General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Hyde Pharmacy, Thornley Street, HYDE, Cheshire, SK14 1JY

Pharmacy reference: 1099027

Type of pharmacy: Community

Date of inspection: 05/07/2019

Pharmacy context

This is a busy community pharmacy next to a medical centre in a residential area on the edge of the town. 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. The pharmacy stays open for 100 hours per week and is open late into the evening.

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 does not have adequate standard operating procedures for the services it provides and members of the pharmacy team do not follow them.
		1.2	Standard not met	The pharmacy does not report and learn from near misses and dispensing incidents.
		1.7	Standard not met	The pharmacy does not adequately separate and destroy confidential waste and does not store confidential information securely.
2. Staff	Standards not all met	2.2	Standard not met	Some members of the pharmacy team are not qualified or appropriately trained for the activities they carry out.
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 delivers medicines without adequate control and safeguards. The pharmacy assembles and checks multi-compartment devices without reliable audit trails and stores them unlabelled for extended periods.
		4.3	Standard not met	The pharmacy can not provide assurance that the temperature of the medical fridge is appropriately monitored. It does not properly restrict unauthorised access to some medicines and it has not taken steps to comply with the Falsified medicines directive (FMD).
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

Members of the pharmacy team do not have a clear understanding of the pharmacy's operating procedures, their roles and responsibilities and who is accountable for what. This means there may be more risk of mistakes happening. They do not make full records of their mistakes, so may be missing out on some learning opportunities. The team generally keep the records required by law, but some details are missing, which could make it harder to understand what has happened if queries arise. Some team members have not completed training on data protection. So they might not fully understand their role in keeping people's information safe. And confidential information is not always stored or disposed of appropriately which risks breaching patient confidentiality.

Inspector's evidence

The Standard Operating Procedures (SOPs) available in the pharmacy which the responsible pharmacist (RP) confirmed were the current SOPs were incomplete, and there was no indication that they had been read by any of the pharmacy team. Most SOPs were dated 2007 or 2009. There was a stamp to indicate that some SOPs had been reviewed in 2011 and 2017, but others did not have a record of any review. Roles and responsibilities of staff were not clearly set out in SOPs. Some SOPs required under the responsible pharmacist regulations were missing, e.g. there was no delivery SOP, and there was no procedure stating the identification of members of the pharmacy team who were competent to perform certain tasks such as giving advice about medicinal products. The pharmacist superintendent (SI) told the inspector, in a phone call during the inspection, that SOPs produced following the previous inspection in 2017, which had been available in an electronic form, had been lost due to a technical problem, but he had explained the procedures verbally to the team. Most of the staff were not wearing uniforms or name badges indicating their role, which meant people might be unclear what their role and level of qualification was. There were two notices on display indicating two different responsible pharmacists (RP), so this might cause confusion in the event of a query or problem and was not in line with RP regulations.

There was a SOP which covered actions to take in the event of a near miss or dispensing error. This was not followed. The number of errors for each member of the pharmacy team was recorded on a tally chart. The RP said the chart was used to record who had made near misses and minor dispensing errors such as wrong strength or quantity. He said this was discussed with the individual concerned but not recorded. The details of near misses and some dispensing errors were not recorded or reviewed, so opportunities to identify and mitigate risks might be missed. The RP said he would not make a record of any error on the patient's medication record (PMR), so there might not be any record that an error had taken place. He said if a serious error occurred then it would be reported to the SI, but he did not know what action he took.

There was no notice on display highlighting the complaints procedure or how to give feedback, but it was outlined in practice leaflet. One of the MCAs said she would refer any complaints to the pharmacist. A customer satisfaction survey was taking place. Results from the April 2017- March 2018 survey was available on the www.NHS.uk. website. An area of strength was service received from the pharmacist and an area identified which required improvement was providing advice on physical exercise. The pharmacy's published response was "We will actively advise our patients about the

benefits of physical exercise and why it is important to lead and maintain a healthy lifestyle".

The certificate of professional indemnity insurance available in the pharmacy had expired. Following the inspection, the SI provided confirmation that public liability and professional indemnity insurance was in place. The RP record was appropriately maintained. Private prescription records were maintained electronically but the prescriber details were incorrect or missing on the sample checked, so did not provide an accurate audit trail. Two private CD prescriptions supplied in April 2019 and May 2019 had not been submitted to the relevant authority at the end of the month, which was not in line with CD requirements. Headers were missing from the tops of many of the pages in the CD register which was not in line with CD requirements and increased the risk of incorrect entries. Two CD balances were checked and found to be correct, but balance checks were irregular.

There was no privacy notice on display. There were no records to show staff had signed confidentiality agreements or received training on information governance (IG). A dispenser described the difference between confidential and general waste and said confidential waste was collected in a designated place and then shredded. However confidential waste was seen in the general waste, which had just been torn into two pieces. This risked breaching patient's confidentiality and was removed when the risk was pointed out. A dispenser told the team to stop hand shredding and use the electric shredder. There were three students carrying out work experience. One student confirmed that the requirement to maintain patient confidentiality had been explained to her when she started. Another student said it had not been explained to him yet, but it was his first morning in the pharmacy.

The RP said he had completed training on safeguarding children and vulnerable adults, but it was a few years ago and he could not remember which course it was. He knew to contact social services if there was a concern. Other members said they would report any concerns to the pharmacist but they had not received any training on safeguarding, so they might not always know what signs to look for. An MCA said she did not know if the pharmacy had a chaperone policy but said she would accompany a patient in a consultation with the pharmacist, if the patient or pharmacist requested it.

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

Summary findings

The pharmacy has enough staff to manage its workload. But training is not well organised, and some members of the team are doing tasks that they aren't trained or qualified to do, which increases the chances of mistakes happening. Whilst the pharmacy team has opportunities to discuss issues informally, these communications are not always recorded, so it may not always act on any issues raised.

Inspector's evidence

There was a regular locum pharmacist (RP), three NVQ2 qualified dispensers (or equivalent), two medicines counter assistants (MCA) and a delivery driver on duty at the time of the inspection. The staff level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other and the patients. Absences were covered by re-arranging the staff rota. Some members of the team were part-time so there was flexibility to cover absences. The RP said he worked three days a week in the pharmacy and there were two other regular locum pharmacists who worked the other days. The SI usually worked one evening each week.

The SI described the duties of two of the medicine counter assistants (MCA) and these included putting medicines away on the dispensary shelves and dispensing. But they had been carrying out these duties for more than three months and were not enrolled onto a dispensing assistant course. This was not in line with GPhC minimum training requirements or GPhC guidance. There was no structured ongoing training other than accredited qualification courses and training was not necessarily recorded. The pharmacy team members did not have regular protected training time but were given some time when requested to complete their courses. There were no formal discussions with team members about their performance and development. A dispenser said issues were discussed informally and she would feel comfortable talking to a pharmacist or another dispenser (the brother of the SI) about any concerns she might have. She said she felt comfortable admitting errors.

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 didn't feel under pressure to achieve targets for services such as Medicine Use Reviews (MUR).

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a professional environment for people to receive healthcare. The pharmacy has a private consultation room that enables it to provide members of the public with the opportunity to have confidential conversations.

Inspector's evidence

The pharmacy premises including the shop front and facia were reasonably clean and in an adequate state of repair. The retail area was free from obstructions, professional in appearance and had a waiting area with some bench seating. The temperature and lighting were adequately controlled. Maintenance problems were reported to the SI who would contact the owners of the building if necessary. There was an intermittent bleeping which members of the pharmacy team said was because a smoke detector needed its battery changing. It was not clear if this had been reported to the SI or not. The lack of action might increase the risk of fire and the bleeping risked distracting members of the team.

Staff facilities were limited to a small kitchen area, and a WC with a wash hand basin and hand wash. There was a separate dispensary sink for medicines preparation with hot and cold running water. A dispenser did not know if there was hand sanitizer available but said she wore disposable gloves when assembling multi-compartment devices to ensure they were hygienically prepared. The consultation room was equipped with a sink, and was uncluttered, clean and professional in appearance. The availability of the room was highlighted by a sign on the door. An MCA explained they would use this room when carrying out the services and when customers needed a private area to talk.

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

Summary findings

The pharmacy offers a range of healthcare services which are easy for people to access but these are not always well managed. The pharmacy does not routinely make records or get signatures when delivering medicines to people's homes, so it may be difficult to deal with any queries or problems that arise. The pharmacy team does not prepare and store multi-compartment devices appropriately and this increases the risk of errors. The pharmacy gets its medicines from reputable sources and generally manages them safely. But the fridge temperature is not properly monitored so the pharmacy cannot show that it stores fridge medicines in appropriate conditions.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. There was an automatic door. Some of the services provided by the pharmacy were advertised in the window of the pharmacy with the opening hours, and services were also listed in the practice leaflet. There was a range of healthcare leaflets and information on bowel cancer screening, prostate cancer support and support for domestic abuse. The pharmacy team were clear what services were offered and where to signpost to a service not offered e.g. needle exchange. An MCA said signposting and providing healthy living advice were not recorded. It was therefore difficult to monitor the effectiveness of the health promotional activities. Part of the pharmacy team were multilingual speaking Bengali, Hindi, and Urdu, which assisted some of the non-English speakers in the community.

The pharmacy offered a repeat prescription ordering service and an MCA confirmed that all patients were contacted before their prescriptions were ordered, to check their requirements. This was to reduce stockpiling and medicine wastage. There was a delivery service but there were not records of what was delivered and signatures were not obtained from the recipient to confirm safe receipt. The delivery driver said that signatures were obtained for CDs, but this could not be verified as records of this were not on the premises. He said a note was left if nobody was available to receive the delivery and the medicine was returned to the pharmacy. There was no delivery SOP.

Space was limited in the dispensary, but the work flow was organised into separate areas with a designated checking area. Dispensed by and checked by boxes were generally initialled on the medication labels to provide an audit trail. Different coloured 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. Laminates were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. The RP said a note was attached to the assembled prescription if he wished to counsel the patient or make any extra checks. He said he would telephone the patient if the medicine was being delivered. He said he checked the dosage for warfarin if the patient brought their yellow book to the pharmacy, but INR levels were not usually requested or recorded when dispensing warfarin prescriptions. The RP was aware of the valproate pregnancy prevention programme. He said an audit had been carried out and no patients in the at-risk group had been identified. He was not able to locate the valproate information pack and care cards but said he would print some information off to ensure female patients were given the appropriate information and counselling.

One of the dispensers who assembled multi-compartment devices said she had not seen a written procedure for the process but said the SI had explained the procedure to her. Around four carrier bags full of assembled multi-compartment devices were located on top of the fridge. The original packaging was not retained from the time of assembly and none of the devices were appropriately labelled with the names of the medication. This breached labelling regulations and might increase the risk of error. The dispenser explained that the devices were assembled from the previous prescription and then labelled from the correct prescription prior to supply, which could be up to a week later. This practice increased the risk of error. There was only a partial dispensing audit trail on the devices which meant 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. And this might limit what could be learned from things that go wrong. The RP said he accuracy checked against the master sheet rather than a prescription which further increased the risk of errors. There was only a partial 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 and packaging leaflets were not included, despite this being a mandatory requirement. And meaning patients and carers might not have easy access to information they need.

An MCA had some idea what questions to ask when making a medicine sale but needed prompting before she remembered to check if the patient was taking any other medicines. She said she always referred the patient to a pharmacist if she was unsure. She was clear which medicines could be sold in the presence and absence of a pharmacist and was clear what action to take if she suspected a customer might be abusing medicines such as a codeine containing product.

CDs were stored in a CD cabinet which was securely fixed to the wall/floor. Date expired CDs were segregated and stored securely. There was a denaturing kit available for the destruction of CDs. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled. 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) and the RP did not know what it was. When it was explained to him he said he did not think the pharmacy had any of the required equipment to allow scanning of medicines to verify or decommission them and did not know what action the SI was taking in regard to this.

There was a large medical fridge. There was a notice on the fridge stating that the fridge temperature was being recorded electronically via a logger and an alert would sound when outside the range. The logger was not recording a temperature during the inspection and none of the pharmacy team were able to access a current reading or historic fridge temperature records. So, it was not possible to verify whether the logger was working, and the fridge was within range, and had been throughout the previous months. This meant the pharmacy team was not able to demonstrate that thermolabile medicines were stored at the appropriate temperature.

Medicines were generally stored in their original containers at an appropriate temperature. Date checking was carried out and documented. Short dated stock was highlighted. Dates had been added to opened liquids with limited stability. Expired medicines were segregated. The RP said alerts and recalls were received via faxes from the NHS clinical commissioning group (CCG). He said these were read and acted on by a member of the pharmacy team but were not retained so they would not easily be able to respond to queries and provide assurance that the appropriate action has been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has adequate equipment to provide its services safely.

Inspector's evidence

Current British National Formulary (BNF) and BNF for children were available and the team could access the internet for the most up-to-date information. The most recent BNF was not available in the consultation room, so there was a risk out-of-date information might be accessed, but the RP said he used an App on his mobile phone to access the electronic BNF.

There was a selection of clean glass liquid measures with British standard and crown marks. 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 less easy to clean. The pharmacy had a small range of equipment for counting loose tablets and capsules, with a separately marked tablet triangle that was used for cytotoxic drugs.

Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected and the RP said these were changed monthly. 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.