General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Wellcare Pharmacy, 2 Castle Avenue, BRIGHOUSE, West Yorkshire, HD6 3HT

Pharmacy reference: 1101446

Type of pharmacy: Community

Date of inspection: 07/06/2023

Pharmacy context

The pharmacy is in a residential area in Rastrick. Pharmacy team members dispense NHS prescriptions and sell a range of over-the-counter medicines. They provide medicines to people in multi-compartment compliance packs to help them take their medicines safely. And they deliver medicines to people's homes.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy doesn’t adequately manage all the risks associated with its services, especially when providing people with medicines in multi-compartment compliance packs. The pharmacy does not have written procedures available to help team members manage some key risks. And team members do not always read or follow the procedures that are available.
		1.2	Standard not met	Pharmacy team members do not have robust arrangements to learn from mistakes. They do not record or analyse their mistakes. And they do not make effective changes to their practices to help make the pharmacy's services safer.
		1.6	Standard not met	The pharmacy does not appropriately maintain all its records. And it does not accurately record and report controlled drug related incidents.
2. Staff	Standards not all met	2.2	Standard not met	Some pharmacy team members are not suitably trained or enrolled on training courses appropriate for their role.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy is cluttered and untidy. Pharmacy team members do not make effective use of the limited space available. And this introduces unnecessary risks.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not manage the dispensing and preparation of multi-compartment compliance packs safely. Pharmacy team members do not plan this workload well. And they often prepare packs under pressure and without access to appropriate information. This means there is a significant risk of mistakes being made.
		4.3	Standard not met	The pharmacy does not always store and manage its medicines appropriately. It doesn't have a robust process to check for expired medicines. And there is evidence of out-of-date medicines on the shelves. The pharmacy does not routinely provide people with the necessary information to help them take their medicines safely. So,

Principle	Principle finding	Exception standard reference	Notable practice	Why
				there is a risk of medicines being supplied to people that are not fit to use and that they may not know how to use properly.
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 adequately identify and manage all the risks associated with its services. It has not sustained the improvements to its ways of working following feedback at previous inspections. I t does not have written procedures to help pharmacy team members manage some of these risks. And pharmacy team members do not always follow the procedures that are available. Team members rarely discuss the errors they make in the dispensing process, and they do not record or analyse their mistakes. So, they may miss opportunities to learn and make improvements. The pharmacy keeps the records required by law, but not all its records are accurately maintained. Pharmacy team members suitably manage people’s confidentiality. And they generally understand how to protect vulnerable adults and children.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs) in place. The superintendent pharmacist (SI) had implemented the SOPs in 2017. And they had reviewed them in 2021. But the pharmacy did not have SOPs for some key processes, such as managing medicines expiry dates and handling of confidential waste. The pharmacy had records available that showed some pharmacy team members had read and understood the procedures. Two trainee team members had started working in the pharmacy in the last six months and were primarily engaged preparing and dispensing multi-compartment compliance packs. One trainee had read and signed some, but not all SOPs, but the other trainee admitted they had not read any of the procedures. Ways of working in the pharmacy often did not match the SOPs, which introduced risks, including how multi-compartment compliance packs were managed and prepared, the way team members responded to near-miss and dispensing errors, and how they managed checking medicines expiry dates. Pharmacy team members were observed preparing multi-compartment compliance packs without up-to-date prescriptions or labels available. And they were preparing packs under pressure due to a lack of robust systems to ensure packs were prepared in a timely fashion before they were due to be supplied to people. In addition, the pharmacy's dispensing workflow was disorganised. Several of the pharmacy's benches where prescriptions were prepared were cluttered and untidy. These factors increased the likelihood of errors and people receiving the wrong medication in their compliance packs. Some of these issues had been raised at the pharmacy's previous inspections. It had made some progress addressing the areas for improvement, but this had not been sustained.

The pharmacy had a documented procedure explaining how to handle near miss errors made by team members while dispensing. But team members were not following the procedure. They rarely recorded their near miss errors. The SI admitted they did not record any mistakes made by trainee pharmacy team members as they did not want to put them off working at the pharmacy. So, they spoke quietly to the team member involved to tell them what they had done wrong. Other team members did not learn from each other’s mistakes, and they could not give any examples of changes they had made recently to prevent mistakes happening again. The SI did not analyse any near miss information to establish patterns of risk. The pharmacy had a written procedure to help team members manage and record dispensing errors, which were errors identified after the person had received their medicines. But the procedure was not being followed. The SI admitted that dispensing errors had been made that had not been discussed or recorded. And the team members could not describe changes they had made to prevent similar dispensing errors happening again. This meant the team may miss opportunities to

learn and make the pharmacy's services safer.

The pharmacy had a procedure to deal with complaints handling and reporting. A poster in the retail area explained the company's complaints procedure. Pharmacy team members could not give any examples of any changes they had made to improve services in response to people's feedback.

The pharmacy had up-to-date professional indemnity insurance. Its controlled drug (CD) registers were generally in order. But there were multiple entries in the methadone register that did not include all the necessary information. The pharmacy kept running balances for all CD registers. Pharmacy team members audited these balances against the physical stock quantity each time they supplied or received a CD and made an entry in the register. But this meant that the team did not regularly audit registers for CDs that were not often used. For example, the register for Oxycodone 50mg/ml ampoules had last been audited in September 2022, and the register for Matrifen 12mcg/hour patches was last audited in April 2021. A sample of five registers were checked against the physical stock during the inspection. Four were found to be correct and one contained a discrepancy of one capsule. After the inspection, the SI contacted the inspector to explain that one capsule had been destroyed after it had been dropped while a team member had been preparing a multi-compartment compliance pack. The destruction had taken place without the presence of an authorised witness and without informing the CD accountable officer, and it had not been recorded in the corresponding CD register. The pharmacy kept a register of CDs returned by people for destruction. It accurately maintained a responsible pharmacist record electronically. Pharmacy team members monitored and recorded fridge temperatures. The pharmacy kept private prescription and emergency supply records, which were complete and in order.

Pharmacy team members used a shredder to destroy confidential waste. The SI had spoken to pharmacy team members about privacy and confidentiality. The pharmacy had a documented procedure to help pharmacy team members manage their information governance responsibilities, but the procedures did not cover how to handle and destroy confidential waste. When questioned, the team members understood how important it was to protect confidentiality, and how to effectively destroy confidential waste.

A pharmacy team member gave some examples of signs that would raise their concerns in both children and vulnerable adults. They explained how they would refer their concerns to the pharmacist. The SI said he would assess the concern and refer to local safeguarding teams. The pharmacy displayed a list of local contacts and a procedure for reporting safeguarding concerns. The SI had completed training in 2022. But other team members were unsure when or whether they had completed formal safeguarding training.

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

Summary findings

Some pharmacy team members are not properly trained or undergoing training appropriate for their role. And they are carrying out activities which they are not appropriately qualified or trained to do. Pharmacy team members complete training ad hoc as they do not have time to undertake training during the working day. And they do not regularly reflect on their own performance or mistakes. So, they may not be keeping their knowledge and skills up to date and may miss chances to learn and improve.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the superintendent pharmacist (SI) and three trainee dispensers. The SI worked as the regular RP at the pharmacy. Two of the trainees were employed on a full-time basis and one on a part-time basis. The pharmacy also employed a part-time qualified dispenser and two team members who worked at the pharmacy every Saturday. The trainee dispensers were enrolled on appropriate accredited training programmes. But the team members who worked at the pharmacy on Saturdays were not enrolled on training courses relevant to the activities they were undertaking. These activities included speaking to people about their health and medicines, selling over-the-counter medicines to people and putting stock medicines orders away on the shelves.

Pharmacy team members explained it was difficult to find time to complete training and ongoing learning during the working day because of a lack of time. The pharmacy did not have an appraisal or performance review process. But pharmacy team members said they would ask the pharmacist if they had a learning need.

Pharmacy team members explained they would raise ideas or professional concerns with the SI. But they were unsure about whether their ideas or concerns would be considered, or whether changes would be made as a result. The pharmacy had a whistleblowing policy. And pharmacy team members were aware of how to access the procedure. The SI did not ask the team to achieve any targets.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy does not provide a suitable working environment. Some areas where team members prepare prescriptions, and the stairs and passageways are cluttered and untidy. And pharmacy team members do not use the limited space available in the most efficient way to help make sure they are working safely. The pharmacy has consultation rooms. But these rooms are used for storage which means team members cannot use them to have private conversations with people. The retail area and exterior are generally professional in appearance.

Inspector's evidence

The pharmacy occupied two floors of the same building. Pharmacy team members carried out general dispensing tasks on the ground floor. And they prepared multi-compartmental compliance packs on the first floor.

The pharmacy was poorly organised. It did not have a clear workflow in operation in the ground floor dispensary, and the only bench space free of clutter was in the compliance pack preparation room. The clutter was being caused by medicines being stored on the benches, and stacks of baskets containing stock and prescriptions at various stages of the dispensing process. This increased the risks of errors being made. Throughout the pharmacy, floors and passageways were cluttered with boxes and wholesaler totes containing large quantities of stock. The landings at the top and bottom of the stairs were cluttered and blocked, presenting a health and safety risk to pharmacy team members.

The pharmacy had two private consultation rooms. But the rooms could not be used as they were full of stock and clutter. This meant that the pharmacy did not have a suitable space to speak to people privately. There was a clean sink in the ground floor dispensary used for medicines preparation. And a WC which provided a sink with hot and cold running water and other facilities for hand washing. Heating and lighting in the pharmacy were maintained to acceptable levels. And the appearance of the retail area and exterior was generally professional.

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

Summary findings

The pharmacy does not manage its multi-compartment compliance pack dispensing service safely. And it does not routinely provide people receiving compliance packs with patient information leaflets to help them take their medicines safely. The pharmacy does not always store its medicines in an organised manner and manage them appropriately. And it does not have a robust process for checking the expiry date on medicines, so there is a risk that it may provide people with out-of-date medicines. The pharmacy can be easily accessed by most people, and it generally manages its other services safely.

Inspector's evidence

The pharmacy was accessed by a ramp from the street. It did not have a bell or signs to tell people how to attract staff attention if they needed assistance. Pharmacy team members said they would see someone at the door and would go and help.

The pharmacy supplied medicines to people in multi-compartment compliance packs when requested. It had a documented procedure for preparing packs, but this did not match the process being carried out by pharmacy team members. Team members explained the system in place to make sure prescriptions were ordered and received for packs provided to people each month. But prescriptions for weekly packs were not received with enough time to prepare the medicines, so team members often assembled these packs without having the prescription to refer to.

The pharmacy usually received electronic repeat dispensing (RD) batch prescriptions for medicines supplied to people in multi-compartment compliance packs. But them members did not download and print the most up-to-date prescriptions to use when they prepared each pack. And they often referred to old prescriptions that had been printed some time ago, as well as hand-written records of what had been prescribed. Some of these hand-written records were untidy and unclear, with scribbled changes to medicines, strengths, and doses which made them difficult to read. Examples included packs which were due to be supplied during week commencing 5 June 2023 that had been assembled using prescriptions dated 12 January 2023, 22 February 2023 and 11 April 2023. Pharmacy team members explained that the superintendent pharmacist (SI), usually downloaded and printed the most up-to-date prescriptions when they completed their final check of the assembled packs. This was also when the SI printed the dispensing labels and attached them to the packs, immediately prior to supply. A sample of packs was checked against the electronic prescriptions available. Most showed that up-to-date prescriptions were available on the NHS spine. But several showed that RD batches had not been downloaded for some time, indicating they had not been downloaded and printed when previous packs had been dispensed and checked. This indicated a lack of robust processes and safeguards in place for dispensing multi-compartment compliance packs. And meant there was a significant risk that changes to someone’s medicines or discrepancies would be missed.

Some packs were found that had been dispensed without any prescription available, most notably medicines being dispensed into Pivotell carousel-type compliance packs. The team member who was responsible for preparing the Pivotell packs stated that they usually prepared the pack under pressure, for supply the same day or within two days after preparation. They felt they did not have time to check for the most up-to-date prescription or generate labels for the dispensed items. They explained the pharmacist completed these steps at the end of the process. This meant the dispenser used only the

handwritten record of what had been prescribed when assembling the packs. There was no indication of when handwritten records had last been updated. Several Pivotell packs that had been prepared were checked against the ETP prescriptions available. Most had an up-to-date prescription waiting to be downloaded. But there were several examples where the pharmacy had received a six- or twelve-month batch of RD prescriptions some time ago and none of these prescriptions had been downloaded. One completed pack was found to have no current prescriptions available and was due to be supplied to the patient the following day. A team member gave their assurance that Pivotell packs were supplied with a set of dispensing labels each time they were dispensed. During the inspection, there were several completed Pivotell packs waiting to be checked that had only one label attached showing only the patient's name and address.

One incidence was noted where packs for someone who had recently been discharged from hospital had been prepared using a prescription dated prior to the patient's admission to hospital. The SI said the pharmacy had not requested a new prescription from the GP because the patient's medicines had not changed. When asked how they had confirmed that medicines had not changed, the SI said they had received a hospital discharge summary. But the SI could not provide a copy of the discharge summary, and there were no records that any team members had completed checks to ensure that the patient's medicines had remained the same.

Pharmacy team members usually prepared packs in batches of four weeks at a time. Once prepared, these were stored on shelves in a room on the first floor of the pharmacy, waiting for the SI to check them. Team members explained they placed patient information leaflets (PILs) with the completed packs for the SI to use when they checked the contents, and they provided the PILs to people with the first of four trays each month. But several examples were seen where PILs had not been supplied at the start of the cycle. And the SI admitted that they did not routinely supply PILs to people who received their medicines in a pack.

The pharmacy was storing a significant quantity of stock on makeshift shelves above one of the benches on the first floor. The shelves were used primarily to store split packs of medicines used during the preparation of multi-compartment compliance packs. The shelves were full and overflowing and stock of split packs had spread out along the back of the adjoining benches. Packs were stored in an unorganised fashion, where look-alike and sound-alike medicines were mixed in the same or adjacent stacks of cartons. Several stock bottles of medicines were stored on the bench, with no clear organisation system. This significantly increased the risks of team members making a picking error during dispensing. These issues had been identified at previous inspections.

The pharmacy did not have a documented procedure in place for checking the expiry dates of medicines. Team members explained they tried to check medicines every two months, but this was not always possible. They did not record when they had made their checks. But they had made a list of medicines that were due to expire each month to the end of 2023. Team members used their list to remove expired items during their month of expiry. A search of the shelves identified four out-of-date medicines. Three of these had expired in April 2023 and one had expired in October 2022.

Pharmacy team members signed the dispensed by and checked by boxes on most dispensing labels. This was to maintain an audit trail of staff involved in the dispensing process. But they did not do this when preparing multi-compartment compliance packs, when the SI attached the dispensing labels at the end of their final accuracy check. So, the pharmacy did not have a robust audit trail of the team members involved in dispensing and preparing packs. And this meant it would be difficult to ensure that team members learnt from their mistakes.

Pharmacy team members used dispensing baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacist questioned people receiving prescriptions for valproate that were at risk of becoming pregnant. And they provided them with the necessary counselling and advice. They checked to make sure people were enrolled on a pregnancy prevention programme. And referred people to their GP if they were not enrolled. The pharmacy had a supply of printed material available to give to people to help them understand the risks of taking valproate during pregnancy. The pharmacy delivered medicines to people. It recorded the deliveries it made. The delivery driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the necessary equipment available for the services it provides. It manages and uses its equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. The resources it had available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had a set of clean, well-maintained measures available for medicines preparation. And it had a separate set of measures for measuring methadone. It had a suitable shredder available to destroy its confidential waste. It kept its password-protected computer terminals and bags of medicines waiting to be collected in the secure areas of the pharmacy, 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.