Registered pharmacy inspection report

Pharmacy Name: Aberdour Pharmacy, 30 High Street, ABERDOUR,

Fife, KY3 OSW

Pharmacy reference: 1042042

Type of pharmacy: Community

Date of inspection: 02/05/2019

Pharmacy context

This is a community pharmacy in a village. The area is growing due to new homes being built. Most of the people who use the pharmacy are older people. But there are increasing numbers of young families moving into the area. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It also supplies medicines in multicompartment medicine devices. Other services that the pharmacy offers include the chronic medication service (CMS), minor ailments service (eMAS), travel vaccination, flu vaccination during the flu season and some aesthetic procedures e.g. Botox[®]. A satellite GP session runs once per week in the pharmacy. The pharmacy had changed ownership the previous year.

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	N/A	N/A	N/A
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 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

Pharmacy team members usually follow processes for all services to ensure that they are safe. Some written processes are not clear, and some do not apply to this pharmacy. Some team members have not read new written processes. This means there could be mistakes. Pharmacy team members record mistakes to learn from them. They make changes to avoid the same mistake happening again. The pharmacy keeps all the records that it needs to by law and keeps people's information safe. Pharmacy team members help to protect vulnerable people.

Inspector's evidence

Standard operating procedures (SOPs) were in place for all activities/tasks. The inspector observed two sets of SOPs, one set recently received and intended to supersede the other. The previous set had been read and signed by relevant staff members. However, some detail was observed to be lacking e.g. areas where templates should have been completed or amended such as how often controlled drug running balances were audited. These SOPs had been reviewed annually and were signed off by one of the directors. All staff members had signed them individually. The new set of SOPs had been signed by pharmacists but were not yet signed by all staff members. Signatures were captured on one sheet at the front of the folder, stating that all SOPs had been read. They included several English processes e.g. Medicines used reviews (MURs), new medicines service (NMS), and electronic prescribing (EPS). A controlled drug SOP stated that running balances were audited weekly, but this was being done monthly.

The main activity undertaken in this pharmacy was dispensing, and this followed logical processes. There was an audit trail in place for dispensed medicines in the form of dispensed and checked by signatures on labels.

Business continuity planning was in place to address maintenance issues or disruption to services.

Near miss logs were kept and error reporting was in place. No evidence was seen of regular or formal review of these. But strategies were described and observed that had been put in place to reduce repeat incidents. These included separating different forms of paracetamol, and an additional label generated for all paracetamol prescriptions reminding dispensing staff to doublecheck the form e.g. capsule or caplet. Prednisolone tablets had been moved to a separate area to minimise the chance of these being supplied in error. This was following incidents elsewhere. The pharmacist present during the inspection had worked in the pharmacy for three weeks and intended to undertake monthly reviews of new misses.

Staff members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist.

There was a complaints procedure in place. People were able to give feedback to the pharmacy, and there were boxes in the retail area for feedback or suggestions. No examples were provided, but there was a letter on the dispensary wall from a person complementing the pharmacy team. The pharmacy superintendent had told team members that there had been examples of positive feedback recently.

Indemnity insurance certificate (NPA) was displayed, expiring December 2019. The following records were maintained in compliance with relevant legislation: responsible pharmacist notice displayed; responsible pharmacist log; private prescription records, including records of emergency supplies and veterinary prescriptions; unlicensed specials records; controlled drugs registers, with running balances maintained and regularly audited; records of patient returned controlled drugs. The electronic patient medication record (PMR) was backed up each night. Alterations to records were attributable, by staff initials or passwords or electronic controlled drug records.

Staff members were aware of the need for confidentiality and had undertaken training on the subject. There was an SOP included in the new folder. No person identifiable information was visible to the public. Confidential waste was usually segregated for secure destruction.

The pharmacist was aware of local processes to be followed to raise any safeguarding concerns and knew where to find contact details. She was PVG registered.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough qualified and experienced staff to safely provide its services. The pharmacy compares staff numbers and qualifications to how busy the pharmacy is and makes changes. This ensures skilled and qualified staff provide pharmacy services. Pharmacy team members have access to training material to ensure that they have the skills they need. Team members can share information and know how to raise concerns if they have any. They discuss incidents and learn from them.

Inspector's evidence

Staff numbers present at time of inspection: Two regular locum pharmacists, one worked three days per week and had been in this pharmacy for around three weeks; the other had worked in the pharmacy for several years and worked two and a half days per week; one full-time pharmacy technician; one part-time dispenser, 8.30am to 2pm each day; one part-time driver, working a half day each day.

Staff members were observed to manage the workload. Part-time dispenser had scope to work additional hours to cover for the pharmacy technician's absence. Alternatively, a relief dispenser, or dispenser from another branch provided cover during absence.

An employee handbook, and human resource policies were observed. Staff members were aware of these and knew they could access them online as well as in the pharmacy. Staff members had access to the National pharmaceutical Association (NPA) continuing professional development (CPD) hub. They could undertake training modules of their choosing, that were relevant to their own training needs. Mandatory topics such as information governance and safeguarding were included. Members often undertook this training in their own time at home but could do it within work time. They were required to undertake 12 modules each year and submit evidence of this to the superintendent pharmacist.

Development meetings were held twice per year to identify and address training needs. Team members were encouraged to use training modules to address these. They explained that these meetings were informal, and concerns or suggestions could easily be raised with management. Appropriate responses were given to scenarios posed regarding raising concerns.

An employed pharmacist within the organisation had interest in a variety of pharmacy activities. He had recently run a training session for pharmacists and pharmacy technicians on anticoagulants. The pharmacy technician explained that this had been well attended and useful, enabling her to offer better advice and counselling to people who took these medicines.

The pharmacist, who worked in another pharmacy in the organisation mostly, ran clinics in this pharmacy offering travel vaccination, flu vaccination and some aesthetic services. He had provided basic information to staff to enable them to deal with queries. Usually a staff member contacted him for information which was relayed to enquirers. The pharmacist ran the clinics when there was demand.

The various individuals were observed going about their tasks in a systematic and professional manner. They described understanding the importance of reporting mistakes. Team members felt comfortable owning up to mistakes and knew this helped with learning and safety. A lot of sharing of information and discussion was observed during the inspection.

Targets were not set.

Principle 3 - Premises Standards met

Summary findings

The pharmacy is safe and clean and suitable for its services. The pharmacy team members use a private room for some conversations with people. People cannot overhear private conversations. The pharmacy usually protects people's information. The pharmacy is secure when closed.

Inspector's evidence

These were average sized premises, incorporating a very small dispensary, retail area, consultation/treatment room, waiting room and staff facilities. The consultation/treatment room was equipped with a desk, chairs, bench, computer and a range of diagnostic equipment used by a GP who ran a weekly clinic.

The waiting room was used by people waiting to see the GP at the weekly clinics. At other times this room was used for some dispensing, particularly large or bulky prescriptions, and storage of multicompartment medicine devices. These were kept in locked cupboards with no person identifiable information visible. Shelves within the cupboards were labelled with individual people's names. There were sinks in the dispensary, consultation room, staff room and toilet. These had hot and cold running water, soap, and clean hand towels.

People were not able to see activities being undertaken in the dispensary. The premises were observed to be clean, hygienic and well maintained. Prescription medication waiting to be collected was stored in a way that prevented patient information being seen by any other patients or customers.

At the time of inspection, following a GP clinic, clinical waste and confidential waste were observed in a bucket under the desk in the consultation/treatment room. The pharmacy technician explained that she went through the bucket after GP clinics and removed confidential waste for secure destruction, but she was not protected from the risks associated with clinical waste e.g. blood on cotton wool which was observed.

The pharmacy was alarmed and had a panic alarm in the consultation room. Shutters protected the dispensary, and the front door was protected by a locked external door when the pharmacy was closed. There were bars on a window at the rear of the premises. Temperature and lighting were comfortable.

Principle 4 - Services Standards met

Summary findings

The pharmacy helps people to ensure they can all use its services. The pharmacy displays community information and healthcare information so that people know what is available locally. The pharmacy team provides safe services. Team members give people information to help them use their medicines. They provide extra written information to people with some medicines. Some people get their medicines supplied in packs that help them take their medicines. The pharmacy team has good processes in place to make sure these are safe and ready in time. The pharmacy gets medicines from reliable sources and stores them properly. But the pharmacy does not comply with the requirements of the Falsified Medicines Directive (FMD).

Inspector's evidence

There was good physical access by means of a ramp at the entrance and assistance given with the door if required. Services provided were displayed. Leaflets on a range of topics were available. The pharmacy displayed posters on behalf of community organisations locally. Large print labels could be provided for people with impaired vision.

The dispensary was small but dispensing work flow was managed in a logical manner. Baskets were used to keep people's medicines separate, and different colours allowed these to be prioritised. Dispensing audit trails were in place in terms of initials on dispensing labels of personnel who had dispensed and checked medicines. Owings were usually assembled later the same day or the following day.

Pharmacy staff had access to the prescribing part of the local GPs' electronic records. When people requested repeat prescriptions from the pharmacy, this request was put into the prescribing system which generated a prescription. Prescriptions were dispensed and stored in individual baskets in a clearly labelled area until they were signed by the GP. The unsigned prescriptions were delivered to the GP practice for review, authorisation and signing. If there was a message that the person required a review of medicines, this was marked on the prescription for the GP to see. When signed prescriptions were returned to the pharmacy they were filed alphabetically and then matched to the original request forms and dispensed medicines. These were then checked by the pharmacist in the usual way. There was no risk of items being supplied to people before signed prescriptions was received as the process was observed to be robust, and items stored on well labelled shelves. While they were being stored they were labelled and signed by a dispenser but no pharmacist signature and there was no prescription present. One advantage of this system was that medicines were supplied to people quickly. When the prescriptions were ordered, the labelling generated an order of stock which ensured that by the time the signed prescription was received there was stock to fulfil the whole prescription in the pharmacy. In these cases, if there was stock to follow, baskets were stored in an adjacent area which was clearly marked to this effect.

There was a delivery service and signatures were obtained on receipt. The driver used a cool box to maintain the cold chain of items requiring cold storage. Separate records of delivery were kept for these items and controlled drugs.

Multicompartment medicine devices were assembled offsite at a hub. Four were assembled at a time.

When prescriptions were received they were checked for completeness and accuracy with any omissions queried by the dispenser or pharmacist technician with the GP practice. Information was put onto the labelling system in the usual way, although labels were not generated. This was checked for accuracy and clinical appropriateness by a pharmacist who signed the prescription to confirm this. The pharmacy sent this information electronically to the hub, and actual prescriptions were delivered to the hub by the delivery driver. This was usually around two weeks before the first device was required. After assembly by a robot, a pharmacist or accuracy checking technician undertook an accuracy check of the dispensing. They initialled the backing sheet within the device, and a label on the exterior. People receiving medication in this manner were aware that it was assembled at different premises. The address of the hub was on the backing sheet, and the address of the pharmacy was on the outside of the pack. This process took around a week, so completed devices were received back into the pharmacy a week before the first supply. As noted elsewhere these were stored in locked cupboards on clearly labelled shelves. Devices containing controlled drugs were not sealed at the hub. They were closed securely using elastic bands and the pharmacy added the controlled drugs on the day of supply. An accuracy check of all items was undertaken at this stage.

Methadone instalments were poured weekly by the pharmacy technician and checked by a pharmacist. Instalments were labelled with date of dispensing and date of supply and were stored in a controlled drug (CD) covered.

There were a variety of other medicines supplied by instalment. These were dispensed in entirety on receipt and individual instalments placed in bags clearly labelled with date of supply. These were stored in individual patient baskets on clearly labelled shelves in the dispensary.

Clinical checks were undertaken by a pharmacist and people receiving high risk medicines including valproate, methotrexate, lithium, and warfarin were given appropriate advice and counselling. Written information and record books were provided if required. The valproate pregnancy prevention programme was in place. A search had been undertaken and this identified only one person on this medication who was not of childbearing capacity. The non-steroidal anti-inflammatory drug (NSAID) care bundle had been implemented and written and verbal information was given to people supplied with these medicines over-the-counter, or on prescriptions. 'Sick day rules' were also discussed with people on certain medicines, so that they could manage their medicines when they were unwell.

The pharmacist was observed to provide effective counselling and information to people during the inspection.

NHS services followed the service specifications and patient group directions (PGDs) were in place for unscheduled care, pharmacy first, smoking cessation, emergency hormonal contraception and chloramphenicol ophthalmic products. These were current, and the pharmacists had been trained and signed them. Private PGDs were in place for travel vaccination, flu vaccination and aesthetic services. These were not seen during inspection as they only applied to the pharmacist who provided these services on a sessional basis. There were some people receiving medicines on chronic medication service (CMS) prescriptions. These were dispensed the week before the expected date of supply. Prescriptions were stored alphabetically and marked with date of collection and date of next supply. These were checked weekly to enable prescriptions to be dispensed in advance. There were no compliance issues, with people usually collecting on the day that items were due. The pharmacy was registering people for the service, but no pharmaceutical care issues were identified. A brief bespoke questionnaire was used with people completing this themselves to start the consultation.

Staff members were empowered to deliver the minor ailments service (eMAS) within their competence.

This was observed. Smoking cessation consultations were undertaken by pharmacists. There was currently one person accessing the service and receiving nicotine replacement therapy. As noted elsewhere vaccinations were undertaken by a pharmacist from another branch who visited the pharmacy on a sessional basis. There were plans to train the two locum pharmacists to deliver the flu vaccination for the following season. The sessional pharmacist ran clinics when there was demand. So far there had been no demand for aesthetic services.

A GP ran a satellite surgery using the consultation room in the pharmacy as noted above. This was one morning per week. Pharmacy staff members were not involved in this. People made appointments through the surgery in the next village and accessed the waiting room in the pharmacy. Sometimes pharmacy staff directed them to the waiting room. Pharmacy team members ensured that the waiting room was tidy, cupboards locked and no person identifiable information visible before the session.

Invoices were observed from licensed suppliers such as AAH.

The pharmacy did not comply with the requirements of the Falsified Medicines Directive (FMD). It was registered, and hardware had been obtained. But the supplier was having issues with the software, so implementation had been delayed. Staff were aware but did not yet know the details of this legislation. Records of date checking, and stock rotation were observed, and items inspected were found to be in date. Medicines were stored in original packaging on shelves/in drawers. Items requiring cold storage were stored in a fridge with minimum and maximum temperatures monitored and action taken if there was any deviation from accepted limits.

Controlled drugs (CDs) were stored in a small CD cabinet, with the key kept in a key safe. Space was well used to segregate stock, dispensed items and obsolete items but it covered was congested. There was no space to put any person returned medicines should they be received.

Pharmacy (P) medicines were protected from self-selection. Sale of P medicines was as per sale of medicines protocol.

MHRA recalls and alerts were actioned on receipt and records kept. Patients were contacted following patient level recalls. Items received damaged or faulty were returned to suppliers as soon as possible.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment it needs for the delivery of its services. The pharmacy looks after this equipment to ensure it works.

Inspector's evidence

Texts available in the pharmacy included current editions of the British National Formulary (BNF) and BNF for Children. There was internet access allowing online resources to be used.

A carbon monoxide monitor maintained by the health board, was kept at the medicines counter and was used discreetly in the consultation room or back shop area by people accessing the smoking cessation service. The pharmacist explained that it was nearly due for calibration.

ISO and Crown stamped measures were kept by the sink in the dispensary, and a separate marked one (ISO) was used for methadone. Crown stamped measures were used for water. Clean tablet and capsule counters were also kept in the dispensary, and a separate marked one was used for cytotoxic tablets.

Paper records were stored in the dispensary. Computers were never left unattended and were password protected. Screens were not visible to the public. Care was taken to ensure phone conversations could not be overheard.

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.	