General
Pharmaceutical
Council

Registered pharmacy inspection report

Pharmacy Name: Spiral Stone Pharmacy, 122 Brinton Road, SOUTHAMPTON, Hampshire, SO14 0DB

Pharmacy reference: 1031838

Type of pharmacy: Community

Date of inspection: 09/10/2019

Pharmacy context

This is a community pharmacy located in a residential area of Southampton in Hampshire. The pharmacy dispenses NHS and private prescriptions. It sells some over-the-counter (OTC) medicines, provides advice, delivers medicines and offers seasonal flu vaccinations. The pharmacy also supplies multi-compartment compliance aids to people.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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 failed under the relevant principles. Staff are not routinely working in line with the pharmacy's standard operating procedures.
		1.7	Standard not met	The pharmacy is not routinely safeguarding people's confidential information and there is insufficient evidence that governance arrangements are in place for this. There is confidential information constantly left in an unlocked consultation room, the team is storing dispensed prescriptions in a location and way that enables sensitive information to be accessed from the retail area and there are no specific documented details to support the management of confidential information. The pharmacy does not inform people about how their private information is maintained, staff are not trained on recent developments in the law, team members are sharing NHS smart cards to access electronic prescriptions and passwords are known. People's sensitive information can be seen from the way signatures are obtained during the delivery service
		1.8	Standard not met	The pharmacy team members cannot fully demonstrate that they are trained to safeguard the welfare of vulnerable people, they have little understanding about this, there are no local contact details for the safeguarding agencies or local policy information and the pharmacist is not trained to an appropriate level to be delivering clinical services
2. Staff	Standards met	N/A	N/A	N/A
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. There are dirty and untidy areas in the pharmacy

Principle	Principle finding	Exception standard reference	Notable practice	Why
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Pharmacy services are not managed or delivered safely and effectively. The pharmacy is not providing the influenza vaccination service in a safe way as informed consent from people is not being obtained before they are vaccinated, multi-compartment compliance aids are left unsealed overnight, insufficient checks are made to determine whether some medicines are suitable for inclusion and patient information leaflets are not routinely provided when people are supplied with their medicines inside compliance aids
		4.3	Standard not met	The pharmacy has not been storing medicines that require refrigeration at the appropriate temperatures
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy doesn't effectively manage risks associated with its services. It has written instructions to help with this. But members of the pharmacy team are not always working in line with them. Pharmacy team members deal with their mistakes responsibly and seek to learn from them. But, they are not always formally reviewing them. 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. And, the pharmacy's team members don't understand enough about how to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately. The pharmacy is not adequately maintaining all of its records, in accordance with the law. This means that team members may not have all the information they need if problems or queries arise.

Inspector's evidence

Apart from the retail space, all other areas of the pharmacy were extremely cluttered (see Principle 3). The workflow involved counter staff passing walk in prescriptions through a hatch into the dispensary and repeat prescriptions were processed and dispensed in batches. Staff explained that they scanned prescriptions into the pharmacy system, relevant details were checked during assembly before they were passed to the responsible pharmacist (RP) for the final check for accuracy.

Near misses were routinely recorded. Dispensing staff described asking the RP to return their prescriptions to them so that they could find their own mistakes. This helped to facilitate their learning. According to the team, errors happened when medicines were stored in the wrong place and staff had previously been instructed to take more care when putting medicines away. The team's awareness had also been raised about common errors when medicines were similar in name or packaging, such as with different strengths of sertraline. Once highlighted, they were separated, and other stock was placed in between them. Staff also described highlighting prescriptions when different forms of common medicines were seen or with unusual medicines. This helped reduce the likelihood of mistakes taking place. However, there were no details documented to verify the review of near misses.

The RP handled incidents, her process involved apologising, discussing the situation with the person, recording details on the pharmacy system and informing the pharmacy's head office. Staff were informed about the situation. However, the pharmacist stated that if the person had taken anything incorrectly, their GP would not be informed. This was discussed at the time. A previous error involved the incorrect strength of a medicine being supplied, this was rectified, the root cause was identified as due to rushing and staff being distracted. In response, staff were advised to slow down during the dispensing process. There was no information on display about the pharmacy's complaints procedure. This could mean that people may not be able to raise their concerns about the pharmacy's services easily.

A range of documented standard operating procedures (SOPs) were present to support the services provided. The SOPs were last reviewed in 2018 and staff had read and signed them. Team members generally understood their role and responsibilities. They knew when to refer to the RP and which activities were permissible in the absence of the pharmacist. The correct RP notice was on display and this provided details of the pharmacist in charge on the day. However, the team was not always

following the SOPs (see Principle 4).

When team members were asked about safeguarding the welfare of vulnerable people, they mentioned the chaperone policy and stated that they had not been trained on this topic. On prompting, in the event of a concern, they would refer to the RP and stated that they may have read some information about the topic in the past but could not recall any further information. There was an SOP about safeguarding people, but no local contact details present about the safeguarding agencies or local policy information. The RP stated that she was trained to level one in safeguarding vulnerable people through the Centre for Pharmacy Postgraduate Education (CPPE). There was no chaperone policy on display or seen in the pharmacy.

The team shredded confidential waste. Dispensed prescriptions awaiting collection were stored behind and underneath the front counter. However, sensitive information from generated labels on the bags could be seen by people waiting at the front counter, particularly if they leaned over it. Staff stated that they had not been trained on the EU General Data Protection Regulation (GDPR) and there was no information seen about this or about the pharmacy's information governance policy. There was no information on display to inform people about how their privacy was maintained and one person’s NHS smart card to access electronic prescriptions was left within a computer terminal and was being used by the team. This member of staff was not on the premises at the time and their password was known. This limited the ability of the team to control access to people's private information.

The pharmacy’s professional indemnity insurance was through the National Pharmacy Association (NPA) and this was due to be renewed after the 31 March 2020. A sample of registers checked for controlled drugs (CDs) were maintained in line with the Regulations. Balances for CDs were checked, and details seen documented generally every two weeks. On randomly selecting CDs held in the cabinet, their quantities matched the balance recorded in corresponding registers. The documented RP record had last been completed on 12 September 2019 however, the electronic record was maintained in full. Records for supplies made against private prescriptions were largely compliant with statutory requirement except that the date of the supply was missing from some records. Records of unlicensed medicines only included the dispensing label, details to whom the medicine had been supplied and the prescriber’s information were missing from all the records seen.

Principle 2 - Staffing ✔ Standards met

Summary findings

In line with its workload, the pharmacy has enough staff to manage its workload safely. Once team members have completed basic training, the pharmacy provides them with some resources to help keep their knowledge and skills up to date.

Inspector's evidence

The pharmacy's staffing profile consisted of a regular locum pharmacist, a full-time trained dispensing assistant, two part-time medicines counter assistants (MCAs) who had very recently started and two delivery drivers shared with another of the pharmacy's branches. One of the MCAs was present during the inspection and explained that she had worked at the pharmacy for a period before but had only been trained through in-house processes. Before selling OTC medicines, the MCA knew to ask relevant questions such as whether anything had been tried before, about the symptoms, how long the person requesting advice or medicines had been experiencing the symptoms and whether they were taking any other medicines. Every sale or advice was checked with the RP.

Certificates of qualifications obtained for trained members of the team were seen. Staff described completing modules online from CPPE, attending previous training events and undertaking ongoing training every month. They were kept informed about updates through the RP, via email and newsletters every month that were received from their head office. However, the inspector was told that the team had not had any appraisals or performance reviews for several years. Following the inspection, evidence was received that a performance review had last taken place in 2019.

Principle 3 - Premises Standards not all met

Summary findings

In general, the pharmacy's premises are adequate for delivering healthcare services. But, pharmacy team members are not maintaining the premises in a safe manner. They are keeping the consultation room 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 mistakes happening.

Inspector's evidence

The pharmacy premises consisted of a medium sized retail area with a hatch where prescriptions could be handed through to the dispensary. The latter was very small although, since the last inspection, it had been extended to one side to allow a separate area for the RP to accuracy check prescriptions. The dispensary was overstocked, cluttered and untidy. This included the area where the RP conducted the final accuracy check. There were also baskets of prescriptions stored on the floor which were a trip hazard and medicines could become damaged. After highlighting this, the RP placed them into totes or moved them onto shelves. The premises also included a basement that was no longer used by the team. Disused items were stored in there, such as old mannequins and wigs.

The consultation room was signposted and led into the dispensary. The room was large and of a suitable size for its purpose. It was used to provide services, for private conversations and by staff for dispensing. It was kept unlocked and the entrance was left wide open although there was a sign that stated 'staff only' here. However, there were significant amounts of confidential information present and the room was extremely untidy. The latter detracted from the overall professional use of the room. The RP stated that before the room was used, the team cleared the consultation room of the confidential information and placed it onto a table that was situated in the back corner of the room. There was also a sharps bin on the floor, this was moved during the inspection when the risk of a needle stick injury was highlighted. However, one member of the public was observed to stand in the entrance of the consultation room to speak to the pharmacist in private and no attempt at moving any of the prescriptions or confidential information that was within the vicinity was made.

The pharmacy was suitably lit and appropriately ventilated. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity. This helped to prevent the self-selection of these medicines. However, the staff WC needed cleaning, the carpet in the retail space was stained and dirty and the fixtures and fittings in the pharmacy were dated.

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

Summary findings

The pharmacy team is helpful and generally ensures that people with different needs can easily access the pharmacy's services. The pharmacy obtains its medicines from reputable sources. But, it doesn't always provide its services, prepare or store its medicines in a safe and effective way. Temperature sensitive medicines are not stored appropriately and although the pharmacy makes some checks to ensure that medicines are not supplied beyond their expiry date, they are inadequate and its records are unsatisfactory. The pharmacy is not adequately assessing the risks involved when supplying some medicines in compliance aids. And, it cannot show that it tells people about those risks. The pharmacy's procedure for assembling compliance aids is also unsatisfactory and potentially unsafe. In addition, the pharmacist is not giving people enough information to gain their permission before they are vaccinated.

Inspector's evidence

The pharmacy's front entrance was accessed via a ramp and a wide front door. There was also clear, open space inside the premises and this assisted people using wheelchairs to easily access the pharmacy's services. There were two seats available for people to wait for their prescriptions if needed. The pharmacy's correct opening hours were listed on the front door. Staff could speak Urdu, Punjabi, Nepalese and Polish and were observed using these languages to help communicate with the local population. The team described printing labels with a larger sized font for people who were visually impaired, they spoke clearly for people who were partially deaf and checked their understanding.

For the influenza vaccination service, there was relevant equipment present such as a sharps bin and adrenaline in the event of a severe allergic reaction to the vaccine. However, the RP was not following the pharmacy's SOP when administering influenza vaccinations. She explained that once people had filled in the relevant forms in the retail area, they were brought into the consultation room, the RP checked the details but vaccinated people first before providing advice or confirming that people understood the risks and benefits of the service. There was a risk therefore, that the pharmacist had not obtained informed consent from people before vaccinating them. At the point of inspection, the RP had vaccinated around 10 people but had not signed the private or NHS Patient Group Directions (PGD) that authorised her to vaccinate people. They were signed during the inspection and a lengthy discussion was held with the RP about her practice, safety and knowledge of this service.

Staff stated that multi-compartment compliance aids could be supplied to anyone who wanted this. There was no assessment for suitability being made. The pharmacy ordered prescriptions on behalf of people, when they were received, details on prescriptions were cross-referenced against either individual records or a copy of the repeat request to help identify any changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Descriptions of the medicines were provided. Mid-cycle changes involved the compliance aids being retrieved, amended, re-checked and re-supplied.

However, patient information leaflets (PILs) were not routinely supplied. Compliance aids were sometimes left unsealed overnight and several compliance aids were seen left in this manner from the last few days at the point of inspection. Staff were dispensing Epilim, in the compliance aids for four weeks supply at a time. The RP was aware of stability concerns with this medicine and described checking the suitability of this with the NPA. However, there were no details documented to confirm

this and the team had not discussed the situation with the prescriber. Nor was there any evidence that the pharmacy had carried out a risk assessment about the situation.

The pharmacy provided a delivery service and audit trails to verify this service were maintained. CDs and fridge items were identified however one of the drivers was described as taking prescriptions for CDs out on delivery with them. There was a risk that the prescriptions could become lost and diversion of CDs could happen. People's signatures were obtained when they were in receipt of their medicines. However, there was a risk of access to confidential information from the way people's details were laid out on the audit trail. Failed deliveries were brought back to the pharmacy, notes were left to inform people about the attempt made and medicines were not left unattended.

The team used baskets to hold prescriptions and medicines during the dispensing process and this helped prevent any inadvertent transfer. A dispensing audit trail through a facility on generated labels was being used and this identified staff involvement in processes. Dispensed prescriptions awaiting collection were stored in an alphabetical retrieval system. Other than the RP, staff were unaware of the risks associated with valproates. There was educational literature present to provide to people at risk and according to the RP, females in the at-risk group, were identified and counselled appropriately before supplying the medicine. Prescriptions for higher-risk medicines were identified to enable pharmacist intervention, counselling took place and relevant parameters were checked where possible. However, there were no details recorded to verify this. Fridge items and CDs (Schedules 2-3) were largely identified, Schedule 4 CDs were not routinely marked to identify their 28-day prescription expiry and counter staff could not recognise them. Uncollected prescriptions were removed every four months.

Medicines were obtained from licensed wholesalers such as Alliance Healthcare, AAH and Sigma. Unlicensed medicines were obtained through Alliance. The team was aware of the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed, relevant software and equipment was in place and staff were complying with the decommissioning process.

The pharmacy's medicines were generally stored in an organised manner on the dispensary shelves. Staff stated that they had previously date-checked medicines for expiry every three months in the dispensary and every four months in the retail space. However, this had not been taking place for some time and the schedule to demonstrate this was blank. This process was therefore, not being followed in line with the pharmacy's SOP. Short-dated medicines were not routinely being identified although both the RP and dispensing staff were checking the expiry dates of medicines during the dispensing and accuracy checking process. There were no date-expired medicines or mixed batches of medicines seen although the occasional loose blister of medicine was present. In general, CDs were stored under safe custody. Drug alerts were received via email, action was taken as necessary and there was an audit trail to verify the process.

The pharmacy's stock levels were observed to be high in comparison to their volume of dispensing and there were concerns with the pharmacy fridge. This was small, medicines were evenly stored here, however, there were gaps in the temperature records for the previous month. In addition, although the team had previously been monitoring the minimum and maximum temperatures of the fridge, readings of between 10, 14 and 26 degrees Celsius were seen recorded with no details documented about the action taken in response. According to staff, they had emailed their head office about the fridge temperature fluctuations and in the last few months had been sent a new thermometer. Since this however, the temperatures were still reading higher than the required two to eight degrees. This was also failed at the last inspection and presents a risk that medicines are not being stored at the appropriate temperature.

Once accepted, the team stored returned medicines requiring disposal within designated containers. There was a list available for staff to identify and appropriately dispose of hazardous and cytotoxic medicines. The MCA was unsure where to refer people returning sharps for disposal. Returned CDs were brought to the attention of the RP before being segregated in the CD cabinet.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

In general, the pharmacy has the appropriate equipment and facilities it needs to provide its services safely. Its equipment is kept clean.

Inspector's evidence

Current versions of reference sources and relevant equipment were seen. This included clean, crown stamped conical measures for liquid medicines and counting triangles. The team described using the NPA's information services if further information was required. Computer terminals were generally positioned in a way and location that prevented unauthorised access. There were cordless phones which helped conversations to take place in private if required. The dispensary sink used to reconstitute medicines was clean. There was hot and cold running water available. There were issues with the pharmacy fridge as described under Principle 4.

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.