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: 18/06/2019

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 carries out health checks.

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 does not routinely assess key risks to patient safety from its activities and services. Standard operating procedures for dispensing, checking and handing out prescriptions are not being followed. And this creates a significant risk.
		1.6	Standard not met	The pharmacy does not keep all its records fully in line with legal requirements.
		1.7	Standard not met	The pharmacy does not always manage confidential information properly or securely dispose of confidential waste. This could result in people's personal information being disclosed.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough suitably qualified staff to ensure that its services and workload are managed safely.
		2.2	Standard not met	All team members do not have the appropriate qualifications for the tasks that they carry out.
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 also blocked which presents a risk in the event that the pharmacy needs to be evacuated.
		3.2	Standard not met	The consultation room does not fully protect the privacy of people who use the pharmacy.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not fully manage the risks associated with dispensing and with the multi-compartment compliance pack services.
		4.3	Standard not met	The pharmacy does not always keep its medicines securely and in accordance with legislation. And cannot show that it always stores medicines which require refrigeration appropriately.

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

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

Summary findings

The pharmacy's records that it must keep by law are not all complete or accurate. The pharmacy does not have written procedures for all the services it provides. And team members do not always follow the procedures they have. This could increase the risk of something going wrong. 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. The pharmacy doesn't protect people's private information properly.

Inspector's evidence

The pharmacy had up-to-date standard operating procedures (SOPs); team members had read and signed the ones that were relevant to their roles. However, there were no SOPs in place for the multi-compartment compliance pack service or how the pharmacy dealt with complaints. There was only one SOP for the management of controlled drugs (CDs) and this related to dealing with patient returned CDs. The responsible pharmacist (RP) said that he thought that there were more SOPs but was unable to locate them. The team members were not following the SOP relating to handing out medicines (see Principle 4 below). And it did not adequately manage the potential risks around protecting people's personal information and storing medicines.

In the event that a near miss was identified the RP said that he would look to see who was involved and what could be changed or if there was an alternative way of working which would help to avoid reoccurrence. The RP said that he would also speak to everyone involved and notify the team of what had happened. The last recorded near miss was from February 2019 but the RP said that there had probably been other near misses since then which had not been recorded.

Dispensing incidents were recorded on the patient medication record (PMR electronic system). The RP said that that he would inform the team of what had happened and complete a root cause analysis. As a result of an error the team had changed the way in which stock was stored on the shelves and moved cetirizine and citalopram apart on the shelves. However, a recent error which had been reported to the pharmacy had not been investigated or reported.

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. 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. Previous feedback had been in relation to the waiting time for collecting prescriptions.The RP had increased the number of chairs in the waiting area and for the repeat prescription service had changed the workflow so that some prescriptions were ready before the person presented to collect.

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. Records for emergency supply and unlicensed specials were well maintained. Controlled drug (CD) registers were mixed with a number of different brands recorded within one register. Entries had not been made in some CD registers since March 2019. And there were entries on the electronic patient medication record (PMR) system to suggest that some supplies had

been made since this time. Responsible pharmacist records were not accurate. Pharmacists were not routinely signing out. On some days when there was a locum pharmacist working, records for the following day showed that the RP had not signed in until much later in the day.

The RP said that CD balance checks were carried out weekly but the most recent recorded checks found were from February 2019. A random check of a CD medicine did not comply with the balance recorded in the register. Following the inspection, the RP confirmed that this had been resolved. CDs that people had returned were recorded in a register as they were received.

Assembled prescriptions were stored under the medicines counter and were not visible to people using the pharmacy. The shredder was not working and some confidential waste was being segregated. However, confidential waste including copies of prescriptions were found in the general waste bin. Computers were password protected, however, the computer in the consultation room was logged into the PMR. 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 RP had spoken to the team about this. The RP had attended lectures before the General Data Protection Regulation had come into place.

The RP had completed a level two safeguarding course and verbally briefed the team. The RP said that he thought details for the safeguarding boards were available but could not locate these.

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

Summary findings

The pharmacy does not have enough staff to cope with its workload following an increase in the number of items dispensed. Some members of the team are doing tasks that they aren't trained for or qualified in. Staff are given some ongoing training. But this is not very structured, and they are not given time set aside for 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, a medicines counter assistant (MCA) and another member of staff who had worked at the pharmacy since November 2018 but had not been enrolled on or completed any accredited training programmes. The team member was observed to help in the dispensary including dispensing methadone and buprenorphine. Another MCA came in part-way through the inspection.

The RP said that the number of items the pharmacy dispensed had increased recently, and staffing levels had not been reviewed in line with this. The RP agreed that the pharmacy did not have enough dispensary staff. The RP was observed to complete most dispensing and checking on his own. There was a constant queue of people through the course of the inspection and a number of people had to wait for some time before their medicines were supplied. Prescriptions for most people were dispensed as they waited including for those who had ordered their prescriptions in advance.

Staff performance was managed informally by the RP unless he received a complaint about a team member. The RP said that once a year he had a sit down with each team member and see if there was any particular area that they wanted to learn more about, after which he would try and find them the relevant information. The RP said that he also passed information sheets from pharmacy magazines to the team.

One of the MCAs counselled patients on the use of over-the-counter medicines and asked appropriate questions before recommending treatment. She would always refer to the pharmacist if unsure or for any requests for multiple sales. Another MCA who had been working at the start of the inspection was observed to sell medication without any questioning. The MCA said that the RP provided information on new products.

Team meetings had previously been held after opening hours. The RP said that this had not been done recently. The RP discussed things as they came up with the team 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 premises are largely kept secure. But some areas of the pharmacy are cluttered and disorganised. And there is little or no clear dispensing space. This could increase the risk of mistakes happening.

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 dumped on shelves. There was also a considerable amount of dust on the shelves. The RP was seen to dispense prescriptions without using any bench space. Multi-compartment compliance packs were prepared in the consultation room. The RP said that cleaning was done by some team members.

Staff toilet facilities were cluttered and used to store open yellow bins. The fire exit was blocked. The consultation room was not lockable and the door was open at the start of the inspection. The items inside were not all kept 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 obtains its medicines from reputable sources. But it does not always keep them securely. The team members do not regularly reset the fridge thermometer. This means that they are less able to show that the medicines inside have been kept at the right temperatures and are still safe to use. They do not always refer to the prescription when they are dispensing or checking a medicine. So, this could increase the risk that a mistake is made.

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. These were then dispensed by the RP who checked his work after this. He described then leaving the dispensed prescription for one of the other team members to double check and handout. The MCA was observed to check dispensed medication without the prescription form at the counter. She was also seen to attach labels to a box of insulin at the counter without referring to the prescription. The box of insulin was brought out of the fridge and given to her by the RP. This was then handed out by the MCA without a final check being carried out. This was not in accordance with the SOPs in place for dispensing and checking prescriptions. The RP said that no matter how busy it was he tried to get a second check. He also tried to keep abreast of commonly occurring near misses and shared this information with the team.

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 reduce the risk of errors.

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. However, these stickers were not available at the pharmacy. This may mean that people do not get all the information they need to take this medicine safely. The RP said that he had spoken to two people who fell in the at-risk group, however, no records had been made of this.

When supplying high-risk medicines, the RP tried to hand the dispensed medicines out himself. He added that he would ask to see the yellow book for people on warfarin and make a note on their electronic patient medication record (PMR). The RP was unsure of how to bring these notes up on the system. The records of two people on warfarin were seen and no relevant notes were found.

Multi-compartment compliance packs were prepared by a dispenser who worked part time. Once these had been prepared they were checked by the RP. Prescriptions were ordered for people by the dispenser. If the dispenser was due to be away she prepared packs in advance. The dispenser prepared trays some time before they were due to be supplied to people. A prepared tray which had been labelled had been prepared for someone in March 2019 and had been annotated to say that it was due to be taken from 26 June. The dispenser was not aware of how long the medicines were stable inside the blisters. This person also received some of their medicines in their original packs, such as warfarin. A record was not found on the PMR of these medicines having been dispensed. The RP said that PMR

for this person had been 'wiped' and he had discussed it with the electronic record provider. People were asked to notify the pharmacy if there had been any changes to their medicines or if they had been admitted to hospital. The dispenser said that the team were not always notified if someone was admitted into hospital. In some cases, the pharmacy received a discharge summary. Records of hospital admissions were not found annotated anywhere. The pharmacy did not always keep a record of communications with the prescribers. So, some members of staff or other pharmacists may not know what has been discussed and agreed with other healthcare professionals.

Assembled packs observed were labelled with product descriptions and mandatory warnings. Patient information leaflets were handed out monthly. There was no audit trail in place to show who had dispensed and checked the packs. So, this could make it harder for the pharmacy to show who had done these tasks if there was a query. Electronic prescription tokens were shredded once the packs had been checked. 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, they can't check what was originally prescribed and ensure that the prescription is still valid.

Deliveries were carried out by a designated driver who obtained signatures when delivering medicines. In the event that someone was not home medicines were returned to the pharmacy.

The pharmacy had a number of prescriptions for which items were owed to people. Some prescriptions dated back to early May 2019. The RP said that he had spoken to one of the team members about checking through these prescriptions on a weekly basis.

The RP was seen to measure methadone whilst holding the measuring cylinder mid-air. When asked the RP said that he made sure that the liquid lined up against marks on either side of the measure.

Medicines were obtained from licensed wholesalers. Fridge temperatures were monitored and recorded daily. Recorded temperatures were within the required range for the storage of medicines. A number of entries were identical over a period of dates. The RP said that the temperature probe was not routinely reset. At the time of the inspection the maximum temperature was 10.5 degrees Celsius, the actual was 6.7 degrees Celsius and the minimum was 3.7 degrees Celsius. CDs were not always stored in accordance with the relevant legislation.

Medicines (Creon) were found to be stored in amber bottles, 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 was done by one of the assistants. Short-dated stock was marked and recorded. The date checking matrix had not been updated since January 2019. A date expired medicine was found on the shelves checked. A number of expired supplements were also found in the retail area.

The pharmacy was not compliant with the Falsified Medicines Directive (FMD). The RP said that he had ordered a new system but had not been given a date as to when this was to be installed. He said that he hoped to have this in place by the end of June.

Out-of-date and other waste medicines were segregated at the back of the pharmacy and then collected by licensed waste collectors. However, the waste containers were blocking the fire exit.

Drug recalls were received via email. The RP said that he had set up a folder to store printed recalls once they had been actioned but was unable to locate this. The RP could not recall the last actioned alert.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides. It generally maintains them properly. But it could do more to ensure that measuring and counting equipment is kept clean at all times.

Inspector's evidence

Two calibrated measures were both were labelled for ‘methadone’ use. One had mould around the label around the outside of the measure and the other had a deposit at the bottom of a yellow substance. There was no separate measure available for other liquids. This could increase the chance of cross-contamination if the measures were not regularly cleaned.

Tablet counting triangles were also available but these had a thick film of tablet dust. A fridge of adequate size was available. Up-to-date reference sources were available including access to the internet. The RP said that there were two blood pressure monitors available. One was new and the other was older. The RP said that the older monitor was generally used. The carbon monoxide monitor was calibrated by the local smoking cessation team.

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.