# Registered pharmacy inspection report

# Pharmacy Name: CloudRx, 1 Hawthorn Park, Coal Road, Leeds, West

Yorkshire, LS14 1PQ

Pharmacy reference: 9011284

Type of pharmacy: Internet / distance selling

Date of inspection: 07/07/2022

### **Pharmacy context**

This pharmacy is an internet pharmacy and access to the premises is closed to the public. The pharmacy provides a prescribing platform for private prescribers to generate electronic private prescriptions following a consultation with a person. The pharmacy team contacts people directly following receipt of the prescription. And the pharmacy delivers medicines to people's homes. Prescribers mainly access the pharmacy's website, but people can access it to find out the pharmacy's telephone and email contact details.

### **Overall inspection outcome**

✓ Standards met

### Required Action: None

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 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**

The pharmacy generally identifies and manages the risks associated with its services, including making relevant checks on the prescribers accessing its services. And it completes some audits to confirm the prescriptions it dispenses are prescribed safely. The pharmacy has up-to-date written procedures that the pharmacy team follows and it completes all the records it needs to by law. The pharmacy team members respond well when errors occur. They discuss what happened and they take suitable action to prevent future mistakes. However, the team doesn't have complete information from the prescribers and clinics about their prescribing. And so, it may miss out on opportunities to make pharmacy services safer.

### **Inspector's evidence**

The pharmacy provided a platform for UK based private prescribers to generate electronic prescriptions. The pharmacy had overall control of the running of the platform. Prescribers wishing to use the service registered with the pharmacy before gaining access to the platform and generating private prescriptions. Most of the prescribers worked for clinics, including ones providing menopause and slimming treatments. The prescribers were separately registered with the pharmacy and several prescribers provided face-to-face consultations. The pharmacy also provided the service to a large online prescribing clinic that used an online questionnaire for consultations with people.

The pharmacy had completed risk assessments (RAs) covering the provision of the service and had separate RAs for the online clinic it provided the service to. The team members had a good understanding of the services provided by the clinics and prescribers and they had sight of the prescribing policies for the online clinic but not of the completed questionnaires. So, the pharmacy team wouldn't know, for individual prescriptions, if the prescribers were working to their own prescribing policies or within prescribing guidelines when completing a consultation.

The pharmacy completed some audits on certain high risk medicines that it regularly received prescriptions for. These audits confirmed the online prescribers were adhering to the pharmacy's procedures or clinical guidelines for those medicines. The pharmacy didn't extend the audit process to other treatment areas or prescribers as it didn't have the prescribing policies from the clinics and prescribers using its services. The criteria for the audit of amoxicillin prescribing included a check if a person received more than one supply a month. But it did not check if the person was getting repeated supplies across several months. This meant the pharmacy may not identify a person who needed a referral to an more specialised clinical service.

The pharmacy had a risk register for some of the different therapies the prescribers provided treatment for. The register identified risks such as the person not taking the medication correctly or the risk that the person may abuse the prescribed medication. The register recorded the actions taken by the pharmacy to mitigate the risks and these included monitoring the frequency of prescribing of medication identified as being liable to abuse. Since the last inspection the pharmacy had updated the register to define what was meant by low level abuse. With specific risks, the register stated all prescribers registered with the pharmacy had to have patient identification systems in place and had to meet the standards set by the Care Quality Commission (CQC) for safe prescribing. The pharmacy team explained how they would share any concerns about prescribers to the relevant organisations such as the GMC.

As part of the pharmacy's procedures to ensure the safe supply of medication to people the team completed a series of checks prior to registering a prescriber to enable them to access the prescribing platform. The pharmacy checked the prescriber's registration status, obtained passport or driving licence photograph identification and details of their professional indemnity insurance. The team checked for any fitness to practice concerns. And flagged on to the pharmacy's system any restrictions on a prescriber's practice such as medicines the prescriber could not prescribe. The pharmacy reviewed the prescriber's professional registration status and indemnity insurance every six months. This ensured the prescribers the pharmacy worked with remained fit to practise and could legally prescribe. The pharmacy checked the registration status of the clinic the prescribers worked from with the Care Quality Commission. The team used social media and other external information sources to see the feedback people gave about the prescribers and the medical treatment they provided. This helped identify any areas of concern, other than regulatory fitness to practise concerns, that may prevent the prescriber registering with the pharmacy. The registration process included confirmation from the prescriber that they understood the pharmacy's terms of use which were detailed on its website.

The pharmacy had a range of up-to-date SOPs that provided clear and detailed information to the team to perform the tasks supporting the delivery of pharmacy services. The pharmacy updated the SOPs in response to changes to its services or when new ways of working were introduced. Most team members had read and signed the SOPs signature sheets to show they understood and would follow them. A new team member was in the process of reading the SOPs and signing the signature sheet. The team members demonstrated a clear understanding of their roles and worked within the scope of their role.

The pharmacy had a procedure for managing errors identified at the accuracy check of the prescription known as near miss errors. The pharmacist and accuracy checking technician recorded the near miss errors on a paper log before transferring the details to a spreadsheet. The information captured included details of the error and who in the team was involved. The pharmacy recorded dispensing incidents that reached the person on to a separate spreadsheet. The pharmacy used the information from both spreadsheets to identify common errors. The team members regularly met to examine the data from the spreadsheets and were encouraged to suggest and agree actions to reduce the risk of similar errors. For example, team members were reminded when putting stock away to check the label on the shelf matched the product being placed on the shelf. The pharmacy had a procedure for handling complaints raised by people receiving the pharmacy services. The pharmacy provided people with information on how to contact the pharmacy team via email or telephone. Or the person could raise their concern through the prescriber. The team promptly answered the telephone and were able to manage people's queries in a timely manner. The team escalated any concerns raised by people to the regular pharmacist and pharmacy manager.

The pharmacy had up-to-date indemnity insurance. A sample of records required by law such as the Responsible Pharmacist (RP) records and controlled drug (CD) registers met legal requirements. The pharmacy kept the CD register in an electronic format and the team regularly checked the balance of stock in the register against the physical stock. This helped to spot errors such as missed entries. A random check on the day of the inspection of the CD stock matched the balance in the CD register. The pharmacy kept specials records for the unlicensed medicines it ordered and supplied to people.

The pharmacy team members were aware of the importance of keeping people's private information secure. The pharmacy had several "Think Privacy" posters displayed to re-enforce the team's awareness and the pharmacy website included a privacy notice. All team members had signed the pharmacy's SOPs covering confidentially and data protection. The pharmacy stored confidential waste in a

dedicated bin for shredding off site. The pharmacy kept all records of prescriptions on a secure internal database.

The pharmacy had safeguarding procedures and guidance for the team members to help them understand their role in protecting vulnerable people. And team members had access to contact numbers for safeguarding teams. The pharmacists had completed level 2 training from the Centre for Pharmacy Postgraduate Education (CPPE) on protecting children and vulnerable adults in 2020.

# Principle 2 - Staffing ✓ Standards met

### **Summary findings**

The pharmacy has a team with an appropriate range of experience and skills to support its services and manage the workload. Team members work well together and are good at supporting each other in their day-to-day work. The pharmacy supports its team members to complete further training so they can develop their knowledge and skills. The pharmacy encourages team members to share ideas on how to improve the delivery of its services. And they are comfortable making suggestions.

### **Inspector's evidence**

A full-time pharmacist and a part-time locum pharmacist covered the opening hours. The Superintendent Pharmacist (SI) often worked in the pharmacy. The pharmacy team consisted of a fulltime accuracy checking technician (ACT), one trainee pharmacy technician, three full-time qualified dispensers, a customer service team member, and a new member of the team. The ACT was the pharmacy manager and one of the dispensers was the purchasing manager. The customer service team member had been in post since January 2022 and during the inspection was observed attaching dispensing labels to some medicines. However, they were not enrolled on to an appropriate training course. The SI reported after the inspection that this team member had been enrolled on to an accredited training course. Team members worked well together in an organised way and could manage the workload. The team rotated tasks throughout the day. This ensured the team members maintained their focus and had a range of skills to support the pharmacy services in times of absence.

Team members completed regular ongoing learning related to the safe running of the pharmacy and the medicines dispensed in the pharmacy. The team had protected time for training and often used a room away from the main dispensary when accessing their training. The SI identified some brief training for the pharmacists when a new clinic and prescribers registered with the pharmacy. This was when the treatments prescribed were new to the pharmacy team and in significant volumes. The pharmacists also spent time gathering information through online reference resources and communications with the prescriber. But this information and training was not always shared with the wider team so they could be confident dispensing prescriptions once they started to arrive at the pharmacy. The RP demonstrated instances where they had questioned the suitability of a treatment on a prescription and contacted the prescribing clinic for further information. The pharmacist and team members such as the ACT wouldn't be aware and may contact the prescriber with the same question.

The pharmacy team met with some of the prescribers once they registered with the service, as part of the quality assurance process. The team explained how the pharmacy's prescribing platform operated and explained the pharmacy's procedures for dispensing prescriptions. This approach provided a basis for the pharmacy team to establish a working relationship with the prescribers for future communications such as prescription queries. For example, the ACT had recently contacted a prescriber who prescribed patches that had to be cut in half. The ACT looked at the manufacturer's information and after speaking to the prescriber concluded the appropriate method was to cut the patch diagonally rather than in half. The ACT shared this information with the team to ensure it was clearly printed onto the dispensing label. The team reinforced these directions through a conversation with the person.

The team held regular meetings including a clinical review meeting. Team members were encouraged

to suggest changes to processes or discuss new ideas of working at these meetings. Team members felt comfortable raising concerns or sharing ideas. For example, a team member had suggested rearranging the storage of all the HRT treatments so they were in the same place. This was agreed and implemented which helped with the efficient dispensing of prescriptions for these products. The pharmacy provided performance reviews for the team which gave team members a chance to receive individual feedback and discuss their development needs. The pharmacy supported peer discussions amongst the team members who had protected time to hold these discussions.

# Principle 3 - Premises Standards met

### **Summary findings**

The pharmacy premises are large and appropriate for the services provided. And the pharmacy is suitably clean, hygienic, and secure. The pharmacy's website provides relevant information about its private prescribing platform. And people using the pharmacy can find up-to-date contact information there.

#### **Inspector's evidence**

The pharmacy was within a modern office block and in a good state of repair. The dispensing area was large, bright and airy with plenty of bench space for the team to work from. The team members kept the pharmacy clean and tidy. And they kept floor spaces clear to reduce the risk of trip hazards. The pharmacy had separate sinks for hand washing, with hot and cold water available. The pharmacy had air conditioning and heating to provide a comfortable temperature for working. And it provided the team with facilities to have lunch breaks.

The pharmacy had systems installed to secure the premises. It had frosted windows to prevent anyone outside from seeing into the pharmacy. And it had an intercom to manage visitors and access to the premises. People had to ring the buzzer to gain access to the pharmacy. There was a communal reception area used with one other company in the same building.

People could not arrange a consultation with a prescriber via the pharmacy and the website didn't signpost people to any of the clinics that used its services. The pharmacy website was aimed at clearly providing information to private prescribers about the pharmacy's prescribing platform. And it contained testimonials from some of the clinics that used its services. The pharmacy's interaction with the person receiving the medicine only came once the prescriber was registered with the pharmacy. And when they sent the person's electronic prescription to the pharmacy could access the website for details about the pharmacy. The website provided details of the pharmacy GPhC registration number and the name and GPhC registration number of the SI. The website was secure and complied with data protection regulations and information security management guidelines.

### Principle 4 - Services Standards met

### **Summary findings**

The pharmacy team has some good systems to manage the pharmacy services safely. The team members make sure people receive their medicines when they need them. And they have robust procedures to ensure people receive relevant information about their medicines. The pharmacy gets its medicines from reputable sources and it stores them properly. And the team carries out checks to make sure medicines are in good condition and suitable to supply. The pharmacy has the necessary safeguards in place to monitor supplies it makes against prescriptions, but it could have more information from some prescribers to support the pharmacist's clinical check.

#### **Inspector's evidence**

The pharmacy was closed to the public which meant people could not access the pharmacy in person. People could contact the pharmacy team for advice or support via telephone and email, the details of which were published on the pharmacy website. The pharmacy had several telephones which meant team members could quickly answer the phone and they regularly checked the emails throughout the day to ensure urgent ones were not missed.

On completion of the registration process the prescriber received secure and unique access to the pharmacy's prescribing platform. The pharmacy platform prevented anyone other than the registered prescriber from sending the prescription to the pharmacy and ensured there was a clear audit trail on who generated the prescription. The registered prescriber could amend or cancel the prescription at any point and they could monitor the progress of the prescription at the pharmacy. The prescribers could also see their previous prescription orders. The prescriber's electronic signature was non-modifiable. The pharmacy completed due diligence checks on interested clinics and prescribers before they were registered. But it did not formally request details of the prescriber's scope of practice or any specialist training they'd completed. The pharmacy didn't routinely ask for the prescribing guidelines from the clinics and prescribers using its services to use as part of the dispensing process. The SI explained the pharmacy requested the guidelines for prescribers. The pharmacy didn't have access to the prescriber's clinical documentation records, for example consultation questionnaires, to refer to when dispensing and checking prescriptions. But the pharmacist team could request further information when a query emerged.

Following a consultation, the registered prescriber obtained consent from the person to send their electronic prescription to this pharmacy or to another pharmacy the person chose. The prescriber provided the pharmacy with the person's contact details and the team emailed or sent a text message to the person advising of the receipt of their prescription and requesting payment. The pharmacy took a secure payment before the prescription was dispensed. The pharmacy regularly reminded people by email and telephone calls if no payment was made, to ensure they had the opportunity to receive their medicines in a timely manner. The prescriber had the option to create repeat prescriptions on the prescribing platform. This meant the person could contact the pharmacy when they needed more medication. And the pharmacy would issue the next supply from the repeat prescription.

Once the payment was made the pharmacist completed a clinical check of the prescription before it was released for dispensing. The pharmacy had a set of clinical guidelines embedded in the SOPs for the

pharmacists to follow. The guidelines included when a clinical decision should be made on the maximum number of supplies of certain medication. The pharmacy had updated the SOP to reflect national guidelines produced by organisations such as the National Institute for Health and Care Excellence (NICE). For example, the pharmacy's clinical guideline for salbutamol inhalers was changed from a maximum of three supplies a month to no more than one inhaler to be supplied a month. The pharmacists and pharmacy technicians were aware of the professional requirements for some higher risk medicines. They had the required knowledge to clinically check and dispense certain medicines including the weight loss product, Saxenda. They knew the dosage regime and checked the dispensing history to ensure the dose and volume for the person was appropriate for the stage in their treatment. The prescriptions issued from the online clinic for weight loss products were following an online consultation questionnaire where details of BMI and other clinical details were taken on face value. The clinic did require additional measurements from the person, and these reinforced the accuracy of the BMI submitted. And the BMI was sometimes added to the prescriptions the pharmacy received. However, the pharmacy's current prescribing platform meant the pharmacists and pharmacy technicians didn't have access to the person's records to check clinical information. So, they relied on the prescriber to prescribe within the licenced recommendations and on the understanding the pharmacy had about the clinic's processes and prescribing protocols. The team didn't know on an individual basis if prescribers were adhering to their protocols or if the prescriber had liaised with the person's GP about treatment.

The pharmacist used the pharmacy's patient medication record (PMR) to check the person's history of the medicines supplied to help ensure the prescription was appropriate and to monitor the frequency of supplies. The pharmacist contacted prescribers with queries on individual prescriptions. And the team sometimes discussed matters such as an increase in the prescribing of individual medication. But the pharmacist didn't always record the intervention with the prescriber on the person's PMR. The pharmacy system highlighted people with similar names and people with different names at the same address and postcode. This enabled the team to ensure the supplies were made to the correct person. And to identify individual people with duplicate accounts.

Following the clinical check, a dispatch note and barcode delivery labels were printed and put in dispensing baskets. This prevented the loss of items and stock for one prescription mixing with another. And it meant the prescription information and delivery address were checked at each stage of the dispensing and checking process. The team used different coloured baskets for separate clinics. The team provided people with clear advice on how to use their medicines. All the information written by the prescriber that was relevant to the person was added to the dispensing label. The pharmacy team sometimes received queries from people either by telephone or email. And the pharmacist provided additional counselling to the person about their medication by speaking to them or via an email. The team signposted some queries to the prescribers and helped people resolve their questions with the prescriber if required. Pharmacy team members were allocated a number when initialling the dispensed by and checked by box on the dispensing labels. This enabled the pharmacy to easily identify who in the team had dispensed and checked the prescription, especially when an error occurred.

The team used different baskets depending on the courier used. This enabled the team to prioritise prescriptions for couriers that collected earlier in the day. Most supplies were made as a next day tracked delivery service via recognised couriers. When this was not possible the team contacted the person to advise them of the delay. The team stored the medicines for different delivery options separately and in an organised manner. The pharmacy used discreet, sturdy cardboard boxes of varying sizes to deliver people's medicines. Medicines requiring cold storage were delivered in appropriate packaging to maintain the correct temperature during transit. The pharmacy team scanned the barcode on the delivery label which triggered an email or text message to advise the person the supply was on

its way. Some people requested a safe space for their delivery and this was recorded on the PMR. The courier's tracking service provided a photograph of the package in the safe space to confirm delivery. When the person was not at home to receive the medication, they were notified and invited to rearrange the delivery. The courier returned the package to the pharmacy after several failed deliveries or when the person had not responded. The courier recorded on the package why it was returned. The team checked the packaging for damage before signing for receipt of the returned medication and contacted the prescriber to advise the medication had been returned.

The pharmacy obtained medication from several reputable sources. The team ordered most medicines as a bulk order. The purchasing manager monitored the items prescribed to identify trends and make appropriate changes to the order quantities to ensure the pharmacy could supply people with their medication. The team checked the stock levels regularly throughout the day and ordered additional stock when required. The team emailed people to advise when medication was out of stock. This triggered the person to contact the pharmacy to discuss options such as waiting for all the medication or to receive what was in stock. The pharmacy didn't flag this email communication to ensure the person had received the email and responded. This meant some people may not be aware the medication was not available until they queried why it hadn't arrived. The team held incomplete prescriptions in baskets in a dedicated area. The team members labelled the baskets in date order so they could prioritise the prescriptions for dispensing when the stock arrived.

The pharmacy team kept the shelves holding medicine stock neat and tidy. The shelves were labelled with the medicine's name to help the team accurately select the product. The pharmacy team regularly checked the temperature of the fridges and kept an electronic record. The records looked at were within the required range. The team members regularly checked the expiry dates of medicines and recorded when these checks had been completed. They usually marked medicines with a short expiry date to prompt them to check the medicine was still in date and they kept a list of short-dated stock. No out-of-date stock was found. The pharmacy advised people when the quantity prescribed could not be fully supplied when the expiry date of the medicines available in stock would be reached before the person had completed the treatment. The person was provided with a refund and the prescriber was informed so a new prescription could be issued if required. The team clearly marked medication containers to indicate when a quantity was removed. And clearly labelled plain boxes holding medicines removed from the original manufacturer's pack including the expiry date and batch number. Pharmacy team members received medicine recall alerts by email and actioned them appropriately. They recorded their actions on a spread sheet for reference. The team advised prescribers of any alerts that affected the products they prescribed. And generated a list of people prescribed the affected products to advise them accordingly.

## 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 references sources and access to the internet to provide the team with up-to-date clinical information. The pharmacy had equipment available for the services provided that included a range of CE equipment to accurately measure liquid medication. The pharmacy computers were password protected and data was encrypted to ensure people's confidential information was protected. The pharmacy computer system was regularly backed-up as a Cloud base and there was 24 hour, seven days a week access to IT support.

### 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.	