General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Day Lewis Pharmacy, Berrow Medical Centre, Brent Road, Berrow, BURNHAM-ON-SEA, Somerset, TA8 2JU

Pharmacy reference: 1106805

Type of pharmacy: Community

Date of inspection: 06/09/2019

Pharmacy context

This is a community pharmacy located adjacent to a medical centre in Burnham-on-Sea. It serves its local population which is mostly elderly. The pharmacy opens six days a week. The pharmacy sells a range of over-the-counter medicines, dispenses NHS prescriptions and supplies medicines in multi-compartment compliance aids for people to use living in their own homes.

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 identify and manage risk well. It is not clear that the pharmacy team learn from their errors.
		1.7	Standard not met	The pharmacy does not manage information to protect the privacy of its patients.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy team do not have enough staff to provide pharmacy services effectively.
3. Premises	Standards not all met	3.1	Standard not met	Some areas in the pharmacy are disorganised and represent a trip hazard to staff.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy's services are not provided effectively and multiple complaints were made about service provisions during the inspection. The pharmacy team do not regularly provide warning labels on medicines contained with multi-compartment compliance aids.
		4.3	Standard not met	The pharmacy team cannot demonstrate having carried out date checking and expired medicines were found on the dispensary shelf.
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 identify and manage risk well. The pharmacy has written procedures to help them learn from mistakes that happen but it is not clear that these are utilised effectively so that learning opportunities can be identified. Pharmacy team members are clear about their roles and responsibilities. The pharmacy does not protect people's private information adequately. Pharmacy team members are clear about their roles and responsibilities. The pharmacy asks its customers and staff for their views and uses this to improve services. The pharmacy has appropriate insurance to protect people when things go wrong.

Inspector's evidence

Near misses were logged when they occurred and the incidents would be discussed with the members of staff involved. The near miss log was displayed in the pharmacy and examples were seen as being recorded by the pharmacy team. But because there had not been a regular pharmacist for some time, it was not clear how staff communicated the learning from these errors to the pharmacy team. The pharmacy team had 3 dispensing errors reported on 6, 7 and 13 August 2019 respectively. When questioned about this, a dispensing assistant reported that staffing pressures were a potential contributing factor (see also principle 2).

The pharmacy team reported all dispensing errors online using the Day Lewis reporting system. The dispensing error process included a root cause analysis to elucidate why the error may have happened. Error reports were stored in the pharmacy and demonstrated to the inspector.

There was an established workflow in the pharmacy where labelling, dispensing and checking activities were carried out at dedicated areas of the work benches. Dispensing labels were also seen to have been signed by two different people indicating who had dispensed and who had checked a prescription.

SOPs were in place for all the dispensary tasks and were reviewed on a regular basis by the company's head office. All staff were aware of their roles on questioning. A complaints procedure was in place within the SOPs and the staff were all aware of the complaints procedure. Feedback was gathered annually using Community Pharmacy Patient Questionnaires.

An indemnity insurance and public liability certificate from the NPA was held and was valid and in date. Controlled drug records were retained. A sample of a random CD was checked for record accuracy and was correct at the time of the inspection. CD balance checks were generally completed monthly.

The pharmacy team reported that they carried out routine date checking of medicinal stock but could not demonstrate any records to show this. There were two out of date medicines that were found on the dispensary shelf (see also principle 4). The fridge temperatures were recorded electronically daily and were within the appropriate temperature range of two to eight degrees Celsius. The stock inside the fridges was laid out in an organised fashion.

The responsible pharmacist (RP) record was seen to be retained electronically. The RP notice was not displayed where the public could see it, but this was promptly corrected by the pharmacist during the inspection. The private prescription and specials records were retained and were in order. The

emergency supply records were not demonstrated as staff were unfamiliar with the patient medical record system.

An information governance policy was in place which the pharmacy team were required to read and sign. But a delivery book containing patient name and address details was left in the retail area during the inspection. This was handed back to staff by the inspector. Staff reported that confidential waste was shredded intermittently using a cross cut shredder. But there were hundreds of labels containing patient confidential information that had been amalgamated into balls around the pharmacy and staff were not clear on how these were destroyed securely. Some of these labels were falling off onto the medicines counter which may increase the risk of label transposition onto other objects. The computer screens were all facing away from the public and access to patient confidential records was password protected. The consultation room was located in the retail area of the pharmacy; it was not lockable and it contained patient confidential information. Assembled prescription bags were stored close to the medicines counter and these were potentially visible to the public (see also principle 3).

There was a safeguarding children and vulnerable adults e-Learning program on the company training website which all the members of staff were required to complete. Staff explained that they were confident of signs to look out for which may indicate safeguarding issues in both children and adults and would refer to the pharmacist as appropriate. Contact details were available for local safeguarding advice, referrals and support.

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

Summary findings

The pharmacy staff have the appropriate skills, qualifications and training to deliver services safely and effectively. But there are not enough staff to provide services because the pharmacy team regularly fall behind on their work. They are comfortable about providing feedback and raising concerns and are involved in improving pharmacy services.

Inspector's evidence

At the time of the inspection there was one pharmacist and two dispensing assistants present in the pharmacy. Staff reported that they were around two days behind on their dispensing activity at the time of the inspection. The pharmacy team reported that they often felt staffing pressure and that one staff member was on holiday at the time of the inspection which had not been covered. In addition, the pharmacy had not had a manager or regular pharmacist for some time and that they had to rely on locum pharmacists to continue to provide services. Staff reported that they often fell behind on their dispensing activity and that they were three days behind earlier on in the week. The pharmacy was very disorganised (see principle 3 and 4) and staff were observed struggling to find assembled prescriptions to hand out to people. There were large queues throughout the majority of the inspection and the inspector observed one member of staff being verbally abused. 3 people complained whilst the inspection was taking place. The pharmacy team reported that these types of incidents were becoming more commonplace.

The staff reported they were required to complete online training modules when they became available. But staff did not have time to regularly complete training as they reported that they were always busy. A dispensing assistant reported having recently learnt about mometasone nasal spray which had recently been made available for purchase over the counter.

The company had an annual staff survey which was an opportunity for the staff to feedback any opinion they had about their roles and the company anonymously. Staff explained they were happy to raise any concerns they had with the area manager. There was a company whistleblowing policy in place and staff were aware of this.

There were targets in place at the pharmacy but the team explained that they did not feel any pressure to deliver these targets and would never compromise their professional judgement to achieve targets.

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

Summary findings

The pharmacy premises is disorganised and untidy which is creating unnecessary trip hazards to staff. The pharmacy team do not adequately protect people's private information. The premises can be secured and safeguarded from unauthorised access.

Inspector's evidence

The pharmacy had a dispensary which was separated from the retail area by a medicines counter to allow for the preparation of prescriptions in private.

A significant number of assembled bags of prescriptions, multi-compartment compliance aids and totes of stock were stored on the floor all around the dispensary which created unnecessary trip hazards to staff. Staff were also observed struggling to find prescriptions as there was no discernible system to locate assembled bags of prescriptions that had not been appropriately stored in the retrieval area as per the company SOPs.

Medicines were stored on the shelves in a generic and alphabetical manner. There were sinks available in the dispensary with hot and cold running water with sanitiser to allow for hand washing.

The consultation room was accessible from the retail area of the pharmacy and was not lockable. It contained patient confidential information which was potentially accessible to the public. In addition, the assembled prescription bags were stored close to the medicines counter and these were potentially visible to the public.

The ambient temperature was suitable for the storage of medicines and the lighting throughout the store was appropriate for the delivery of pharmacy services.

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

Summary findings

Pharmacy services are accessible to patients but not always effectively managed and delivered consistently. The pharmacy team regularly falls behind on its dispensing activity. Its pharmaceutical stock is generally appropriately obtained. But there are out-of-date medicines on the dispensary shelves and staff cannot demonstrate having carried out date checking. The pharmacy team do not supply multi-compartment compliance aids with the appropriate warning labels for the medicines contained within the compliance aids.

Inspector's evidence

Pharmacy services were displayed on leaflets and posters around the pharmacy. Access to the pharmacy was step free. There was space for the movement of a wheelchair or pushchair in the pharmacy and seating for patients and customers who were waiting. The pharmacy team reported struggling with the workload and said that they would regularly fall behind on dispensing activity particularly when there was staff sickness or holiday.

The pharmacy team supplied multi-compartment compliance aids to around 60 patients in their own homes. One compliance aid was examined and an audit trail to denote who dispensed and who checked the compliance aid was complete. Descriptions were routinely provided for the medicines contained within the compliance aids. Staff reported that patient information leaflets were routinely supplied. BNF advisory warning labels were not regularly included for the medicines in the compliance aids.

The pharmacy team had an awareness of the strengthened warnings and measures to prevent against valproate exposure during pregnancy. Valproate patient cards were not available for use during valproate dispensing to all people who may become pregnant. The pharmacy team agreed to address this. The pharmacist reported that he would check that that the patient's prescriber had discussed the risks of exposure in pregnancy with them and they are aware of these and query if they were taking effective contraception.

There were destruction kits available for the destruction of controlled drugs and designated bins for storing waste medicines were available and being used for the disposal of medicines returned by patients. A bin for the disposal of hazardous waste was also available for use. Waste collection was regular and the team explained they would contact the contractors if they required more frequent waste collection.

Medicines were obtained from the Day Lewis Warehouse, AAH and Alliance. Specials were obtained via Eaststone specials. Invoices were seen to demonstrate this. The pharmacy team were aware of the European Falsified Medicines Directive (FMD). The pharmacy team had the relevant hardware and software in place.

The majority of medicines and medical devices were stored in an organised fashion within their original manufacturer's packaging. Co-trimoxazole 160/800mg tablets were stored in a container without a batch number and expiry date. It was not clear that pharmaceutical stock was subject to date checks because staff could not demonstrate records for these. The following expired medicines were found on the dispensary shelf:

Mesalazine 400mg tablets expired end of July 2019
Nitrofurantoin 25mg/5ml suspension expired on 26 July 2019

MHRA alerts came to the pharmacy electronically through the company's internal email system and the pharmacist explained that these were actioned appropriately. But records and audit trails to demonstrate what action had been taken and when were not regularly kept.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has access to the appropriate equipment and facilities to provide the services offered. These are used in a way that helps protect patient confidentiality and dignity.

Inspector's evidence

There was a satisfactory range of crown stamped measures available for use. Separate measures were in use for dispensing CDs. Measures were seen to be clean. Amber medicines bottles were seen to be capped when stored and there were counting triangles available for use. Electrical equipment appeared to be in good working order and was PAT tested annually. Pharmacy equipment was seen to be stored securely from public access.

Up-to-date reference sources were available online and this access included the BNF, the BNF for Children and the Drug Tariff. Internet access was available should the staff require further information sources.

There were two fridges which were in good working order and the maximum and minimum temperatures were recorded daily and were seen to be within two to eight degrees Celsius.

Designated bins for storing waste medicines were available for use and there was sufficient storage for medicines. The computers were all password protected and patient information was safeguarded.

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.