General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Dears Pharmacy, 85 High Street, Dunfermline, KY12

7DR

Pharmacy reference: 9011400

Type of pharmacy: Community

Date of inspection: 22/10/2024

Pharmacy context

This is a community pharmacy on the high street of Dunfermline in Fife. Its main activity is dispensing NHS prescriptions. And it supplies medicines in compliance packs to some people who need help remembering to take their medicines at the right times. The pharmacy offers a medicines delivery service. And it supplies a range of over-the-counter medicines. The pharmacy team advises on minor ailments and medicines' use. The pharmacy team provides a number of additional private healthcare services, which includes a travel health clinic, vaccinations, ear wax removal, blood tests, vitamin B12 injections and botulinum toxin injections. The pharmacy also dispenses a large volume of private prescriptions for people accessing treatment through a separate online prescribing service.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 demonstrates a significant and serious lack of governance and due diligence in relation to working with private online prescribing services. It does not properly assess the risks of providing medicines to people against prescriptions from a private online prescribing service. And it does not have adequate written procedures for these services to help team members effectively manage these risks.
		1.2	Standard not met	The pharmacy does not actively audit or monitor its private dispensing services to ensure it provides them safely. It does not have access to the right information to be able to conduct any audits effectively.
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 have adequate safeguards and assurances in place to make sure people receive medicines against online private prescriptions that are safe and appropriate for their needs.
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 properly assess the risks of providing medicines to people against prescriptions from a third-party online prescribing service. It does not have adequate written procedures for these services. And it does not have the appropriate governance and due diligence arrangements in place to ensure people receive these medicines safely. The pharmacy does not actively audit or monitor private prescribing services to ensure it provides them safely. The pharmacy adequately identifies and manages the risks with providing its NHS and other private services. And team members generally follow suitable written procedures. The pharmacy keeps people's private information secure and understands how to protect vulnerable people accessing its NHS services.

Inspector's evidence

The pharmacy had a set of written standard operating procedures (SOPs), and it could show that team members had read and agreed to follow them. The SOPs covered tasks such as dispensing controlled drugs (CDs), providing the NHS Pharmacy First service and responsible pharmacist (RP) regulations. Team members described their roles within the pharmacy and the processes they were involved in and accurately explained which activities could not be undertaken in the absence of the responsible pharmacist. The pharmacy employed an accuracy checking pharmacy technician (ACPT). Team members described the process for prescriptions being clinically checked by the pharmacist prior to dispensing and how this was clearly marked on the prescriptions. This enabled the ACPT to complete the accuracy check. The pharmacy had a business continuity plan to address disruption to services or unexpected closure. Team members described the process for branch closure when there was no responsible pharmacist available.

A large volume of the pharmacy's workload was providing medicines to people prescribed through a third party online prescribing service. The pharmacy had not properly assessed the risks of providing medicines against prescriptions from the online prescribing service company. And it had not carried out any documented risk assessments relating to providing this service to people at a distance before implementation, or since providing the service. The pharmacy's due diligence checks and other aspects of the service had primarily been based upon information received from the online prescribing service company and were not independently verified. The pharmacy was not sure if the online prescribing service was registered with an independent regulator. Pharmacy team members did not make any ongoing checks to ensure that prescribers remained registered with the General Medical Council, and in what capacity. And they did not have evidence of prescribers training or competence to prescribe. The online prescribing service company's website, which people used to access the service, was transactional, and did not meet GPhC guidance. Conditions treated on the website included weight loss, erectile dysfunction, hormonal contraception, hormone replacement therapy, sexual health, hair loss and asthma. The pharmacy did not have any SOPs for dealing with prescriptions received from the online prescribing service. Team members explained they would follow the pharmacy's established dispensing SOPs. However, the process team members followed for labelling, dispensing and checking these prescriptions was distinctly different to usual dispensing process. And it did not refer to risks of providing a service from a distance including for higher risk medicines such as injections for weight loss medicines. The pharmacy team did not have access to prescribing policies, to support team members to make decisions about whether quantities or frequencies of supplies were acceptable. The Superintendent Pharmacist (SI) forwarded on policies following the inspection, but these had no

reference to the pharmacy or the online prescribing service, no version control and there were no details of who had created them or reviewed them. These policies were not implemented into the working practices of the pharmacy.

The pharmacy has not completed any audits or monitoring of the supplies it made through the online prescribing service. So it could not identify any potential inappropriate prescribing, excessive or inappropriate supplies of medicines it made. And without knowledge of prescribing policies, and no SOPs, it would be difficult for the pharmacy to conduct these audits effectively. The pharmacy was unclear about the system in place for people to contact the pharmacy in the event of a dispensing error. There was no process for people to be able to contact the pharmacy directly. The labels attached to medicines dispensed by the pharmacy displayed a telephone number for the online prescribing company's customer services. The pharmacy did not provide people with information they could use to contact the pharmacy directly. There was no system in place to define if or when a person would be directed to the pharmacy and when queries or concerns would be dealt with by customer services without the pharmacy's knowledge.

Team members kept records about dispensing mistakes that were identified in the pharmacy, known as near misses. And they recorded errors that had been identified after people received their medicines. Records were made by the individual team member responsible for the error, so that they could reflect and learn from it. They reviewed all near misses and errors each month to learn from them and they introduced strategies to minimise the chances of the same error happening again. The pharmacy had a complaints procedure and welcomed feedback. An electronic device next to the healthcare counter allowed people to provide feedback on the service they had received. And responses were sent to the pharmacy's head office team to review. Team members then received feedback from the company's operation team. But the device wasn't working during the inspection. Team members tried to manage complaints informally within the pharmacy and they knew to provide the contact details for the SI's office if people wished to escalate the complaint.

The pharmacy had current professional indemnity insurance. The pharmacy displayed the correct responsible pharmacist notice and had an accurate responsible pharmacist record. From the records seen, it had accurate private prescription records for people physically presenting prescriptions in the pharmacy. This included records about emergency supplies and veterinary prescriptions. But team members could not access a private prescription register relating to supplies to people obtaining treatment through the private prescribing service during the inspection. The SI forwarded a database of supplies following the inspection that met the requirement for private prescription records. The pharmacy kept complete records for unlicensed medicines. It kept digital CD records with running balances. A random balance check of three controlled drugs matched the balance recorded in the register. Stock balances were observed to be checked on a weekly basis. The pharmacy had a CD destruction register to record CDs that people had returned to the pharmacy.

Pharmacy team members were aware of the need to protect people's private information. They separated confidential waste for secure shredding. No person-identifiable information was visible to the public. A privacy notice on the waiting room wall provided assurance that the pharmacy protected people's personal information. The pharmacy had a documented procedure to help its team members raise any concerns they may have about the safeguarding of vulnerable adults and children. The pharmacist was registered with the protecting vulnerable group (PVG) scheme. A team member explained the process they would follow if they had concerns and would raise concerns to the RP. And the delivery driver gave a number of real-life examples of how they reported back to the pharmacy team when they had concerns for the people they delivered to. Team members knew how to raise a concern locally and had access to contact details and processes. The pharmacy did not have any specific

procedures in place to help safeguard people from various parts of the UK, accessing medicines via the third-party prescribing service. The pharmacy had a chaperone policy in place and displayed a notice telling people this.					

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy's team members have the necessary qualifications and skills to safely provide the pharmacy's services. They manage their workload well and support each other as they work. And the pharmacy has adequate procedures in place to help its team manage the workload in the event of staff absence.

Inspector's evidence

The pharmacy employed one full-time pharmacist manager, a part-time ACPT, four full-time dispensers, a part-time medicines counter assistant, and a full-time delivery driver. Also present during the inspection was a relief dispenser who was covering planned leave, and a student pharmacy technician who was on a split placement through the NHS between the pharmacy and general practice. Relief pharmacists employed by the pharmacy provided additional pharmacist cover every weekday. Both pharmacists present on the day of inspection were relief pharmacists. The pharmacy reviewed staffing levels regularly with the head office support team. It used rotas to manage staff levels depending on workload. Company-employed relief team members worked flexibly to provide contingency for absence.

The pharmacy planned learning time during the working day for all team members to undertake regular training and development. Team members undertaking accredited courses were provided additional time to complete coursework. A trainee dispenser was observed being supervised in their role and described the training plan that they were working through. Team members received training for specialist services from external nurse practitioners. The pharmacy maintained a training record for each team member with certificates of course completion, such as for phlebotomy services. And they had annual meetings with the pharmacy manager to identify any learning needs. Team members were observed to work on their own initiative, for example to phone the GP practice to ask about missing prescription items. They asked appropriate questions when supplying over-the-counter medicines and referred to the pharmacist when required. They demonstrated an awareness of repeat requests for medicines intended for short term use. And they dealt appropriately with such requests.

Team members felt able to make suggestions and raise concerns to the manager or operations manager. The pharmacy team discussed incidents together and how to reduce risks. The pharmacy had a whistleblowing policy that team members were aware of. The team had regular team meetings.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are suitable for the services it provides. They are clean, secure, and well maintained. And the pharmacy has several suitable, sound-proofed rooms where people can have private conversations with the pharmacy's team members.

Inspector's evidence

These were large-sized premises which included a retail area, large dispensary, four consultation rooms and large back shop area including storage space and staff facilities. The premises were clean, hygienic and well maintained. There were sinks in the dispensary, staff room and toilet. These had hot and cold running water, soap, and clean hand towels. The pharmacy's overall appearance was professional. The pharmacy had clearly defined areas for dispensing and the RP used a separate bench to complete their final checks of prescriptions. A room accessed directly from back of the dispensary had been adapted to be used by team members exclusively to dispense private prescriptions for people accessing treatment through an online prescribing service.

People in the retail area were not able to see activities being undertaken in the dispensary. The pharmacy had four private consultation rooms which were fitted to a good standard, each with a desk, chairs and a sink. Some of the rooms contained recliner chairs and treatment benches which could be used when providing phlebotomy services. It provided a suitable environment for the administration of vaccinations and other services. The doors to each room were kept locked to prevent unauthorised access. The pharmacy also had a separate area for specialist services such as substance misuse supervision. Temperature and lighting were comfortable throughout the premises.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not have adequate safeguards or assurances in place to make sure people receive medicines that are safe and appropriate for their needs. It does not make adequate checks to ensure the medicines it supplies for the private prescribing service are safe and clinically appropriate for people using these services. And pharmacy team members do not access records to make effective clinical assessments. The pharmacy suitably manages its NHS services. And it stores and manages its medicines appropriately

Inspector's evidence

The pharmacy had good physical access by means of a level entrance and an automatic door. The pharmacy advertised some of its services and its opening hours in the main window. It also used digital screens in the front window and in the retail area to advertise the services it offered. The pharmacy provided a delivery service and people signed to acknowledge receipt of their medicines. A team member prepared the day's deliveries and entered details onto an electronic record which could be accessed by the driver on a mobile device, and by team members in the pharmacy. This ensured that team members were aware of the day's scheduled deliveries. This was useful if people called the pharmacy asking about their expected delivery. The pharmacy used a 24-hour collection point machine and team members sent text messages to let people know their medication was ready for collection. People collected their prescriptions from the machine using a unique PIN code. This was at their own convenience even when the pharmacy was closed. The pharmacy excluded some medications such as CDs and items that required refrigeration. And team members regularly checked the machine for uncollected items which they removed and contacted people to let them know.

The pharmacy provided a large volume of prescriptions to people via an online prescribing service. The pharmacy dispensed these prescriptions using a labelling system that had been provided by the online prescribing service company. It kept records of the supplies it had made on this system. But the system did not record clinical interventions made by pharmacy team members. And it did not provide team members with information about interactions or contraindications. Team members were unsure about whether the system allowed team members to see someone's full medication history of all the items they had been prescribed through the service or whether it only showed medicines that had been dispensed by the pharmacy. The pharmacy had not asked or sought assurance that this was a complete dispensing history for the patient, which is important to know to base decisions on, such as overprescribing. The pharmacy was unclear about the systems and process the prescribing service company employed to determine someone's identity who was accessing the service. Or the system in place to verify the information people provided about their medical history or other diagnostic parameters, such as height and weight used to automatically calculate BMI. And this meant there was a risk that people could enter false information to obtain a supply of medicines inappropriately. Both pharmacists present during the inspection explained their final check of prescriptions covered the legal requirements of the prescriptions and the accuracy of dispensing, and they would only query unusual quantities. They did not check records to consider previous supplies or to check for information relating to BMI for weight loss medicines.

The inspector reviewed approximately fifteen prescriptions from the online prescribing service that were being prepared during the inspection. And following the inspection, reviewed data of the

prescriptions they had dispensed between 1 July 2024 and 22nd October 2024. The review of prescriptions and data showed several concerns. The pharmacy dispensed medicines to people for chronic conditions which included asthma, treatment of high blood pressure and type 2 diabetes. This made up over 50% of the total prescriptions received from the online prescribing service. The pharmacy was not aware of how prescribers working for the online prescribing service obtained information about checks on diagnosis, monitoring and contact with the person's NHS GP. And team members did not have any knowledge of how prescribers of the online prescribing service company maintained ongoing monitoring for these people to ensure that ongoing supply was safe and appropriate. This information was not available on the prescription records viewed by the inspector during the inspection. The prescription data showed people had received repeated supplies of salbutamol inhalers which should have prompted an intervention with the person for a review of their condition. But the pharmacy did not have access to information about why salbutamol was being prescribed, whether someone's asthma or COPD was well controlled, how their condition was being monitored and by who, or whether they were prescribed any other medicine to help manage their condition. The inspector accessed people's completed questionnaires that were submitted to the prescribers. But pharmacy team members did not access this information as part of the dispensing or checking process. Records showed several examples of potential inappropriate and excessive supplies of medicines. The information entered by people on six out of the fifteen prescriptions reviewed by the inspector was inconsistent and should have prompted an intervention or accuracy check of the data submitted by patient. It included people being supplied with a weight loss injection despite using the same BMI value over several consecutive weeks. Team members could only provide evidence of one intervention they had made on a person's prescription. The pharmacy had received a prescription for a weight loss injection and tablets to be taken together. The pharmacy had received a reply from a non-clinical member of the prescribing service's customer care team which stated the doctor has signed this off as okay. There was no confirmation the query had been viewed by a clinician and no clinical reason or patient history to justify why these medicines were prescribed together. The pharmacy could not demonstrate it had sufficient safeguards in place to make sure the right people receive medicines that are safe and appropriate for their needs.

Pharmacy team members followed a logical and methodical workflow for dispensing. They used coloured baskets to differentiate between different prescription types and separate people's medicines and prescriptions. And they attached coloured labels to bags containing people's dispensed medicines to act as an alert before they handed out medicines to people. For example, to highlight the presence of a fridge line or a CD that needed handing out at the same time. Team members initialled dispensing labels to provide an audit trail of who had dispensed and checked all medicines. Some people received medicines from Medicines Care Review (MCR) serial prescriptions. The pharmacy dispensed these in advance of people collecting them. Team maintained records of when people collected their medication. This meant the pharmacist could then identify any potential issues with people not taking their medication as they should. The pharmacy notified the GP practice for a further prescription when all episodes of the prescription were collected.

The pharmacy supplied medicines in multi-compartment compliance packs and pouches for people who needed extra support with their medicines. Pharmacy team members managed the dispensing and the related record-keeping for these on a four-weekly cycle. They kept master backing sheets for each person for each week of assembly. These master sheets documented the person's current medicines and administration time. And they maintained notes of previous changes to medication, creating an audit trail of the changes. Multi-compartment compliance packs were labelled so people had written instructions about how to take their medicines. These labels included descriptions of what the medicines looked like, so they could be identified in the pack. And team members provided people with patient information leaflets about their medicines each month. Shelving to store the packs was kept

neat and tidy. The pharmacy supplied medicines in multi-dose compliance pouches which consisted of individually labelled and sealed pouches with people's medicines required for each dose. The roll of individual pouches was contained in a cardboard box. The medicines were assembled at an off-site hub pharmacy before being returned to the pharmacy. The details were entered at the pharmacy and then the medicines were assembled in the pouches at the off-site pharmacy hub. The pharmacy team was responsible for the accuracy of the data entered into the computer for prescriptions dispensed at each hub pharmacy. And the pharmacist was required to make sure the prescription was clinically appropriate before it was sent.

Team members had knowledge of the Pregnancy Prevention Programme for people in the at-risk group who were prescribed valproate, and of the associated risks. They knew to apply dispensing labels to valproate packs in a way that prevented any written warnings being covered up. The pharmacy supplied patient information leaflets and patient cards with every supply. The pharmacy had patient group directions (PGDs) for unscheduled care, emergency hormonal contraception (EHC), and the Pharmacy First service, which included treatment of urinary-tract infections and impetigo. The pharmacy team members were trained to deliver the Pharmacy First service within their competence and under the pharmacist's supervision. They referred to the pharmacist as required. Two of the pharmacists were independent prescribers and provided the NHS Pharmacy First Plus service. They treated several common clinical conditions including those affecting the ear, nose and throat. They were trained to carry out clinical examinations and worked to a national service specification and prescribed to a local formulary. They used NHS prescriptions with a unique prescriber number so their prescribing activity could be reviewed and audited. All consultations were documented, and a summary was sent to the person's regular GP. The regular pharmacist provided a private travel clinic using private PGDs. They maintained electronic and paper records of consultations and any vaccines administered or medication supplied. The pharmacy provided blood testing in conjunction with external providers for allergy screening and general wellbeing. Blood samples were sent to laboratories and people were contacted directly by the provider if they required further intervention or treatment.

The pharmacy obtained medicines from recognised suppliers. It stored medicines in their original packaging on shelves, in drawers and in cupboards. And team members used space well to segregate stock, dispensed items, and obsolete items. The pharmacy protected pharmacy medicines from self-selection to ensure sales were supervised. And team members followed the sale of medicines protocol when selling these. The pharmacy stored items requiring cold storage in a fridge and team members monitored and recorded minimum and maximum temperatures daily. They took appropriate action if these went above or below accepted limits. Team members regularly checked expiry dates of medicines and those inspected were found to be in date. The pharmacy had disposal bins for expired and patient-returned stock. The pharmacy actioned Medicines and Healthcare products Regulatory Agency (MHRA) recalls and safety alerts on receipt and kept records about what it had done.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs to provide safe services. And it uses its facilities to suitably protect people's private information.

Inspector's evidence

The pharmacy had access to the internet which provided electronic resources which included the British National Formulary (BNF) and BNF for Children. This provided the pharmacy team with the most recent guidance and information on medicines.

The pharmacy kept equipment required to deliver pharmacy services in the consultation rooms where it was used with people accessing its services. This included a blood pressure meter, digital otoscope and blood testing equipment. Equipment was replaced as per the manufacturer's guidance, and team members demonstrated the hygiene control measures used to keep equipment clean. Team members kept clean crown-stamped measures by the sink in the dispensary, and separate marked ones were used for substance misuse medicines. The pharmacy used a pump for measuring doses on a daily basis. Team members cleaned it at the end of each day and poured test volumes before use. The pharmacy team kept clean tablet and capsule counters in the dispensary and kept a separate marked one for cytotoxic tablets.

The pharmacy stored dispensed medicines in a way that prevented members of the public seeing people's confidential information. The computers were password protected to prevent any unauthorised access. The pharmacy stored paper records in a locked filing cabinet in the dispensary inaccessible to the public. The pharmacy had cordless phones, so that team members working in the dispensary could have conversations with people without being overheard by people in the waiting area.

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.