General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: L.C. & J. Clark, 10 Cheveley Park, Belmont, DURHAM, County Durham, DH1 2AA

Pharmacy reference: 1029426

Type of pharmacy: Community

Date of inspection: 05/12/2019

Pharmacy context

The pharmacy is in a parade of shops with other local businesses on a housing estate. It dispenses NHS and private prescriptions and sells over-the-counter medicines. And provides advice on the management of minor illnesses and long-term conditions. It delivers medicines to people's homes. And supplies medicines in multi-compartment compliance packs. These help people remember to take their medicines. And it provides NHS services such as supervised consumption of methadone and flu vaccinations.

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's standard operating procedures have not been suitably reviewed. And the team members have not read and signed these. So, they may be unclear about the safest and most effective ways to carry out tasks.
		1.2	Standard not met	The pharmacy team does not record mistakes in a regular manner. And it has limited arrangements in place to learn from mistakes. So, the team may miss opportunities to improve and make services safer.
2. Staff	Standards not all met	2.2	Standard not met	All staff must be qualified for their roles and undertake formal training in accordance with the General Pharmaceutical Council's minimum training requirements.
3. Premises	Standards not all met	3.1	Standard not met	There are risks of trip hazards within the premises. These may be detrimental to people using the consultation room or when drivers make deliveries.
4. Services, including medicines management	Standards not all met	4.3	Standard not met	Arrangements to ensure stock remains fit for purpose are insufficient. The pharmacy has not recorded fridge temperatures for a period of time therefore there is some risk that it is not storing fridge-line medicines at appropriate temperatures, rendering these items unfit for purpose.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has some written procedures to identify and manage the risks to its services, but the team members have not read and signed these. So, there is no assurance that they are clear about the safest and most effective ways to carry out tasks. The team members discuss mistakes they make during dispensing. But the pharmacy keeps limited records of these. And there is not enough detail about why these mistakes happen. So, they may miss opportunities to improve and make services safer. The pharmacy generally keeps all the records as required, by law in compliance with standards and procedures. It provides people using the pharmacy with the opportunity to feedback on its services. The pharmacy team members look after people's private information. And they know how to protect the safety of vulnerable people.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) which the pharmacy owner had revised in the last year. And printed out. But the revised SOPs did not all show the relevant dates of updates and changes in the version numbers. The SOP for ordering pharmacy stock of controlled drugs (CD) showed version 3.1, with the next date of review in August 2021 and the date of preparation 2014. The SOP for assembly and labelling prescriptions showed version 1.0 with a date effective from as January 2017 and a review date of January 2019. The pharmacist advised the owner had reviewed the SOPs around March 2019. The team advised that they were aware of the SOPs but had not read the revised versions this year. A regular locum had signed all the SOPs this year. The team members could advise of their roles and what tasks they could do. They advised they worked as a small team and asked if they were unclear on any task.

The pharmacy workflow provided different sections for dispensing activities with dedicated benches for assembly and checking, with a separate area for compliance pack preparation. The team utilised the space reasonably well, but the pharmacy was cluttered in parts and the shelf space was poorly used. The pharmacy team members used baskets throughout the process to keep prescriptions and medicines together. They used different colours of baskets with green for people waiting, blue for call backs and red for delivery to distinguish people's prescriptions by degree of urgency. They also used a numbered peg system to ensure they processed items in order. This helped plan workload.

The pharmacy sporadically recorded near miss errors. It had the tools in place to do so. And the process was detailed in the SOP. This was generally done when the regular locum, who had read and signed the SOPs, was present. He followed the process in the SOPs, but the rest of the pharmacists and team did not regularly complete paperwork for near misses. Although they discussed any errors and were able to provide some examples of errors and learning. The team members present advised the locum used the sheet. He got them to complete the log themselves. But this was only done on days he was present. There were no formal reviews as stated in the SOP. Examples included bezafibrate with the wrong quantity, sildenafil 100mg with wrong drug and hypromellose with the wrong drug. The detail on the examples was limited. The team had limited detail of the cause of near misses with comments such as 'miss read' and 'double check'. There had been about eight recorded over a month.

The pharmacy had a practice leaflet, but the team could not locate it during the inspection. It displayed

a notice in the pharmacy which explained the complaints process. It provided information about the Patient Advice and Liaison Service (PALs).The team explained what they would do if they received a complaint. And the pharmacy kept forms with details in a folder for this purpose. The pharmacy had current indemnity insurance with an expiry date of May 2020.

The pharmacy displayed the correct responsible pharmacist (RP) notice. And the pharmacist completed the responsible pharmacist records as required. A sample of controlled drugs (CD) registers looked at found that they met legal requirements. The pharmacy usually checked CD stock against the balance in the register after each dispensing. The register indicated the pharmacy undertook some stock audits but not regularly. Physical stock of an item selected at random agreed with the recorded balance. The pharmacy kept a record of CDs which people had returned for disposal and it had a process in place to ensure the team destroyed these promptly. And did not allow a build-up in the CD cabinet. The pharmacy undertook few private prescriptions. And entries looked at recorded sufficient detail such as the dates of dispensing and of the prescription. The pharmacy kept special records for unlicensed products with the certificates of conformity completed.

The pharmacy displayed information on the confidential data kept and how it complied with legislation.

The team members demonstrated how they looked after private information. And the computer was password protected. The pharmacy team stored confidential waste in separate containers. And they shredded this regularly. The pharmacists had undertaken level 2 CPPE training. But the rest of the team had not completed any formal training on safeguarding. They advised they had discussed the issues and had a good awareness. There was a notice in the dispensary with some safeguarding information including local contact numbers, but this was dated May 2016. And may be out-of-date.

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

Summary findings

The staffing at the pharmacy is inadequate as one of the team who is working regularly in the dispensary has not completed a formal training qualification in accordance with the General Pharmaceutical Council's minimum training requirements. Pharmacy team members complete ongoing training on an ad-hoc basis. And the pharmacy doesn't provide structured ongoing training. And the team do not record any training undertaken. So, team members may miss opportunities to complete learning relevant to their role. The pharmacy team members support each other in their day-to-day work. And they feel comfortable raising any concerns they have. But the provision of a more structured whistleblowing policy would assist the team.

Inspector's evidence

There was one pharmacist and three other pharmacy team members working in the pharmacy. One of the pharmacist owners worked three days a week and the other one day a week. A regular locum covered the additional days. One dispenser had worked 14 years in the pharmacy. And the other had worked for about two years in this pharmacy but had worked as a dispenser for another pharmacy company and completed training there. They worked 32 and 24 hours each week. There was another dispenser who worked 24 hours who was not present. Another member of staff who worked 32 hours a week was working in the dispensary. She had worked as the driver previously. And had then started working on the counter. And was now working in the dispensary. And had done so for about two years. She had not completed any formal counter or dispensing course. She was aware of the courses available and had understood that the pharmacist owner would register her for one. She advised she had reminded the owner and asked if she could start the course. But this had not occurred. She appeared suitably competent and the pharmacist and the team supported her in her work. She asked questions and checked anything she was not sure of. In addition, there was a technician who was currently on maternity leave. The untrained dispenser had filled this staffing gap in the last year. The team members advised that the staffing was sufficient but if one of the team was on leave it was challenging managing the workload. But advised it should improve when the technician returned.

Team members described how they read through magazines and leaflets from suppliers and other third parties, but this was not recorded. Team members received limited training time in the pharmacy. And often read booklets such as the Counter Skills, at home for interest and their ongoing knowledge. One dispenser had recently read booklets on incontinence, mother and baby and vitamins, minerals and supplements. The pharmacist provided them with certain information to keep them up-to-date such as services for the quality payment scheme. The team had completed the oral health training pack. The team were reading the toolkit on the new NHS service, Community Pharmacy Consultations Service (CPCS). The pharmacy had an appraisal scheme. but the team members could not recall when they had last received any review. Two of the team had requested to do a First Aid course. And they had undertaken and completed a course for this.

The team followed the sales of medicines protocol when making over-the-counter (OTC) recommendations and referred to the pharmacist when necessary. The team carried out tasks and managed their workload in a competent manner discussing any issues which arose and dealing with any telephone queries. The team worked closely together and said they could discuss issues with the

pharmacist owners. But the owner had forgotten about the reminder about training for the unqualified member of the team. The pharmacist present was one of the partners in the business and she could not believe that the time had passed so quickly, and that no arrangements had been made for the staff member to undertake a formal course. The team had advised the heating and air conditioning was insufficient. The owner reviewed this, and the pharmacy had a new heating and air conditioning system. The boiler had broken down the previous day. And the team had reported this. It was being attended to. Although it looked like the part was obsolete. And the pharmacy may require a new boiler for the water heating.

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

Summary findings

The pharmacy environment is insufficient. There are risks related to trip hazards within the premises which may be detrimental to people using the consultation room or when deliveries are being made. In addition, hygiene could be compromised because there is an animal present in the pharmacy. But the pharmacy's premises are of a suitable size for the services it provides. And people can have private conversations with the team in a consultation room.

Inspector's evidence

The pharmacy was reasonably clean and tidy. The public area presented an acceptable appearance. The fixtures and fittings were adequate but worn in parts. In the dispensary the carpet had several sections which the team had taped down due to the edges lifting up. But there were several areas which had no tape, and these presented a trip hazard. There were also chipped tiles on the floor in part of the dispensary. The carpet in the public area was in reasonable order. The room temperature was comfortable, and the pharmacy was well lit. The team advised they undertook cleaning when required.

There was a dog present in the dispensary. The dog spent the majority of the time in a basket in the rear section of the premises, but it got up every time a delivery driver came to the rear door. The drivers were often carrying several boxes. And the dog generally walked over to them when they entered the premises. And walked in front of them. This could cause trips. The pharmacy had a reasonable sized, signposted, sound proofed consultation room which the team used. There was a notice about the chaperone policy asking patients if they would like a family member or chaperone present. The pharmacy team kept the consultation room locked from the public when not in use. The dog also spent time in the consultation room which had materials for the flu vaccination service on a table. And this could be a hygiene risk. The dog had toys on the floor of the consultation room. And these could cause a trip hazard.

The dispensary had adequate space for working in. And there were several benches for dispensing. But the area where the compliance packs had boxes on the floor to store compliance packs. The pharmacy had limited shelving for storage of these . And completed packs waiting a final check were being stored in cardboard boxes in the middle of the floor. Once the pharmacist had checked the compliance packs they were then moved into another box for storage.

The sink in the dispensary for preparation of medicines was clean. The hot water boiler had broken down the day before and the team had reported this. This was being looked into. And the team were boiling water from a kettle for washing items used during dispensing in the interim. The pharmacy had separate hand washing facilities in place for the team. These were older but adequate with hot water and paper towels for use. The team could observe people entering the pharmacy. And people could not access the dispensary due to the layout of the counter.

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

Summary findings

The pharmacy does not check the temperatures in the medicine fridges. So, there is a risk that the pharmacy is not storing fridge-line medicines at appropriate temperatures, rendering them unfit for purpose. The pharmacy's services are accessible to people. And it displays some information about health-related topics. The team members take steps to identify people taking some high-risk medicines. And they provide people with advice. They take care when dispensing medicines in to multi-compartment compliance packs to help people take their medication. And they keep audit trails for the packs to ensure they supply medicines as required. The pharmacy sources its medicines from reputable suppliers.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchairs. There was an automatic door at the entrance for easy access. This had just been fixed. And there was a notice on the door to advise people entering that it was working. There was some customer seating. The pharmacy displayed its services in the window and within the pharmacy. The hours of opening were on the door. There was a range of posters with a variety of health-related information. The information included some local events. The team signposted to other healthcare services such as Emergency Hormonal Contraception (EHC) which was not available through a Patient Group Direction (PGD). The pharmacy had a defined professional area. And items for sale were mostly healthcare related. The pharmacy kept the pharmacy medicines behind the counter and the team assisted people with purchase of such items.

The pharmacy undertook a few Medicine Use Reviews (MUR) and provided the New Medicines service (NMS) but did not undertake many. This was mainly due to other tasks taking priority. One of the pharmacists provided the flu vaccinations. And people were told of the day he worked. And came on that day if they required a vaccination. The team provided a smoking cessation service with the vouchers. The pharmacy undertook the Minor ailments service with paracetamol and treatments for head lice most common. They advised the service seemed more used in the winter months. The pharmacist was reading the information for the new Community Pharmacy Consultation Service (CPCS). And had not made any supplies.

The pharmacy supplied medicines to around 70 people in the community with multi-compartment compliance packs to help them take their medicines. The doctors generally undertook assessments on people who wished to receive their medication in compliance packs. The pharmacy would refer people to the doctor. The compliance packs were generally prepared by one of the dispensers. She kept records for each individual person, and these showed details of any changes made. The dispenser made up four weeks at a time. And most people received four weeks together. The backing sheets included descriptions of the medicines. And the pharmacy supplied people with patient information leaflets (PILs) with the four weeks supply. Most people had the compliance packs delivered to them. The compliance packs were all assembled and checked at the pharmacy. And the pharmacist no longer took any to the other branch, for checking, as had occurred previously. The dispenser kept the boxes with the details together with the prescriptions for the pharmacist to check. Once the dispenser had prepared the packs, she placed them in to a large cardboard box. And the pharmacist checked them,

then put them in to another cardboard box awaiting supply. The pharmacist initialled the compliance packs after checking. The boxes to store the packs were in the middle of the floor in the rear of the dispensary and the area was a bit cluttered. The shelving in the rear area was untidy and not used well. This could store the completed packs on. And this would clear the floor space. And aid in locating the packs for delivery. The pharmacy offered a substance misuse service and had a few people who used this service. The pharmacist made up the methadone the day before ready for supply.

There was a clear audit trail of the dispensing process. The team completed the 'dispensed by' and 'checked by' boxes which showed who had performed these roles. And a sample of completed prescriptions looked at found compliance with this process. There were some alerts stickers used to apply to prescriptions to raise awareness at the point of supply. These ensured patients received additional counselling. The team members used CD and fridge stickers on bags and prescriptions to prompt the person handing the medication over that some medication required to be added to complete the supply. They also kept a list of completed prescriptions and made any notes on it which ensured that passed information on to people. When the pharmacy could not provide the product or quantity prescribed in full, patients received an owing slip. And the pharmacy kept a copy with the original prescription to refer to when dispensing and checking the remaining quantity. The pharmacy contacted prescribers if items were unobtainable to ask for an alternative. The pharmacy team members were aware of the valproate Pregnancy Prevention Programme. And they had clearly marked the shelf where they kept the stock to raise awareness of the risks. There was also an alert reminder on the computer. The team explained the information they provided to the people in the 'at-risk' group. The pharmacy kept a delivery sheet as an audit trail for the delivery of medicines from the pharmacy to patients. This included a signature of receipt of the delivery. The driver used a separate delivery sheet for controlled drugs.

The pharmacy obtained medicines from reputable sources. The pharmacy team checked expiry dates on products and had a rota in place to ensure all sections were regularly checked. They had stickers on boxes which indicated expiry dates up to May 2020. And they took items off the shelf prior to the expiry date. The team members marked liquid medication with the date of opening which allowed them to check to ensure the liquid was still suitable for use. The pharmacy generally stored medicines in an organised way, within the original manufacturers packaging and at an appropriate temperature. But there were a few amber bottles with items for the compliance packs which had insufficient information such as no batch number or expiry date. The dispenser advised that the pharmacist would dispose of these items.

The pharmacy had a refrigerator from a recognised supplier. This was appropriate for the volume of medicines requiring storage at such temperatures. The pharmacy team members advised they recorded readings. They showed the record sheet on the door which was for July 2019. They had not recorded any readings since July. The fridge temperature at the time of the inspection was within an acceptable range.

The pharmacy team were aware of the Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed. It had scanners in place but was not scanning. The team members were not sure when they would implement the process. And said that the other branch scanned medicines. The team used appropriate medicinal waste bins for patient returned medication. The contents of the bins were securely disposed of via the waste management contractor. The pharmacy had appropriate denaturing kits for the destruction of CDs. The pharmacy had a process to receive drug safety alerts and recalls. The team actioned these and kept records of the action taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the pharmacy services it provides. There are provisions in place to maintain people's privacy. But the team require to obtain their own NHS Smart cards for use.

Inspector's evidence

The pharmacy team members had access to a range of up-to-date reference sources, including the British National Formulary (BNF). They used the internet as an additional resource for information such as the Electronic Medicines Compendium (EMC) for patient information leaflets (PILs). The pharmacy had measuring equipment available of a suitable standard including clean, crown-stamped measures. It had a separate range of measures for measuring methadone. It also had a range of equipment for counting loose tablets and capsules. The equipment for the flu vaccinations was in a basket and kept on the table in the consultation room. The team members had access to disposable gloves and alcohol hand washing gel.

The pharmacy stored medication waiting collection on shelves in the dispensary. They used a raffle ticket system with a corresponding list which they update daily. This list included additional information such as if they required to add a fridge line or if an item was large and stored in a separate location. The team advised this was efficient for retrieving and locating items when people came in. The computer in the consultation room was screen locked when not in use. The team used cordless phones for private conversations.

The computer screens in the dispensary were out of view of the public. The dispensers had not all got NHS smart cards. They pharmacist uses hers and one of the dispensers had one. The team members advised that the responsible pharmacist left hers for emergencies but that they needed to get their own. They advised that they could only access to a certain level as they had to put in passwords, and this restricted what information they could see.

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.