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: 21/03/2022

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. The inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 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 for are being followed, or that team members are familiar with them. And this increases the risk to people using the pharmacy's services.
		1.2	Standard not met	The pharmacy does not regularly review and monitor the safety and quality of its 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 not all met	2.2	Standard not met	The pharmacy does not always enrol its team members on the right training courses in a timely manner.
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. Team members do not always refer to the prescription when dispensing owed items or checking dispensed medicines. And the pharmacy does not ensure that its dispensed medicines are all labelled properly.
		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	Standards	5.2	Standard	The pharmacy's equipment for measuring

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	not all met		not met	liquids is not all fit for purpose.

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

Summary findings

The pharmacy does not appropriately identify and mitigate the risks associated with its services. Team members are not all familiar with the pharmacy's written procedures and they do not always follow them. This could increase the risk of something going wrong. The pharmacy does not properly keep and maintain the records it needs to. And it does not always keep its records on the premises. It does not store people's personal information securely or dispose of it properly. The team members generally respond appropriately when mistakes happen during the dispensing process. But they don't always record these mistakes. So, they might be missing opportunities to learn and make the services safer.

Inspector's evidence

The pharmacy standard operating procedures (SOPs) were overdue for review. All team members had not read and signed SOPs that were relevant to their roles. The trainee pharmacist had briefly looked through the SOPs. But when asked, other team members said they had not read through these since starting work at the pharmacy. The team were observed to not follow the SOPs consistently. For example, when dispensing prescriptions, dispensing items owed to people, or referring to the prescription form when handing medicines out. Team members were not observed to use personal protective equipment (PPE). The responsible pharmacist (RP) who was also the owner had previously explained that the necessary risk assessments to help manage Covid-19 had been completed. And this included occupational ones for the staff.

The pharmacy was not recording dispensing mistakes which were identified before the medicine was handed out (near misses) or those where the medicine was handed to a person (dispensing errors). The trainee pharmacist described the steps she would take if a near miss occurred. She described keeping a few records of her own personal near misses for her own audit. These were not seen at the inspection. A team member described how near misses had occurred recently but these had not been recorded. At a previous inspection it was found that dispensing errors were recorded on the electronic patient medication record (PMR) system. However, no records had been made recently despite the RP saying that there had been an error where a person was supplied with the wrong strength of a medication.

The correct RP notice was displayed. The team members were not aware of the tasks that could and could not be carried out in the absence of the RP. And this was discussed with the team members at the time. 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. The pharmacy completed annual patient satisfaction surveys.

Private prescription records were not available as the RP said he was in the process of completing his VAT returns and had taken these home. Electronic records seen on the PMR showed that no private prescriptions had been dispensed since January 2022. The RP said this was not the case. There were no records for emergency supplies and the RP said these were not given. The pharmacy did not have any records for unlicensed specials dispensed as these had not been dispensed for some time. The RP described the records he would make for an unlicensed special, as there was one which had been ordered and was waiting to be dispensed. Some controlled drug (CD) registers had a number of different brands recorded within one register. Entries had not been made in some CD registers for an

extended period of time. The RP said that CD register entries had not been made since February 2022. There was no entry made in one register since December 2021. And the quantity of the stock found for this medication did not match the recorded balance in the register. Responsible pharmacist records had not been made since 14 March 2022. In the records that had been completed, pharmacists were not routinely signing out.

The RP said that a CD balance check was carried out in February 2022, however, there was no documentary evidence found for this. A random check of three CD medicines found that the quantity in stock did not comply with the balance recorded in the register. CDs that people had returned were recorded in a register, but the RP said that these had also not been recorded for some time.

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. Team members were seen to be using the smartcard of a team member who was on extended leave. 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 RP had attended lectures about the General Data Protection Regulation before it had come into place. The computer in the dispensary was password protected and out of view of patients and the public. The computer in the consultation room was set up to log out after a period of inactivity. A shredder was available. Some confidential waste was seen in the general waste bin. 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 RP gave assurances he would look into safeguarding courses for the other team members. The trainee pharmacist had completed level two and three safeguarding training at her previous placement. The RP had not been aware of this. Details for local safeguarding contacts were available in the pharmacy.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy does not make sure that people start the relevant training for their role within the required timeframes. Staff receive some ongoing training, but this is not always very structured 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 trainee pharmacist. Neither of the counter assistants had been enrolled on or completed any accredited training programmes despite having worked at the pharmacy for a prolonged period of time. A trainee dispenser started their shift during the inspection. The RP was observed to complete most dispensing and checking on his own. Other team members who were not present included a part-time trainee dispenser, a part-time pharmacy technician, a part-time trained dispenser, a part-time trained medicines counter assistant and another counter assistant who had not completed or been enrolled on any training. One of the dispensers was on maternity leave at the time of the inspection and her position had not been filled. Staff performance was managed informally by the RP. Team members described how the RP routinely provided them with feedback. Team members felt able to give feedback and suggestions but did not feel this was always listened to.

Counter assistants were observed to ask appropriate questions before recommending treatment with over-the-counter medicines. They were also seen to refer to the pharmacist if unsure or for any requests for multiple sales.

The trainee pharmacist was provided with set-aside time to complete her training. The RP discussed things with the team members as they came up and verbally briefed them if there was a change in legislation or any other changes. There were no numerical targets set for the services offered.

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

Summary findings

The pharmacy is cluttered and disorganised. And there is little or no clear dispensing space. This could increase the risk of mistakes happening. The pharmacy's fire exit is not kept clear, which increases the risk if the premises need to be evacuated. 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. The RP was seen to dispense prescriptions using very little bench space near the computer and checking items directly in the basket. Multi-compartment compliance packs were prepared in the consultation room. The RP said that cleaning was done by some team members, team members were observed wiping surfaces during the inspection. Pharmacy-only medicines were kept behind the counter.

Staff toilet facilities were cluttered and used to store dispensing labels and other items. Dispensing bottles, some of which were uncapped, were also stored in the toilet. The fire exit was blocked, with a number of large cardboard boxes stored in front of it.

The consultation room was lockable but the door was open at the start of the inspection, despite the pharmacy being advised of this a number of 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 attach labels to all containers of medicines it dispenses. This means that people may not know how to take all their medicines properly. The pharmacy does not always keep its medicines secure or store them properly. The team members do not regularly record the fridge temperature and there is evidence that the fridge temperature is not kept within 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 does take action in response to safety alerts. But it does not always record the action taken, which could make it harder for it to show what it has done in response.

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. At the start of the inspection the RP was self-checking items they had dispensed. At the request of the inspector the trainee pharmacist was asked to help with the dispensing. Team members were seen to dispense owed items ('owings') without referring to the prescription form. The RP also initially checked an owing without referring to the form and once prompted by the inspector referred to the electronic copy. Dispensing labels were not attached to all boxes of medicines when multiple packs were dispensed. A bag was found in the area where prescriptions ready for collection were kept contained nine boxes of Epilim of which only one box had been labelled. This would mean that the person would not have instructions on how to take their medicine if the labelled box was used up first.

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.

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 change in guidance for dispensing sodium valproate and was also aware of the need to use the warning stickers.

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. Assembled packs observed were labelled with product descriptions and mandatory warnings. The RP said patient information leaflets were handed out monthly, but no leaflets were found in one of the bags checked. The RP showed another bag which had the leaflets included. Prescription forms were attached to some but not all bags of medicines waiting to be collected. SOPs required team members to check the prescriptions at the point of handing out the medication. And

they could not do this without a copy of the prescription. So, it would make it harder for them to check what was originally prescribed and ensure that the prescription was still valid.

Deliveries were carried out by a designated driver. Signatures were not obtained from people when delivering medicines to help with infection control. In the event that someone was not home, the medicines were returned to the pharmacy.

Medicines were obtained from licensed wholesalers. Fridge temperatures were said to be monitored and recorded daily. However, only temperature records for two days could be found. At the time of the inspection the probe used to measure the temperature was showing the maximum temperature to be 18.4 degrees Celsius, the current temperature was 9.6 degrees Celsius and the minimum was 17.0 degrees Celsius. A team member said the probe was not working. CDs were not always stored in accordance with the relevant legislation. 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. Date checking had been done by the trainee pharmacist and this activity had been recorded. A date-expired medicine was found 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. The RP had previously set up a folder to store printed recalls once they had been actioned. However, this had not been done for some time. The RP gave assurances that he had taken the necessary action for recent recalls but not made a record. Not keeping a record could make it harder for the pharmacy to show that the appropriate action had been taken in response.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

The pharmacy's measuring equipment is not all fit for purpose. It uses plastic measures for some liquids, and the measures are not appropriately calibrated. Otherwise, the pharmacy has the equipment and facilities it needs for the services it provides. And it generally maintains them properly.

Inspector's evidence

A calibrated glass measure was available for liquid CDs, but other measures used were all plastic and not calibrated. The RP said that he had ordered these plastic measures as the glass measures kept on breaking. 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, this was said to be replaced annually although no records were seen to show this.

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.