General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Shah Pharmacy, 732-736 Hertford Road,

Freezywater, ENFIELD, Middlesex, EN3 6PR

Pharmacy reference: 1034875

Type of pharmacy: Community

Date of inspection: 30/05/2019

Pharmacy context

The pharmacy is in a parade of shops, on a busy road close to residential housing. It provides NHS and private prescription dispensing mainly to local residents. It supplies medicines in multi compartment compliance trays to about 100 people. It has a home delivery service. The pharmacy has a dispensing robot.

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	There were no up-to-date written procedures in place for staff to access to see how they should perform day-to-day tasks.
		1.7	Standard not met	The pharmacy cannot show that the way it stores or disposes of confidential waste is effective or legal.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy doesn't store all its medicines safely or in keeping with legislation. The pharmacy cannot demonstrate that medicines which require cold storage are stored correctly.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not fully identify and manage the risks associated with its services. Most members of the pharmacy team are clear about their roles and responsibilities. But they don't have ready access to written procedures, so they may not always be completing tasks as intended. And staff only log some of the mistakes they make during the dispensing process. So it may be harder for them to learn and improve from these events. The pharmacy cannot show that the way it disposes of confidential waste is effective or legal. And the pharmacy could do more to keep its records up to date.

Inspector's evidence

The pharmacy had written procedures to tell the team how they should undertake the work in the pharmacy. The procedures were dated 2008 and had been signed by the staff. The staff felt that there should be a more up-to-date file of procedures, but they could not find them. When the dispensers made dispensing mistakes that were discovered by the pharmacist checking the prescription, the mistakes were discussed in the team. But these events were generally not recorded. So analysing and learning from trends was difficult. The superintendent pharmacist visited on a monthly basis and staff said he reviewed the processes in the pharmacy.

The pharmacy conspicuously displayed the responsible pharmacist notice and the record required by law was up to date and filled in correctly. Most of the pharmacy team members were aware of their roles. But the owner started work at 6.30am and the pharmacist did not arrive until 9am. There was no guidance about what tasks could be undertaken at that time. The owner said that he went in early to take prescriptions to the surgeries, but the surgeries did not open until 9am.

No customer surveys were posted on the NHS choices web-site. The staff did not know what actions had been taken on the last survey, although they said they had handed out questionnaires to people in the shop for them to fill in in the last year. The pharmacy had professional services insurances in place.

The pharmacy team recorded private prescriptions and emergency supplies in a book. The last entry was made in January 2019. But there were a lot of prescriptions dispensed in the months between then and the inspection waiting to be recorded. This was outside the time-scale defined in law. There was a facility to record these prescriptions on the PMR computer system, but the staff were not using it. The controlled drugs registers were up to date and legally compliant. A spot check showed that the recorded balance was the same as the actual stock.

The staff present during the inspection had had confidentiality training during previous employment and had signed confidentiality agreements in this pharmacy but had not had other any training from this employer. Staff were seen to share their NHS smart cards which gave them access to the electronic prescriptions. The owner who was not a registrant was asked if he still had access to Summary Care Records, and he said that he thought that he did . As a non-pharmacist he had no right to access this information, although there was no evidence found that he had tried to. Some confidential material was kept in the dispensary, where it was not accessible to unauthorised people. However, there was also some material in the unlocked consultation rooms where it could be accessed. Confidential waste was segregated by the pharmacy team members and put into black sacks marked "C". These were then

stored in the WC until the delivery driver took them to burn. There was no audit of this process to ensure that confidential information was protected from people who should not have access to it. The pharmacy did not have any licenses from the Environment Agency to transport or destroy waste.

The pharmacist and some staff had undertaken safeguarding training to the appropriate level and had access to telephone numbers for the safeguarding leads in the local authority.

Principle 2 - Staffing ✓ Standards met

Summary findings

Some of the pharmacy's team members do not have the required training for the roles they undertake. The staff are aware of their roles and responsibilities but sometimes need more support than they get to fulfil these roles. The lack of a formalised approach to training may make it harder for staff to keep their skills and knowledge up to date.

Inspector's evidence

At the time of the inspection, there was a regular pharmacist locum, a full-time dispenser, and a counter assistant who had started work about a month before the inspection. A part-time dispenser was off that day. The staff reported that sometimes a member of staff from one of the other pharmacies owned by the same people came to help out, and that they had anaccuracy checking qualification. When they came they got involved in dispensing rather than checking, which increased the checking for the pharmacist present, but got some of the backlog done. They were also supposed to be in charge of the robot management, but this did not happen due to the need for dispensing and the infrequency of the visits. The owner was also present and was observed dispensing prescriptions. He had previously been a pharmacist but was no longer on the register. He had not done an accredited dispenser course, which did not comply with the GPhC support staff training policy.

The staff said that they saw the superintendent pharmacist about once a month, when he visited to see what was happening in the pharmacy. The staff said that they could speak to the superintendent pharmacist about issues they had. Staff training consisted of reading pharmacy magazines, but there was no time allocated for this activity and there were no records of what was studied. There were no targets set for the staff.

Principle 3 - Premises ✓ Standards met

Summary findings

The premises are generally clean and provide a safe and professional environment for patients to receive healthcare. But access to some parts of the premises is not well controlled. And the level of clutter in the consultations rooms does not give a good impression of the pharmacy.

Inspector's evidence

The premises were over two shop units. A remote supply cabinet was in an unregistered area, but the unit was not used at all. The owner said that he would have to get the company back to provide more training on it, as he could not remember how it worked.

There were two consultation rooms which were both untidy and kept unlocked . An area near the toilet was used for storage. There was a sign stating that the public should not enter this area, but it was open to the public and there were over-the-counter (OTC) medicines, and some medicines waiting for destruction kept there.

Behind the counter was the dispensary which had plenty of dispensing bench space, but most of it was covered in part-dispensed prescriptions in baskets. There was a dispensing robot, which had an automatic loading facility in the far stock room.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy gets its medicines from reputable sources. Pharmacy team members are helpful and give advice to people. But checks are not always made when supplying higher-risk medicines. So some people may not receive appropriate advice about the medicines they receive. The way medicines are stored is not always secure.

Inspector's evidence

Access to the pharmacy was level from the pavement and was via an automatic door. Access in to the consultation rooms would be large enough for a wheelchair. Services were advertised on the window of the pharmacy.

The pharmacy sometimes used a dispensing audit trail to identify who had dispensed and checked each item, but it was not consistently done. The team sometimes used baskets to help ensure that prescription items were kept together and were easy to move from one area of the dispensary to another. Again, their use was not consistent.

People were being supplied with multi-compartment compliance trays. These were not labelled with the information the person needed to take the medicines in the correct way as the statutory warnings were not put onto the labels. They also had no tablet descriptions to identify the individual medicines. Only one member of the team regularly dispensed the trays and knew which ones were due to be dispensed each week. This means that if she was absent without notice the rest of the staff might not know which trays were due to be dispensed. The trays were dispensed in one of the consultation rooms, on a temporary table, with the medicines stored in there, in carrier bags which were accessible to anyone in the room. These medicines included some Schedule 4 controlled drugs. No prescriptions were seen with the trays, so it was unclear how they were checked against valid prescriptions. There was no audit trail to show who had dispensed and checked each tray.

People taking warfarin, lithium or methotrexate, who brought their own prescriptions into the pharmacy or had their prescription on repeat, were not always asked about any recent blood tests or their current dose. So the pharmacy could not show that it was monitoring the patients in accordance with good practice. People who were receiving prescriptions for valproate were not routinely counselled regarding pregnancy prevention where needed. There were no cards or warning stickers available to use on repackaged medicines. The owner said that he thought that they were a sample, so they had used them up and had not ordered any more.

The pharmacy got its medicines from licensed wholesalers, stored them in a robot and on shelves which were very dusty.

Medicines which required cold storage were kept in two fridges. Fridge temperatures were recorded as being within the required range of 2 to 8 degrees C, but when checked the thermometers showed much higher maximum temperatures and much lower minimum ones i.e. minus 5.9 and minus 2.6 degrees C and 10.5 and 8.2 degrees C.

The robot was used as a storage facility rather than an aid to accurate dispensing. As well as other prescription-only medicines it was used to store Schedule 4 and 5 controlled drugs and some schedule 3 medicines not requiring safe custody which were used for dispensing. There were also some patient

returned controlled drugs of all Schedules in a box in the robot. Robots are usually used to dispense one item at a time and that item be labelled before the next item is supplied by the robot. This was not the case in this pharmacy because it was reported that the robot took too long to pick the items, and there were a lot of items not stored in the robot. This meant that staff labelled a whole prescription or two before putting the labels on the packets, meaning that the chutes were full of packets of medicines waiting to be dispensed, increasing the risk of cross-labelling.

The staff did not know how to date check the contents of the robot, and so this was not done. Medicines expiring from 2016 to May 2019 were found in the robot and removed by the inspector for disposal by the team. Other checks for out-of-date medicines on the shelving were reported to be done occasionally.

The pharmacy was not ready to implement the Falsified Medicines Directive. Team members said that they were waiting for AAH, their computer supplier, to facilitate this. Controlled drugs returned by people were not recorded anywhere, in accordance with best practise, and were not stored safely, in accordance with the law. The owner said that he received alerts about faulty medicines and medical devices, however there was no evidence of one being actioned from 13 May 2019 which had been a Class 2 recall. He, and the pharmacist immediately subscribed to the MHRA alert service.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the right equipment for its services although it does not use some of it to its best effect for patient safety.

Inspector's evidence

There were various sizes of glass, stamped measures with separate ones labelled for methadone use, reducing the risk of cross-contamination. The pharmacy had a separate triangle marked for use with methotrexate tablets ensuring that dust from them did not cross contaminate other tablets.

The pharmacy had access to up to date reference sources. This meant that people could receive information which reflected current practice. The remote collection point was not used, and the robot was not used in a way which helped to reduce dispensing errors.

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.	