General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: My Pharmacy, Hesketh House, 1a Hesketh Street, Great Harwood, Blackburn, Lancashire, BB6 7DW

Pharmacy reference: 9011853

Type of pharmacy: Internet / distance selling

Date of inspection: 31/10/2022

Pharmacy context

This is a distance selling pharmacy located in the town of Great Harwood, Lancashire. The pharmacy dispenses both NHS and private prescriptions. It dispenses medicines for its private online prescribing service, which offers treatments for various conditions such as asthma and weight loss. It sells over-the-counter medicines. The pharmacy premises are closed to the public, so people access the pharmacy's services through its website, www.mypharmacy.co.uk or by telephone. It supplies some medicines in multi-compartment compliance packs to help people take their medicines and it delivers 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 consistently identify and manage all the associated risks with its private online prescribing service. And it fails to identify when some people receive treatment outside of its prescribing guidelines. So, there is a risk that people receive medicines that are not suitable for them.
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 doesn’t have enough safeguards in place for its private online prescribing service to ensure people receive medicines appropriate for their needs. This includes insufficient checks during the dispensing process to make sure prescribers follow the pharmacy’s prescribing guidelines. And it does not have robust processes to support people whose treatment requires ongoing monitoring to ensure treatment is suitable for them. This includes for weight loss and asthma.
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 identify and manage all the risks with its private online prescribing service. It makes some changes to processes following audits of prescribing to improve the safety and quality of this service. But it doesn't identify when these changes are not being followed. So, people receive medicines that may not be suitable for them. The pharmacy keeps most of the records required by law and team members keep people's private information secure. And they have adequate processes in place to help team members safeguard vulnerable adults and children.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs). The SOPs were relevant to the services the pharmacy provided, which included both NHS and private services. The pharmacy's SOPs included processes involving controlled drugs (CDs), responsible pharmacist legislation (RP), dispensing and other services including an SOP for the pharmacy's private online prescribing service. The SOP for the online prescribing service was clearly written and described the checks the team was required to do when managing this service, for example, if an identity (ID) check wasn't successful. There wasn't an index available which made it difficult to find a specific SOP. The SOPs seen were in date and had been prepared by the pharmacy's superintendent pharmacist (SI). They were reviewed by the SI every two years, and they had been updated since the last inspection. These included updating the dispensing SOPs on how the team used the updated patient medication record (PMR) dispensing system using barcode technology. The pharmacy had a training declaration sheet, where team members confirmed they had read and understood the SOP. But the newest team member had not read the SOPs relating to their role. Team members completing roles that did not require formal pharmacy qualifications, such as printing and attaching the postal labels had not read a SOP for the roles that they performed. The pharmacy had completed a risk assessment relating to the introduction of the new PMR dispensing system. It had put measures in place to mitigate these risks, such as checking the accuracy of the system during a trial period.

The private prescribing service was only accessible via the pharmacy's website, www.mypharmacy.co.uk. The pharmacy had a risk assessment for the prescribing service, that had been reviewed in August 2022. It had identified some risks associated with providing its online prescribing service and it had identified examples on how to reduce the risks and implemented some changes. Following a review of the risk assessment, the pharmacy had reduced the scope of treatments it was providing. For example, the pharmacy was no longer providing treatment for bacterial vaginosis due to the risk of the development of antibiotic resistance. Since the last inspection, the pharmacy had contracted remote based independent pharmacist prescribers to manage most consultations and they issued most of the private prescriptions associated with the service. The SI, who was also an independent pharmacist prescriber, had scaled back their own personal volume of prescribing since the last inspection. The pharmacy had not updated its risk assessment follow these changes and had not identified some of the risks with this change, such as monitoring compliance with prescribing guidelines. The pharmacy dispensed all the prescriptions issued by the prescribers. There was no option

for people to take the prescription to another pharmacy. The prescriptions supplied by the pharmacy covered a wide range of medicines prescribed for various conditions. This included orlistat and Saxenda for weight loss, nitrofurantoin and trimethoprim for cystitis, and inhalers for asthma. The SI reported the most popular condition treated was asthma. People completed a questionnaire-based consultation to obtain treatment. The questions within the questionnaire could be answered using 'yes' or 'no' responses. A red warning appeared at the end of the consultation if a negative answer was selected. The warning explained to the user that the pharmacy couldn't supply the medicine and for them to consult their GP. The pharmacy had made some improvements to the questionnaire since the last inspection. It had implemented an option for people to free type any information for the prescriber to consider, for example, any allergies a person may have wanted to disclose. And there was a system to identify instances where people had changed their answers so prescribers could take this into consideration when deciding to prescribe. However, the prescribers were only made aware of these instances if people had resubmitted a questionnaire with changed answers after five attempts. And so, the prescribers may not have all the relevant information they need to determine if supplies were appropriate. Once people had completed the consultation-based questionnaire successfully, they created an account. This allowed the pharmacy to complete some identity and suitability checks. The pharmacy had an identity (ID) policy and all people using the online prescribing service had their ID checked by a recognised third-party provider.

The pharmacy had a 'Medication Guidelines' document available to team members who were involved in providing the prescribing service, including each of the prescribers. The guidelines document was designed to help prescribers in their decision making if they observed that medicines were being ordered sooner than set time scales documented within the guide. The process was designed to help prevent people ordering too many medicines too soon. Prescribers and pharmacy team members had read and signed to confirm they understood the guidelines document. Since the implementation of remote prescribing, the responsibility lay with the prescriber and the RP to ensure prescribing levels fell within thresholds of the document. This process was manual and relied on them identifying any issues from past dispensing records. If a prescriber refused a supply, the person was informed by email and a refund for their purchase was issued. Since the last inspection, the pharmacy had completed some audits to ensure the guidelines were being followed. The pharmacy used these audits when reviewing the guidelines. And some changes were made as a result. For example, the pharmacy had reduced the maximum number of salbutamol inhalers a person could be supplied for asthma in a three-month period from two inhalers to one. Although there were several instances where the prescribers were seen to be following these guidelines, there were other occasions where the pharmacy had supplied medicines to people outside the scope of its guidelines, without a documented reason. Since the pharmacy had implemented the reduction in the maximum number of salbutamol inhalers, there had been at least seven occasions within the last three months, from the sample checked, where people had received more than one inhaler. There were no documented explanations why these had been supplied outside of the scope of the pharmacy's guidelines by either the prescriber or the RP clinically checking the prescriptions. Additionally, the pharmacy's guidelines stated weight loss treatment with orlistat should be discontinued after 12 weeks if a person had not lost at least 5% of their body weight from the beginning of their treatment. But on at least 14 occasions within the last three months, from the sample checked, people had received these medicines when they had not lost the required amount of weight. On one occasion, the pharmacy had continued to supply a person with orlistat when they had gained weight since starting treatment.

Team members were given roles and responsibilities, with the new team member referring a telephone query about the side effects of a medicine to the RP. The accuracy checking dispensers were clear about which prescriptions they could check. These was either highlighted electronically on the IT system or for some prescriptions the RP initialled the printed prescription. The team members, who did not have formal dispensing qualifications, were seen packing the medicines and producing postal address labels.

They were clear about the remit of their roles and confirmed they were not involved in dispensing. The correct RP notice was on display.

The pharmacy held near miss error records, with entries seen for each month. It held historical records on paper in both private and NHS dispensary areas and it held more recent records electronically. The electronic records held more information about the causes of errors and the actions taken to reduce the risks of similar mistakes. A dispenser demonstrated how the different strengths of ibuprofen were stored on different shelves, due to the similarity of packaging and to avoid selection errors. The number of selection errors had reportedly reduced following the introduction of scanning the barcodes on medicines, and no selection errors were seen in the sample of near miss records seen. It was noted there had been previous errors where incorrect postal address label application had occurred, but there was no evidence of the pharmacy reviewing the process to ascertain if there was a safer way to work. The pharmacy had two recently reported dispensing errors reported with details of learnings and actions taken.

The new team member, who responded to email and telephone queries demonstrated how they dealt with concerns. And they confirmed concerns rarely needed to be escalated. Most concerns raised were about missing deliveries and refusal of sales of Pharmacy (P) medicines. And they were confident in resolving these situations, sometimes with the help of the accuracy checking dispenser. The pharmacy had received over 12,000 online reviews and most reviews were positive. The SI responded personally to any negative reviews with an apology and a brief description as to why the pharmacy may not have met the person's expectations.

The pharmacy had up-to-date indemnity insurance. However, one of the prescribers was not listed on the insurance certificate. This was resolved following the inspection. The pharmacy kept an up-to-date controlled drug (CD) register. Some of the register headings had not been completed as required. The physical balance matched the CD register balance for two medicines checked. The quantity in the CD register had been seen to have been altered on a couple of occasions, rather than changes being annotated as required. The pharmacy recorded the destruction of CDs returned by people, and the record matched the returned CDs that were being stored in the CD cabinet. The pharmacy kept an electronic private prescription record for its private online prescribing service, and this also included private prescriptions it received from other private prescribers, such as veterinary prescriptions. From the sample seen the RP record was complete.

The RP and SI had completed level 2 safeguarding training. Team members knew to refer concerns to the RP and to obtain details of local safeguarding contacts on the internet. The RP described how requests for emergency hormonal contraception (EHC) through the private online prescribing service by a male were highlighted and queried. This was to help the team identify and report any potential safeguarding concerns. People who may not receive their EHC medicines in time for them to be clinically suitable were contacted to upgrade to next day delivery. If they declined or this was not suitable, then the team referred them to their local pharmacy to obtain prompt treatment.

Principle 2 - Staffing ✔ Standards met

Summary findings

Team members working in the pharmacy have the appropriate skills to provide its services. And they have some opportunities for ongoing training to keep their knowledge up to date. They manage the workload well and support each other as they work. But the pharmacy does not complete checks on the prescribers it uses for its private online service to make sure they can appropriately prescribe the treatments it offers on its website.

Inspector's evidence

The RP during the inspection was a regular locum pharmacist. The SI was present for part of the inspection. There were five other team members working in the pharmacy, two were accuracy checking dispensers and one was a relatively new team member who had not yet been enrolled on a recognised qualification. This team member's role was mainly administrative such as giving refunds for cancelled orders, but they also spoke directly with people on the telephone. They were helping people with queries about medicines and getting advice from the RP. Their role also included checking the validity of veterinary prescriptions that arrived through the post. They had received some training in the different types of prescriptions and some dispensing training as part of the induction process. The team member had not yet read the pharmacy's SOPs. The SI decided to enrol the team member onto a recognised qualification course. Two team members present, worked in roles that didn't require a formal dispensing qualification, such as producing postal labels for packages. They confirmed they did not help with any dispensing tasks. The pharmacy also had an employed delivery driver, who delivered NHS prescriptions to people living in the locality.

The pharmacy contracted two remote based pharmacist prescribers to assist with the online prescribing service. Team members based at the pharmacy premises had the contact details of each of the prescribers and reportedly could contact them quickly to help resolve a query. There were two separate dispensing teams, one for the NHS services and one for the Pharmacy (P) medicine sales and online private prescribing service. And they worked in two separate areas of the pharmacy, with clearly defined workstations. Several team members had left since the previous inspection. Team members were seen working well together and managing the workload and the dispensers were able to work across the different areas to cover absences.

The SI kept up to date with his knowledge and skills as part of his continuing professional development (CPD) for professional revalidation. He explained this included checking prescribing guidelines issued by National Institute for Health and Care Excellence (NICE) for medicines supplied by the pharmacy. However, the SI had not checked when contracting the prescribers' services whether they had the appropriate skills to prescribe for the conditions the pharmacy offered treatment.

Other team members didn't have a formal ongoing training plan to keep their knowledge up to date. They described how the SI trained them on any new systems that were introduced and any changes in the law or service provision. They regularly spoke together as a team, including about the ways services were provided and a team member described how they felt comfortable sharing ideas or raising concerns with the SI. Team members had received an appraisal in the last year, and in the meeting had discussed their performance, planned how to improve and what support was needed. The SI spoke with the prescribers on an ad-hoc basis via telephone calls. They discussed company related news and

discussions related to the pharmacy's prescribing guidance. The SI described plans to implement regular, formal meetings with the prescribers. The pharmacy didn't set any targets for services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are suitable for the services provided. They are clean, hygienic, and secure. The pharmacy's website is professional and easy for people to use. And it is mostly accurate and suitable for the services provided.

Inspector's evidence

The pharmacy was closed to public access and the entrance was secured to unauthorised admission. The pharmacy was in an adequate state of repair. On the ground-floor there was a large dispensary with a good amount of bench space and medicines storage for the workload. Medicines were stored in a very tidy way, with space between different medicines and strengths. There were many rooms that were unused, and these were accessible through one door that kept the area separate from the area the pharmacy team used for services. There was a risk of team members being locked into this area as the dividing door locked on closing with no ability to exit from the other side.

There were staff facilities with hot and cold running water and hand washing facilities. The dispensing area had a separate sink and hot and cold running water. The main pharmacy area was of a suitable temperature, with heaters high on the walls. There was sufficient lighting.

People accessed services through the pharmacy's website. The pharmacy's website displayed the voluntary GPhC logo. The name and physical address of the pharmacy was displayed on the website, and it was designed so the registration status of the pharmacy could be found by following the link from the GPhC logo. However, the pharmacy's registration number was incorrect. This was brought to the attention of the SI during the inspection. The website displayed the details of the pharmacy team, and the name and photograph of the SI was clearly displayed on the 'about' page. The registration status of the SI and the other prescribers could be found by clicking on their names.

People accessed the consultation questionnaire from a page listing the conditions the pharmacy treated. People were asked to answer a series of questions to help prescribers determine their suitability for treatment. The consultation questionnaires were mostly suitable for the treatments prescribed.

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

Summary findings

The pharmacy doesn't have enough safeguards in place to ensure it always manages its private online prescribing service appropriately. And it doesn't make sure people with ongoing treatment are suitably monitored. So, people may receive medicines that are not right for their needs. The pharmacy manages its other services appropriately. It obtains its medicines from appropriate sources. And team members carry out regular checks on medicines to make sure they are fit for purpose.

Inspector's evidence

People accessed services through the pharmacy's website and by contacting the pharmacy by telephone and email. The pharmacy's website detailed how to access both NHS and private services. This included explaining how to access the private online prescribing service and for the sale of medicines. The pharmacy had an NHS distance selling contract. It delivered all the medicines it dispensed either via a courier or its own delivery driver.

Prescribers worked remotely and had access to people's responses to the online consultation questionnaires and their summary care records to confirm suitability of treatment. Prescribers were also provided with a copy of the pharmacy's medication and guidelines document and people's previous ordering history to support them in making clinical decisions. There were examples of prescribers documenting the details of communication they had with people, on the person's electronic medical record. For example, on several occasions, one of the remote prescribers had provided people with instructions on how they should take their weight loss medicines. The pharmacy's interactions with people were limited. Some documented examples were provided of prescribers rejecting an order which was clinically unsuitable. An example was seen where a request for emergency hormonal contraception had been rejected Or, where the pharmacy had signposted people to another service provider.

In some instances the pharmacy relied on people's answers in the questionnaire rather than clinical test results and the prescribers based their decision to prescribe on this. For example, people completed the questionnaire for the treatment of cystitis were asked to self-declare they had taken a urine test and confirm a positive result. However, the pharmacy didn't make any independent checks to confirm the result or check to make sure people had properly completed the test. Additionally, the pharmacy didn’t always undertake ongoing checks with people prescribed weight loss medicines to ensure the treatment continued to be suitable for them. People prescribed weight loss medicines were not offered the option for contact with a prescriber, for example, via a video consultation or telephone. On several occasions the pharmacy had supplied people with weight loss medicines when they had a BMI below a score of 28 or they have not achieved a 5% reduction in weight after 12 weeks of treatment. This was not in line with the pharmacy’s guidelines document. The prescribers didn’t document a follow up review for people who didn’t lose the appropriate amount of weight to continue treatment.

Once a prescription had been authorised by a prescriber, it was sent electronically to the pharmacy for dispensing. The RP completed a check of the prescriptions. The RP explained the check he completed was based on the information on the prescription and the RP didn't routinely complete any clinical checks using information recorded on the system. So, checks were not made on the person's previous

supplies and the consultation questionnaires were not checked. It was difficult for the RP to ensure supplies were appropriate and in line with the pharmacy's medication guidelines document. For example, there were no checks on body mass index (BMI) changes.

The dispensing for the pharmacy's private online prescribing service and Pharmacy (P) medicines sales was managed in a separate room from the dispensing of NHS prescriptions, to ensure the services were kept separate. The pharmacy used baskets for the dispensing of all prescriptions and the processing of Pharmacy (P) medicines sales. This was to avoid different people's medicines from being mixed up. It had separate workstations for team members, in both areas and there was a clear workflow to reduce risk of error. Team members demonstrated their individual logins that allowed access to the electronic PMR system. This created an audit trail of tasks completed in case of queries or for learning following errors. Login was controlled by the team member's role and so this meant clinical checks could only be completed by a pharmacist. Prescriptions were not released for dispensing until a pharmacist had completed the clinical check. The workflow of all dispensing and checking was clearly visible in the workflow plan in the dispensing system. The RP had good visibility of the workload and the tasks being completed by each of the team members. The RP had knowledge of the risks associated with dispensing valproate for people who may become pregnant. He described how he took this into consideration when completing the clinical check on prescriptions before they were released for dispensing. But he didn't use the system to add notes for the dispensers and passing messages on relied on the individual pharmacist. The RP was not aware whether the pharmacy dispensed valproate for people requiring a pregnancy prevention programme and described somewhat relying on care home staff to monitor any prescribing of valproate for people living there.

The PMR system used barcode technology throughout the dispensing process, so barcodes were printed on the dispensing and name and address bag labels. This tracked people's medicines through the dispensing and delivery process. For example, for NHS services, the team knew which medicines had been delivered to and been received by the care homes. Team members scanned the manufacturer's barcode as part of the labelling process, to helped identify any selection errors before the final check. The dispensers working in the pharmacy were accredited accuracy checkers. They completed the final accuracy check, using the barcode technology. They checked medicines dispensed in split packs, fridge lines and other medicines such as valproate, as authorised through the clinical check. They were not authorised to check CDs. The pharmacist completed the final accuracy check on medicines that the accuracy checkers had dispensed, including for multi-compartment compliance packs. There was a manual process of inputting the invoice number on the prescription to print the postal label, as there was no barcode associated with this system. The team members packing and labelling the prescriptions for delivery by post and courier, made a series of checks as they worked to reduce errors.

The pharmacy dispensed medicines in multi-compartment compliance packs for people living in the community and one of the dispensers organised this workload. They used the PMR system to record when the prescriptions were ordered and then used these details to check the accuracy of the prescriptions they received back from the surgery. This was completed in advance of the packs being needed, so they had time to query any missing items with prescribers in good time. The pharmacy printed backing sheets with details of the name of the medicine, the time of administration and with descriptions of what the medicines looked like. The details of how to take medicines included the mandatory warning labels, but the font on some of the warning labels was small and people may have difficulty in reading it. This was highlighted at the last inspection. The dispenser scanned the manufacturer's barcode prior to assembly to help ensure they had selected the correct medicines. The pharmacy supplied medicines for people living in care homes in the original manufacturer's packs and supplied these with medication administration records (MARs).

An employed delivery driver delivered to people who lived locally. This was mainly for NHS prescriptions and included delivering to people living in care homes. The pharmacy used the postal service and a recognised courier for delivery of medicines for its private services and medicine sales. People had the option of 48 hour delivery or the use of a courier for more urgent deliveries within 24 hours. Team members processed prescriptions requiring different delivery methods separately. The pharmacy had the ability to track prescriptions delivered by post and couriers, and by their delivery driver. Since the last inspection, the pharmacy had introduced an electronic delivery solution for prescriptions delivered by the employed delivery driver. It was clear which prescriptions were being delivered that day and the system held records of completed and failed deliveries. The driver took photographs of signatures and packages on the doorstep as evidence of a successful delivery.

The pharmacy obtained medicines from recognised wholesalers. It had medicinal waste bins for pharmaceutical waste, stored appropriately. But reportedly, there had not been a pickup for several months. It had an up-to-date rota for checking expiry dates and the team regularly used red stickers to highlight short-dated stock. No out-of-date medicines were found on the shelves. The pharmacy had a large, glass-fronted medical fridge, which was reading within the required range during the inspection. The team recorded the fridge temperature daily as seen by the records. The pharmacy had appropriately investigated a reading outside the accepted range. The fridge was kept tidy, using baskets to keep medicines separated.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for its services. And it uses its equipment appropriately to protect people's confidentiality.

Inspector's evidence

The pharmacy had reference resources and use of the internet to obtain up-to-date information. It had a clean glass CE marked measuring cylinder for liquids, but also had two plastic non-CE marked measures that had not been replaced since the last inspection. The pharmacy had password-protected computers and used the correct NHS smart card for the dispenser working.

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.