Registered pharmacy inspection report

Pharmacy Name: 4 Court Pharmacy, Blackburn Service Station,

Whalley Banks, BLACKBURN, Lancashire, BB2 1NT

Pharmacy reference: 1093283

Type of pharmacy: Community

Date of inspection: 29/09/2020

Pharmacy context

The pharmacy is located on a petrol station forecourt on a main road close to Blackburn town centre. It is open extended hours seven days a week. During the COVID-19 pandemic the pharmacy's main focus is to dispense NHS prescriptions. It supplies some medicines in multi-compartment compliance packs to help people to take them properly. And it delivers medicines to people's homes. The pharmacy sells over-the-counter medicines and provides advice to people about minor ailments.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 does not identify and manage the risks around purchasing and sales of codeine linctus as it should. And it does not have suitable governance arrangements to protect vulnerable people from buying it.
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 not all met	4.2	Standard not met	The pharmacy does not have adequate safeguards in place for the purchase and sales of codeine linctus
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 identify or manage all the risks with the services it provides. It does not adequately manage the sales of codeine linctus, a medicine that can be misused. So, people may take this medicine and cause themselves harm. The pharmacy has up-to-date written procedures for the team members to follow to help deliver its services safely. It keeps people's private information secure and makes the records it must by law. Pharmacy team members understand their role in helping protect vulnerable people. They respond appropriately to feedback about the pharmacy. And they record and discuss mistakes they make. Team members mostly make appropriate changes to the way they work to improve the services they provide and help make them safer.

Inspector's evidence

The pharmacy was inspected during the COVID-19 pandemic. It had identified risks associated with transmission of coronavirus and had made some changes to its ways of working. The pharmacy had a full height hard plastic screen, the full length of the counter, and another at the separate prescription hand out area. It was limiting the number of people allowed in the pharmacy at one time and there was a sticker on the floor to help people with social distancing. Posters on the window and at the entrance to the pharmacy provided information about COVID-19. Some of the team members were wearing face masks. Once the inspector entered the dispensary the other team members put on visors. They could mostly social distance, although there was one narrow passage area where the pharmacy counter, substance misuse hand out area and the dispensary merged where the team were seen on occasions to struggle with social distancing. The pharmacy had documented risk assessments completed for its individual team members.

The pharmacy stored its standard operating procedures (SOPs) electronically. It had SOPs for Responsible Pharmacist (RP) regulations, controlled drug (CD) requirements and self-care and sale of medicines. Not all team members had signed to confirm that they had read the SOPs, this included the drivers and the pre-registration pharmacist. There was a date of release of September 2018 documented on the SOPs. But the SOPs did not indicate a date for review. The SOP for self-care and sale of medicines indicated a range of circumstances when the team member should refer sales to the pharmacist. This included for over-the-counter (OTC) medicines that were liable for abuse such as codeine and pseudoephedrine. The team members explained how they referred medicines liable to misuse, including codeine linctus to the RP. The RP worked two days a week and recognised there had been an increase of requests for sales of codeine linctus over time. He had discussed it with the team members he worked with to manage these requests. The team explained how sales of codeine linctus were refused, although some sales continued. The pharmacy was open for 100 hours over seven days with shift changes in staff and different pharmacists working. The whole team, working across the different days, hadn't discussed the matter together. And the regular pharmacists hadn't discussed the demand for codeine linctus either. The RP agreed that there could be opportunities for people to represent at the pharmacy to request additional sales of codeine linctus. The pharmacy didn't have a process to record sales or refusals of codeine linctus or any other audit process to monitor sales of this medicine. The inspector subsequently spoke with the superintendent pharmacist (SI). He stated he had been unaware of the significant volumes of codeine linctus being purchased, before this had been highlighted during the inspection. As SI he didn't have visibility of any wholesaler reports to identify any anomalies or trends in purchasing. No audits on high-risk medicine purchases were conducted that

could have highlighted these high volumes. The SI had organised a meeting with the RP working during the inspection to discuss next steps. And informed the inspector that he would notify the team to stop all sales of codeine linctus and tell them to signpost people accordingly.

The pharmacy recorded near-miss errors on a paper record. The form didn't have sections to complete to highlight what was prescribed and what was dispensed. This made it difficult on some occasions to understand what had gone wrong. It was more difficult to spot trends. This had not improved since the last inspection. The pharmacy team recorded some near-miss errors each month to help learn from them. The records had not been used recently to complete a review of these errors to identify any trends. The pharmacist described how the team discussed the errors they had made informally. The team members had separated some medicines on the shelves to help prevent selection errors and attached some alert stickers. For example, highlighting ramipril capsules and tablets. The pharmacy had a process and form for recording any dispensing incidents. It had no records of any incidents since 2017.

The pharmacy displayed the correct Responsible Pharmacist notice. The pharmacy team members worked within their roles and competence during the inspection. They gave appropriate advice and referred people to the pharmacist when they needed to. The pharmacy had a written procedure to manage complaints and a complaints form to help the team members record details. They kept historical forms for reference. The team members knew how to try and resolve a concern themselves and described how they would refer serious concerns to the pharmacist. They explained how the majority of people had been understanding during the pandemic. The pharmacy asked people to feedback using an annual questionnaire. It displayed the results of its 2017-2018 survey on the NHS website, but not in the pharmacy. The results were positive about the pharmacy's services and team.

The pharmacy had up-to-date indemnity insurance in place. Records for private prescriptions and the supply of unlicensed medicines complied with requirements. The pharmacy kept an electronic CD register. The records met the requirements for the entries checked. A check on the physical quantity of one CD matched the register entry. The pharmacy completed weekly balance checks, in line with the SOP. It recorded all of these in the electronic register. This had been implemented since the last inspection. The pharmacy kept an up-to-date RP record, but there were a couple of omissions from the legal record. The information was captured on the NHSE 100 hour form. The pharmacy had a patient returns CD destruction register, but it wasn't kept up to date. There were no CDs awaiting destruction.

The pharmacy had procedures relating to Information Governance and General Data Protection Regulation (GDPR) and displayed a privacy notice. The pharmacy team separated confidential waste from general waste. It had a shredder and some confidential waste was removed by a third party company for shredding. The pharmacy had a child protection policy and a SOP regarding safeguarding vulnerable adults, for the team to refer to. The regular pharmacists had completed the CPPE Level 2 safeguarding course in 2019. The pharmacy had the contact details of the local safeguarding team clearly displayed close to the substance misuse hand out area.

Principle 2 - Staffing ✓ Standards met

Summary findings

Overall, the pharmacy team has the qualifications and skills to provide its services safely. Members of the team work well together to manage the workload. And complete some ongoing training to keep their skills up to date. They feel comfortable sharing ideas to improve the way they work and in raising any concerns should they need to. But they do not always make adequate changes on individual concerns they identify, such as with the sales of codeine linctus.

Inspector's evidence

During the inspection the RP was a regular locum pharmacist, working two days a week. He had a dispenser and two medicines counter assistants supporting him. Two dispensers, a trainee dispenser, a pre-registration pharmacist, and three delivery drivers worked at the pharmacy but weren't present during the inspection. The pharmacy had another regular pharmacist, who was employed working two days a week. It used regular locums to cover the other opening hours. The pharmacy opened extended hours with different team members working different shifts. Team members covered each other when necessary and the regular pharmacists organised any rota changes. The pharmacy wasn't busy with people waiting for their prescriptions as many had their medicines delivered so there were fewer challenges organising the staff rota. The team members were observed managing the workload in an organised manner during the inspection.

The pharmacy had enrolled members of the team on Buttercups training modules to complete ongoing learning. The regular pharmacists had completed training relevant to their roles and the services provided. These included training relating to safeguarding, LASA medicines and providing flu vaccinations. The pharmacy had enrolled the regular pharmacists on a leadership course. The team shared information and knew how to raise concerns. Team members felt comfortable sharing their ideas with the pharmacist. The pharmacist was under no pressure to meet targets. He used his professional judgement to provide services to people.

Principle 3 - Premises Standards met

Summary findings

The pharmacy is suitably clean and hygienic. Team members clean the pharmacy more frequently and with a greater thoroughness to improve infection control during the pandemic. They have appropriate facilities to have private conversations with people.

Inspector's evidence

The pharmacy was generally clean and properly maintained. The team had been cleaning the pharmacy more frequently during the pandemic, with a thorough disinfectant clean of all the benches at least once a day. The pharmacy had two entrances for people. A main entrance off the forecourt and a separate entrance to access the substance misuse service. People gained admittance to this separate area using a buzzer. The team released the door to allow one person admittance at a time. This helped with social distancing. People didn't wear face coverings in this area, but the team was protected by a hard plastic screen. This area was reasonably dark with scuff marks on the walls. The retail area of the pharmacy portrayed a more professional appearance. The positioning of the pharmacy had enough bench and storage space for the workload. The benches were clear from clutter. There were no slip or trip hazards. The temperature and lighting throughout the premises was sufficient. The pharmacy had clean toilet facilities with hot and cold running water. The pharmacy had a sink in the back dispensing area with hot and cold running water for staff use and medicines preparation. These two activities were kept separate.

The pharmacy had an adequately-sized soundproof consultation room. It was suitable for the services the pharmacy usually offered, with seating for people. People accessed the room from the retail area. There was a separate entrance from the rear dispensing area for use by the pharmacy team. Neither of the doors were locked during the inspection. This had been the same at the last inspection. The risk of unauthorised access to staff only areas was minimised due to the presence of team members and the restriction of numbers of people accessing the pharmacy at one time. The pharmacists were not using the consultation room routinely during the pandemic. There were areas in the pharmacy retail area where private conversations could be held.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy mostly manages and delivers its services safely and effectively. But it doesn't have adequate safeguards in place to manage sales of codeine linctus. So repeat sales to people may go unchecked. The pharmacy safely manages the dispensing of people's medicines. And it has suitable processes to protect people when it delivers medicines to people's homes. The pharmacy mostly sources, stores and manages its medicines appropriately.

Inspector's evidence

The pharmacy premises had level access from the petrol forecourt outside. The pharmacy was set to one side and there was some dedicated parking outside the pharmacy. The pharmacy advertised its opening times and services in the window. It opened extended hours over seven days a week. It displayed posters in the window with government health messages relating to the pandemic. The pharmacy delivered a high volume of its medicines to people's homes. This had helped limit the number of people coming into the pharmacy during the pandemic. To abide with social distancing, the drivers were currently not obtaining signatures from people on receipt of their medicines. They stepped back from the door and waited until the person collected their medicines before leaving. The pharmacy kept a record of the medicines it delivered to people.

The pharmacy had good range of over-the-counter medicines. The team members and pharmacist were seen giving appropriate advice and making sales of medicines during the inspection. The pharmacy kept a stock of codeine linctus. The team members when questioned about sales of codeine linctus confirmed that they informed the RP when they received any requests for codeine linctus, in line with the SOP. They were not confident about the numbers of codeine linctus requests and sales per week. One team member thought that when she was working her 20 hours, there were approximately ten requests per week, and of those a couple of sales were made. She confirmed the RP working at the time was informed each time. The RP, who worked regularly two days a week in the pharmacy, explained how he had recognised an increase in requests for codeine linctus. He had spoken with the team members he worked with regularly to share his concerns and to ensure that all sales were referred to him. He explained how he would refuse sales and that he felt comfortable doing so when necessary. The team members confirmed their knowledge that codeine linctus was liable for misuse. They explained how some requests for codeine linctus appeared rehearsed and for some the person had presented previously. They said that these sales were refused. Team members confirmed they referred all sales to the RP. The team confirmed some sales of codeine linctus were made when the person asked for it by name and said that it was for a dry cough for themselves or a relative. No requests for codeine linctus were made during the inspection. The RP completed a search on the patient medication record (PMR) system that indicated no dispensing of codeine linctus in the last 90 days.

The pharmacy stored medicines appropriately. Pharmacy (P) medicines were stored behind the counter, which had a large hard plastic screen in situ. Two bottles of codeine linctus were on these shelves offset to one side, not in general view of people standing at the counter and priced at £2.99. One team member described how OTC medicines were ordered on the computer by her or another team member when stock was running low. The RP confirmed that he wasn't involved in this process and so didn't monitor the level of purchases of codeine linctus. There was no dispensing stock bottles of codeine linctus seen. Liquid medicines were stored neatly in the dispensary, with dates of opening

annotated on the containers. The pharmacy had a separate area for its wholesaling business. This area was clearly separate from the dispensing activities. The RP confirmed that codeine linctus was not supplied as part of this separate business and this was confirmed by information on its website.

The pharmacy had an organised workflow with separate areas in the dispensary for labelling, assembly and checking. The team members mostly socially distanced from each other as they completed their tasks. Pharmacy team members used baskets throughout the dispensing process, to help reduce the risk of error. They kept a dispensing audit trail as the team members signed the dispensed by and checked by boxes on the dispensing labels. The pharmacist was aware of the requirements of the valproate safety alert and for people at risk to be on a pregnancy prevention programme. The pharmacy had completed an audit prior to the pandemic of people taking valproate to review the support they were receiving. The pharmacy had information cards for people taking valproate on the pharmacy counter. The pharmacy dispensed medicines into multi-compartment compliance packs to help people take their medicines correctly. Each person had a medication record sheet indicating which medicines were to be dispensed into the packs and at what times. When the person had a change in their medication the team member updated the record and signed and dated the change. So, the pharmacy had an audit trail of changes. The pharmacy team members annotated the descriptions of the medicines on the packs. And they supplied patient information leaflets (PILs) monthly. The pharmacy had a popular substance misuse service. The team dispensed people's medication using the automated MethSmart system. The machine was secured to the bench and kept locked. This had improved the safe storage arrangements since the last inspection.

The pharmacy obtained its medicines and medical devices from licensed wholesalers. It stored medicines requiring cold storage in a medical fridge and kept a daily record of fridge temperatures. The records showed the temperature was kept within the required range. There was another fridge storing foodstuff and a small amount of medicines. The RP explained the medicines needed to be disposed of. The pharmacy team completed date checking of the dispensary and retail stock. They kept a record of short-dated stock so they could remove it before it expired. No out-of-date medicines were found from the sample checked. The record the team kept of when date checking had been completed and in which areas of the pharmacy, was not up to date. The pharmacy team had removed a few medicines from the original manufacturer's pack and not appropriately labelled the containers, including no batch number and expiry date. These were removed from the shelves by the RP. This had been highlighted at the last inspection. The pharmacy didn't have the equipment, such as scanners, to comply with the Falsified Medicines Directive (FMD). The pharmacy was aware of the requirements, but plans had been delayed by the pandemic. The pharmacy had medicinal waste bins available for returned medication and denaturing kits for CDs. The pharmacy had appropriate processes to action medicine recalls and safety alerts. The team signed and dated printed copies of the alerts as an audit trail of their actions.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. And it regularly makes checks on the accuracy of its equipment, so people receive the right dose of their medicines.

Inspector's evidence

Pharmacy team members had access to up-to-date reference resources to refer to. And they used the internet to access up-to-date clinical information. The computers were password protected and located away from any unauthorised view. People in the retail area couldn't see people's names and addresses on medication awaiting collection. The pharmacy had a telephone with a portable hand-set which facilitated private conversations.

The team had access to personal protective equipment (PPE), including masks and visors. It used singleuse equipment for dispensing into compliance packs and stored these appropriately. The pharmacy had clean glass crown-stamped measures of various sizes for pouring liquids. The range and standard of measures had improved since the last inspection. There was no evidence of electrical safety testing, but the electrical wiring was free from wear and tear. The pharmacy team calibrated the MethSmart machine three times a day to ensure its accuracy.

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.	

What do the summary findings for each principle mean?