Registered pharmacy inspection report

Pharmacy Name: Boots, 23-25 High Street, NEWHAVEN, East Sussex,

BN9 9PD

Pharmacy reference: 1036247

Type of pharmacy: Community

Date of inspection: 07/01/2020

Pharmacy context

This is a medium sized branch of Boots in the centre of Newhaven and is accredited as a Healthy Living Pharmacy (HLP). It dispenses NHS and private prescriptions, sells a range of over-the-counter medicines and provides health advice. The pharmacy offers flu vaccinations in the autumn and winter seasons. It dispenses some medicines in multi-compartment compliance aids for people who have difficulty managing their medicines. The pharmacy provides most of its services to people living within the town. It also offers a home delivery service for those who are unable to get to the pharmacy themselves.

Overall inspection outcome

✓ Standards met

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	1.2	Good practice	Well-written records of errors, near misses and other patient safety incidents are regularly reviewed. Detailed records are kept showing what has been learned, what has been done, and how they have been used to improve the safety and quality of services provided
		1.6	Good practice	Records are kept of all communications and contact with General Practitioners (GPs), carers and others about patients which improves their quality of care. Those records are kept in a communications logbook and copied as required to individual PMRs.
2. Staff	Standards met	2.2	Good practice	Planned learning and development is actively encouraged and relevant and useful learning and development is arranged for the staff to access. Records show that staff complete regular ongoing training, relevant to their roles, to help keep their skills and knowledge up to date
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards met

Summary findings

The pharmacy provides its services in line with clear, up-to-date processes and procedures which are being followed by its team members. They are clear about their roles and responsibilities. And they work to professional standards, identifying and managing risks effectively. The pharmacy keeps good records of the mistakes it makes during the dispensing process. The 'Patient Safety Champion' regularly reviews them with the manager and members of the team so that they can learn from them and avoid problems being repeated. The pharmacy manages and protects confidential information well and tells people how their private information will be used. Team members understand their role in helping to protect the welfare of vulnerable people. The pharmacy has adequate insurance in place to help protect people if things do go wrong.

Inspector's evidence

There were Standard Operating Procedures (SOPs) in place to underpin all professional standards, seen as signed and read by staff. Several had been updated in November 2018 and due a review in November 2020 with others, notably the SOPs for controlled drugs (CDs) dated Nov 2019 and due to be reviewed in Nov 2021. There were also signed training logs present in the folder for the new SOPs verifying that each member of staff had read and understood them. Staff roles and responsibilities were all set out in a matrix within the SOP folder, and staff were all clear on the correct procedures to follow.

Errors and near misses were seen to be regularly recorded on a report form kept by the dispensing workstation. The registered technician, who was the 'patient safety champion,' reviewed them and completed the 'Patient Safety Review' (PSR) every month for head office. Copies of the last three reviews were on a clip in the dispensary for all staff to read. Errors and near misses were discussed during a monthly team meeting. The recent near miss incident logs highlighted the need to ensure that all product barcodes were scanned when dispensing. The manager explained that they had recently introduced the new Columbus patient medication record (PMR) system. If the barcode on the medicine pack didn't scan successfully, they made a note on the pharmacist information form (PIF) attached to the prescription, to prompt an additional check of the product itself. They highlighted 'Look Alike Sound Alike' (LASA) drugs on the PIF to help avoid picking errors. They had also put 'select and speak' signs on cartons adjacent to the LASAs as a prompt when picking those items.

A business continuity plan was in place and a file with emergency contact details was in a red offline folder in the control office. The emergency contact list was also on the dispensary wall for easy access. People working in the pharmacy were able to clearly explain what they do, what they were responsible for and when they might seek help. The RP log was seen to be complete and up to date. Staff were able to describe what action they would take in the absence of the responsible pharmacist, and they explained what they could and could not do. The responsible pharmacist notice was correct and clearly displayed for patients to see.

Results of the latest Community Pharmacy Patient Questionnaire (CPPQ) were not on display in the pharmacy but were available online. Results of the 2018/19 questionnaire showed that 96% of respondents rated the pharmacy as excellent or very good. There was a complaints procedure in place, and this was detailed in a patient guide leaflet in the leaflet stand by the dispensary reception. It included contact details for the company's head office, Patient Advice and Liaison Service (PALS) and

the Independent Complaint Advocacy Service. There were also feedback leaflets from the NHS and local council in the stand. Credit card style prompt cards for seeking feedback were also available at the prescription reception counter and in the consultation room. A certificate of professional indemnity and public liability insurance from XL Insurance Co. Ltd was held electronically on the company's intranet.

Private prescription records were maintained electronically on the Patient Medication Record (PMR) system. A sample of records were checked, and some were seen to have the incorrect prescriber details recorded. This was discussed and the manager made notes to brief the rest of the team. Emergency supply records were also maintained electronically, complete with details of the emergency and the reason for supply. Some of those records did not contain enough detail within the reason for supply. The manager noted this and agreed to ensure that more detail would be recorded in future.

The controlled drug (CD) register was seen to be correctly maintained. Running balances were checked weekly in accordance with the SOP. Stock balances of two random samples were checked and found to be correct. Records of CDs returned by patients were seen to be made upon receipt and subsequent destruction documented and witnessed. Records of unlicensed 'specials' were not checked as the pharmacy ordered very few and the paperwork was stored with other invoices. The manager explained that the new Columbus system prompted them to record the necessary details whenever a 'special' was labelled, and it also ensured that the associated paperwork was reconciled as it arrived. Access to the CD keys was recorded daily in the CD key log, stored within the pharmacy duty folder.

All staff were able to demonstrate an understanding of data protection and had undergone General Data Protection Regulation (GDPR) training. They were able to provide examples of how they protect patient confidentiality, for example taking patients aside or speaking quietly when discussing sensitive information. Confidential waste was kept separate from general waste and shredded offsite. The annual Data Security and Protection (DSP) toolkit had been completed, and there was a privacy notice on display by the prescription reception counter for people to see. There was also an NHS data use notice on display. Completed prescriptions awaiting collection were stored below the prescription reception counter where they were not visible to those waiting at the counter.

There were safeguarding procedures in place and contact details of local referring agencies were in the safeguarding section of the pharmacy duty folder and on a notice in the dispensary for staff to see. All registrants had been trained to level 2 and all other staff members had undergone level 1 Boots e-learning. Staff were able to describe some of the signs to look for and knew when to refer to the pharmacist. All staff were dementia friends.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Pharmacy team members are welltrained and have a good understanding of their roles and responsibilities. They can make suggestions to improve safety and workflows where appropriate.

Inspector's evidence

There was one pharmacy advisor (manager) one registered technician and the responsible pharmacist (RP), on duty during the inspection. The RP was a self-employed locum pharmacist who worked in the pharmacy from time to time as required. The size of the team appeared to be appropriate for the workload. In the event of staff shortages, they could contact the area manager for support such as using relief dispensers or borrowing staff from another branch. All staff wore badges showing their names and role.

Certificates to confirm staff qualifications were available both online and in paper files to show the levels of training completed. Ongoing training consisted of e-learning modules for staff to complete online. The manager explained that they were just implementing a new online training system, 'pharmacy unscripted' which included quizzes to check understanding. The new system also enabled the manager to monitor staff progress with training. Staff were able to demonstrate an awareness of potential medicines abuse and could identify patients making repeat purchases. All members of staff were seen to serve customers and asking appropriate questions when responding to requests or selling medicines.

The pharmacist confirmed that he was comfortable with making decisions and did not feel pressurised to compromise his professional judgement. He emphasised that he would only conduct a medicines use review (MUR) if he felt it to be clinically appropriate and of benefit to the patient. There were targets in place but they were applied sensibly. Team members were involved in open discussions about their mistakes and learning from them. Team members said that they could raise concerns and that there was a whistleblowing policy available for them if needed. The manager conducted periodic reviews with her team to discuss performance and areas for development. Each member of staff had an up-to-date personal development plan in place.

Principle 3 - Premises Standards met

Summary findings

The pharmacy's premises provide a safe, secure and professional environment for people to receive its services. The premises include a private room which the team uses for some of its services and for private conversations.

Inspector's evidence

There was step-free access into the pharmacy through two sets of doors, one set of which opened automatically. This ensured that the premises were easily accessible to people with pushchairs or those with mobility issues. The manager pointed out that a lot of young mums with pushchairs used the pharmacy and found the automatic doors very helpful. The pharmacy premises were clean, tidy and in a reasonable state of repair. The dispensary was sufficiently large to allow for separate assembly and checking areas, which were reasonably tidy and free of clutter. There was sufficient space to work safely and effectively and the layout was suitable for the activities undertaken.

There was a small health promotion area with posters highlighting current local health priorities. The current HLP event being promoted was 'Dry January'. The pharmacy was also promoting a separate health initiative jointly with Public Health England called 'it's time for a reboot'. There was a consultation room for confidential conversations, consultations and the provision of services. The glass door could not be locked but there were no sharps bins or confidential information present. The view through the glass door could be obscured by a curtain to protect patient confidentiality and dignity when the room was in use. There was a tray in the dispensary containing swabs, gloves and a box of adrenaline ampoules for use in an emergency. The tray was taken into the consultation room whenever the pharmacist provided a flu vaccination, and then returned to the dispensary afterwards.

The sink in the dispensary was clean, had hot and cold running water and handwash available. Room temperatures were appropriately maintained by combined heating and air-conditioning units, keeping staff comfortable and suitable for the storage of medicines.

Principle 4 - Services Standards met

Summary findings

The pharmacy delivers its services in a safe and effective manner, and people with a range of needs can access them. The pharmacy sources, stores and manages its medicines safely, and so makes sure that all the medicines it supplies are fit for purpose. It responds well to drug alerts or product recalls so that people only get medicines or devices which are safe for them to take. It identifies people supplied with high-risk medicines and records the checks that it makes so that they can be given extra information they may need to take their medicines safely.

Inspector's evidence

There was a sign in the shop window listing the pharmacy's opening hours. There was a range of leaflets providing general health information and the services available from the pharmacy. The pharmacy provided a limited range of services including seasonal flu vaccinations which were available during the autumn and winter.

Controls were seen to be in place to reduce the risk of picking errors, such as highlighting LASAs on shelf with 'select & speak' labels. The manager explained how their new Columbus dispensing system also helped to prevent picking errors when the medicines were scanned as they were selected, and near misses had reduced accordingly. The manager explained that the Columbus system also highlighted the screen in colour when a prescription for a child or baby was being dispensed, to prompt the pharmacist to make any extra checks that may be necessary. The team used PIFs to communicate messages about the patient's medicines to the pharmacist. These were used to highlight new medicines, changes to their medicines, any allergies or whether the patient was eligible for further services, such as an MUR. The form also had a blank box to write any further information that the dispenser thought the pharmacist should be aware of. They used baskets to keep individual prescriptions separate, and prescription labels were initialled to show who had dispensed and checked them. The system also endorsed the prescription tokens with prompts for the staff to sign showing who had labelled, clinically checked, assembled and completed the final check. They also initialled the bag label on the finished prescriptions to complete the audit trail, signifying who had filled the bag and checked that it was complete and correctly labelled. There was a separate signature to show who then handed the bag out to the patient. All of this helped to identify who had been involved at each stage in the process if any query arose after the prescription had been handed out. Private prescriptions were manually endorsed with the 'quad stamp' for recording the same audit trail as recorded on NHS prescriptions. All of the pharmacy's prescriptions were dispensed onsite as they were not using the company's centralised dispensing support pharmacy.

Owings tickets were in use when medicines could not be supplied in their entirety. The prescription was completed as soon as the missing item was back in stock. The manager explained how they checked stock availability every day through the Columbus system, and would obtain some of those items from other local branches if they had spare stock. If the item was likely to be unavailable for some time, the patient would be signposted to their GP for an alternative. The manager confirmed that they were aware of the Serious Shortage Protocol (SSP) but had not yet received any prescriptions for the affected items.

Prescriptions for CDs or fridge lines in retrieval awaiting collection were highlighted with laminated

prompt cards and some put in a separate envelope so that staff would know that there were items to be collected from the fridge or CD cupboard. The pharmacist demonstrated the process to ensure that controlled drug prescriptions weren't handed out after their 28-day expiry. There were prompt stickers on the bags which included the date after which the prescription could not be handed out. The dates on Schedules 2 and 3 CD prescriptions were highlighted with their expiry date. There were no schedule 4 CDs such as zopiclone or diazepam in retrieval at the time of inspection, but the manager confirmed that they were highlighted. The prescription retrieval shelves were cleared every week of anything over five weeks old. One of the dispensary team would send a reminder text to the patient if possible before the medication was returned to stock and the EPS prescription returned to the NHS spine.

Staff were aware of the risks involved in dispensing valproates to women in the at-risk group, and all such patients were counselled and provided with leaflets and cards highlighting the importance of having effective contraception. The pharmacy had recently completed an audit of valproate patients and all interventions were recorded on the PMR system.

Patients on warfarin were asked if they knew their current dosage, and their INR records were recorded on the PMR system. Some patients didn't always collect their own prescriptions, and their representative wouldn't know their INR result. Patients taking methotrexate and lithium were also asked about blood tests. All of these interventions were recorded on the PMR. There were laminated prompt cards to go with the PIF to ensure that staff checked, and the key points were listed on the reverse to remind them.

The pharmacy provided substance misuse services to a number of local people, including a very small number who participated in the supervised consumption service. If anyone missed their doses for three days, then the pharmacist would contact their key workers. The manager explained that this wasn't normally a problem, although they had experienced a number of 'no shows' over the Christmas holiday period.

The pharmacy supplied some medicines in multicompartment compliance aids to a number of people. The manager outlined the process for ensuring that the prescriptions were ordered from the surgeries on time. There was a 'Medisure' folder containing records of each persons' medication, when they were taken, any known allergies, any discharge information from the hospitals and contact details. She explained how they used this information to ensure that all of the necessary prescriptions had been received. The data entry (labelling) part of the process was only completed after they had received all of the required prescriptions, and the pharmacist had completed a clinical check to ensure that everything was as it should be. The compliance aids were then assembled in sufficient time for them to be ready for collection or delivery when needed. They included product descriptions and patient information leaflets (PILs).

Medicines were obtained from licensed wholesalers including Phoenix, AAH, Alliance. Unlicensed 'specials' were obtained from Alliance Specials. The pharmacy was using the 'Columbus' PMR system and was not yet using it to decommission stock in accordance with the requirements of the EU Falsified Medicines Directive (FMD). The manager was expecting to start decommissioning later this month once she had familiarised herself and her team with the process.

Routine date checks were seen to be in place, and record sheets were seen for each quarter. Items within three months of their expiry date were recorded on monthly sheets, and any left in stock one month prior to expiry were then disposed of.

Fridge temperatures were recorded daily, and all seen to be within the 2 to 8 degree Celsius range. Staff

explained how they would note any variation from this, completing the 'store checklist for investigation of fridge or freezer anomalies' form if necessary. The manager explained that as a result of an incident where the fridge door opened overnight, they completed a safety review and amended their procedures to ensure that the fridge door was always locked before leaving the premises at the end of the day. Pharmacy medicines were displayed behind the medicines counter, preventing unauthorised access or self-selection of those medicines.

Patient-returned medicines were screened to ensure that any CDs were appropriately recorded, and that there were no sharps present. Patients returning sharps were signposted to the local council for disposal. There was a tray containing protective gloves and goggles to help staff safely sort through any returned medicines. The pharmacy had no separate purple-lidded hazardous waste container for the disposal of medicines classified as hazardous waste. And there was no list of those medicines available for staff to refer to. The manager agreed to obtain them.

The pharmacy had valid patient group directions (PGDs) in place for both the NHS and private seasonal flu vaccination services. They named the pharmacists accredited to provide the service and were valid until the end of March 2020. The pharmacy kept signed patient consent forms in a file, together with the vaccination records themselves.

The pharmacy received drug alerts and recalls from the MHRA via 'my calendar' on 'Boots Live', printed copies of which were kept in a file. Each alert was annotated with any actions taken, the date and initials of those involved. The team knew what to do if they received damaged or faulty stock and they explained how they would return them to the wholesalers.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the right equipment for the range of services it provides, and it makes sure that it is properly maintained. The pharmacy takes reasonable steps to ensure that people's private information is kept safe and secure.

Inspector's evidence

The pharmacy equipment and facilities were seen to be appropriate for the services provided. The consultation room was clean and tidy. There was a range of crown stamped measuring equipment, counting triangles (including a separate one for cytotoxics, and separate measures marked in red for methadone). Reference sources were available, including the BNF and BNF for children. The pharmacy also had internet access and used this as an additional reference source.

Access to PMRs was controlled through individual passwords, which had been changed from the original default password. Computer screens were positioned so they were not visible to the public. Staff were seen to take precautions such as moving to the rear of the dispensary when making telephone calls so as not to be overheard. NHS smartcards were seen in use with no sharing of passwords, and they were not left on the premises overnight.

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.	