General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Bilton Pharmacy, 120 City Road, BRADFORD, West Yorkshire, BD8 8JT

Pharmacy reference: 1111785

Type of pharmacy: Community

Date of inspection: 25/11/2021

Pharmacy context

The pharmacy is in the suburbs of Bradford city centre. Pharmacy team members dispense NHS prescriptions and sell a range of over-the-counter medicines. They provide medicines for people in multi-compartment compliance packs. And they deliver medicines to people's homes. The pharmacy provides a substance misuse service. It provides some private consultations for people as part of a private prescribing service. The inspection was completed during the COVID-19 pandemic.

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 does not routinely assess the key risks associated with its private prescribing service and does not have proper governance arrangements in place. The pharmacy does not have a written risk assessment and it doesn't have prescribing policies to manage the risks associated with the wide areas of prescribing. This includes for the higher risk medicines being prescribed and for any medicines requiring monitoring and diagnostics. The pharmacy does not complete regular prescribing audits.
		1.6	Standard not met	The pharmacy's prescribing service does not keep complete and robust clinical records of all consultations to help ensure the safety of its prescribing. And the pharmacy's private prescription records are incomplete. This means private prescriptions are not dispensed or recorded in accordance with the law.
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 to make sure its prescribing service is operating safely and effectively. It does not have robust processes to effectively monitor people's health, including those prescribed higher risk medicines. Pharmacy team members do not have enough knowledge about the prescribing service. So, it is difficult for them to establish whether medicines are being supplied safely and appropriately.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy identifies and manages risks with most of its services. But it does not adequately identify and manage the risks associated with providing its private prescribing service. It does not have a written risk assessment for the service. And it does not complete prescribing audits to support safe prescribing. Its clinical records are incomplete and brief. The pharmacy does not adequately manage private prescriptions in accordance with the law. Pharmacy team members keep people's private information secure. And they adequately understand their role in safeguarding vulnerable people. Pharmacy team members mostly record mistakes that happen when dispensing. And they discuss their learning to help prevent future mistakes.

Inspector's evidence

The responsible pharmacist (RP) explained that the pharmacy had completed a risk assessment at the beginning of the Covid-19 pandemic to help them manage the risks of infection. But a copy of the documented assessment was not available during the inspection. Pharmacy team members were wearing a mask while at work. The pharmacy had a plastic screen at the pharmacy counter to protect people from virus transmission. It provided hand sanitiser in various location in the pharmacy to help people maintain good hand hygiene.

The pharmacy had a set of SOPs in place for most of the services it provided. The sample checked were last reviewed in 2018. And there were no records of when the next scheduled check was to take place. Pharmacy team members had signed to confirm they had read and understood the SOPs. The pharmacy defined the roles of the pharmacy team members in each SOP.

The pharmacy provided some private consultations, as part of a private prescribing service for people. The pharmacy dispensed prescriptions that were written as part of this service. The pharmacy team members present during the inspection were unable to provide any information about the service and did not have a SOP to refer to. They said it was operated by the pharmacy's superintendent pharmacist (SI). And he usually provided the service when he worked at the pharmacy on a Sunday. The pharmacy did not advertise the service to people. After the inspection, the SI provided additional information about the pharmacy's prescribing service. The SI explained that he usually provided the service on a Sunday, where he carried out the role of independent prescriber and responsible pharmacist (RP) at the same time. The SI provided a standard operating procedure (SOP) for private consultations and prescribing. There were no records that the SOP had been read or signed by other pharmacy team members. The SOP did not consider all aspects of the prescribing service, for example prescribing high-risk medicines to people. Or for the variety of clinical areas being presented. The SOP also did not refer to any risk assessment completed by the pharmacy to help manage the service's risks. The pharmacy didn't have a documented risk assessment in place to help manage the service safely. It didn't have any audits of prescribing, for example for antibiotic or higher risk medicine prescribing. The pharmacy didn't have prescribing policies to refer to. This means it was difficult to identify and manage the risks with providing this service.

The SI explained that he asked people for their consent to share details of their consultations and prescriptions with their GP. And that people's wishes were respected. Some electronic clinical consultation records from the beginning of 2020 were provided. These were brief. Records from before

this date were unavailable. From the records available, consent to share information with people's GP was recorded. And most commonly, people refused consent to share information with their GP. The SI didn't record how this affected his professional judgement to prescribe, particularly for higher risk medicines. The SI confirmed that no audits had been carried out to determine any patterns, for example of how commonly people refused consent to share information with their GP. This means people may obtain medicines from a variety of sources without the proper controls in place. The SI did not keep records of consultations when he had decided not to prescribe medicines for people. And did not record the reasons for such decisions and any subsequent action he took. The SI had access to the person's summary care records (SCR) to help him making a prescribing decision. He didn't generally have any other medical records.

Pharmacy team members dispensed private prescriptions for people. These were mostly written following access to the pharmacy's prescribing service. The team recorded some private prescriptions in a paper register. But it did not keep accurate, up-to-date records of all the private prescriptions it dispensed, as required by law. Several prescriptions were seen in the pharmacy that had been dispensed but not recorded. And several dispensed prescriptions were not legally valid because they had not been signed or dated by the prescriber. The SI explained that he sometimes telephoned the pharmacy and asked them to transcribe prescriptions for people, with the intention of signing them later when he was at the pharmacy. He admitted that on reflection, this process was not robust, and these prescriptions had not been signed later. There were no written processes in place to help safeguard vulnerable people frequently seeking prescriptions for higher risk medicines, despite the SI prescribing these medicines. Following the inspection, the SI identified that the risks associated with the prescribing service had not been adequately identified or managed. After considering the inspector's questions, speaking to his peers, and reflecting on how the pharmacy's prescribing service was operating, the SI decided to immediately suspend prescribing from the pharmacy.

Pharmacy team members highlighted near miss and dispensing errors they made when dispensing. They had documented procedures to help them do this effectively. They discussed their errors and why they might have happened. And they used this information to make changes to help prevent the same or similar mistakes from happening again. One example of changes they had made was reorganising the way they delivered medicines to nursing homes to help prevent them being delivered to the wrong home. The pharmacy had records of near miss error made up to August 2021. But there were no records after this. And pharmacy team members admitted that not all near miss errors were recorded. In the records of near miss and dispensing errors that were available, pharmacy team members did not always capture much information about why the mistakes had been made or the changes to prevent a recurrence to help aid future learning. But they gave their assurance that these details were always discussed. The pharmacy did not analyse the data collected to look for patterns.

The pharmacy did not have a documented procedure in place for handling complaints or feedback from people. Pharmacy team members explained feedback was usually collected verbally. And any complaints were immediately referred to the pharmacist to handle. There was no written information available for people about how to provide the pharmacy with feedback. The pharmacy had up-to-date professional indemnity insurance in place. The pharmacy kept controlled drug (CD) registers complete and in order. It kept running balances in all registers. Pharmacy team members audited these against the physical stock quantity at least once a month. The pharmacy kept and maintained a register of CDs returned by people for destruction. And it was complete and up to date. The pharmacy maintained a responsible pharmacist record electronically. And this was also complete and up to date. The pharmacist displayed their responsible pharmacist notice to people. Pharmacy team members monitored and recorded fridge temperatures daily. They kept emergency supply records electronically.

The pharmacy kept sensitive information and materials in restricted areas. It incinerated confidential

waste. The pharmacy had a file containing key information about the General Data Protection Regulations (GDPR) and information governance for team members to read. Pharmacy team members had completed training in 2021. They clearly explained how important it was to protect people's privacy and how they protected confidentiality.

Pharmacy team members gave some examples of symptoms that would raise their concerns about vulnerable children and adults. They explained how they would refer to the pharmacist. The pharmacy had a documented procedure explaining how team members should manage a safeguarding concern. Team members would use the internet to find contact information for local safeguarding teams. They completed training via e-learning in 2021. The RP had completed training in 2017 and was aware that their training may require updating. The SI was aware that some people he held private consultations with may be vulnerable and he informally assessed this during the consultation. But the pharmacy had no written procedures relating to safeguarding for this service.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members are suitably qualified and have the right skills for their roles. And they complete ongoing training ad hoc. They reflect on their own performance, discussing any training needs with the pharmacist and other team members. And they support each other to reach their learning goals. Pharmacy team members feel able to raise concerns and use their professional judgement.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the responsible pharmacist and four dispensers. Pharmacy team members kept their skills and knowledge up to date by completing e-learning modules ad hoc throughout the year. Some recent examples included training about antimicrobial stewardship and General Data Protection Regulations (GDPR). Pharmacy team members explained they also discussed topics with the pharmacists and each other. Pharmacy team members completed an appraisal with the superintendent pharmacist each year. And they set objectives to address any learning needs identified. A dispenser gave an example of setting and objective recently to help them improve being able to deal with difficult situations. They were currently developing these skills by observing and learning from others.

A pharmacy team member explained they would raise professional concerns with any of the pharmacists who worked at the pharmacy regularly or the superintendent pharmacist. They felt comfortable sharing ideas to improve the pharmacy's services or in raising a concern. And they were confident that their points would be considered. A dispenser explained how an idea for improvement had been taken forward and this had resulted in a more efficient way of managing medicines owed to people. And it had improved bench tidiness and reduced the risks of prescriptions being mixed up. The pharmacy did not have a whistleblowing policy. Pharmacy team members were aware of organisations outside the pharmacy where they could raise professional concerns, such as the NHS or GPhC. Pharmacy team members communicated with an open working dialogue during the inspection. The pharmacy owners did not ask pharmacy team members to meet any performance related targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It provides a suitable space for the health services provided. And it has a suitable room where people can speak to pharmacy team members privately.

Inspector's evidence

The pharmacy was clean and well maintained. All areas of the pharmacy were tidy and well organised. And the floors and passageways were free from clutter and obstruction. The pharmacy had a safe and effective workflow in operation. And clearly defined dispensing and checking areas. It kept equipment and stock on shelves throughout the premises. The pharmacy had a private consultation room available. Pharmacy team members used the room to have private conversations with people. The room was signposted by a sign on the door. The pharmacy had installed clear screens at the retail counter to help prevent the spread of coronavirus.

The pharmacy had a clean, well maintained sink in the dispensary which was used for medicines preparation. It had a toilet, which provided a sink with hot and cold running water and other facilities for hand washing. The pharmacy provided team members with hand sanitiser in various locations to help them regularly maintain good hand hygiene. Heat and light in the pharmacy was maintained to acceptable levels. The overall appearance of the premises was professional, including the exterior which portrayed a professional healthcare setting. The professional areas of the premises were well defined by the layout and well signposted from the retail area.

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

Summary findings

The pharmacy manages and delivers most of its services safely and effectively. But it doesn't have the necessary safeguards in place for its prescribing service to reassure people that medicines are being prescribed safely and appropriately. Pharmacy team members do not have adequate knowledge of the service to be able to suitably manage the dispensing of these private prescriptions. The pharmacy's services are easily accessible, and members of the team help people by speaking with them in their preferred language. The pharmacy generally sources, stores and manages its medicines appropriately.

Inspector's evidence

The pharmacy had ramped access from the street. Pharmacy team members explained how they would support people who may have difficulty accessing the pharmacy services. They explained how they would communicate in writing with people with a hearing impairment. And provide large-print labels to help people with a visual impairment. Pharmacy team members were also able to speak several languages spoken locally, including Urdu, Punjabi, Bengali and Gujrati as well as English. They explained they had also used Google Translate to help communicate with people, often who spoke eastern European languages, such as Polish.

The pharmacy provided private prescribing consultations to a small number of people a month. The superintendent pharmacist (SI) was the prescriber. And after writing a prescription, he often completed the clinical and accuracy check during the dispensing process. This is not good practice as described in the GPhC In Practice: Guidance for Pharmacist Prescribers (November 2019). And the SI had not assessed the risks of this practice. The pharmacy received prescriptions from this service for a wide range of clinical conditions and medicines, such as various anti-hypertensives and diabetic medicines. He prescribed some higher risk medicines such as zopiclone, zolpidem and on occasion morphine 10mg/5ml oral solution. The SI had access to the person’s summary care records (SCR) but generally no other medical records. He provided some consultations over the phone, rather than in person. There were no formalised systems in place to manage the safety of providing remote consultations to people. The SI explained that he usually prescribed for people who were away from home and could not access their normal medicines. But from the sample of prescriptions seen, there was evidence of repeat and long-term prescribing. The SI could not provide any information about how he monitored people’s health long-term. Or made sure that people were up to date with their regular reviews and tests with their usual prescriber. Often, people also refused consent to share information with their GP. This meant they may be unaware of the pharmacy’s involvement and unable to monitor people properly. Pharmacy team members knew very little about the pharmacy’s prescribing service despite dispensing prescriptions written as part of the service. The pharmacy had no documented procedures regarding their role in providing the service. And there was no discussion between team members and the SI about how the service was operating. The pharmacy on occasions transcribed prescriptions following a telephone conversation with the prescriber and dispensed prescriptions without a valid signature on the prescription.

Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing. This was to maintain an audit trail of the people involved in the dispensing process. They used dispensing baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacist counselled people receiving prescriptions for valproate if appropriate. And they

checked if the person was aware of the risks if they became pregnant while taking the medicine. They advised they would also check if they were on a pregnancy prevention programme. The pharmacist also checked for records of a negative pregnancy test from someone presenting with a prescription for isotretinoin. They explained this was usually documented on the prescription. And would check with the GP if the necessary information was not available. The pharmacy supplied medicines to people in multi-compartment compliance packs when requested. It attached backing sheets to the packs, so people had written instructions of how to take their medicines. Pharmacy team members included descriptions of what the medicines looked like, so they could be identified in the pack. But they did not routinely provided people with patient information leaflets about their medicines. A team member explained leaflets were provided when a medicine was new, but not routinely after that. Pharmacy team members documented any changes to medicines provided in packs on the person's master record sheet and on their electronic records. The master record card was a documented record of the person's medicines and the times of administration. The pharmacy also provided medicines to several nursing homes. These medicines were supplied in their original containers. A dispenser explained that the homes ordered their own prescriptions. And they dealt with any discrepancies directly with the GP surgery. Pharmacy team members documented any changes to these people's medicines by completing a new master record sheet. But they did not always keep an audit trail of any changes made long-term to help them deal with future queries.

The pharmacy delivered medicines to people. The delivery driver recorded the deliveries they made. Under normal circumstances, people signed to confirm receipt of their deliveries. But this was not currently happening to help protect people from transmission of coronavirus. 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. Pharmacy team members highlighted bags containing controlled drugs (CDs) to the delivery driver.

The pharmacy obtained medicines from licensed wholesalers. It stored medicines on shelves. It kept all stock in restricted areas of the premises where necessary. The pharmacy had adequate disposal facilities available for unwanted medicines, including CDs. Pharmacy team members monitored the minimum and maximum temperatures in the medicines' fridge each day. And they recorded their findings. The temperature records seen were within acceptable limits. Pharmacy team members checked medicine expiry dates every three months. And up-to-date records were seen. Pharmacy team members highlighted and recorded any short-dated items up to three months before their expiry. And they removed expiring items during the next date check or if a team member noticed a highlighted pack in the meantime. This meant there was a risk of some medicines remaining on the shelves after they had expired. After a search of the shelves, the inspector did not find any out-of-date medicines. The pharmacy responded to drug alerts and recalls. It quarantined any affected stock found for destruction or return to the wholesaler. It recorded any action taken. And records included details of any affected products removed.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available for its services, which it properly maintains. And it manages and uses the 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 equipment available to help prevent the transmission of COVID-19. These included gloves, hand sanitiser and face masks. The pharmacy had a set of clean, well maintained measures available for medicines preparation. It kept its computer terminals in the secure areas of the pharmacy, away from public view. And these were password protected. The pharmacy's fridge was in good working order. It restricted access to all equipment and it stored all items securely.

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.