# General Pharmaceutical Council

# Registered pharmacy inspection report

Pharmacy Name: Oakley Pharmacy, Heswall and Penbby Group

Practice, 270 Telegraph Road, Heswall, Wirral, Merseyside, CH60 7SG

Pharmacy reference: 9010044

Type of pharmacy: Community

Date of inspection: 11/10/2023

## **Pharmacy context**

The pharmacy is situated inside a GP practice, in the town of Heswall. The pharmacy premises are accessible for people, with adequate space in the retail area. And there is a consultation room available for private conversations. The pharmacy sells a range of over-the-counter medicines and dispenses both private and NHS prescriptions. The pharmacy changed ownership in July 2021. This was an intelligence-led targeted inspection which focussed primarily on management of controlled drugs. The inspection did not cover all of the standards for registered pharmacy premises.

## **Overall inspection outcome**

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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

# Summary of notable practice for each principle

| _   |                          |                                    |                     |  |
|---|--------------------------|------------------------------------|---------------------|--|
| Principle                                   | Principle<br>finding     | Exception<br>standard<br>reference | Notable<br>practice | Why  |
| 1. Governance                               | Standards<br>not all met | 1.1                                | Standard<br>not met | The pharmacy SOPs do not always reflect current practice.  |
|   |                          | 1.2                                | Standard<br>not met | The pharmacy cannot provide any evidence to show how it learns from things that go wrong.  |
|   |                          | 1.6                                | Standard<br>not met | The pharmacy does not keep appropriate controlled drug (CD) records and the responsible pharmacist (RP) record is incomplete.                      |
| 2. Staff                                    | Standards<br>not all met | 2.1                                | Standard<br>not met | The pharmacy is operating without a superintendent pharmacist.   |
| 3. Premises                                 | Standards<br>met         | N/A                                | N/A                 | N/A  |
| 4. Services, including medicines management | Standards<br>not all met | 4.3                                | Standard<br>not met | Some stock medicines have been repackaged and are not adequately labelled. So the pharmacy cannot provide assurance that they are fit for purpose. |
| 5. Equipment and facilities                 | Standards<br>met         | N/A                                | N/A                 | N/A  |

# Principle 1 - Governance Standards not all met

#### **Summary findings**

The pharmacy does not have appropriate governance arrangements in place. It does not keep all of the records that are needed by law. Responsible pharmacist records are incomplete and the pharmacy does not maintain the necessary records for the controlled drugs it obtains and supplies. It has written procedures in place for its services. But they do not always reflect current practice, so members of the team may not always work effectively. The pharmacy does not identify or manage all of the risks involved with providing services safely. And it does not review the safety or quality of the services it provides.

#### Inspector's evidence

There were standard operating procedures (SOPs) in place for some of the services provided. But they were the SOPs that had been in place under the previous ownership and did not always reflect current practice. For example, the pharmacy had installed a dispensing robot and a new patient medication record (PMR) system in January 2023. But the SOPs had not been updated to reflect these changes. There were SOP sign off records showing that some members of the pharmacy team had read and accepted them. But two members of the team who had commenced their roles as trainee dispensers in the last 18 months had not read or signed the SOPs. When questioned, a dispenser was able to clearly describe her duties.

Dispensing errors and near miss errors had not been recorded since the installation of the dispensing robot. Therefore, the pharmacy could not provide assurance that its systems were effective, or that the pharmacy team had the opportunity to learn from things that went wrong.

The correct responsible pharmacist (RP) notice was displayed conspicuously. The emergency supply record and private prescription record were in order. There was no record of unlicensed medicines (specials) available. One of the dispensers said they only had one patient who received an unlicensed medicine. The RP record was incomplete, with several dates between March 2023 and the inspection date having no record to identify the pharmacist on duty when the pharmacy was trading. And there was no RP record available prior to March 2023. This meant the pharmacy was not able to demonstrate who was responsible at specific times.

The pharmacy did not have a controlled drug (CDs) register available when it was visited two days prior to the inspection, on 9 October. At the time of inspection, an electronic CD register was in place and entries had been made for four strengths of Methylphenidate XL. But no other electronic CD records had been made. The pharmacy also had some old paper CD registers which related to the previous owner as the last date of entry seen as April 2021. A dispenser who was acting as pharmacy manager believed the pharmacy did have a paper CD register in place until around January 2023, at which time an electronic CD register had been introduced, but he was unsure where these were. He explained that the electronic CD register was working initially on a trial, but it had not worked since the trial had ended and records made during the trial period were no longer available. The pharmacist explained that she had only recently qualified and had worked at the pharmacy as a locum a couple of days a week since August 2023. She had not made any CD register entries whilst working at the pharmacy. She said that the person she believed to be the pharmacy owner had asked her to place all CD invoices and CD prescriptions in a basket in the dispensary and that he would deal with them when he was next in the

pharmacy. She believed he was making the appropriate entries in the CD register. There was a basket full of CD invoices and dispensed CD prescriptions kept on a dispensary bench. The pharmacist agreed to immediately start maintaining a CD register herself, making sure all CD stock received, and CD prescriptions supplied were entered correctly, and was observed entering several CD transactions into the electronic register. Patient returned CDs were recorded in a paper register up until August, when the previous regular locum had left their employment.

## Principle 2 - Staffing Standards not all met

#### **Summary findings**

The pharmacy has enough staff to manage its workload safely. But it is currently operating without a nominated superintendent, which means there is a lack of accountability and leadership for the safe and effective provision of services.

#### Inspector's evidence

There was a locum pharmacist, a dispenser who was acting as pharmacy manager, a second dispenser and two trainee dispensers on duty. This was the usual staffing level. The superintendent resigned from their role on 25 September 2023 and the pharmacy was operating without a nominated superintendent.

The team were not completely clear about the ownership structure. The pharmacist and pharmacy team members said they believed that the pharmacy owner was a pharmacist who worked in the pharmacy each week, on the days that the locum was not present. According to the Companies House website, the pharmacy was owned by a body corporate, and the pharmacist who worked in the pharmacy when the locum was not present, was not named as a director, and the company had a non-registrant sole director.

## Principle 3 - Premises ✓ Standards met

#### **Summary findings**

The pharmacy is generally clean and tidy. It has a consultation room so that people can have a conversation with a member of the pharmacy team in private.

## Inspector's evidence

The pharmacy was generally clean and tidy. It had a waiting area. The temperature in the pharmacy was controlled by heating units. Lighting was adequate. The pharmacy team cleaned the floor, dispensing benches and sinks regularly.

The premises were maintained in an adequate state of repair. Maintenance problems were reported to the pharmacy manager. The pharmacy team had use of a kettle and fridge. A WC with wash hand basin and antibacterial hand wash was available in the GP practice. The consultation room was uncluttered and clean in appearance.

## Principle 4 - Services Standards not all met

#### **Summary findings**

The pharmacy has some stock medicines that have been re-packaged and are not adequately labelled. This means it cannot provide assurance that these medicines are fit for purpose. And expiry date checks are not always recorded. So there may be an increased risk that expired medicines could be supplied.

## Inspector's evidence

The pharmacist explained that prescriptions for warfarin, methotrexate and lithium were not routinely highlighted. This meant there was a missed opportunity for counselling of these medicines upon collection. The pharmacy team were aware of the risks associated with the use of valproate during pregnancy. And patient information resources for valproate were present.

The workflow in the pharmacy was organised into separate areas for the assembly of multi compartment compliance aids, dispensing and a designated checking area for the pharmacist. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. Baskets were used to separate prescriptions, to reduce the risk of medicines becoming mixed up during dispensing. Multi-compartment compliance aids included patient information leaflets and a dispensing audit trail, but no individual medicine description. This meant it was more difficult for people to identify individual medicines. A dispenser explained how the prescription delivery service was provided. A delivery record book was kept as an audit trail for deliveries, and if a patient was not at home when a delivery was attempted, the medicines were returned to the pharmacy.

Stock medications were sourced from licensed wholesalers and specials from a licensed manufacturer. Stock was stored tidily inside the dispensing robot and on dispensary shelves. CDs were stored appropriately. Patient returned CDs were destroyed using denaturing kits. There was a clean medicines fridge, equipped with a thermometer. The minimum and maximum temperature was recorded daily. Patient returned medicines were stored tidily in clinical DOOP bins. The pharmacy had at least five containers of decanted stock medication. Some had no medicine labels on, and the others had hand written labels with the drug name but no batch number or expiry date details included. This meant the pharmacy could not show when the medicines hd been re-packaged or whether they were fit for purpose.

The stock medicines in the dispensing robot were regularly date checked and a record kept. But there was no date checking record for stock medicines that were not stored in the dispensing robot, such as creams, dressings, fridge medicines and CDs. And short-dated medicines were not highlighted if not kept in the robot. No out-of-date stock medicines were present from a number that were sampled. The pharmacy manager explained that date checking records had not been kept for some time. This meant there no assurance of this task being completed and may increase the possibility of supplying a medicine that is not safe or fit for purpose.

## Principle 5 - Equipment and facilities ✓ Standards met

#### **Summary findings**

The pharmacy has the equipment it needs to provide services safely. And it is used in a way that protects privacy.

### Inspector's evidence

The pharmacy team used the internet to access websites for up-to-date information. For example, Medicines Complete. Any problems with equipment were reported to the pharmacy manager. The dispensing robot and all electrical equipment appeared to be in working order.

There was a selection of liquid measures with British Standard and Crown marks. Computers were password protected and screens were positioned so that they weren't visible from the public areas. A cordless telephone was present, and it was used to hold private conversations with people when 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.  |  |