General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Jhoots Pharmacy, Brierley Hill Health & Social Care Ctre, Off Little Cottage Street, BRIERLEY HILL, West Midlands, DY5 1RG

Pharmacy reference: 1102644

Type of pharmacy: Community

Date of inspection: 29/09/2020

Pharmacy context

This is a community pharmacy within a busy health and social care centre in Brierley Hill, West Midlands. The pharmacy is open extended hours over seven days. It dispenses NHS prescriptions and people using the pharmacy are from the local area. The pharmacy also acts as a 'hub' and dispenses medicines in multi-compartment compliance packs for collection from other Jhoots pharmacies. And it provides some other NHS funded services such as seasonal 'flu vaccinations and a minor ailment scheme. The inspection was completed during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 risks associated with the hub and spoke compliance pack service are not adequately identified and managed. The SOPs do not cover all aspects of the compliance pack service and the team does not follow the ones that are available.
		1.2	Standard not met	The pharmacy does not undertake audits or regularly review the risks associated with the compliance pack service. The pharmacy does not thoroughly investigate errors or have a clear procedure to ensure that the hub is made aware of any errors that are identified at the spoke pharmacy. And the pharmacy team does not record its near misses or effectively use these as learning opportunities.
		1.3	Standard not met	It is not clear which pharmacist is accountable and responsible for each part of the hub and spoke compliance pack service. So, it is difficult to verify who is responsible for managing the patient's care and it may be difficult to know who was involved if things go wrong.
		1.7	Standard not met	Confidential waste is not disposed of securely. Procedures for obtaining people's consent for the compliance pack are unclear. And people may not always know which pharmacy dispenses their prescriptions or which legal entity holds their personal information.
		1.8	Standard not met	Vulnerable people are not adequately safeguarded. The lack of accountability surrounding the hub and spoke compliance pack service means that opportunities to safeguard vulnerable people and identify issues may be missed.
2. Staff	Standards not all met	2.2	Standard not met	Pharmacy staff are not always enrolled on accredited training courses within 12-weeks of starting in their role in keeping with GPhC requirements. Staff members are not supported to complete their accredited training within the time scales suggested by

Principle	Principle finding	Exception standard reference	Notable practice	Why
				the course provider. Staff do not always receive basic induction training when they start working at the pharmacy, such as reading the SOPs.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	There are various patient safety issues with the compliance pack service. The current process for dispensing different parts of the prescription in different pharmacies does not always meet legal requirements. People do not necessarily receive the information and advice they need to take their medicines safely. And the pharmacy does not provide people receiving compliance packs with medicine leaflets. Some of the dispensing processes are unhygienic and risk cross-contamination.
		4.3	Standard not met	Controlled drugs (CDs) are not always stored in accordance with the safe custody requirements. Methadone instalment containers are sometimes re-used; this practice is unhygienic and increases the risk of cross contamination. CDs are not always effectively managed or disposed of correctly. CD discrepancies are not investigated promptly, and a recent witnessed destruction of expired CDs was not carried out in accordance with the CDAO's instructions.
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 identify and manage the risks associated with its services, particularly in relation to the compliance pack service. The pharmacy's written procedures do not cover some parts of the service delivery, and the pharmacy team members do not receive appropriate training on the procedures or follow them in practice. And the team does not effectively learn from its mistakes. This increases the likelihood of things going wrong. The pharmacy does not always make it clear who is accountable for what. This means safeguarding issues might be missed as most people receiving compliance packs are vulnerable. Procedures for obtaining people's consent for the compliance service are unclear. And the pharmacy team does not always dispose of confidential information properly.

Inspector's evidence

The pharmacy was part of Jhoots group which included Jhoots Pharmacy ltd, Jhoots Chemist Ltd, Jhoots Healthcare Ltd, Pasab Ltd, and Billingham Health Ltd. The Responsible Pharmacist (RP) during the inspection was the company's Business Development Director and he had worked regularly at the pharmacy since the start of the year. The superintendent (SI) pharmacist did not work at the pharmacy regularly.

A range of standard operating procedures (SOPs) were available which covered some of the operational activities of the pharmacy and the services provided. The SOPs were stored on the company intranet. But pharmacy support staff did not know how to access the intranet and they did not know what SOPs were used for. They confirmed that they had not read them, and that their training had been mainly on-the-job.

The written procedures available for the hub and spoke supply model did not address the concerns that had been identified at previous inspections and these concerns were still ongoing. There were no additional SOPs or procedures available that explained the hub and spoke model. Processes such as the prescription ordering process, procedure for managing missing items or dose changes, business continuity plan, patient counselling, error reporting, complaints, and individual accountabilities were not formalised or documented. Prescriptions for fridge items and controlled drugs were labelled at the pharmacy and a copy of the prescription and dispensing labels were provided to the 'spoke' pharmacy to be dispensed there. This was not covered by the SOPs and raised questions about the legality of this, as some of the spoke pharmacies belonged to separate legal entities, This meant the incorrect pharmacy details would have been included on the medicine label, and the prescription would be processed for payment at the pharmacy but dispensed elsewhere.

It was unclear who had overall accountability for the care of the patient as there were different teams, pharmacists and superintendents involved in the process. This means people might be confused about who provided the service and it may not be clear who was responsible if things go wrong. In addition, people might not be aware that their personal information was being shared with different legal entities. And safeguarding issues might be overlooked.

The process described by the pharmacy support staff for near miss recording was different to the process explained by the RP, and neither of these reflected the process outlined in the SOP. The RP said that the pharmacy team were supposed to record any near misses using a function on the patient

medication record (PMR) so that any patterns and trends could be analysed. Three near misses had been recorded in the past 12-months which was very low considering the number of items dispensed and the number of trainees within the pharmacy, suggesting that near misses were not being recorded. A dispenser said that if a picking error was identified during the assembly process it would be corrected and checked by another person before assembly started. This meant that the person who made the picking error would not be made aware of their mistake and be able to use it as a learning opportunity. The team member also confirmed that they did not know that they were supposed to record near misses.

Dispensing incidents were recorded using a function on the PMR and an example was discussed. The error had been discussed with the pharmacy team during a team briefing. But the information recorded was vague and did not include details such as the pharmacist involved in the error or any practical next steps or actions to prevent reoccurrence. The RP explained that errors about multi-compartment compliance packs that the 'spoke' pharmacy had been informed about were submitted to the pharmacy by email for investigation. But the process for dealing with errors and complaints identified at the spoke pharmacies was not formalised or documented.

The complaints, comments and feedback process was explained in the SOPs. People could give feedback to the pharmacy team in several different ways; verbal, written and the annual NHS CPPQ survey. The pharmacy team tried to resolve issues as they occurred and would refer to a company director or the superintendent if they could not resolve the complaint themselves.

The pharmacy had up-to-date professional indemnity insurance arrangements in place. The RP notice was clearly displayed. At the start of the inspection, it did not display the correct pharmacist's details, but this was promptly rectified. The RP log was recorded electronically and complied with requirements.

Controlled drugs (CD) registers were generally in order and recorded a running balance. A sample of registers reviewed indicated that balance checks were completed regularly, but other issues were identified. A patient returns CD register was also in use and previous destructions had been signed and witnessed.

The pharmacy had some information governance (IG) procedures available amongst the SOPs and through discussion team members demonstrated an understanding of confidentiality. A dispenser discussed several ways in which she would make sure people's private information was kept safe. And team members held their own NHS smartcards. Confidential waste was segregated and shredded on the premises. On the day, a dispensing label containing patient identifiable data was identified in a general waste bin. The RP confirmed that this was an error and the label was removed and placed for suitable disposal. Confidential waste was also found in the DOOP bins in the staff bathroom, so it was not disposed of correctly.

The SOPs had been amended so that verbal consent would be obtained when transferring a patient from the spoke pharmacy to the hub pharmacy. The PMR system was in the process of being updated so that people would be sent an email to tell them where their medicine had been dispensed to make it clearer. There was an error within the new MDS transfer SOP, and it referred to obtaining written consent on page one and verbal consent on page two. This could make it difficult for the pharmacy teams to follow.

Pharmacy team members provided a suitable response to a hypothetical safeguarding scenario. But they had not completed any safeguarding training and were hesitant when discussing some of the other types of concerns that might be identified. This may make it more difficult for team members to

effectively identify potential safeguarding concerns amongst vulnerable people. Team members said that they would discuss any potential concerns with the RP.

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

Summary findings

The pharmacy has enough staff to provide its services. But pharmacy team members do not complete the training they need to do their jobs. They are not always enrolled on an accredited training course within the required timescales and they do not have protected time to complete ongoing training. So, they might find it harder to develop the skills necessary for their role and keep their knowledge up to date.

Inspector's evidence

The pharmacy team comprised of two regular pharmacists (one of them was the RP and the company director), additional weekend pharmacists, two dispensing assistants, four trainee dispensing assistants and four apprentices. Most of the pharmacy team, including the pharmacists, had joined the pharmacy since the last inspection in January 2020; some were newly recruited to the company, and some had transferred from other Jhoots pharmacies. There were several inexperienced members of the team including recently recruited trainee dispensing assistants and apprentices that had worked at the pharmacy for up to 12-months, and they had not received details about their enrolment on an accredited training course. Members of staff who were enrolled on accredited training courses had not completed their course within the time frame suggested by the course provider. Another member of the team said that she did not have any protected training time away from the dispensary and that their training was done by the RP within the dispensary.

Annual leave was booked in advance and support staff from head office were available to cover if needed. Part-time staff were asked to work over-time or change their hours to cover absence or annual leave. The pharmacy team had set roles within the dispensary so there was continuity with that task, and there were other people that were trained to cover for them if they went on annual leave.

The team appeared to work well together during the inspection and were observed helping each other and moving onto the healthcare counter when there was a queue. The RP was observed making himself available to discuss queries with people in the pharmacy and giving advice to patients when he handed out prescriptions.

Pharmacy staff had regular discussions in the dispensary to communicate messages and updates. The pharmacy staff said that they could discuss any concerns with the pharmacists. Staff said they would speak to the pharmacists or head office if they had serious concerns. However, they were not sure what the company whistleblowing process was. One team member said that it would be hard to complain about the regular pharmacist as he was also the owner.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and suitable for the services provided. It has a consultation room to enable it to provide members of the public with access to an area for private and confidential discussions.

Inspector's evidence

The pharmacy was generally smart in appearance and appeared to be well maintained. Any maintenance issues were reported to head office. The dispensary was an adequate size for the services provided; an efficient workflow was seen to be in place. Dispensing and checking activities took place on separate areas of the worktops and there was ample storage space for prescriptions waiting to be assembled. There was a large shop area and all of the shelving was empty. The owner was changing the stock layout and planned to install some large TV screens for health promotion messages. The retail stock had originally been returned to head office for a stock change, but it had not been replaced due to the COVID-19 pandemic and the additional cleaning that holding additional stock would have involved. The pharmacy displayed a poster on both entrances to say that due to the pandemic, access was limited to three people at a time. The pharmacy was generally quiet but there were some occasions during the inspection where this rule was not enforced. Information on the symptoms of coronavirus was also displayed at the pharmacy entrance and a portable Perspex screen had been installed around the till area on the medicine counter. The pharmacy was currently only permitting card payments during the pandemic.

There was a private soundproof consultation room which was used throughout the inspection. The consultation room was signposted and professional in appearance. Access was controlled as the door was behind a barrier.

The pharmacy was generally clean and tidy with no major slip or trip hazards evident. Some tote boxes containing dressings sent from other Jhoots pharmacies were being stored in the shop area, these were generally stacked against the walls and access was clear for members of the public.

The pharmacy was cleaned by pharmacy staff. The sink in the dispensary and staff area had hot and cold running water, hand towels and hand soap were available. The pharmacy had air conditioning and the temperature in the dispensary felt comfortable during the inspection. Lighting was adequate for the services provided. Prepared medicines were held securely within the dispensary and pharmacy medicines were stored behind the medicines counter.

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

Summary findings

The pharmacy opens early and stays open later than usual, so its services are readily accessible. The hub and spoke model for dispensing multi-compartment compliance packs is not well managed, and some of the pharmacy's working practices are unsafe. The current process for dispensing different parts of the prescription in different pharmacies does not always meet legal requirements. People do not always receive all the information that they need to take their medicines safely. And the pharmacy does not provide people receiving compliance packs with medicine leaflets. This means that people might not have easy access to all the information they need to take their medicines. The pharmacy generally sources and stores most of its medicines appropriately, but it must improve the way it manages and handles controlled drugs.

Inspector's evidence

The pharmacy was situated within a medical centre. It had an automatic door and step-free access from the street and a second entrance directly from the medical centre. A home delivery service was available for people that could not access the pharmacy. The pharmacy opened for longer hours than most other local pharmacies which included late nights, and Saturday and Sunday. The pharmacy staff used local knowledge and the internet to refer people to other providers for services the pharmacy did not offer. The pharmacy had become a palliative care hub during the pandemic. This meant that local healthcare providers knew that the pharmacy had the medicines from the local end-of-life formulary in stock. There were various posters and banners about COVID-19 displayed in the pharmacy and in the pharmacy windows.

The RP administered several 'flu vaccinations during the course of the inspection and was offering a 'walk-in' service so that it was convenient for members of the public. He was able to easily manage the additional workload of this service. There were two services available; the NHS flu vaccination service and a 'business to business' service. The service specifications for the flu services were not available for reference and the RP was not named on the actual PGD, but he was reminded these documents should be available.

An electronic audit trail had been implemented to track the progress of prescriptions through the dispensing process and to the spoke pharmacy. Barcodes were used to track this and the time and date that the barcode was scanned were recorded on the system. The teams could input the patient details into the system and see where the prescription was. This was linked to the 'spoke' pharmacies. A number of completed compliance packs were checked and there were multiple instances where neither the dispensed by or checked by boxes had been completed, so it was unclear which pharmacist had performed a clinical check or an accuracy check of the prescription. The RP demonstrated that the barcode scanning system could be used to check which dispenser had assembled the compliance pack, but the pharmacist details would need to be identified using the RP log. Multiple pharmacists worked each day due to the extended opening hours, so using this system to hold pharmacists accountable for errors was not robust.

Up to 45 other pharmacies were supplied with compliance packs for onward supply. All of the compliance packs for a specific pharmacy were assembled and delivered back to that pharmacy during the same week. The start dates of each pharmacy's prescriptions were displayed in the dispensary so

that the team could keep track of their workload. Each stage of the compliance pack assembly process was explained by members of the team. The process was broken down into labelling, picking, preparing, checking and bagging. The stages were carried out by different team members as they felt that this was the best way to pick up on errors. A specialist pharmaceutical delivery company delivered the completed prescriptions to the spoke pharmacies and used electronic delivery notes to track them.

Some of the spoke pharmacies ordered the repeat requests for their patients, others were ordered by the hub. So there was no clear system, this increased the likelihood of errors when medicines were ordered. The spoke pharmacies did not have access to the latest PMR record for the patient so there was a risk that the spoke pharmacies would not be aware of dose changes or stopped items and they might order medicines in error because of this. Prescriptions were labelled and the dispenser usually identified any missing items or dose changes using the PMR system. The dispenser emailed a list of queries to the spoke pharmacy once all of the prescriptions had been labelled and held the prescriptions with queries in a separate pile until she had received a response. But there was some evidence that things had gone wrong as the GPhC had received several concerns about compliance pack issues and errors and during the last nine months.

Prescription forms, backing sheets and labels were put into a colour coded basket for each person and the medicines required were picked and added to the basket. Another dispenser then assembled the compliance pack. They explained that they checked the information on the backing sheet matched the prescription form. And the stock that had been picked was correct. The pharmacy team had tweezers available for assembly, but they did not know if they had gloves. They were observed putting medicines into the palm of their hands and dispensing from there. This appeared to be their usual process and there was no mention of additional hand washing or hygiene measures due to the pandemic. Handling the medicines increased the risk of cross contamination. The dispensed compliance pack was then put into a separate area for the pharmacist to check. Patient information leaflets were not routinely supplied, and these were discarded during the checking process. Supplying patient information leaflets is a legal requirement.

Additional items, such as creams or inhalers were dispensed at the pharmacy and supplied to the spoke with the compliance packs. The procedure that the pharmacy followed if the prescription contained a controlled drug or a fridge item was different. The dispensing label and prescription form were attached to the completed prescription bag and sent to the spoke pharmacy for local dispensing. The details on the dispensing label would be incorrect as they contained the details of the hub pharmacy, rather than the spoke. This process would be particularly troublesome in the event of a controlled drug error investigation. For instance, the prescription was not marked with the correct date at the time the supply was made, and endorsement details on the electronic prescription form did not correspond with the CD register entry. This practice did not comply with the regulations, and people collecting prescriptions could not sign the back of the prescription form as confirmation of collection, in keeping with good practice.

The arrangement for high-risk medicine counselling had not been formalised for compliance pack patients and people prescribed valproate were not routinely being counselled about the pregnancy prevention plan. The RP said that it was the spoke pharmacy's responsibility; however, the prescription bags were not highlighted when they contained valproate or a high-risk medicine and prescription forms were not supplied (unless it was for a CD or fridge item) so this was not workable in practice. This was another area where the accountabilities of the hub and spoke pharmacies had not been made clear and this could have a negative impact on the service provided to a patient.

Medicines were obtained from a range of licenced wholesalers and a specials manufacturer. The RP provided verbal assurance that the over-stocks of medicines received from other Jhoots' pharmacies for

sorting, date-checking and redistribution were only from Jhoots Chemist pharmacies and would only be supplied to Jhoots Chemist pharmacies. The pharmacy did not hold a MHRA wholesaler dealers' licence so it could not redistribute to any other pharmacy company. The tote boxes were not marked and did not come with any paperwork so their origin could not be verified.

Medicines were stored in an organised manner on the dispensary shelves. Medicines were stored in their original packaging. The RP explained that he was trialling the Falsified Medicines Directive (FMD) software in one of the other pharmacies and was working with the software developer as there had been some teething problems. Due to the complex nature of the hub and spoke model, he planned to only start using FMD at this pharmacy when he was certain it worked properly. Patient returned medicines were stored separately from stock medicines in designated bins. The CD cabinets were secure and a suitable size for the amount of stock held. Medicines were stored in an organised manner inside the cabinets. But CDs were not always stored securely. The pharmacy received MHRA drug alerts by email from head office. Drug alerts were checked and filed in a separate email folder as evidence of completion. There was a fridge which was used to store stock medicines and assembled medicines. The medicines in the fridge were stored in an organised manner. Fridge temperature records were kept, and records showed that the pharmacy fridges were working within the required temperature range of 2°C and 8°Celsius.

Substance misuse prescriptions were dispensed in advance and this helped reduced workload pressure and the risk of dispensing incorrect doses when the person came to collect the prescription. Dispensing bottles that had been used for supervised consumption of methadone were being re-used for the same person for several days before being discarded, which increased the risk of contamination.

There was evidence that out of date CD stock had been destroyed in May 2020 by a pharmacist and that the RP had been the 'authorised witness' for the destruction. The RP had working at the pharmacy regularly in the month prior to witnessing the destruction so should not have acted as an authorised witness at this pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. The pharmacy team uses the equipment in a way that keeps people's information safe.

Inspector's evidence

The pharmacy had a range of up to date reference sources, including the BNF and the children's BNF. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. A range of clean, crown stamped measures were available. Fluid resistant facemasks and visors were available for staff to wear, or they could wear their own. Computer screens were not visible to the public as they were excluded from the dispensary. Cordless telephones were in use and staff were observed taking phone calls in the back part of the dispensary to prevent people using the pharmacy from overhearing.

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.