General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Bridge Cottage Ltd, 41 High Street, WELWYN, Hertfordshire, AL6 9EF

Pharmacy reference: 1109308

Type of pharmacy: Community

Date of inspection: 11/06/2019

Pharmacy context

The pharmacy is situated within a surgery building. The surgery and pharmacy share the same entrance, but the pharmacy can be open when the surgery is closed. The pharmacy has a 100 hours contract with the NHS. It provides NHS and private prescription dispensing, mainly to local residents. The pharmacy supplies medications in multi-compartment compliance packs for lots of people who need help taking their medicines. It also offers a home delivery service to the surrounding villages and delivers prescriptions to the Kimpton Surgery which acts as a collection point. The pharmacy provides Medicines Use Reviews and the New Medicine service for people. Two inspectors undertook the inspection of the pharmacy.

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 manage its risks appropriately. It has not embedded into practice the actions it took to address issues found on previous inspections. For example, there are issues around the safe management of confidential material, storage of medicines, learning from errors, and sharing NHS cards.
		1.7	Standard not met	The pharmacy does not store people's personal information securely. This could increase the risk that it is accessed by unauthorised people.
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 not all met	4.2	Standard not met	The pharmacy does not consistently supply medicines in a safe way. They do not always put advisory and caution labels onto people's medicines, and at-risk people taking sodium valproate are not routinely counselled about pregnancy prevention.
		4.3	Standard not met	The pharmacy does not always store its medicines appropriately. This could increase the risk that the medicines are not safe for people to use.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy takes some steps to provide its services safely, but it is not managing its risks effectively or protecting people's personal information properly. It had addressed issues raised in previous inspections at the time, but not embedded them into practice, meaning that improvements are not sustained. However, the pharmacy generally keeps its records up to date. Team members are clear about their own roles and responsibilities. And they know how to protect vulnerable people. But the pharmacy doesn't always record mistakes that happen during the dispensing process. And this means that team members may be missing out on opportunities to learn and could find it harder to know how to prevent a recurrence.

Inspector's evidence

Standard Operating Procedures (SOPs) were up to date. Members of the team had read and signed SOPs relevant to their roles, with the exception of the second pharmacist. She said that she had read SOPs at another branch; this was owned by a different company but had some of the same directors. The pharmacist thought the standard operating procedures used at the other branch were the same. There were no SOPs in place for the superintendent pharmacist's prescribing activity or for the pharmacy's supply of dispensed medicines to the Kimpton collection point and how people using them would be supported. Team roles were defined within the SOPs. The superintendent pharmacist said that the SOPs were in the process of being reviewed.

The written procedures said that the team members should log any mistakes made in the dispensing process in order to learn from them. A small number of near misses had been recorded in the past few months, but there was no recorded learning from these near misses. The small number and lack of learning had been raised on previous inspections. The superintendent pharmacist said that the individual incidents were discussed with the member of staff who had made them, and sometimes action was taken to prevent a recurrence such as separating stock with similar names. The individual errors were not discussed with the whole team. Not all errors which reached the public were recorded or learned from.
The pharmacy conspicuously displayed the correct responsible pharmacist notice. The responsible pharmacist record required by law was up to date and filled in correctly. The pharmacy team members were aware of their roles and they were observed asking the pharmacist for advice when needed.

The pharmacy had current professional indemnity insurance. The superintendent pharmacist was an independent prescriber and he confirmed that he was covered for his prescribing activities through his personal cover. A copy of the certificate for the pharmacist 's insurance was sent to the inspector following the inspection.

The pharmacy had a complaints procedure and also completed annual patient satisfaction surveys. Previous feedback had been in relation to prescriptions not being ready on time and the time taken for the pharmacy to answer the phone. These issues were being resolved by making the processes in the pharmacy more efficient and freeing up time. For example, the pharmacy had made the storage of dispensed prescriptions more streamlined, meaning that they were more easily retrievable.

Records for unlicensed specials and records and controlled drug (CD) registers were well maintained.

The superintendent pharmacist said that they made private prescription records using a program called Pharmasmart. These records were not up to date and a number of them still needed to be made. However, the patient medication record (PMR) system automatically made entries and if they were accurate they would comply with the legal requirements. The PMR records were up to date but the prescriber details and dates that the prescriptions were issued were not always accurate. Emergency supply records did not always have a reason recorded as to the nature of the emergency. This could make it harder for the pharmacy to show why the supply was made if there was a query. CD running balance checks were carried out regularly. A random check of a CD medicine complied with the balance recorded in the register.

Assembled prescriptions were stored away from the view of people who used the pharmacy. Team members had been trained on the General Data Protection Regulation by one of the owners and his wife. An information governance toolkit was in place which was reviewed annually. The dispensary team members had individual smartcards. The superintendent pharmacist's card was initially being used when he had not been present; this had been raised on previous inspections but despite the earlier assurances given, sharing was still occurring. The individual PIN numbers used to access the NHS site had been shared, and this meant that the pharmacy could not keep an accurate audit trail of who had accessed the NHS information. Some medication returned from care homes which included people's private information was found to be not stored securely. This had been raised on previous inspections.

The pharmacists had completed level 2 safeguarding training and details for the local safeguarding boards were displayed in the dispensary. Team members had watched a video on safeguarding.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough qualified staff to provide its services safely. Its staffing rotas enable it to have handover arrangements and effective staff communication. Team members do some ongoing training, but this is not structured or recorded. This could make it harder for the pharmacy to identify and address any gaps in the team's knowledge or skills.

Inspector's evidence

At the time of the inspection the pharmacy team comprised of the responsible pharmacist, four dispensers and two medicines counter assistants (MCA). The superintendent pharmacist came into the pharmacy during the course of the inspection. Following the inspection, he said that the pharmacy had employed two regular pharmacists in addition to him so that he could concentrate on the operation of the pharmacy. One of the dispensers concentrated on the management of the multi-compartment compliance packs. Three of the dispensers had been enrolled on the accredited checking technician course.

The superintendent pharmacist said that there were enough team members for the services provided. The pharmacy had taken on a contract to provide medicines to an additional 150 people in a nearby care home.

Staff performance was managed informally by the superintendent pharmacist who gave team members feedback. Team members said that they had received formal appraisals prior to the superintendent pharmacist joining the team.

The MCA described handing out prescriptions. She said that she would check with the responsible pharmacist before handing out a prescription for a CD and said that she would obtain two signatures on the prescription. She was unsure as to how long a prescription for CDs was valid for. She said that CD prescriptions were flagged with 'CD' stickers; however, this was not observed on all prescriptions for Schedule 4 CDs. This could make it harder for team members to know if one of these prescriptions was still valid when handing the medicine out.

There was no formal process for ongoing structured training. Team members were given pharmacy magazines which they looked through, but no records were kept for this. Team members did not have numerical targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are generally clean and provide a safe, secure and professional environment for patients to receive healthcare. But the pharmacy could do more to make sure that the consultation room is kept clean at all times.

Inspector's evidence

The pharmacy was clean in the main. There was ample workbench space available which was organised and a dedicated area was used to prepare multi-compartment compliance packs. A sink was available. Medicines were stored on shelves in a generally tidy and organised manner. The premises were kept secure from unauthorised access.

A consultation room was available. This was called ‘The Pod’ and the superintendent pharmacist said that it was shared with the surgery. There was no confidential information held in the room. The table in the room was dirty and there was very limited space available in the room. The amount of space was adequate for one-to-one consultations and provided a level of privacy.

The premises were kept secure from unauthorised access. The room temperature and lighting were adequate for the provision of healthcare. Air conditioning was available to help regulate the temperature. The temperature in the two rooms which were not part of the registered premises but were used to store prepared multi-compartment compliance packs and excess over-the-counter medicines was not monitored. The room used to store excess medicines had a number of hot-water pipes running through. This had been raised on previous inspections and some monitoring had occurred and then ceased. This was discussed with the pharmacist during the inspection.

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

Summary findings

The pharmacy takes some steps to provide its services safely, but it doesn't always give additional information to people taking some higher-risk medicines. And it doesn't always put the required warnings on the labels on the multi-compartment compliance packs. So, people may not have all the information that they need to take their medicines safely. The pharmacy doesn't manage all its medicines properly. It doesn't always store them in appropriately labelled containers This could make it harder for the pharmacy to react to safety alerts or date-check the stock properly. It does not always keep fridge medicines at the right temperatures. So, there may be an increased risk that these medicines are not safe to use. The pharmacy has supplied people with warfarin strengths which do not correspond with the dose they should be taking. However, the pharmacy does take the right action in response to safety alerts.

Inspector's evidence

The pharmacy was accessible from the surgery. Services were displayed on a board outside the pharmacy.

The superintendent pharmacist was an independent prescriber and worked in an out-of-hours service as well as his role in this pharmacy. He told the inspector that he did not prescribe and dispense for the same patient. But one prescription was found which he had written and then also checked the dispensed medicine. There were no written procedures to cover this activity, and this made it harder for the pharmacy to show that any potential risks were being managed properly.

The pharmacists were aware of the change in guidance on pregnancy prevention for dispensing sodium valproate but the rest of the team were not. The pharmacy was not supplying additional literature such as warning stickers and cards to people in the at-risk group. The pharmacy had some people in the at-risk group who took valproate. And they were not routinely counselled about pregnancy prevention. The superintendent pharmacist said he would order the relevant stickers and cards to supply to people.

For people collecting prescriptions for high-risk medicines such as warfarin, the superintendent pharmacist said that the INR and other blood tests were checked and recorded. However, records showed that this had not always happened, and the last entry made on some records was from February 2019. This could make it harder for the pharmacy to keep track of people's previous blood test results. There was no process in place to check blood test results for people who were delivered their medication. One person had been supplied different strengths of warfarin in accordance with the prescription, but this did not match the dosage that needed to be taken as per the recommendation from the INR clinic. Schedule 4 CD prescriptions were not highlighted. This could make it harder for the team member handing out the medicine to know if the prescription was still valid.

The pharmacy used an electronic system to track prescriptions once they had been dispensed. The system automatically sent people text messages to notify them that their prescription was ready if they were enrolled on the service and this also helped team members know where the prescription was stored.

Multi-compartment compliance packs were prepared by a dispenser who was training to become an

accuracy checking technician. He said that he prepared around 50 packs each week (200 people in total). The packs were prepared at the rear of the dispensary, in a quieter area. Prepared packs to be delivered the following week were stored in this area. He said that he had been training his colleague so that she could take over preparing packs when he was on holiday. He described referring to the prescription when preparing trays. Assembled multi-compartment compliance packs observed were labelled with product descriptions. However, the required cautionary and advisory warnings were missing. This had been raised on previous inspections. And it could mean that people do not get all the information they need to take their medicines safely.

Deliveries were carried out by one of two designated drivers who worked opposite shifts. Signatures were obtained electronically for medicines delivered and these were uploaded to the system. This helped the pharmacy show that the medicines had been delivered safely. But this system was not in place for people collecting their medicines from the Kimpton surgery. So, this could make it harder for the pharmacy to show that these people had received their medicines safely.

Medicines were obtained from licensed wholesalers. There were two fridges and although temperatures were monitored and recorded daily, these were only the current temperatures rather than the minimum and maximum ones. The temperatures on the day of the inspection had been recorded as 2.2 degrees Celsius for the first fridge and 2.3 degrees for the second. The thermometer in the first fridge showed a minimum temperature of 1.6 degrees Celsius and a maximum of 17.5 degrees. The thermometer in the second fridge showed a minimum temperature of 1.7 degrees Celsius and a maximum of 14.6 degrees. There was no record to show that the thermometers had been reset each day. Accurate recording of fridge temperatures, and storage of medicines requiring refrigeration had been raised on previous inspections.

Medicines were generally stored tidily. But some medicines were found to be stored on shelves in loose blisters and some medicine boxes contained mixed batches. A number of strips of tablets did not have either the expiry date or batch number recorded. One of the strips did not have any indication as to what the medication inside actually was. The storage of medicines outside their original packaging had been raised on previous inspections. Not all the pharmacy's medicines were stored securely. Date checking was done by the dispensers every three months and this was supported by records. No date-expired medicines were observed on the shelves sampled.

The pharmacy was not compliant with the Falsified Medicines Directive (FMD), the pharmacy had recently upgraded the computers and received new scanners. Team members said that they were waiting for training by the company whose system it was. Out-of-date and other waste medicines were segregated at the back of the pharmacy and then collected by licensed waste collectors.

Drug recalls were received on Pharmasmart. These could be accessed by any of the pharmacists. The last actioned alert was for co-amoxiclav suspension. But the system was not always updated with the action that had been taken. This could make it harder for the pharmacy to show that it had taken the right steps in response to the safety alerts.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the right equipment for its services. And it largely maintains it properly.

Inspector's evidence

The pharmacy had a glass measure, but it was not stamped to indicate it had been calibrated and so could not be shown to be accurate. The superintendent pharmacist said that the measure was washed daily but mould was visible. The superintendent pharmacist said that he would clean the measure following the inspection and order new measures. Tablet counting equipment was available; this had a film of tablet dust. This could result in medication becoming cross contaminated. The superintendent pharmacist said that they would also be cleaned.

A blood pressure monitor was available in the consultation room. The superintendent pharmacist said that this belonged to the surgery and was managed and calibrated by them.

Up-to-date reference sources were available including access to the internet. The pharmacy had a domestic fridge and a larger pharmacy fridge with adequate storage for their medicines.

The computers in the dispensary were password protected and out of view of people using the pharmacy. Confidential waste was collected in a separate labelled bin and sent for destruction.

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.