General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Burnham Health Pharmacy, 30 High Street, BURNHAM, Berkshire, SL1 7JP

Pharmacy reference: 1029095

Type of pharmacy: Community

Date of inspection: 09/10/2024

Pharmacy context

This is a community pharmacy in the centre of the large village of Burnham, Berkshire. The pharmacy dispenses NHS and private prescriptions. It sells over-the-counter medicines and provides advice. The pharmacy also offers local deliveries and supplies people with their medicines inside multi-compartment compliance packs if they find it difficult to take them. This inspection was conducted following receipt of concerns about unauthorised access to confidential information and prescription-only medicines (POMs).

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 is not identifying and managing several risks associated with its services. Staff are not routinely working in line with all of the pharmacy's standard operating procedures (SOPs). And there is evidence that things have gone wrong because of this.
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. Staff are not routinely recording details about incidents, complaints or near misses. And there is little to no evidence that appropriate remedial activity is taken or learning occurs in response to mistakes.
		1.7	Standard not met	The pharmacy does not sufficiently protect the privacy, dignity and confidentiality of people who use the pharmacy's services.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.2	Standard not met	The pharmacy's facilities for private and confidential conversations and services are not sufficient to protect the dignity and confidentiality of people.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy's services are not managed or delivered safely and effectively. There are risks associated with the delivery service and the preparation and assembly of multi-compartment compliance packs. And there is evidence that mistakes have subsequently happened.
		4.4	Standard not met	The pharmacy cannot demonstrate that it has appropriate procedures in place to raise concerns when medicines or medical devices are not fit for purpose. There is limited evidence to verify that the pharmacy team has been dealing with and appropriately acting upon the drug alerts issued by the Medicines and Healthcare products Regulatory Agency.
5. Equipment	Standards	N/A	N/A	N/A

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	met			

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

Summary findings

The pharmacy does not effectively identify and manage all the risks associated with its services. The pharmacy has written procedures in place to help guide its team members, but staff are not always following them. It is unable to fully demonstrate that it records all its mistakes or learns from them. And the pharmacy does not sufficiently protect people’s confidential information. But members of the pharmacy team understand how to safeguard the welfare of vulnerable people.

Inspector's evidence

The pharmacy was inspected because of a number of concerns that had been raised with the GPhC; an inspection was subsequently carried out to assess the situation. The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The pharmacy had a range of current standard operating procedures (SOPs) to provide its team with guidance on how to complete tasks appropriately. Most of the staff had read and signed them to confirm this. However, recently employed staff including one of the accuracy checking technicians (ACTs) had not seen nor read them despite working at the pharmacy for a few weeks in this capacity, and the latter was unaware whether there was an SOP to cover her role. In addition, team members were not always working in accordance with the SOPs (see below and under Principle 4).

In response to incidents, the regular responsible pharmacist (RP) described speaking to people, apologising, taking more care, and placing details on people's individual medication records. However, it was evident that pharmacists were not managing incidents appropriately nor was their process in accordance with the SOPs. The company who owned the pharmacy had provided the GPhC with some written details of explanations following some of the complaints made. However, this information, in some cases was insufficient. People directly involved had not been informed about the incident, the superintendent pharmacist or directors completing the details had not identified the root cause nor sought measures to fix this, there were no documented details about these incidents present at the pharmacy, staff could not recall specific details about the incidents, this included the root cause, and they could not bring up the records for all the people involved. In addition, the pharmacy's SOP stated to record and retain details within incident forms but only one adverse event form from 2023 was present. Blank templates for incident reports were seen.

Once prescriptions had been processed and assembled, the ACTs as well as pharmacists could carry out the final accuracy-check. Before this task was undertaken, the RP clinically checked the prescription(s) before other staff assembled it. The clinical check was marked on the prescription by the RP which helped identify that this stage had been completed. The ACTs confirmed that they were not involved in any other dispensing process other than the final check. The pharmacy's team members were observed to work in set areas. There were separate sections for the pharmacists (and ACTs in this role) to undertake the final accuracy-check of assembled prescriptions which helped minimise distractions. From these positions, pharmacists could also supervise retail transactions easily. Staff said that after prescriptions were processed, one person selected stock and others dispensed where possible to help minimise the risk of making mistakes. Staff were informed about prescriptions requiring priority. However, team members were observed using generated dispensing labels to select stock against as opposed to prescriptions, the dispensary was cluttered, there were concerns noted with the pharmacy's stock (see Principle 4) and every workspace was full of baskets containing prescriptions and stock. This

left limited space for staff to work safely.

Team members described separating medicines which looked-alike and sounded-alike and highlighted certain common medicines with shelf-edge prompts (such as amlodipine and amitriptyline). Errors that occurred during the dispensing process (near miss mistakes) were said to have been passed back to staff for them to identify and record. However, the last recorded records were from August 2024 and only included two entries. Prior to this, most entries only included a few details whereas in previous years, more entries had been recorded. The pharmacy had become busier since then and these entries were not in accordance with the pharmacy's current volume of dispensing. There were also no details recorded to indicate that a review of mistakes was frequently taking place.

The pharmacy's chaperone policy was on display. Staff had been trained to safeguard the welfare of vulnerable people, they could recognise signs of concerns and knew who to refer to in the event of a concern. Contact details for the local safeguarding agencies were easily accessible. One pharmacist was trained to level two for this but the regular RP was unsure what level training to safeguard vulnerable people she had completed. She believed this was level two and was advised to check and complete this to this level if needed.

The pharmacy was registered with the Information Commissioner's Office (until January 2025) and team members used their own NHS smartcards to access electronic prescriptions. However, complaints that had been made to the GPhC involved data protection breaches. During the inspection, the inspector witnessed the pharmacy team and people employed by the pharmacy failing to adequately protect people's confidential information. People were frequently brought into a small area in front of the consultation room to discuss certain matters, however this area was adjacent to the dispensing bench where several assembled prescriptions were awaiting a final check. People's details could be clearly seen when people stood in this area. The pharmacy had not identified this risk nor sought to implement suitable measures to prevent people from viewing this information. Bagged prescriptions awaiting collection were stored with people's bag labels facing the retail area.

In addition, a person employed by the pharmacy to carry out vaccinations frequently breached people's confidential information. COVID-19 and flu vaccinations were being administered at the front of the pharmacy (see Principle 3). Several people were seated here waiting for their vaccination and whilst they waited, the inspector observed the person vaccinating to approach people with a sheet containing people's names and sensitive information. He was seen to bend down, point to people's names, and ask people to confirm who they were without covering other people's details whilst he did this. From where the inspector was standing and people were sitting, it was clear that confidential details of other people using this service could be clearly seen. There was no evidence that this person had received any training about data protection or signed any confidentiality clause.

The pharmacy had current professional indemnity insurance. A sample of registers seen for controlled drugs (CDs) and the RP record had been maintained in accordance with legal requirements. On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding registers. Records of CDs that had been returned by people and destroyed at the pharmacy had also been suitably maintained and records verifying that fridge temperatures had remained within the required range had been completed. However, there were incomplete details about prescribers within the electronic private prescription register and missing details for records of unlicensed medicines. This was discussed during the inspection.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy’s team members have a range of skills and experience. The pharmacy provides them with some support, and they feel confident to raise concerns. But they do not have access to any resources so that they can complete regular and ongoing training. This could affect how well the team conduct tasks and adapt to change with new situations.

Inspector's evidence

On the day of the inspection, two pharmacists were present, one of whom was a director of the company who owned the pharmacy, the other was the regular employed RP. There were also two ACTs, a trained dispensing assistant, a pharmacy student who usually worked on the weekend and two medicines counter assistants (MCAs), one of whom was very newly employed. This was a busy pharmacy. Staff were a few days behind with the workload and the inspector was told that there had been some upheaval with the team as some staff had left, others had been recruited and new people had started. The pharmacy's volume of dispensing had also increased significantly due to other pharmacies in the local area struggling to obtain stock.

The MCAs asked relevant questions before selling medicines and they referred appropriately. Some long-standing staff had received formal performance reviews, others had not had any but described being able to raise concerns easily. The team communicated verbally and received updates when needed. However, there appeared to be no training resources provided for staff to regularly complete ongoing training. Some team members explained that they had received formal training (for example on safeguarding vulnerable people) through previous employment and others looked up things for themselves. This risked staff not keeping their skills and knowledge up to date.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy does not provide suitable spaces for private conversations or services to take place. But, in general, the pharmacy's premises provide an adequate environment for the delivery of healthcare services.

Inspector's evidence

The pharmacy was situated inside a listed building. The lighting and ambient temperature within the pharmacy was adequate for storing medicines. However, the layout was convoluted. The retail area was arranged around a central enclosed staircase which led to the upper floor. This held office, staff areas and storage space. An open-plan dispensary was situated at the very rear of the ground floor on a mezzanine level. The dispensary was small with limited space for staff to carry out dispensing tasks safely. The pharmacy premises' façade, décor, fixtures, and fittings were dated in appearance, but this did not present a significant risk to the pharmacy operating safely. A room which was off one side of the dispensary and behind the medicines counter was being used as the pharmacy's consultation room. This room was small and not signposted to indicate its use or presence. However, as stated under Principle 1, staff were frequently observed using the space outside the consultation room and between the dispensary to hold conversations with people and discuss services. This was an unsuitable area to do this in. In addition, a makeshift room had been erected at the very front of the store for vaccinations to take place. This was partly open so people could be viewed whilst they had their vaccinations and rendered limited privacy or confidentiality.

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

Summary findings

The pharmacy cannot always show that all its services are provided safely or that its medicines are always stored in a safe and effective way. The pharmacy cannot show that it safely delivers medicines to people, or that it assembles its compliance packs in a safe way. The pharmacy cannot show that it routinely deals with safety alerts appropriately. This risks people receiving medicines and devices that are not safe to use. But the pharmacy obtains its medicines from reputable suppliers.

Inspector's evidence

People could enter the pharmacy from the street but there were two parts to the retail area, with steps to access the medicines counter and dispensary. This meant that people using wheelchairs could not easily enter this area. Staff described physically assisting people when needed. There were some chairs inside the pharmacy if people wanted to wait for their prescriptions, the pharmacy's opening hours were on display and services were advertised. Staff could make suitable adjustments for people with diverse needs, they provided details verbally or in a suitable written format and used representatives when needed.

The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer. Once staff generated the dispensing labels, there was a facility on them to help identify who had been involved in the dispensing process. Team members routinely used these as an audit trail.

People's medicines were delivered to them, and the team kept records about this service. This helped verify and trace who had received their medicines in this way. CDs and fridge lines were highlighted but failed deliveries were not always brought back to the pharmacy. The inspector was told that the driver called the pharmacy to check the next step in this event, CDs and fridge lines were not left unattended, team members contacted people and advised them that they could not leave medicines outside and attempted to rearrange. However, the pharmacy permitted medicines to be posted through people's letterboxes. There were no details documented to help justify this practice. No relevant checks were made to mitigate risks or determine whether this was safe (i.e., whether any pets or children were present) and this was not in accordance with the pharmacy's SOP for deliveries which specifically stated to not leave failed deliveries unattended. This SOP or practice had also not been reviewed considering one of the incidents reported to the GPhC.

The pharmacy also provided people with their medicines inside multi-compartment compliance packs once a need for this had been identified. The team ordered prescriptions on behalf of people, but some staff could not inform the inspector of how changes were identified. All the medicines were de-blistered into the compliance packs with none supplied within their outer packaging. However, the compliance packs were often left unsealed overnight, and this was evident at the inspection. This risked the contents being tipped, mistakes and potential contamination occurring. Descriptions of the medicines inside the compliance packs were inaccurate and patient information leaflets (PILs) were only supplied if medicines were new. Routinely supplying the latter is a legal requirement. These practices risked people not receiving the full details or being unable to potentially identify their medicines.

Staff were aware of the additional guidance when supplying sodium valproate and the associated Pregnancy Prevention Programme (PPP). They ensured the relevant warning details on the packaging of these medicines were not covered when they placed the dispensing label on them, but it was unclear if the pharmacy had identified people at risk, who had been supplied this medicine. Team members explained that prescriptions for people which required counselling were highlighted but people prescribed other higher-risk medicines or medicines that required ongoing monitoring were not routinely identified unless they were new. The team did not routinely ask relevant questions or details about their treatment nor was this information regularly recorded.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. The team checked medicines for expiry regularly and there were records to verify when this had taken place. Short-dated medicines were identified and on randomly selecting some of the pharmacy's stock, there were no medicines seen which were past their expiry date. CDs were stored securely and the keys to the cabinet were maintained in a way which prevented unauthorised access. Medicines which were returned to the pharmacy by people for disposal, were accepted by staff, and stored within designated containers. This did not include sharps or needles which were redirected appropriately. However, medicines in the dispensary were stored in a disorganised way. There were loose blisters on shelves, a basket that was full of medicines which had been removed from their original containers and were poorly labelled with missing expiry dates and batch numbers as well as vaccines requiring cold storage which had been stored in the fridge used to store the team's food. Drug alerts were received electronically via email. Staff explained the action the pharmacy took in response, but the alerts seen on the pharmacy's email system were unopened.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has a suitable range of equipment and facilities available. And it's equipment is appropriately maintained.

Inspector's evidence

The pharmacy had the relevant equipment needed and it was appropriately maintained. This included access to the internet, counting triangles which could have been cleaner, standardised, conical measures, pharmacy fridges, a legally compliant CD cabinet and a clean sink that was used to reconstitute medicines. Hot and cold running water was available as well as hand wash. The pharmacy's computer terminals were positioned in a way and location that prevented unauthorised access. Cordless phones were also available so that private conversations could take place away from the retail space if needed.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.