General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Moss Bank Pharmacy, 833 Moss Bank Way, BOLTON, BL1 5SN

Pharmacy reference: 1111747

Type of pharmacy: Community

Date of inspection: 10/07/2019

Pharmacy context

This is a very quiet community pharmacy located in a small parade of shops in a residential area. Most people who use the pharmacy are from the local area. The pharmacy dispenses mainly NHS prescriptions and sells a range of over-the-counter 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	1.2	Standard not met	The pharmacy does not report and learn from near misses and dispensing incidents.
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	4.2	Standard not met	The pharmacy assembles and checks multi-compartment devices without reliable audit trails and stores them unlabelled and unsealed for extended periods. It supplies higher risk medicines without appropriate clinical checks and counselling.
		4.3	Standard not met	The pharmacy does not always store medicines safely so it might not appropriately restrict 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 manages some risks associated with the services it provides. But the pharmacist does not record or review mistakes made in the pharmacy, which could make it harder to understand what has happened if a problem arises. And they may be missing out on some learning opportunities. The pharmacy generally completes the records that it needs to by law. It has written procedures on keeping people's private information safe and the pharmacist has completed training to help him understands how he can help to protect the welfare of vulnerable people.

Inspector's evidence

There were electronic standard operating procedures (SOPs) for the services provided. They were prepared in 2016 and there was no record that they had been reviewed since, so might not be fully up-to-date. There was no record that pharmacy team members had read the SOPs, but the RP confirmed he had read them when he was a pre-registration pharmacist in the pharmacy, around three years ago. Roles and responsibilities were set out in SOPs. The name of the responsible pharmacist (RP) was displayed as per the RP regulations. There was a SOP for near misses and dispensing errors, but it was not followed, and the RP said neither errors or near misses were recorded or reviewed. He said he knew they should be recorded and understood the reasons for recording them, but did not provide any explanation as to why the SOP was not followed.

There was a dealing with complaints SOP. A notice was on display in the pharmacy with the complaint's procedure and the details of who to complain to. The RP said he would e-mail one of the partners if he received a complaint about the pharmacy. A customer satisfaction survey was carried out annually. The results were available on www.NHS.uk. website. An area of strength was the pharmacist and advice given by the pharmacist. An area identified which required improvement was providing living on healthy living. The RP did not know of any changes made as a result of feedback.

Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy. Private prescription records were maintained electronically but the prescriber details were missing on the sample checked, so they did not provide an accurate audit trail. The RP record was appropriately maintained. Three controlled drug (CD) balances were checked and found to be correct. Patient returned CDs were recorded and denaturing kits were available.

There was a data protection and confidentiality SOP. The RP did not know if the delivery driver had read this or signed a confidentiality clause, but he said he had explained patient confidentiality to him. The RP said he would discuss the design of the delivery sheet with the driver, as there was a risk that people could see each other's details when they signed to confirm receipt of deliveries. Confidential waste was collected in a designated place and shredded. Prescriptions awaiting collection were not visible from the medicines counter. Paperwork containing patient confidential information was stored appropriately.

The pharmacist had completed centre for pharmacy postgraduate education (CPPE) level 2 training on safeguarding on children and vulnerable adults. There was a safe guarding policy in place containing the contact numbers of who to report concerns to in the local area. There was nothing on display

highlighting that the pharmacy had a chaperone policy, but the RP said he would allow someone to accompany a person in a private consultation if they requested it.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy does not have any permanent support staff and the pharmacist usually works alone. But the workload is manageable, and the pharmacist is able to seek support and raise concerns if needed.

Inspector's evidence

There was a regular locum pharmacist (RP) on duty at the time of the inspection. He was the only member of the pharmacy team and managed the volume of work during the inspection without any problems. But the lack of other competent team members meant that the RP was required to self-check all the prescriptions. He said he generally assembled in the morning and checked in the afternoon to allow a good break between assembling and checking and most prescriptions were collections or deliveries, with very few 'walk-ins' so this was usually possible. The RP said there had been a pre-registration pharmacist for a six-month period up to June 2019, and she was still available to work some hours when required. Two dispensing assistants from a neighbouring pharmacy, also owned by the pharmacist superintendent (SI), helped in the dispensary when required. The RP said he did not think they were qualified dispensers and was not sure if they were on accredited training courses. Subsequent to the inspection the RP confirmed that they were both undertaking the Buttercups level 2 dispensing course.

The RP said he worked most days in the pharmacy and had done since February 2019. The SI visited once or twice a month and he could communicate with him or another owner by phone or e-mail when required. He said he would feel comfortable talking to any of the pharmacy owners about any concerns he might have. There was a raising concerns SOP. He said there was no formal discussions about his performance and development and there was no regular pharmacy team to train and develop. The RP said he had recently submitted his continuing professional development (CPD) which included training on taking medication during Ramadan and mometasone nasal spray change from prescription only medicine (POM) to pharmacy medicine (P). He said he had also completed CPPE training on supervised consumption and emergency hormone contraception (EHC) during the previous year.

The RP said he felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations, e.g. refusing to sell a pharmacy medicine because he felt it was inappropriate. He said he was encouraged to undertake medicine use reviews (MUR) but he didn't feel didn't feel under any pressure to complete them, and the owners were understanding of the low numbers because the pharmacy was so quiet.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are generally safe and provide an adequate environment for people to receive healthcare. But fixtures and fittings are old and worn which may detract from the professional image.

Inspector's evidence

The pharmacy premises were in a poor state of repair and presented a poor professional image. The retail area had a waiting area with two chairs, one of which was stained, and the carpet was not clean. The flooring was uneven and damaged in both the front and back dispensary. The storage area behind the back dispensary was in a very poor state of repair. Maintenance problems were reported to the pharmacy's owner, but the RP said the pharmacy was on the market for sale and the owners had not invested any money in the pharmacy for some time. The post office adjoining the pharmacy, which could be accessed from the pharmacy's retail area, had closed down a few months ago and was empty. The temperature and lighting were adequately controlled. The first floor, which was not accessible to the public contained a WC for staff use, and the RP confirmed it was in working order. There was a separate dispensary sink for medicines preparation with hot and cold running water.

There was a consultation room and a sign highlighting the facility. The door was poorly fitting. It contained an empty large metal accessory stand, cardboard boxes, a tote box full of empty medicine packaging and appeared cluttered and unprofessional. The RP said the room had been used for the assembly of some multi-compartment devices, which was why the empty medicine packaging was there. He said the consultation room was offered to patients having supervised consumption of methadone and buprenorphine, but this usually took place at the medicine counter as the patients preferred that, and this wasn't an issue as the pharmacy was usually empty.

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

Summary findings

The pharmacy offers a small range of healthcare services, but these are not always well managed. It does not prepare, label and store multi-compartment devices appropriately and this increases the risk of contamination and error. The pharmacist doesn't always counsel patients taking higher-risk medicines or carry out additional checks. So people might not get all the advice they need about how to use their medicines safely. Some medicines are not stored safely which might not appropriately restrict unauthorised access.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. The RP spoke Urdu which assisted some of the non-English speakers in the community, but he said most people in the community spoke English.

A list of the services provided by the pharmacy was displayed in the window of the pharmacy, but included services which were no longer offered, which could be misleading to people. There was a small range of healthcare leaflets on topics such as cancer awareness and screening, and some posters advertising local services. The RP was clear what services were offered and where to signpost to a service not offered e.g. needle exchange and EHC. He said signposting and providing healthy living advice were not recorded, so the pharmacy could not demonstrate improved outcomes for patients.

The pharmacy offered a repeat prescription ordering service and patients were contacted before their prescriptions were ordered to check their requirements. The exception to this was patients who received their medicines in multi-compartment devices. These patients were only contacted if they had 'extra' medication which did not go in their device such as inhalers and creams. There was a delivery service with associated audit trail. Each delivery was recorded, and a signature was obtained from the recipient in line with the delivery SOP.

Space was limited in the dispensary. Baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available. Dispensed by and checked by boxes were generally initialled on the medication labels to provide an audit trail but not on methadone and buprenorphine or multi-compartment devices. So, it was not clear who had dispensed, accuracy and clinically checked them, and it might not be possible to identify who was responsible for any incident or error. This might limit what could be learned from things that go wrong.

Stickers were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. The RP said most patients in the pharmacy had taken their medication regularly for a long time, so counselling was not usually required, and he did not routinely target high-risk medicines such as warfarin and methotrexate for extra checks and counselling. INR levels were not requested and recorded when dispensing warfarin prescriptions. The RP was aware of the valproate pregnancy prevention programme. He said there were no regular female patients in the at-risk group. The valproate information pack and care cards were not available, but the RP said he would print them off if required, to ensure female patients were given the appropriate information and counselling.

Multi-compartment devices were not well managed. The RP produced a SOP which had been prepared in 2012 which he believed was the current SOP for multi-compartment devices. It was not being followed. None of the devices were appropriately labelled with the names of the medication during assembly, and were stored unsealed and without labels for up to a month. This breached labelling regulations and might increase the risk of error, contamination and degradation of the medication. The RP explained that four weeks of devices were assembled at the same time, but prescriptions were only received weekly, so they were only sealed and labelled when the appropriate prescription was obtained. He said this was always prior to supply but could be up to four weeks after the assembly. The RP said the devices were assembled and checked using the backing sheet rather than the prescription which increased the risk of error. There was no dispensing audit trail on the devices. There was no audit trail for changes to medication in multi-compartment devices, so It was not always clear who had confirmed the changes and the date the changes had been made, meaning changes might not be accurately implemented. Medicine identification was not completed to enable identification of the individual medicines. Cautionary and advisory labels and packaging leaflets were not included, despite these being mandatory requirements. And meaning patients and carers might not have access to information they need to take their medicines safely.

Date expired, and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled. There was an adrenaline injection in the consultation room which was accessible to the public. The RP said it had been there when the flu vaccination service was offered the season before last. He removed the injection when the risk of unauthorised access was pointed out.

Recognised licensed wholesalers were used for the supply of medicines and appropriate records were maintained for medicines ordered from 'Specials'. No extemporaneous dispensing was carried out.

The pharmacy was not compliant with the Falsified Medicines Directive (FMD). They did not have the hardware available to allow scanning of medicines to verify or decommission them and the RP did not know what action the SI was taking in regard to this.

Medicines were generally stored in their original containers at an appropriate temperature. The RP said the pre-registration pharmacist had carried date checking out on a monthly basis, but this was not documented, so areas of the dispensary might be missed. No out-of-date medication was seen on the dispensary shelves during the inspection. Short dated stock was highlighted. Dates had been added to opened liquids with limited stability. Expired medicines were segregated, and designated bins were available.

Alerts and recalls were received via e-mail messages from the MHRA and some wholesalers. These were read and acted on by the RP, e.g. a recent e-mail had been sent from Colorama. The RP confirmed he had checked and did not have any of the affected medicines, but no record was made of the action taken, so he was not able to demonstrate whether appropriate action was always taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services, but it could do more to ensure counting and measuring equipment is clean and hygienic.

Inspector's evidence

Current British National Formulary (BNF) and BNF for children were available and the pharmacist could access the internet for the most up-to-date information, e.g. the electronic BNF, drug tariff and ssummaries of product characteristics (SPC)

There was a medical fridge. The minimum and maximum temperatures were being recorded regularly and had been within range throughout the month. Electrical equipment generally appeared to be in working order.

There was a selection of glass liquid measures with British standard and crown marks. One did not appear clean, but the RP said it was clean on the inside. Separate measures were marked and used for methadone solution. Plastic measures were also in use which were not accuracy stamped so there was a risk that these might not be accurate and were difficult to clean. The pharmacy had a triangle for counting loose tablets. It was not very clean, risking contamination. The RP pointed out disposable gloves were available for handling cytotoxic drugs. The RP said methotrexate was obtained in foil strips to reduce handling.

Computer screens were positioned so that they weren’t visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. The RPs individual electronic prescriptions service (EPS) smart cards was in use. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.