General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Gt. Berry Pharmacy, Unit 4 Gt Berry Centre, Nightingales, Langdon Hills, BASILDON, Essex, SS16 6SA

Pharmacy reference: 1031017

Type of pharmacy: Community

Date of inspection: 16/05/2023

Pharmacy context

This pharmacy is situated next to a surgery in a residential area. As well as dispensing NHS prescriptions the pharmacy supplies medicines in multi-compartment compliance packs to help people take their medicines safely. It also provides a smoking cessation service and flu vaccinations.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not sufficiently identify and address key risks to patient safety from its activities and services. For example, it does not ensure that its standard operating procedures are being followed, or that team members are familiar with them. And this increases the risk to people using the pharmacy's services.
		1.6	Standard not met	The pharmacy does not properly maintain all the records it needs to.
		1.7	Standard not met	The pharmacy does not always manage its confidential information properly or dispose of its confidential waste securely. This could result in people's personal information being disclosed.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	Areas of the pharmacy including the dispensary are cluttered and disorganised. And this could increase the risk of dispensing errors. The fire exit is not kept clear, which presents a risk if the pharmacy needs to be evacuated.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always provide its services safely. For example, team members do not always refer to the prescription when dispensing owed items
		4.3	Standard not met	The pharmacy does not always store its medicines securely and in accordance with legislation. And it cannot show that it always stores medicines which require refrigeration appropriately.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not appropriately identify and mitigate the risks associated with its services. Its team members are not all familiar with its written procedures and they do not always follow them. The pharmacy does not always store or dispose of people's personal information properly. And it does not maintain the records it needs to or keep them up to date. Team members do not always make records of dispensing mistakes, and this could make it harder for them to learn from them and to make the pharmacy's services safer.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) which were available. All team members had not signed the SOPs that were relevant to their roles to indicate that they had read them. And the team members who were working on the day of the inspection confirmed that they had not read the SOPs. SOPs were observed not to be consistently followed. For example, prescription forms for owings were not retained to be used when dispensing items owed to people. This had previously been flagged to the owner who was also the regular responsible pharmacist (RP).

The pharmacy was not currently recording dispensing mistakes which were identified before the medicine was handed out (near misses). The last recorded near misses seen to be recorded were from January 2023. The RP said there had been more near misses since then. Any dispensing errors (where a mistake had happened, and the medicine had been handed to a person) would be recorded on the near miss log. The RP said there had not been any dispensing errors for some time. Using an incident report form was discussed with the RP as the information recorded on a near miss log was brief.

The correct RP notice was displayed. The team members were aware of the tasks that could and could not be carried out in the absence of the RP, although one of the team members had to be reminded by colleagues. The pharmacy had current professional indemnity insurance. The RP said that he would speak to people if they had a complaint to see if there was anything which could be changed.

Private prescription records had not been made since November 2022. Electronic records seen on the PMR indicated that no private prescriptions had been dispensed. The RP said this was not the case. Private prescription forms which had been dispensed were not available at the pharmacy as these had been taken home by the RP as he was behind with his VAT paperwork. Records of emergency supplies and records for unlicensed medicines dispensed were well maintained. Entries had not been made in some CD registers for approximately a week in some registers, despite there being evidence of supplies having been made over that time. Responsible pharmacist records had not been made since 29 April 2023.

Assembled prescriptions were stored under the medicines counter and were not visible to people using the pharmacy. Computers were password protected. The RP, dispenser and medicines counter assistant had NHS smartcards. The RP had access to Summary Care Records and consent was gained verbally from people to access these. The RP said an information governance policy was in place which was reviewed annually. The computer in the dispensary was password protected and out of view of patients and the public. The computer in the unlocked consultation room was running and had people’s personal data visible on the screen. A shredder was available. Some confidential waste was seen in the

general waste bin. The RP described how the bin was only used to discard paper and was separated out by team members to be shredded. However, when asked, team members said that the bin was used for general waste. And some confidential information was kept in a location which was not secure.

The RP had completed a level two safeguarding course, new team members had not been briefed or completed any safeguarding training. The dispenser explained that she had completed safeguarding training at one of her previous workplaces. Details for local safeguarding contacts were available in the pharmacy.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to provide its services, however the team is relatively new and inexperienced. Team members had not received much training since starting in their roles and there is no structured framework for ongoing training. This could make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

At the time of the inspection the pharmacy team comprised of the RP, two counter assistants and a trained dispenser. Both counter assistants had started two and three weeks before the inspection and the dispenser had started the day before the inspection. Other team members who were not present included the RP's son (a trainee dispenser), a trained dispenser, and a trained medicines counter assistant. And there were two team members who the RP said had started working at the pharmacy a month prior to the inspection and who he planned to enrol on dispenser training programme.

The team was relatively new and had not worked at the pharmacy for very long. Staff performance was managed informally by the RP. Team members had been verbally briefed by the RP when they had first joined on patient confidentiality and operating the till. None of the new team members had read any of the SOPs. on some things. The RP said he planned to enrol team members on relevant accredited courses in due time. The dispenser was heard suggesting new ways of working to the RP which they were due to discuss.

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

Summary findings

The pharmacy does not keep its premises tidy. They are cluttered and disorganised, with little or no clear dispensing space. This could increase the risk of mistakes happening. The pharmacy does not keep its fire exit clear, which increases the risk to staff and people using the pharmacy. However, the premises are kept secure from unauthorised access when closed.

Inspector's evidence

The dispensary was cluttered and there was little room for dispensing. Workbenches were cluttered with paperwork and stock leaving little or no space available for dispensing. Prescriptions and papers were piled on the benches. Multi-compartment compliance packs were prepared in the consultation room. The RP said that cleaning was done by some team members. Pharmacy-only medicines were kept behind the counter. The fire exit was blocked, with a large cardboard box stored in front of it.

The consultation room was lockable, but the door was open at the start of the inspection, despite this being highlighted with the pharmacy several times in the past. The items inside were not all stored securely. The premises were kept secure from unauthorised access. The ambient temperature and lighting were adequate for the provision of pharmacy services. Air conditioning was available to help regulate the temperature

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

Summary findings

The pharmacy does not always provide its services safely. Team members do not always refer to the prescription when they are dispensing or checking a medicine which is owed. This could increase the risk that a mistake is made. The pharmacy does not always keep its medicines secure or store them properly. It cannot show that it keeps medicines requiring cold storage at the right temperatures, and there is some evidence that the fridge temperature has gone out of the appropriate range. This means that the pharmacy is less able to show that the medicines inside have been kept at the right temperatures and are still safe to use. The pharmacy takes action in response to safety alerts.

Inspector's evidence

There was step-free access to the pharmacy. A variety of patient information leaflets were available in the shop area. Services and opening times were clearly advertised. Prescriptions were taken in at the counter and placed so that they could be dispensed in order. Prescriptions were being dispensed by the dispenser and checked by the RP. The RP was also seen to dispense some prescriptions. The counter assistant was seen to carry out a check on a dispensed prescription. The RP explained that this was a third check in addition to his own check. Team members were heard to query where prescriptions were to dispense owed items ('owings'). And when dispensing owings they were not seen to refer to the prescription form to dispense these. This could increase the risk of a dispensing mistake being made and had been highlighted on several previous inspections.

Dispensed and checked-by boxes were available on the labels. These were initialled by the team to help maintain an audit trail. The pharmacy team used baskets for prescriptions to ensure that people's prescriptions were separated and to help reduce the risk of mistakes. A number of bags were checked in the area where prescriptions ready for collection were kept, all the items were seen to be labelled. However, a supply of buprenorphine for supervised administration was not labelled by the RP.

When supplying high-risk medicines such as warfarin or methotrexate, the RP tried to hand the dispensed medicines out himself. He added that he would ask to see person's yellow book if people were taking warfarin. Records of monitoring information was not always made on the electronic patient medication record (PMR). This could make it harder for the pharmacy to check if a person was having the relevant tests at appropriate intervals. The RP was aware of the guidance for dispensing sodium valproate. Sodium valproate was said to be dispensed in its original pack where possible. In the event that people in the at-risk group where not part of a Pregnancy Prevention Programme the RP would refer them back to their prescriber.

Deliveries were carried out by team members and since the previous inspection the pharmacy had cut back on deliveries. Signatures were not obtained from people when delivering medicines. In the event that someone was not home, the medicines were returned to the pharmacy.

People who had been supplied their medicines in multi-compartment compliance packs had undergone a review with the RP. Following the review, a number of people were switched to having their medicines supplied in original packs. Multi-compartment compliance packs were prepared by the pharmacy technician who worked part time. Once these had been prepared, they were checked by the

RP. The pharmacy ordered people's prescriptions for the packs.

Medicines were obtained from licensed wholesalers. Fridge temperatures were said to be monitored and recorded daily. However, no records had been made since 11 May 2023. At the time of the inspection the probe used to measure the temperature was showing the maximum to be 12 degrees Celsius, the current temperature was 8.1 degrees Celsius, and the minimum was 6.6 degrees Celsius. The RP was not aware of how to reset the probe to re-check the temperature. CDs were not always stored in accordance with the relevant legislation. The issues about fridge temperatures and CD storage had been highlighted on previous inspections of the pharmacy. And some prescription-only medicines were not stored securely.

Some medicines in stock were stored in amber bottles but there was no indication of the expiry dates or batch number on these. This could make it harder for the pharmacy to date-check the medicines or respond to safety alerts appropriately. A number of medicines were also seen to be stored outside of their original packs in the blisters on the shelves. Date checking had not been done due to staffing issues, the RP said he had been keeping an eye on it and dates were being checked as part of the dispensing process. No date expired medicines were seen on the shelves checked. Out-of-date and other waste medicines were kept separate from stock, at the back of the pharmacy and then collected by licensed waste collectors. Drug recalls were received via email.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate range of equipment and facilities it needs to provide its services adequately. Its team members keep the equipment clean.

Inspector's evidence

Calibrated glass measures were available with separate one used for liquid CDs to avoid cross-contamination. Tablet counting triangles were available. These were clean and ready for use. A large domestic fridge was available, but this was filled to maximum capacity. Up-to-date reference sources were available including access to the internet. A blood pressure monitor was available, the RP said he only used this for himself and did not use it for any of the services provided.

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.