General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Montu Pharmacy, 140 Wharfedale Road, Winnersh Triangle, Reading, Berkshire, RG41 5RB

Pharmacy reference: 9012316

Type of pharmacy: Internet / distance selling

Date of inspection: 31/07/2024

Pharmacy context

This is an internet pharmacy which is closed to the public. The pharmacy does not have an NHS contract. It specialises in dispensing private prescriptions for specific controlled drugs. And it receives most of these prescriptions from specialist prescribers in Care Quality Commission (CQC) registered clinics. People do not access the pharmacy premises to obtain their medicines, instead the pharmacy arranges delivery of their medicines.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
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 met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy identifies and manages the risks associated with its services. And it has up-to-date documented procedures to ensure it provides its services safely and effectively. Its team members understand their role in helping to safeguard vulnerable people. And they act on people's feedback to help improve the quality of services. The pharmacy suitably protects people's private information. And it keeps the records it needs to by law.

Inspector's evidence

The pharmacy solely dispensed private prescriptions for specific controlled drugs (CDs). The CDs it dispensed were unlicensed medicines, or 'specials.' The pharmacy had close links with a specialist service for prescribing these medicines. But it operated as a separate legal entity to it. While the pharmacy worked closely with this particular prescribing service and its clinic in London, other CQC registered clinics providing a similar service could also use the pharmacy. Each clinic and its prescribers had registered on the pharmacy's website. But the majority of the pharmacy's workload was generated from the CQC registered clinic it was linked to. Many of its prescribers worked remotely. And the pharmacy's digital platform allowed prescribers to securely upload scans of private prescriptions for the specific CDs ahead of providing the pharmacy with a hard copy of the prescription. Hard copies were written on the appropriate CD private prescription form. And the pharmacy did not supply any medicines until it had received the hard copy of the prescription.

The pharmacy had an electronic system for recording its 'near miss' mistakes. Which were mistakes found and corrected during the dispensing process. Team members used the system competently. And they could describe the actions they had taken to reduce the risk of repeating the same or similar mistakes. Follow up actions included improving learning associated with the specific products stocked and ensuring those with similar names and packaging were not held too close together. Pharmacy team members also understood how to respond to, and report mistakes with a medicine which had reached a person. And the pharmacy kept electronic reports of these types of dispensing incidents. Records included details of the investigation and actions taken to reduce the chance of a similar incident occurring again. Team members described how they had responded to an incident involving the wrong patient address. Following the incident, the team introduced a system of producing an extra patient address label in addition to the label attached to the dispensed item. The second label provided an additional cross check to ensure that the item was addressed to the correct person. The team reviewed its near misses and incidents regularly. It discussed issues at its daily briefing meetings and at its twice weekly governance meetings. It also had monthly review meetings which involved the whole team. The Superintendent (SI) described how team members investigated their own mistakes with the support of a pharmacist or technician. But each month the team also shared learnings from each other's mistakes. They did this by investigating and assessing another team member's mistake. And discussing their findings with each other.

The pharmacy employed a dedicated governance manager. The governance manager managed any complaints and any feedback from people. She also monitored the pharmacy's social media accounts and Trust Pilot reviews for comments about the pharmacy's service. By doing this she had identified a recurring problem with delays in deliveries to some remote locations. And so, the team worked with its Royal Mail account managers to ensure that unnecessary delays were avoided. All team members had a

customer facing role. And the dispensing assistants (DAs) answered non-clinical queries from people accessing the service. And they knew to refer queries to the responsible pharmacist (RP), SI or governance manager as appropriate. DAs described their daily tasks of labelling, picking and dispensing medicines. And they dispensed the medicines against the original prescription only after the RP had clinically checked it. And after the appropriate ID checks had been made. And payment taken.

The pharmacy had risk assessments (RAs) to identify and manage the risk of providing a dispensing service for the specific controlled drugs (CDs) it supplied. It had conducted RAs using a template which assessed risks step-by-step. The RA seen identified the risks associated with providing the service at a distance, and it detailed the controls and measures in place. These included measures to help prevent oversupply of medicines to people. The RA included a business continuity plan to ensure continuation of supply of medicines if services were disrupted due to an equipment or an IT failure. The RA also specified risks and mitigations regarding verifying people's identity. The RAs were specific to the controlled drugs dispensed and were dated with the last review date. There was a rolling plan to review each RA regularly and when required.

The pharmacy worked closely with the clinic to identify vulnerable people. And to identify any potential for diversion. And it had limits on the quantity of medicine supplied to one person. Quotas were unique to individuals depending on whether they were identified as vulnerable or new to a medicine. The pharmacy had a set of standard operating procedures (SOPs). The SOPs had all been reviewed since the pharmacy relocated and opened approximately six months earlier. And team members had completed training competencies in relation to the SOPs and had signed to accept they would work in accordance with them. All team members on duty were confident in demonstrating how they completed their tasks and showed a clear understanding of both their own job roles, and of the job roles of other team members. Newer team members were supported initially during their induction process by shadowing colleagues before undertaking tasks themselves. Pharmacy team members were knowledgeable about the types of medicines they handled and understood processes required by law. For example, the requirement to have the original prescription onsite before supplying a CD. Workload was managed well with planned time for the pharmacist to complete clinical checks of prescriptions and accuracy checks of medicines.

The pharmacy had not yet completed any specific clinical audits related to the supply of medicines through its service. But it planned to do so within its first year of operating. Audits would include identification of potential excessive supplies and identification checks to support the ongoing monitoring of the pharmacy's risk management processes. And they would monitor day-to-day performance of the pharmacy's services against a known standard, a key requirement in a clinical audit. The pharmacy submitted the private CD prescriptions to the NHS Business Services Authority every month as required. This was to ensure an external visibility of prescribing activity. And it kept copies of the prescriptions in the pharmacy.

Pharmacy team members engaged in regular team meetings to share learning from patient safety events and the team documented these learning points. The pharmacy had a procedure for managing feedback and complaints. And it provided clear information on its website about how people could contact the pharmacy or raise a concern. The pharmacy's governance manager liaised with the pharmacy team and clinics when resolving these concerns. Concerns were escalated to the SI and the RP as appropriate.

The pharmacy had current indemnity insurance arrangements. A sample of records required by law were examined. The responsible pharmacist (RP) notice was displayed prominently and contained the correct details of the RP on duty. The RP record was held electronically and completed as required.

The pharmacy held completed certificates of conformity for the specials medicines it dispensed. And it stored these securely. The pharmacy kept an up-to-date electronic CD register with daily balance checks of physical stock against the register. Physical balances of CDs checked during the inspection complied with the balances recorded in the register. Entries within the register were seen to comply with legal requirements. The pharmacy had specific procedures relating to information governance and data security. Which set out how it protected people’s confidentiality. Its website contained details of its privacy policy and team members understood how to process people’s confidential information securely. All records were held securely and there was no public access to the building. The pharmacy held confidential waste securely and this was collected periodically by a secure shredding company. The pharmacy had specific SOPs relating to safeguarding vulnerable people. And contact information for safeguarding teams was accessible. Pharmacy team members described how they would identify, and report safeguarding concerns and they had completed some learning on the subject. The pharmacy completed identification checks when people registered to use its services to ensure it was supplying medicines to the correct person. And people could request additional consultations if they needed extra support.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has put suitable measures in place to ensure it manages its workload safely and effectively. And its team members support one another. Team members are comfortable about providing feedback to one another so they can maintain the quality of the pharmacy's services. And they have the right skills and training for their roles.

Inspector's evidence

The SI and the RP worked alongside each other regularly. And both were on duty during the inspection. Other team members present included a third pharmacist, an accuracy checking technician (ACT) who was also the pharmacy manager, two dispensing assistants (DAs), the governance manager, a human resources manager, a dispatch operative and a support associate, who managed administrative tasks. The commercial general manager was also present alongside a director who supported with the general running of the pharmacy. Due to the specialist nature of the business pharmacist cover was provided by the SI, the RP and a well-trained regular locum. And between them they provided cover during busy times and holidays. The SI consistently reviewed levels of staff. And she explained how they had recruited further team members due to increased service demand since the pharmacy opened. The pharmacy maintained a training portfolio with evidence of qualifications and regular e-learning completed by its team members. Team members also received additional product training from individual manufacturers. When locum pharmacists started with the pharmacy, they were required to shadow the RP and the other team members. They were also required to complete specific training to allow them to understand the clinical considerations of providing the specific controlled drugs. This helped ensure they had sufficient knowledge to carry out appropriate clinical checks.

Pharmacists demonstrated evidence of reading they had completed to support them in their role. And they provided some examples of where they had questioned the appropriateness of a prescription. The dispatch operative had completed learning associated with the specific tasks they completed. Team members engaged in regular discussions and learning focussed on patient safety. Pharmacy team members found the SI, RP and pharmacy manager accessible and approachable and felt empowered to make suggestions for improvements. For example, the pharmacy had implemented specific notes to help team members make sure prescriptions were dispensed no later than 28 days after they were written. Pharmacy team members did not have any specific targets to meet, other than to meet its next day delivery deadline. And at the time of the inspection the team was up to date with its workload. The RP felt able to apply their professional judgement when providing the pharmacy’s services. The pharmacy had a whistle blowing policy. And its team members had a good understanding of how to raise concerns and share feedback with one another. They shared their ideas and learned from one another. And team members added information notes to prescription forms to communicate key messages. And to keep one another informed throughout the dispensing process.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are suitable for the provision of the specialist healthcare services provided. And they provide an adequate amount of space for those services. The pharmacy is sufficiently clean, secure. And it is well maintained. The team keeps its workspace and storage areas appropriately tidy and organised.

Inspector's evidence

The pharmacy's website included the name, address, and contact information for the pharmacy. It also provided details of the SI. The pharmacy was secure. It had a doorbell for visitors to use. And after a staff member let them in, visitors signed a visitors’ book. They recorded the time they arrived. And the time they left. The pharmacy had been recently fitted out. So, it was in a good state of repair. It was clean and tidy. And its floor spaces were free of unnecessary clutter. And any trip and fall hazards. It had hand washing facilities available to its team members. And it was bright and well lit. The premises had air conditioning and temperature controls in place. And it had been laid out to provide separate areas for dispensing, clinical checking and accuracy checking. And it had a distinct area for packing and dispatching prescriptions. The team had put tape on the floor to define the dispensing area. And to create a walkway between the dispensing area and the pharmacy’s two offices. And its staff area. The pharmacy had been laid out to provide a clear and logical workflow. And it had three separate dispensing work surfaces with storage underneath. The team kept each section neat and tidy. And it made good use of the space available.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has suitable safeguards to ensure it delivers its services safely. It makes adequate checks to ensure the medicines it supplies are safe and clinically appropriate for people to use. The pharmacy stores and manages its medicines appropriately. And it has systems to manage the safe delivery of medicines to people's homes.

Inspector's evidence

People contacted the pharmacy by telephone, online chat, or email. Team members dealt with initial queries and referred to the RP or the SI for clinical issues or if people needed to ask about their medication. Including when they had questions about side effects or adverse reactions. The pharmacy did not regularly contact people about their medicines after supply. This was generally done by the prescribing clinic. The inspector discussed this with the SI who agreed that this could form part of a future audit. They could do this to assess if people found it helpful to also have regular contact from the pharmacy. This would allow the pharmacy to further explain dosages and offer support.

Prescribers from the specialist clinics wrote their prescriptions on the required NHS CD private prescription forms, known as FP10PCDs. And they sent them by Royal Mail through a secure trackable service. The pharmacy offered its secure digital platform to clinics prescribing these specific CDs. And they used this platform to submit prescription information electronically ahead of providing the pharmacy with a paper prescription form. This allowed the pharmacy to manage stock and plan workload before the paper prescriptions arrived. Clinics were required to register on the platform, as was each prescriber. On receipt of the paper prescription, the RP or SI completed a clinical check to ensure that the prescription was appropriate. It was then passed to a team member who matched the prescription to the electronic record. When the patient had paid for the prescription, it was then released for dispensing. The digital record provided an audit trail of each stage of the process.

The dispensing team completed labelling and assembly tasks prior to medicines being accuracy checked by a pharmacist or the ACT. When labelling, DAs selected the product from the formulary via a drop-down menu. Any unusual or new products would require the formulary to be updated after approval by the RP or SI. Labels contained appropriate adverse warnings and were applied with care to ensure that they did not inadvertently cover any important information on the manufacturer's original pack. The team tasked different team members with the roles of selecting the medication and applying the dispensing label. It did this to keep these tasks separate to reduce the chance of error.

Pharmacists and ACTs had access to medication history records on the pharmacy's IT system. And they referred to these when conducting their final accuracy checks of dispensed medicines. The team packaged the medicines securely with an address label and tracking ID and held the packages securely until collected by the courier. The prescribing clinics could see when individual prescriptions had been supplied by the pharmacy. This helped to prevent the prescribing of medicines before their next due date. The SI described how the prescribing clinics conducted both face-to-face consultations and remote consultations as part of the prescribing process. It checked the registration of medical doctors to ensure they were on the General Medical Council's (GMC's) specialist register as required. And it would conduct regular checks to ensure that prescribers remained on the register. The SI reported that the pharmacy completed onboarding checks before partnering with clinics to ensure that they were

satisfied with the safety and appropriateness of their prescribing policies and procedures. The pharmacy team worked closely with specialist consultants and other prescribers at the clinics. Other prescribers worked according to a shared care agreement. The SI was also a prescriber. And she would often write a prescription for a replacement product if the original item was not available from the supplier. She did this to ensure that people did not go without their medicine. She spoke to consultants regularly and she used the online messaging system to check with them that they were happy with what she proposed to prescribe. She generally did this for people who were stable on their medication. And she followed good practice guidance in doing so.

Pharmacy team members used baskets throughout the dispensing process to keep medicines and their prescriptions together, to reduce the risk of error. The team supplied all medicines in their original, sealed containers. The pharmacy's electronic PMR system captured details of who had been involved at each stage of the process. This showed who had dispensed, labelled, checked and packaged the product. The pharmacy also had processes to support the safe dispensing of owed medicines. This included using the
original prescription throughout the dispensing process when supplying owed medicines. People receiving unlicensed medicines did not receive manufacturer's information leaflets with the products due to the unlicensed nature of the medicines. Dispensing and product labels included information about the risks associated with driving under the influence of the medicine. The pharmacy's website covered additional information on common uses and side effects of each product.

The pharmacy used a secure trackable delivery service, to ensure people's medicines were delivered safely and securely. And it could access delivery information to help answer queries. The pharmacy sourced medicines from licensed specials suppliers. It completed regular assurance checks to ensure specials suppliers held the appropriate licences approved by the Home Office and the Medicines and Healthcare products Regulatory Agency (MHRA). The pharmacy stored its CDs appropriately and a pharmacist was always present during working hours to oversee safe storage and access to medicines. And so, all CDs were under the direct supervision of a pharmacist during the working day. Team members conducted a full stock audit every morning to ensure the quantities in the CD cabinets matched the running balance showing in the register.

Due to the specific CDs being natural products they were vulnerable to environmental factors. The pharmacy stored its medicines securely in cabinets. And it monitored temperatures of the pharmacy environment and its fridge. Team members regularly date checked the pharmacy's stock. And it routinely checked expiry dates during the dispensing process. The SI and inspector discussed the supply of medicines close to their expiry date and the SI agreed that it was important to ensure that medicines would remain in date for the duration of treatment. The pharmacy had an effective system for receiving and acting upon medicine alerts issued by the MHRA. The pharmacy contacted manufacturers following people raising concerns about their medicines. And it updated people with the manufacturer's findings.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has appropriately maintained equipment and facilities for providing its services. And its team members use the equipment in a way which protects people's confidentiality

Inspector's evidence

Pharmacy team members had access to up-to-date electronic reference resources. They could access the internet to help resolve queries and to obtain up-to-date information. The pharmacy's computer systems were password protected and information was regularly backed up. The pharmacy had a range of clean equipment available to support the delivery of pharmacy services. This included calibrated measuring cylinders for measuring liquid medicines. The pharmacy used appropriately robust packaging materials. And electrical equipment was in good working order.

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.