of healthcare services. Most of the pharmacy is extremely cluttered, this includes the consultation room. This has left little clear work and floor space. This situation is unsafe

Principle	Principle finding	Exception standard reference	Notable practice	Why
4. Services, including medicines management	Standards not all met	4.3	Standard not met	Controlled drugs are not stored in accordance with safe custody requirements and there is insufficient evidence that medicines that require refrigeration are stored in appropriate conditions
5. Equipment and facilities	Standards not all met	5.2	Standard not met	The cabinet used to store Controlled Drugs is in breach of the Safe Custody Regulations as it has not been bolted to the wall or floor and is a free-standing unit. In addition, one of the pharmacy fridges has a broken temperature monitor. The pharmacy cannot therefore assess that it is operating at the appropriate temperature of between two and eight degrees Celsius and that medicines have been stored here appropriately

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

Summary findings

The pharmacy doesn't effectively manage all the risks associated with its services. It has written instructions to help with this. But the pharmacy cannot show that its staff have read them. This could mean that they are unclear on the pharmacy's current processes. Members of the pharmacy team deal with their mistakes responsibly. But they are not always recording all the details. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. Team members are inadequately protecting people's private information. But they do understand the need to protect the welfare of vulnerable people.

Inspector's evidence

This was a busy pharmacy with a high-volume workload. During the inspection, queues of people built, and walk-in trade was relatively steady, this was being managed as best possible by the staff present. However, at the point of inspection, the dispensary was extremely untidy and cluttered (see Principle 3), there was limited space to dispense prescriptions and limited systems in place to monitor the safety of the services being provided. There were also several areas of improvement required as described under the relevant Principles.

The pharmacy had incorporated an automated dispensing system (robot) in 2019 to help manage the workload. However, this took up a significant amount of space in the dispensary (see Principle 3). The pharmacy's workflow involved prescription tokens being printed from the electronic system, which were then labelled in batches and placed into baskets. One member of staff processed prescriptions, and another assembled them before they were accuracy checked by the responsible pharmacist (RP) from a designated area. Due to the high volume of dispensing and space constraints, the pharmacy team labelled prescriptions with one or a few items and stored these prescriptions in an alphabetical retrieval system. They were then assembled when people arrived to collect them. Staff described scanning prescriptions to bring up the relevant details when processing them and as the pharmacy system was linked to the robot, incorrect details were highlighted, and staff were informed about mistakes. Team members stated that the robot had therefore helped to reduce the number of near misses and that if mistakes had been seen, for example with different strengths of levothyroxine, they were separated in response.

However, every workspace was extremely cluttered and untidy with stacked baskets of prescriptions that had either been labelled and required dispensing or paperwork, piles of prescriptions, baskets of random bottles and multi-compartment compliance aids. This increases the risk of mistakes happening. The pharmacy team had also been sporadically recording their near misses and there were gaps seen in the near miss records with details about the contributory factors, the learning and action taken missing. There was no evidence that any of them had been reviewed. This meant that the pharmacy was unable to fully verify that any trends or patterns had been identified, or that any remedial action had taken place in response.

The pharmacy had a documented complaints procedure in place and the pharmacist described taking details and escalating if required. Some documented details were seen. However, there was no information on display about the pharmacy's complaints procedure. This meant that people may not have been able to raise their concerns easily.

The pharmacy held a range of documented standard operating procedures (SOPs) to support the services provided. They were dated from 2018. There was no evidence that team members had read them and signed them. The RP stated that they had but this could not be verified. The inspector was told by the delivery driver that he had not read and signed the SOP relevant to his role. In general, though, staff understood their role and responsibilities, they knew when to refer to the responsible pharmacist (RP) and which activities were permissible in the absence of the RP. However, an incorrect RP notice was initially on display and the RP's details were hidden behind other notices and cards. The inspection took place after lunchtime, displaying the correct RP notice is a legal requirement and this situation meant that people were being provided with incorrect details of the pharmacist in charge of operational activities. This was discussed with the RP at the time and subsequently changed.

Dispensed prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the retail area. Confidential waste was segregated before being shredded. However, there was sensitive information present in the consultation room (see Principle 3) that could be easily accessed, no information on display to inform people about how their privacy was maintained, and significant amounts of confidential waste was stored in the dispensary that had not been appropriately disposed of. This included several totes of confidential waste and random piles stored in different locations around the dispensary. In addition, there were risks associated with the delivery service (see principle 4). The inspector was told by the delivery driver that he kept previous records of deliveries at his home, in his bureau as he was preparing lists of people with compliance aids to help assist the pharmacy. According to the RP, he was unaware that this was happening. There is a considerable risk therefore that people's private information is not being stored or disposed of appropriately by the pharmacy.

Staff were trained to safeguard the welfare of vulnerable people. This was through an online training platform. The pharmacist was trained to level 2 to safeguard the welfare of vulnerable people. This was through the Centre for Pharmacy Postgraduate Education (CPPE). However, although team members could access details online, there were no contact details for the local safeguarding agencies present at the pharmacy. This could lead to a delay in the appropriate action being taken.

Records of emergency supplies and a sample of controlled drugs (CDs) were generally compliant with statutory requirements. Details of balance checks were seen recorded. On randomly selecting CDs held in the cabinet, only one of their quantities matched the balance that had been recorded in the corresponding register. Both pharmacists were instructed to investigate the situation, provide confirmation that they had identified the discrepancy or reported it to the CD Accountable Officer. No response was received following the inspection. There were other issues seen with the pharmacy's record keeping. Pharmacists routinely failed to record the time that their responsibility ceased in the RP record. Records of unlicensed medicines were missing details and prescriber details were missing sometimes within records of private prescriptions. The pharmacy's professional indemnity insurance arrangements were through the National Pharmacy Association and due for renewal after 06 February 2020.

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

Summary findings

The pharmacy has some members of its team carrying out tasks that they are not trained for or qualified in. This situation brings risks. It can affect how well the pharmacy cares for people and the advice that it gives. But the pharmacy team is provided with appropriate resources to keep their skills and knowledge up to date. And, members of the pharmacy team understand their roles and responsibilities.

Inspector's evidence

Staff present during the inspection included two pharmacists, one of whom was a locum, the other was the RP who was also the owner as well as the superintendent pharmacist, a pre-registration pharmacist, a trained dispensing assistant and medicines counter assistant (MCA). The team's certificates of qualifications obtained were not seen. The inspector was told by the MCA that in addition to her duties as a counter assistant, she unpacked medicines for the dispensary and put this stock away, the delivery driver was also observed scanning split packs of medicines into the automated dispensing system during the inspection. Neither had been enrolled onto accredited training in line with these roles at the point of inspection. This was not in line with the GPhC's minimum training requirements as any assistant given delegated authority to carry out certain activities should have undertaken or be undertaking an accredited course relevant to their duties within three months of commencing their role.

The MCA knew to ask appropriate questions before selling medicines over the counter and referred to the RP when required. The pre-registration pharmacist felt supported by the RP, he was her tutor, there was a training plan in place, and she was attending training sessions once a month. The pre-registration pharmacist was also provided with set aside time to complete her studies. As they were a small team, details were discussed verbally amongst them, team meetings were held when required and their progress was described as monitored informally. As part of their ongoing training, they took instructions from the RP, read trade publications and completed modules through on an online training platform. The RP described setting a target to complete the maximum number of Medicines Use reviews (MURs).

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

Summary findings

The pharmacy's premises are inadequate for delivering the level of healthcare services it provides. The consultation room is kept in an unsatisfactory way that is inappropriate for the professional use of that space. And, the team is storing confidential information in there. This increases the chance of people gaining unauthorised access to private information. The pharmacy is cluttered, and its workspaces are extremely untidy. This increases the risk of making mistakes.

Inspector's evidence

The pharmacy was in the same building as a community hospital. Its retail space was of an average size and it was professional in its appearance. The pharmacy was bright and suitably ventilated. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity. The pharmacy was clean, but it was extremely untidy. The dispensary was also of an average size, there was limited space and every workspace was cluttered. The robot also took up a significant amount of space here and most of the floor space was taken up with clutter or tote boxes of stock. Some of the latter contained prescriptions or significant amounts of confidential paperwork awaiting disposal. The pharmacy was disorganised at the point of inspection and there was very little space left for storage or clear working spaces for staff and the pharmacist when accuracy-checking. A sign-posted consultation room was available to hold private conversations and services. The door was usually kept open. This area was also untidy and cluttered with paperwork. There was confidential information present. This mean that unauthorised access to people’s sensitive information was possible. This was locked briefly by the RP when highlighted.

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

Summary findings

The pharmacy does not provide all its services in a satisfactory manner. Members of the pharmacy team don't always record information when people receive some medicines. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. The pharmacy is unable to show that temperature sensitive medicines and medicines that should be kept more secure are being stored appropriately. The team does not do enough to be able to demonstrate that they are checking the expiry dates of their medicines. And some of its medicines are held in poorly labelled containers. This makes it harder for the team to check the expiry date, assess the stability or take any necessary action if the medicine is recalled. But the pharmacy team is helpful. And the pharmacy does obtain its medicines from reputable sources.

Inspector's evidence

Entry into the pharmacy was through automatic doors from the street. The pharmacy's retail space consisted of clear, open space which helped people with wheelchairs to use the pharmacy's services. Four seats were available for people waiting for prescriptions and there were plenty of car parking spaces outside the premises. Staff physically assisted people with additional requirements, they used written communication, gestures, google translate and staff spoke several languages such as Persian, Gujarati, Hindi, Punjabi and Filipino to assist people whose first language was not English.

People were supplied with compliance aids once they were assessed by the pharmacist. Once set up, staff ordered prescriptions for people on their behalf and when received, they cross-referenced details against records on the pharmacy system to help identify any changes or missing items. The team checked queries with the prescriber and maintained records to verify this. Compliance aids were not left unsealed overnight. Descriptions of the medicines within the compliance aids were provided and the process for mid-cycle changes involved retrieving the compliance aids, amending them, re-checking and supplying them. However, patient information leaflets (PILs) were not routinely supplied. This was not in accordance with the law and could mean that people may not have all the information they need to take their medicines safely.

The pharmacy delivered medicines via a designated driver. The pharmacy had been keeping records to verify this, CDs and fridge items were identified. People's signatures were obtained once they were in receipt of their medicines. However, there was a risk of access to people's confidential information from the way signatures were obtained due to the way people's details were laid out on the driver's drop sheet. Failed deliveries were brought back to the pharmacy with notes left to inform people about the attempt made and medicines were not left unattended.

Team members were aware of the risks associated with valproates, they stated that they had seen relevant literature to provide upon supply, however this could not be located during the inspection. Prescriptions for higher-risk medicines were not routinely identified and people asked about relevant parameters, such as blood test results. However, the team did not record details about this to help verify this process.

Baskets were used during the dispensing process to hold prescriptions and medicines. This helped to prevent the inadvertent transfer of items. A dispensing audit trail was used to identify the staff

involved. This was through a facility on generated labels. Dispensed prescriptions awaiting collection were stored with prescriptions attached. Uncollected prescriptions were removed every six months. According to staff, CDs (Schedules 2 and 3) and fridge items were identified, however, there were prescriptions seen for CDs without this being marked in any way to indicate this. This included Schedule 4 CDs. The MCA could recognise some prescriptions for these medicines but not all of them.

There were some random, generated labels with people's details stuck on one wall next to the dispensing bench where staff processed prescriptions, team members stated that this was the pharmacy's system to tell them when medicines were due for people receiving compliance aids. However, they could easily become detached and this was not an appropriate method to use for this process.

The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Trident and Phoenix to obtain medicines and medical devices. Unlicensed medicines were obtained from Colorama. Staff were unaware of and had not been trained about the European Falsified Medicines Directive (FMD). The pharmacy was not yet fully set up to comply with the decommissioning process. There was no equipment present to help comply with this process.

The pharmacy's medicines were either stored inside the robot, on shelves around the pharmacy and several were stored haphazardly inside tote boxes in the dispensary. The RP stated that this additional stock had been ordered in over the Christmas period. P medicines could also have been more organised behind the front counter as some General Sales List (GSL) medicines and appliances were mixed in with them. Medicines were scanned into the robot and the system then provided reports about short-dated medicines. Staff stated that the latter were highlighted and that they date-checked medicines for expiry every three months. However, there was no schedule or matrix in place for either medicines in the retail area or dispensary to help verify this. Drug alerts were received by email and according to staff, action taken as required. The documented audit trail could not be located to support this although an audit trail on the email system was seen to verify receipt.

The keys to the CD cabinet were maintained in a manner that prevented unauthorised access during the day as well as overnight. There were some poorly labelled containers with medicines stored in a small shelf space above the CD cabinet that had necessary details (such as batch number and expiry dates) missing. The device that monitored the temperature for one of the medical fridges was broken. The RP stated that this had been the case for the past week. However, on checking the electronic records, both fridges had temperature readings recorded as being within the appropriate range (between four and seven degrees). When questioned, the RP stated that he knew that the temperature had been within this range, hence the records were made, however, without a functioning probe or temperature monitoring system, he had no tangible way of knowing the temperature inside the fridge. The records were therefore false and an inaccurate representation of the situation. The pharmacy therefore cannot demonstrate that it has been storing medicines in this fridge at the appropriate temperatures and that they are safe for people to use or take. The second fridge provided a temperature reading of between four and 15 degrees Celsius. This was re-set at the time.

Medicines returned for disposal, were accepted by staff and stored within designated containers. However, there was no list available for the team to identify hazardous and cytotoxic medicines requiring disposal and no designated containers to store them. People returning sharps for disposal were referred to the local council. Returned CDs were brought to the attention of the RP before being segregated in the CD cabinet.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

The pharmacy does not have all of its equipment in good working order. One of its fridges is not able to measure its inside temperature. And it doesn't have adequate storage facilities for some of its medicines.

Inspector's evidence

There were current versions of reference sources, counting triangles and the sink that was used to reconstitute medicines. There was hot and cold running water with hand wash available. There were two fridges used for medicines requiring cold storage, one was not operating at appropriate temperatures during the inspection and the second's temperature probe had broken as discussed under Principle 4. This meant that temperature measurements could not be taken, and the pharmacy could not verify that medicines were being appropriately stored here. Computer terminals were positioned in a manner that prevented unauthorised access. Cordless phones were available to maintain people's privacy. A small shredder was present to dispose of confidential waste and staff used their own NHS smart cards to access electronic prescriptions. These were taken home overnight.

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.