General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: David Stearne Pharmacy, 27 Hillcrest, Halton Brook, RUNCORN, Cheshire, WA7 2DY

Pharmacy reference: 1029696

Type of pharmacy: Community

Date of inspection: 19/08/2020

Pharmacy context

This community pharmacy is situated in a suburban residential area, serving the local population. It mainly prepares NHS prescription medicines and it manages repeat prescriptions for people who need extra help. A large number of people receive their medicines in weekly multi-compartment compliance packs to help make sure they take them safely. The pharmacy also offers a home delivery service. The inspection was undertaken during the COVID-19 pandemic.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
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 met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

Members of the pharmacy team have written instructions to help them work safely and effectively. The team discusses its mistakes so that it can learn from them. Team members know how to protect people's information. And they understand their role in protecting vulnerable people.

Inspector's evidence

The pharmacy had written procedures that covered safe dispensing, the responsible pharmacist (RP) regulations and controlled drugs (CDs). Several of these randomly selected procedures were issued in April 2018, so they were overdue their review scheduled for April 2020, which was delayed due to the COVID-19 pandemic. Records indicated that most pharmacy team members had read these procedures. According to the RP, who was the resident pharmacist and manager, a trainee dispenser who started working at the pharmacy in January 2020 had also read these procedures. The RP said that they would ask the trainee to sign to confirm they had read them.

The RP said that around March 2020 each team member had received a health risk assessment to help reduce the chances of them having to self-isolate. Staff members regularly used hand sanitiser throughout the working day, and they had face masks and gloves. However, they did not always wear them when they were in the dispensary. The RP was signposted to Public Health England's guidance on personal protective equipment (PPE) for healthcare teams and managing staff during the pandemic, and the PSNC's briefing note on the NHS test and trace system. There was no system to report instances of exposure to Covid-19 in the pharmacy to its head office. The RP said that they would discuss this with the head office.

The dispenser initialled dispensing labels, which helped to clarify who was responsible for each prescription medication they supplied. However, the RP did not always initial these labels to confirm he had checked these medicines, which could make it more difficult to investigate and manage mistakes.

The team discussed the mistakes it identified when dispensing medicines. It addressed each of these mistakes separately, and it had started recording them since the February 2020 inspection. However, the staff did not record all of these mistakes, and the team did not keep records of reviews. So, they could miss or delay additional opportunities to learn and mitigate risks in the dispensing process.

The pharmacy had a complaint handling procedure which the staff had read. However, it did not publicly display any information about how people could make a complaint, so they might not know how to do this.

The pharmacy had professional indemnity insurance for the services it provided. The RP prominently displayed their RP notice, so the public could identify them. The RP log had been maintained appropriately since 21 February 2020. The RP, who started working as the resident pharmacists at the pharmacy in May 2018, could not locate the RP log prior to this time, and they had not made daily entries since this date. They had confirmed that no-one entered the premises until they arrived each morning, so the pharmacy always operated in the pharmacist's presence, and they had records confirming the rare occasions when they were not the RP. They subsequently made retrospective RP long entries from May 2018 to 21 Feb 2020.

The team kept a record of patient-returned CDs. The first entry was dated 20 March 2008, and the latest entry was dated 10 February 2020. The pharmacy maintained the records required by law for CD and private prescription medication transactions. The RP said that they had been making records of medicines manufactured under a specials licence that the pharmacy had obtained and supplied, but they could not provide them because the pharmacy's head office had removed them.

The register for a sealed 500ml bottle of methadone sugar free 1mg/ml liquid stock could not be located. The RP recalled this stock, which they had not used, was in the CD cabinet when he started working at the pharmacy. As new register was set up to reflect the amount held in stock.

The written procedure for CD stock checks stated that each running balance should include any expired CDs, but it did not clarify if they should be identified as expired in the balance to make it easier to account for them. The RP confirmed that they would usually identify and record any expired CDs in the balance. Several randomly selected running balances were all found to be accurate. The appendix to the procedure stated that team members should check the balances each month. The RP said that they checked running balances at the time of each transaction, which was supported by corresponding records. So, most of the frequently dispensed CDs had their balances checked more than once each month. For example, the running balance in the Zomorph 10mg capsules CD register was accurate, and records indicated that staff members had frequently checked this running balance at the time of each transaction in recent months. Records showed that the RP had also checked and confirmed this balance on 8 June 2020 and 13 August 2020.

The CD stock check procedure stated that the team should investigate any balance discrepancies, and it must report any concerns to the superintendent and/or the controlled drugs accountable officer (CDAO) if appropriate.

The written procedure for reporting CD concerns stated that the team must make a record of the concern, follow the guidance from NHS improvement, and seek advice from the superintendent and CDAO if needed. The RP confirmed that they had not discovered any discrepancies since the last inspection on 21 February 2020, and that they would report any unresolved discrepancy or concern to the CDAO and the pharmacy's head office.

The pharmacy publicly displayed information about its privacy notice. Staff had a basic understanding of protecting people's information. They destroyed confidential material and used passwords to protect access to people's electronic data and had their own security cards to access people's electronic NHS information. The pharmacy had policies on GDPR and data security but the staff had not read these, and the pharmacy had not completed the equivalent of a data protection audit. Some confidential papers were left unsecured in the unlocked consultation room, so the public could potentially access it, but the RP said they would address this.

The RP had level two safeguarding accreditation, and staff had read the pharmacy's procedures on safeguarding. The pharmacy had the local safeguarding board's contact details and could access their policies. The team kept compliance pack people's carer or next of kin details. It assumed that it was safe to issue these people twenty-eight days' medication per supply without confirming this with the GP, even though some people might benefit from weekly supplies.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy usually has enough staff to provide services safely and the team members work well together. But, the pharmacy sometimes delays training for new team members when they commence their role. And qualified team members do not have a performance review or access to a structured ongoing training programme to help make sure their skills and knowledge are up to date.

Inspector's evidence

The staff present included the RP and a dispenser. The other staff members who were not present included two trainee dispensers. The pharmacy also shared two delivery drivers with the pharmacy owner's other local pharmacies.

The pharmacy had enough staff to manage its workload. Despite periods of increased workload caused by COVID-19, it usually had repeat prescription medicines, including those dispensed in compliance packs, ready in good time for when people needed them. The pharmacy received most of its prescriptions via the electronic prescription service and it could order prescriptions on behalf of people receiving compliance packs and other vulnerable people, which helped to increase service efficiency. The pharmacy had minimal footfall, which meant the team avoided sustained periods of increased workload pressure and it could promptly serve people. Staff worked well both independently and collectively. They used their initiative to get on with their assigned roles and did not need constant management or supervision. The dispenser efficiently provided the compliance pack service. The pharmacy did not have any targets for the volume of services it provided.

The pharmacy had an effective strategy for covering planned and unplanned leave. It only allowed one of its staff members to be on annual leave at any time. Staff members increased their working hours if one of their full-time colleagues was on leave and said they could comfortably manage maintaining services when a part-time team member was away.

The RP said that both trainee dispensers, one of who had been employed at that the pharmacy since June 2019, had not been enrolled on a dispenser qualification course. They had raised this matter with the pharmacy's head office and the managing director several times since February 2020, who agreed to follow this up. The RP later confirmed that both trainee dispensers had been enrolled on an appropriate course on 25 August 2020. There was no appraisal process or structured ongoing training programme for qualified staff.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean, secure and spacious enough for the pharmacy's services. It has a private consultation room, so members of the public can have confidential conversations and maintain their privacy.

Inspector's evidence

The pharmacy was situated in a retail unit. The retail and dispensary fittings were suitably maintained. It was spacious, bright and professional in appearance. Staff could secure the premises to prevent unauthorised access.

The retail area and counter design could accommodate the typical number of people who presented at any one time. A minimal number of people visited the pharmacy, so maintaining social distancing in the public area since the pandemic was not too difficult. A publicly displayed sign stated that a maximum of one person was allowed in the retail area at any time, and a barrier kept people and staff at a safe distance from each other.

The large open plan dispensary and rear compliance pack dispensing area provided enough space for the volume and nature of the pharmacy's services. This meant these areas were well organised; staff could dispense medicines safely and they could usually keep a safe distance from each other. Systems were in place to carry out the different stages of the dispensing process in separate areas.

The consultation room was accessible from the retail area, and it could accommodate two people. But its availability was not prominently advertised in the front window, so people may not be aware of this facility.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are suitably effective, which helps make sure people receive safe services. It gets its medicines from licensed suppliers and it generally manages them effectively to make sure they are in good condition and suitable to supply.

Inspector's evidence

The pharmacy was open from 9am to 5.30pm Monday to Friday. It had a step-free public entrance and staff members could see anyone who needed assistance entering the premises.

The pharmacy had a written procedure for dispensing higher-risk medicines that covered anticoagulants, lithium and methotrexate. The RP had checked all the people regularly taking valproate and confirmed the pharmacy did not have anyone in the at-risk group. The pharmacy had MHRA approved valproate advice booklets and cards issued in January 2016, but it did not have the latest versions issued in November 2019. So, people might not have access to the most up-to-date information. The team regularly checked if people on anti-coagulants and methotrexate had a recent blood test, understood their dose, and it reminded them about the side-effects to recognise. The pharmacy did not have anyone taking lithium.

The team kept a record of people's current compliance pack medication that also stated the time of day they were to take them, which helped it effectively query differences between the record and prescriptions and reduced the risk of it overlooking medication changes. The pharmacy also kept a record of verbal communications about medication queries or changes for people using compliance packs most of the time. Other notes were usually an annotation of the current medication record, so they were not in a structured format, which could be confusing and meant staff might not always record all the important information needed in the event of a query. The team labelled each compliance pack with the medication they contained, which included enough detail in each description to help people identify individual medicines. The team kept records for compliance pack people's scheduled delivery day to help make sure they received their medication in good time.

The team prompted people to confirm the repeat medications they required, which helped it limit medication wastage and made sure people received their medication on time. It had a record of the latest request for each of these people, which helped the staff to resolve any queries if needed. The team used baskets during the dispensing process to separate people's medicines and help organise its workload.

The pharmacy obtained its medicines from a range of licensed pharmaceutical wholesalers and stored them in an organised manner. But the team only left a protruding flap on part-used medication stock cartons, which could lead to quantity errors. Staff members had completed training on the Falsified Medicines Directive (FMD). However, the pharmacy did not yet have a system for complying with the FMD, and the team had not been told when this might happen.

Staff said that they had regularly checked stock expiry dates throughout 2019, but they did not have any records that supported this. Records indicated that medicines stock had been regularly expiry date checked in the recent months up to March 2020. The RP said that the team now had the time to resume its date checking routine and they recalled that staff members had recently completed a full

expiry date check of all the stock, but they had not recorded it. The team disposed of obsolete medicines in waste bins kept away from medicines stock, which reduced the risk of these becoming mixed with stock or supplying medicines that might be unsuitable. The RP took appropriate action when they received alerts for medicines suspected of not being fit for purpose, but they did not keep any records that confirmed this, so they could not clearly demonstrate these were always managed effectively.

The team was not properly taking medication refrigerator thermometer readings, so it was unclear if both refrigeration facilities were constantly operating within safe temperature limits. Readings taken during the inspection indicated that both refrigerators were working within the correct temperature range. The RP subsequently discussed this with the staff and later confirmed that the team was now recording accurate readings each working day.

The pharmacy suitably secured and organised its CDs. It had a written procedure for disposing of patient-returned CDs. It stated to store them in the CD cabinet and to record the details of their disposal in the CD patient-returned destruction register. The RP said that they segregated any patient-returned and expired CDs. The team had destroyed its date-expired and patient-returned CDs, and it had kits to denature them.

The RP said that they would contact CDAO team to arrange destroying any date-expired CDs. They provided written confirmation from the CDAO team that authorised the RP to destroy these CDs within twenty-eight days. The RP recalled that a staff member had witnessed these destructions and they had made appropriate records. However, the staff member had not signed these records, but the RP agreed to address this.

The RP checked the supply deadline date for CDs at the time they handed them out, so the pharmacy had a basic system to make sure it only supplied CDs when it had a valid prescription. The team used an alphabetical system to store people's dispensed medication, which supported efficiently retrieving people's medicines when needed.

Most methadone patients had been transferred to two-week instalment supplies. Patients were observed taking their methadone in the consultation room from a safe distance. The RP had checked if people had received an NHS letter advising them to shield. Specific delivery arrangements were discussed with patients who were shielding or had tested positive.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services effectively, which it properly maintains. And it has the facilities to secure people's information.

Inspector's evidence

The team kept the dispensary sink clean, it had access to hot and cold running water and an antibacterial hand sanitiser. The team had a range of clean measures, so it had the equipment and facilities to make sure it did not contaminate the medicines it handled, and it could accurately measure and give people their prescribed volume of medicine. The RP had access to the latest version of the BNF and a recent cBNF, which meant they could refer to pharmaceutical reference information if needed.

Staff had access to PPE including face masks. The team disinfected the floor, work surfaces, telephones, light switches and door handles each day. Only one of the two computer terminals were regularly sanitised, but the RP said they would make sure this was done in future.

The pharmacy team had facilities that protected peoples' confidentiality. It viewed their electronic information on screens not visible from public areas and it regularly backed up people's data on its patient medication record (PMR) system. So, it secured people's electronic information and could retrieve their data if the PMR system failed. And it had facilities to store people's medicines and their prescriptions away from public view.

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.