Registered pharmacy inspection report

Pharmacy Name: Cloud Pharmacy, 3 Houstoun Interchange Business

Park, Livingston, West Lothian, EH54 5DW

Pharmacy reference: 9012073

Type of pharmacy: Internet

Date of inspection: 25/10/2023

Pharmacy context

This pharmacy is based in a business centre in West Lothian in Scotland. It provides online prescribing and dispensing services through its website www.cloudpharmacy.com. The pharmacy dispenses private prescriptions, generated by its in-house prescribing service. And it delivers medicines via courier to people living in the UK. It dispenses medicines mainly for conditions such as erectile dysfunction, weight management, hair loss, migraine and asthma.

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	The pharmacy continually monitors and reviews the quality of the prescribing service it provides. And it uses the results of its audits to help improve the safety and quality of the services provided.
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

The pharmacy identifies and manages the risks with its services, including for its associated online prescribing service. It continually monitors and reviews the risks to help improve patient care. The pharmacy is good at completing regular checks and audits to confirm team members follow the pharmacy's procedures. And it shares the outcomes and action points from these checks with the pharmacy team. The pharmacy keeps the records required by law and it keeps people's private information secure. It has adequate processes to help team members protect vulnerable adults and children.

Inspector's evidence

The pharmacy had a set of written standard operating procedures (SOPs), and team members had read and agreed to follow them. Team members described their roles within the pharmacy and the processes they were involved in. A pharmacist independent prescriber (PIP) led the pharmacy's private prescribing services. The pharmacy had reviewed and improved its clinical governance arrangements following the previous inspection.

The pharmacy had completed risk assessments (RAs) for the services and medicines provided to identify and manage the risk of providing services online. And it defined what measures it had put in place to address these risks. The risk assessment for each service followed a methodical template. They considered the risks around providing the service with reference to accessing people's records and the information provided by people on the consultation form. They contained references to recognised clinical guidelines to consider when treatment would not be appropriate. The team carried out annual reviews of the risk assessments or reviewed them earlier if prompted by a service change, such as the introduction of a new treatment. They had processes to review the quality of the prescribing service it provided. This included regular audits of prescribing consultations.

The pharmacy provided a weight loss service which included injectable treatments such as Wegovy. The pharmacy team was aware of the recent national patient safety alert about injections in this group of medicines being restricted for their licensed indications including diabetes. But they only prescribed Wegovy which was licensed for weight loss and not affected by this guidance. The risk assessment highlighted this as a higher-risk medicine with measures in place to address the risks of providing this treatment. The PIP limited starting treatment to a small number of people at a time in order to manage the associated workload required for people on these medicines to be suitably reviewed and managed. The RA required that people obtaining this treatment provided photos to verify the information provided on the questionnaire.

The risk assessment for asthma required people to have a previous diagnosis of asthma. The pharmacy was reliant on people entering this information truthfully. And did not ask for proof of previous supply such as a copy of people's repeat medication record. People could provide GP details if desired, but this was not mandatory. The RA contained measures to help ensure supply was appropriate. The pharmacy required people to complete an asthma assessment at each request.

The pharmacy had processes to review the quality of the prescribing service it provided. The clinical governance team consisted of the superintendent pharmacist (SI), company director, and the PIP. It

met monthly and documented the outcomes from each meeting. Regular audits were conducted to ensure that the prescribing safeguards in place were effective. It looked at clinical and non-clinical reasons prescriptions were rejected. The clinical team had reviewed a rejection audit and identified a person requesting regular treatment using a combination cream containing a steroid and antibiotic. They consulted evidence-based national guidance, including the National Institute for Health and Care Excellence (NICE) and reflected on the current procedures. The RA was updated with specific limits to a maximum of four weeks treatment and referral for face-to-face review. The clinical team had also identified a risk in providing treatment for sexually transmitted diseases remotely. They reviewed local and national guidance for treatment of these conditions and used this to inform the prescribing guidance for these medicines. The risk assessments were updated with maximum order frequencies and the need to test people with recurrent infections. This helped prevent inappropriate supplies of antibiotics.

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, known as dispensing incidents. They discussed all near misses and dispensing incidents with those involved, and occasionally reviewed them as a team to learn from them. They introduced strategies to minimise the chances of the same error happening again. Examples were provided of action that had been taken to help prevent similar mistakes, which included separating the storage of sildenafil away from sumatriptan. The pharmacy had a complaints procedure displayed on their website and welcomed feedback from a variety of sources including an online review platform, email, and phone. The pharmacy manager managed any complaints received. And they knew to provide the contact details for the SI if people wished to escalate the complaint.

The pharmacy had current indemnity insurance. It displayed the correct responsible pharmacist notice and had an accurate responsible pharmacist record. The pharmacy recorded private prescriptions dispensed using proprietary software. From the records seen, it had accurate private prescription records. Pharmacy team members were aware of the need to protect people's private information. They separated confidential waste for collection and secure destruction by a waste carrier. And computers were accessed via individual usernames and passwords. Team members were provided with training on protecting people's confidentiality and an information governance policy was in place and accessible to team members. Team members had completed training about safeguarding vulnerable groups. There were some safeguards in place such as not prescribing for anyone under the age of eighteen. And the pharmacy used a recognised identification verification system to check people's details were entered correctly. People requesting medication who did not pass ID verification had their order cancelled and refunded.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has a small team with the necessary qualifications and skills for their roles and the services they provide. And the pharmacy supports team members' ongoing learning and development needs. The pharmacy provides team members with the opportunity to provide regular feedback to help improve services.

Inspector's evidence

The pharmacy team comprised of two company director pharmacists, one of whom was the superintendent pharmacist (SI) and a prescriber. They both worked part-time as the RP in the pharmacy. A third pharmacist was employed as a pharmacy independent prescriber (PIP) who was responsible for prescribing and providing the clinical services offered on the website. The PIP mostly worked remotely but were available via telephone. And on two days each week, they had responsibility as RP alongside their prescribing role. They were supported on those days by the company's directors, who could step in and provide the final clinical and accuracy check when needed. The PIP separated their workload for prescribing and final checks. During periods when the PIP was absent, the SI provided prescribing cover. The RP on the day of the inspection was a locum pharmacist. They explained they worked two days per week and had a week's induction period when they first started. This consisted of shadowing team members and reading the SOPs to understand the pharmacy's processes. And they had worked alongside the company directors to understand how the pharmacy is provided and how to intervene on prescriptions if required.

Two team members supported the pharmacists. One full-time qualified dispenser, who was also the pharmacy manager, and one full-time trainee dispenser. The full-time dispenser was currently working through the Accuracy Checking for Dispensing Assistants course. Team members explained how they had regular informal discussions with the supervising pharmacist regarding their training and felt supported. They had protected time each week to complete training. The trainee dispenser had experience working in community pharmacies and was enrolled on training after completing her probationary period. They had restricted roles based on their experience. For example, the trainee dispenser did not carry out ID verification checks. Team members had annual appraisals with the company directors where individual learning needs were discussed. They understood the importance of reporting mistakes and were comfortable openly discussing their own mistakes with the rest of the team to improve learning. The team were aware of the whistleblowing policy and felt comfortable to raise any concerns to the pharmacists, manager or SI.

The PIP had peer review sessions with the SI to discuss governance arrangements, record keeping requirements and good practice points for certain conditions. And this was an opportunity for both the PIP and SI to receive peer support and improve their prescribing quality. The pharmacy had monthly clinical governance meetings between the PIP and the company directors and it kept minutes of these meetings. The PIP described using the wider clinical team for support and peer discussion. They provided a documented example when a prescription request was received from an elderly person. The PIP raised their concerns about prescribing for the person with the other clinical team members. And they decided that the person could not be appropriately assessed remotely and was referred to their own GP. The PIP had no targets, incentives, or bonuses to prescribe medicines to patients. This helped ensure there was no risk of compromise to the profession judgement of the PIP.

Principle 3 - Premises Standards met

Summary findings

The pharmacy premises are suitable for the services provided. They are clean, hygienic, and secure. The pharmacy's website looks professional and provides ease of access for people to use.

Inspector's evidence

People accessed private services online through the pharmacy's website. And it provided details about the owners, its physical location and contact details. It also provided the names and the registration details of the SI and the prescribing pharmacist. Prescribing consultations were undertaken via the company's website. The website's layout was clear. It provided information on treatments, and consultations were started from the page for a particular medical condition.

The pharmacy had recently moved to new larger premises that were maintained to a high standard. It was within shared business premises but the pharmacy was not accessible to any other users of the building or members of the public. The pharmacy premises were clean and organised with sufficient work and storage space. There were separate areas for processing and labelling prescriptions, packing and assembling medicines, checking and dispatch. Workbenches were generally kept clutter free. Team members had access to a kitchen with seating area and toilets within the premises. The room temperature and lighting were adequate for the provision of pharmacy services. The pharmacy was secure from unauthorised access.

Principle 4 - Services Standards met

Summary findings

The pharmacy has sufficient safeguards to help ensure people receive medicines that are suitable for them to take. And it makes its services accessible to people through its website. It provides ongoing advice and support for people accessing weight loss treatments to help them lose weight. And it makes suitable checks to make sure the treatment remains right for the person. The pharmacy orders its medicines from reputable suppliers and stores them properly.

Inspector's evidence

The pharmacy's services were accessed through its website www.cloudpharmacy.co.uk. People could also contact the pharmacy by phone and email. The pharmacy operated five days per week, with its opening times displayed on its website. The pharmacy provided information about the conditions it provided treatment for, including weight loss, eczema, psoriasis, and erectile dysfunction. It provided an overview of common causes of the condition, the treatments available and any relevant lifestyle advice.

To obtain a treatment, people started a questionnaire-style consultation from the conditions page. Questions were specific to the condition being treated and were designed to inform the prescriber about the person's past medical history. Most of the question options were simple yes or no answers. When an answer was given that would suggest treatment may not be suitable, people were prompted to give more information using a free text box. Some of the medicines for the conditions treated on the website were pharmacy only (P) medicines. There was no difference in how the website operated between P and prescription only medicines (POMs). The RP authorised requests for P medicines to generate a dispatch label and allow processing by team members. But the system restricted that only prescribers accessed requests for POMs and were able to generate a prescription. There was an audit trail built into the pharmacy's software to show which member of the team had completed each process.

The pharmacy used proprietary software for managing the process of prescribing and dispensing. Access to the pharmacy consultation software was role dependent. This meant only those with prescriber access rights were able to issue a prescription. When the PIP generated a prescription, the system logged the name of the prescriber, and it was date and time stamped to provide a complete audit trail. The software clearly identified who was responsible for reviewing prescription requests and who had issued the prescription. The prescriber reviewed each consultation before deciding whether a prescription could be issued, the request was rejected, or further information was requested before making a decision. The prescriber added notes of any advice given on a consultation notes section on the system. When a prescription was issued by the prescriber, it was filed into a workflow for the dispenser to action. Part of this step included an automated identification process, which used external and recognised identity software for all requests received through the website. If the software identified a failure in the information submitted, the person was required to submit further information including a two-staged ID photo check. The pharmacy relied upon the identity software to prevent medicines being supplied to people under eighteen. A team member showed examples of orders left pending and unable to be dispensed as the PIP had contacted the person by email to obtain more information.

The PIP contacted people obtaining weight loss injections every four weeks before supply to give advice and ensure treatment was appropriate. They provided personalised support to people losing weight and tracked their progress appropriately. And they provided information on dietary suggestions and lifestyle advice. People who had not lost an appropriate amount of weight by twelve weeks had their prescription stopped. The PIP had found people welcomed the individual support and provided evidence of a "yellow card" report submitted when one person experienced a specific side effect. The information collected helped improve wider patient safety for those using the same medication. The PIP demonstrated appropriate refusal when weight loss medicines were not suitable for people. And provided these people with appropriate signposting information. They recorded consultation notes and correspondence on people's records. The pharmacy provided people with additional supporting information when medication had been prescribed. This contained additional information on how to take the medication and any symptoms that would suggest a review was needed. The PIP demonstrated when they had refused to supply if people's responses were not appropriate and referred people to their own GP. And there was a maximum limit of three supplies for asthma inhalers. The pharmacy did not supply any further inhalers to people once this limit was reached. This prevented people using this service for long-term treatment. The pharmacy had a process to identify and record when medication had been requested inappropriately. And the software highlighted any prescription requested using similar credentials. Both the PIP and the RP completing the final check were alerted to people who had requested repeated orders. This prompted an extra check of the person's history to make sure medication continued to be appropriate or was requested too frequently.

The pharmacy team printed each authorised prescription along with dispensing and shipping labels. They used dispensing baskets to separate individual people's prescriptions to avoid items being mixed up. And they initialled dispensed by and checked by boxes on dispensing labels to provide an audit trail. The pharmacist was seen to check the prescriber's notes to help understand whether the prescription was appropriate to supply. The pharmacist felt able to challenge prescribing decisions freely with the PIP if they felt a prescription was not appropriate.

Medicines were obtained from licensed wholesalers. Most medicines were dispensed in original packs. The pharmacy pre-packed some medicines into boxes with smaller quantities, often prescribed by the PIP when people started a medicine for the first time. Or required a specific duration of treatment, such as antibiotics. Pre-packed boxes were labelled with batch number and expiry date. Each time they supplied these medicines, pharmacy team members provided people with an information leaflet. A date checking matrix was signed by team members as a record of completed expiry date checks. The pharmacy used an electronic data logging system to monitor the temperatures in the fridge. This provided an alert if a temperature was outside of expected ranges. The temperature records seen were within acceptable limits. A medical waste bin was available for the disposal of unwanted medicines. Drug alerts were received by email from the Medicines and Healthcare products Regulatory Agency (MHRA). Alerts were printed, and then annotated with the action taken and initialled and signed before being filed in a folder.

Medication was delivered using postal and courier tracked services. The pharmacy could track the status of each delivery and confirmation that it had been received. Any medicines not delivered were returned to the pharmacy for secure disposal. The pharmacy sent some medicines which required temperature control. The pharmacy had processes in place to make sure cold-chain items were transported at the correct temperature. These items were packed in boxes containing cold packs and insulating materials. The packages were clearly labelled as cold-chain items. The pharmacy regularly monitored the integrity of cold-chain packaging by dispatching a package to the pharmacy containing a monitoring device, which was packed with cold packs and insulating materials. The device provided the pharmacy with information to determine whether the package had been maintained at the expected temperature.

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 team had access to the internet for general information. This included access to the BNF, and product license resources. All electrical equipment appeared to be in working order. Computers were password protected. The pharmacy provided medication in maunufacturer's original packs and did not require tablet counting equipment or equipment to measure liquids. The pharmacy used discreet packaging for deliveries to help protect people's confidentiality. The pharmacy ensured the blinds were kept closed so that members of the public were unable to see any confidential information. There was a freezer used to store medicines cold packs used for delivery of medicines requiring cold storage. Team members had self-tested the cold packs to ensure that the temperature remained within the required range during the delivery period.

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.	