

Registered pharmacy inspection report

Pharmacy Name: Jhoots Pharmacy, Westbury Hill Medical Centre,
Westbury Hill, Westbury-On-Trym, BRISTOL, Avon, BS9 3AA

Pharmacy reference: 1093204

Type of pharmacy: Community

Date of inspection: 26/07/2019

Pharmacy context

This is a community pharmacy located inside a medical centre in a suburb of Bristol. The pharmacy dispenses NHS and private prescriptions. It provides some services such as Medicines Use Reviews (MURs) and the New Medicines Service (NMS). And, it supplies multi-compartment compliance aids to people if they find it difficult to manage their medicines.

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. Some of the staff have not read the pharmacy's standard operating procedures (SOPs) and are not appropriately trained on procedures. Team members are supplying some medicines within compliance aids without the relevant checks being made to determine suitability for this. People prescribed higher-risk medicines are not routinely identified, no checks are made about relevant parameters and no details are recorded
		1.2	Standard not met	There is not enough assurance that the pharmacy has a robust process in place to manage and learn from dispensing incidents. Staff are not routinely recording near misses or dispensing incidents, full details are not documented and there is limited evidence of remedial activity, review or learning occurring in response. The regular pharmacist is not routinely informing the superintendent pharmacist (SI) about incidents. This means that the SI is not always involved or able to identify and manage risks associated with the pharmacy's services
		1.6	Standard not met	The pharmacy is not maintaining all of its records in accordance with the law. Staff have not maintained appropriate records for private prescriptions since October 2018
		1.7	Standard not met	The pharmacy is not routinely safeguarding people's confidential information. Confidential information is left accessible from the unlocked consultation room, staff are not preventing unauthorised access into the dispensary, the pharmacy does not inform people about how their private information is maintained, staff are not trained on recent developments in the law and people's sensitive information can be seen from the way signatures are obtained

Principle	Principle finding	Exception standard reference	Notable practice	Why
				during the delivery service
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy has broken fixtures and fittings that have not been appropriately maintained. One of the cabinets in the retail space has a broken glass panel, this means that half the cabinet is left open and people can help themselves to Pharmacy medicines
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Team members are storing some medicines inappropriately, there are loose blisters, poorly labelled containers or some without any labels to indicate the contents and there is no up-to-date schedule in place to verify that medicines have been regularly date-checked for expiry
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 effectively manage risks associated with its services. It has written instructions to help with this. But not all members of the pharmacy team have read them, or they are unable to show that this has happened. This could mean that they are unclear on the pharmacy's current processes. Pharmacy team members are not always recording or formally reviewing their mistakes. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. Team members know to protect people's private information, but they have not been trained on recent updates in the law. And, not all the pharmacy's team members understand how to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately. The pharmacy is not 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

The dispensary was spacious with ample space for dispensing and it was kept clear of clutter. However, there were several concerns seen at the inspection. The pharmacy held a range of electronic standard operating procedures (SOPs) to support its services. On checking the system, the team could easily access the SOPs, and they were from March 2019 or from 2018. Not all of the pharmacy team had read the SOPs and although some said that they had, there was no evidence that this had occurred as the staff declaration/sign-off sheet was not complete.

Staff knew when to refer to the responsible pharmacist (RP). However, one trainee dispensing assistant who had worked at the pharmacy for the past three months did not know which activities were permissible in the absence of the RP. The inspector was told that they would carry on working and dispensing prescriptions in the absence of the RP and if a pharmacist failed to arrive first thing, they could sell medicines over the counter and hand out assembled medicines because they had been checked beforehand by the RP.

The pharmacist's RP notice was on display and this provided details about the pharmacist in charge of operational activities on the day. However, the notice provided a different surname to the pharmacist's actual name that was registered with the General Pharmaceutical Council (GPhC) and this could be misleading to the public. The pharmacist was asked at the outset whether the details on the notice were hers, which was confirmed by her at the time.

Trainee staff explained that they first checked for stock when dispensing prescriptions and the RP was asked if they were unsure. They dispensed one prescription at a time and took their time to help prevent errors. The workflow involved separate areas for the RP to carry out the final check and for staff to dispense prescriptions.

There was no evidence at the inspection that staff were routinely recording their near misses. Only one member of staff confirmed that she was writing her mistakes into the log. There were very few near misses being recorded in line with the volume of dispensing. There was also no evidence available that errors were being reviewed and no details about the action taken in response to these. Other than one member of staff describing moving amlodipine away from amitriptyline, staff were unable to provide examples of trends, patterns or remedial activity taken in response to near misses to help prevent mistakes occurring. They stated that their area or cluster manager reviewed near misses and did not

share this information.

There was no information on display about the pharmacy's complaints procedure. Pharmacists handled incidents. The RP's process was described as using the consultation room, speaking to the person involved, checking relevant details and recording details on the pharmacy's system. However, there were no records about a recent complaint that was made to the GPhC (and retracted) that the inspector discussed with the same RP and only four details about incidents seen recorded since the company had taken over ownership. There were very few details and little meaningful information recorded within the records, for example, most of them recorded the learning points as 'double-check only or 'always double-check and pay more attention'. The root cause for some were not taken into consideration and acted upon. This included for example where the RP had recorded 'less staff', there was no information about the action taken in response or if the error was marked as due to 'similar drug name', details were then recorded as 'to double-check' as the learning point from this. The inspector was also told by the RP that she did not always inform the superintendent pharmacist if dispensing incidents occurred.

One member of staff was trained to identify signs of concern to safeguard vulnerable people, the other was not. The former was through reading safeguarding information from their previous employer. The pharmacy's chaperone policy was on display but on the inside of the consultation room, this meant that people may not have been able to read this information before entering the room. There were no local contact details for the safeguarding agencies seen or local policy information.

Sensitive details on bagged prescriptions awaiting collection could not be seen from the retail space, confidential waste was segregated and disposed of through the company. There was no information on display to inform people about how their privacy was maintained. The inspector was told that staff had not received any training on the EU General Data Protection Regulation (GDPR). There were further concerns about the team's ability to protect people's private information (see Principle 3).

Records for the minimum and maximum temperatures of the pharmacy fridge were maintained and checked daily. A complete record of the destruction of CDs that had been returned by the public to destroy was maintained and records of unlicensed medicines were maintained in accordance with statutory requirements. The pharmacy's professional indemnity insurance was through Numark and due to expire after 7 January 2020.

There were also issues with the pharmacy's other records. There were gaps in the electronic RP record where pharmacists had not routinely signed out to indicate when their responsibility ceased. Some records of emergency supplies made electronically detailed the nature of the emergency, however, some were seen only recorded as 'run' or 'request' and did not justify why a prescription-only medicine had been supplied in this instance. There were missing prescriber details within the electronic private prescription register, staff explained that they were using a bound register, however on checking this, the last entries were from October 2018 and there was a large pile of private prescriptions where no details had been entered into the register.

A sample of registers for Controlled Drugs (CD) were checked and found to be largely compliant with the Regulations. According to the RP, balances for CDs were checked every month. Inspection of the records confirmed this.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has an adequate number of staff to manage its workload. Team members are enrolled onto appropriate training in line with their roles. And, they are provided with some resources to help them with their training needs. But, not all of the team members understand their roles and responsibilities or know what to do in some situations. This could affect the level of care and advice they give.

Inspector's evidence

The pharmacy dispensed 5,000 to 6,500 prescription items every month with around 50 people supplied their medicines inside multi-compartment compliance aids. In addition to the Essential service, the pharmacy was currently only providing MURs and the NMS. The RP described a target to complete 200 MURs, this was manageable and had already been completed.

At the inspection, there were only three members of staff present. This included the RP and two trainee dispensing assistants, one of whom worked 25-30 hours per week and the other was full-time. Both were enrolled onto accredited training with Buttercups, the paperwork that the RP had filled out was seen to corroborate this. There was also a full-time medicines counter assistant (MCA) who was on annual leave. Staff described another full-time dispensing assistant and the delivery driver recently leaving employment. The team was up to date with the workload in general and explained that they were managing with the limited numbers of staff present.

One of the trainee dispensing assistants was not very fluent in English, the RP and the other member of staff explained that they intervened and helped her out where possible. However, as described under Principle 1, this member of staff lacked necessary knowledge about lawful activities when the RP was not present but knew to ask relevant questions before selling medicines over the counter (OTC). She referred to the RP when unsure or when required and demonstrated some knowledge of OTC medicines. To assist with training needs, staff described using resources from Numark, team meetings were held every week and the area manager had reviewed their progress once since the company took over ownership of the business.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy premises are clean, secure and provide a professional environment to deliver services. But, the pharmacy's display cabinet for its 'pharmacy only' medicines does not stop people from helping themselves to them. And, team members are not always protecting people's privacy and confidentiality. People can see confidential information in the consultation room and are being allowed free access into the dispensary.

Inspector's evidence

The premises consisted of a small sized retail space and spacious dispensary with staff kitchenette areas at the rear. In the retail space, there was also a signposted consultation room to one side of the medicines counter. The room was used to provide services and confidential information, however it was unlocked and there was confidential information accessible in here.

The retail space was professional in appearance, fixtures and fittings appeared modern, the pharmacy was clean, bright and suitably ventilated. There was enough space in the dispensary for the pharmacy's current volume of workload.

However, Pharmacy (P) medicines were stored within unlocked glass cabinets in the retail space, one cabinet was broken with one half of the panel missing, this meant that P medicines were readily accessible to anybody. Other cabinets were left open after staff assisted customers. Some of the cabinets were marked to ask for assistance, the rest had no information on them. The RP stated that the broken panel had been raised with the company by the team, but no action had been taken because the pharmacy was due to be re-fitted. There was no barrier in place to prevent people from entering the dispensary. One member of the public came behind the front medicines counter and stood in the dispensary whilst she discussed her prescription with the RP. Team members did not ask this person to step back. There was confidential information in the vicinity.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy sources its medicines from reputable suppliers. But, it does not always store them appropriately. Some of its medicines are held in poorly labelled containers. And, the pharmacy is storing medicines returned by people for destruction in unsealed containers inside the staff toilet. This could increase the risk of theft occurring. In general, the pharmacy provides most of its services appropriately. But, members of the pharmacy team don't always highlight prescriptions that require extra advice or record information when people receive some medicines. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. The pharmacy team sometimes fills compliance aids with medicines that may not be suitable to be packed in this way. And, people can see other people's private information when they sign to receive their medicines during the delivery service.

Inspector's evidence

The pharmacy had changed its opening hours with NHS England recently and was now open from Monday to Friday. People could enter the Medical Centre at street level, the pharmacy was on the ground floor to the left-hand side of the entrance and the clear, open space inside the retail area helped people using wheelchairs to easily access the pharmacy's services. There were some car parking spaces available outside the premises. Staff described using the consultation room for people who were partially deaf, they would physically assist people who were visually impaired, and some members of the team spoke Romanian, Spanish and Italian to help communicate with people if their first language was not English.

The person's GP assessed suitability for initiating compliance aids. Staff ordered prescriptions on behalf of people receiving them and when they were received, staff checked details against records on the system and on individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Descriptions of medicines within the compliance aids were provided. Patient Information Leaflets (PILs) were routinely supplied. All medicines included in the compliance aids were de-blistered and removed from their outer packaging. They were not left unsealed overnight once they were dispensed. Mid-cycle changes involved them being retrieved, amended, re-checked and re-supplied.

However, sodium valproate tablets were provided inside the compliance aids, this was dispensed four weeks at a time. There were no checks made about the suitability of this and no details were documented. This included information about whether this was necessary, the team was unaware about stability concerns and suitability for its inclusion inside the compliance aids and there had been no relevant checks made. The RP was advised to re-assess the pharmacy's processes here, consult reference sources, check with the person or representative(s) and the person's prescriber.

Medicines were delivered. The agency delivery driver was briefly seen. There were records maintained to demonstrate when and where medicines were delivered. The driver obtained signatures from people when they were in receipt of their medicines. However, there was a risk of access to confidential information when people signed from the way sensitive details on the audit trail were laid out. Failed deliveries were brought back to the pharmacy and notes were left to inform people of the attempt made to deliver.

The team used a dispensing audit trail through a facility on generated labels. This identified their involvement in processes. Staff used baskets to hold prescriptions and associated medicines and this helped prevent any inadvertent transfer. Baskets were colour co-ordinated to help highlight priority.

Some staff were aware of risks associated with valproate. The team had completed an audit to identify females at risk, staff explained that three people were identified as supplied this medicine and were counselled accordingly. There was no literature available to offer people if required. Prescriptions for higher-risk medicines were not marked in any way to counsel or to ask people about relevant parameters. This included asking about the International Normalised Ratio (INR) level, for people prescribed warfarin. Some people's records were checked and there were no details seen documented about this. This included people receiving compliance aids.

Dispensed prescriptions awaiting collection were held in an alphabetical retrieval system. Fridge items and CDs (Schedules 2-4) were identified using stickers. Uncollected prescriptions were removed every month. The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Lexon, Phoenix, AAH and Alliance Healthcare. Unlicensed medicines were obtained from Lexon. Staff were unaware of the process involved for the European Falsified Medicines Directive (FMD). It was unclear whether the pharmacy was registered with SecurMed. There was no guidance information present for the team and at the point of inspection, the pharmacy was not yet complying with the process.

Some medicines were stored in a haphazard manner in the dispensary, this included medicines on shelves but there were also loose blisters seen on dispensary shelves, poorly labelled containers with either no information about the medicine, and the expiry date as well as the batch numbers were missing. This included Concerta XL tablets where the RP had supplied the original container to a person against a prescription and failed to record the relevant details on the bottle used to store the remaining tablets. Liquid medicines with short stability such as Oramorph were seen stored outside of their original container with only the name of the medicine and the date it was opened.

Short-dated medicines were identified using stickers and some members of the team described date-checking when they put stock away from wholesalers and every three months. However, there was no up-to-date schedule in place to demonstrate this. The last details seen recorded in the schedule that was on display was from 2018. Staff stated that this had been sent to their head office, but no copy was kept at the pharmacy or seen to verify this. There were no date-expired medicines present. CDs were stored under safe custody. Keys to the cabinet were maintained in a manner that prevented unauthorised access during the day and overnight. Drug alerts were received by email, the team checked stock and acted as necessary. An audit trail was available to verify the process.

Medicines returned by people for disposal were stored in the staff WC inside bags that could easily be tampered with. There were no appropriate receptacles for hazardous or cytotoxic medicines and no list available for staff to identify these medicines. This means that they may not always be disposing of some medicines that could be harmful to the environment appropriately. People bringing back sharps for disposal, were referred to the GP surgery. Returned CDs were brought to the attention of the RP.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely.

Inspector's evidence

The pharmacy was equipped with current versions of reference sources and relevant equipment. This included a range of clean, crown-stamped conical measures available for liquid medicines, a tablet cutter, counting triangles, a separate one for cytotoxic medicines, the CD cabinet which was secured in line with legal requirements, an appropriately operating fridge and a clean sink that was used to reconstitute medicines. Hot and cold running water was available.

There were lockers available for staff to store their personal belongings. Computer terminals were positioned in a manner that prevented unauthorised access, a shredder was present to dispose of confidential waste and cordless phones were available to enable sensitive conversations to occur away from the retail space if needed.

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.