General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Oxenhope Pharmacy, 36 Station Road, Oxenhope, KEIGHLEY, West Yorkshire, BD22 9JJ

Pharmacy reference: 1116807

Type of pharmacy: Community

Date of inspection: 19/06/2024

Pharmacy context

The pharmacy is on a main road in a rural village. It dispenses NHS prescriptions and sells a range of over-the-counter medicines. Pharmacy team members provide other healthcare services including the NHS Pharmacy First Service, Covid-19 vaccinations, ear wax removal, blood glucose, ketone and cholesterol testing, and seasonal flu vaccinations. The pharmacy has a separate dispensary which it uses to dispense private prescriptions for a third-party 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 third-party online prescribing services. It does not properly assess the risks of providing medicines to people against prescriptions from a third-party 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 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 standard operating procedures (SOPs) in place to help pharmacy team members manage the risks of providing its NHS services. The superintendent pharmacist (SI) had reviewed the SOPs in 2023, and they were due to review them again in 2025. Pharmacy team members had signed to confirm they had read and understood the SOPs.

The pharmacy dispensed a high volume of prescriptions for a third-party private prescribing service. People accessed this service via the third-party's website. The pharmacy had some SOPs relating to its private service. But there were several areas of the service that did not have a documented SOP. These included written procedures for managing and recording clinical interventions and for managing ongoing monitoring of people's treatment to establish the safety of repeat supplies. There was no SOP or process to identify and manage overprescribing or to assess the suitability of supply of products, especially those liable to misuse such as cyclizine and Nytol. And medicines requiring ongoing monitoring such as salbutamol, levothyroxine, and medicines for other long-term conditions. There was no guidance, or access to the prescribing service's policies, to support pharmacy team members to make decisions about whether prescriptions were clinically suitable and safe to supply. And to determine if the quantities or frequencies of supplies were acceptable.

The pharmacy had various risk assessment templates available, but these had not been completed. This meant the pharmacy did not have any risk assessments for dispensing for the third-party private prescribing service. And it did not assess the risks of supplying specific medicines and products to people privately. A team member described some overarching assessment of risk, where the pharmacy had made decisions not to dispense medicines requiring cold storage and some higher-risk medicines with the potential of misuse, but this was not documented. The pharmacy had returned prescriptions for GLP1-agonist injections for weight loss back to the prescriber. The pharmacy made checks to ensure that prescribers were registered with the General Medical Council (GMC). It retained information from the GMC register, which showed that although prescribers were registered they were not on the GP register. The pharmacy did not ask prescribers to state which areas they were competent to practice in or ask for evidence of training. Prescribers for the third-party prescribing service worked remotely in different geographical locations. Team members made some rudimentary checks on the internet about the locations of the clinics detailed on prescriptions. But they did not confirm that these clinics or the third-party prescribing service were registered with an independent regulator, such as the Care Quality Commission (CQC) or Health Improvement Scotland (HIS). Their due diligence checks and other aspects of the service had primarily been based upon information received, usually verbally, from the

prescribing service. The prescribing service's website, which people used to access the service, was transactional, rather than condition or consultation driven and did not meet GPhC guidance. And this meant there were risks that people may receive medicines that were not appropriate for them.

The pharmacy did not consider any requirements for ongoing monitoring to establish if repeated supplies were safe and appropriate. And it made no checks to establish the prescribing policies being used by the prescribing service and how the prescribers made decisions about what and when to prescribe or not. The SI showed a record of interventions pharmacy team members had made in relation to prescriptions they had received. The overall number of records made was very small compared to the pharmacy's private prescription dispensing volume. Examples included a patient prescribed HRT and a contraceptive pill together, patients being prescribed orlistat with a recorded body mass index (BMI) of significantly less than 28, and patients being prescribed more than one medicines for erectile dysfunction. There were also several examples of queries about people over 75 years old being prescribed HRT. On each occasion, the pharmacy had continued to dispense these medicines after confirming with the prescriber. But there were no documented assurances that the prescriber had assessed and mitigated the risks of such prescribing, and how the person was being monitored. For example, for cardiovascular risks and risks to their bone density.

The pharmacy recorded private prescriptions from the third-party prescribing service using a labelling system that had been provided by them. The system did not provide information about interactions or contraindications. And the pharmacy was unsure about whether the system allowed team members to see a person's full medication history, 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 would help the team to determine whether supplying the medicine was appropriate. The pharmacy had started to request and record people's BMI if they were prescribed orlistat, after identifying several prescriptions prescribed outside of the manufacturer's product license, for people with a BMI of less than 28. The pharmacy had also returned prescriptions to the prescribers for medicines which they had deemed too high-risk for them to dispense, for example medicines that required cold-storage and injectable medicines for weight loss.

The pharmacy had not completed any audits relating to dispensing for the private prescribing service. It had not conducted any clinical audits to identify trends in prescribing and supplies, including overprescribing. And without knowledge of prescribing policies, and without pharmacy policies around maximum quantities and frequency of supplies, it would be difficult for the pharmacy to conduct these audits effectively. Without assurance that the pharmacy had a complete dispensing history for the patient, any audits completed would be incomplete. After the inspection, the inspector checked some recent private prescription data, about supplies made by the pharmacy against prescriptions from the prescribing service. The data provided several examples of trends and quantities dispensed that would have been appropriate for intervention by the pharmacy. But these trends had not been noticed or queried by the pharmacist or other pharmacy team members. So, the pharmacy was unable to establish the safety and quality of the services it provided.

The pharmacy provided a private ear wax removal service to people. The SI had considered some of the risks of providing the service. But they had not documented their risk assessment to help aid future reflection. The SI was experienced at providing otoscopy and had completed further training and some observed practice to ensure they were competent to provide the service to people safely. The pharmacy partnered with a company who provided the necessary equipment and IT facilities for the service. The equipment was in good working order and was regularly maintained by the partner company. People completed a screening questionnaire to establish their symptoms. They were also asked to provide consent for the pharmacy to share information with their usual NHS prescriber. The SI

explained how they did not routinely share information about people accessing the service unless the person needed referral to their GP based on their findings. During the consultation, the SI took photographs and videos of the person's ear, before and after removing wax. The SI also used the images to establish any symptoms that required referral to a GP. The SI recorded these images and videos for each consultation. But they did not keep any other records of their consultation unless they needed to refer someone for further help. The partner company provided the SI with support online to discuss their findings. These included reference documents and easy access to an otoscopy specialist.

Pharmacy team members highlighted and recorded mistakes identified before people received their medicines, known as near misses. There were documented procedures to help them do this effectively. Team members discussed mistakes and why they might have happened. And they gave some examples of changes they had made to help prevent isolated near miss errors from happening again, such as separating different strengths of citalopram. And by marking prescriptions to help prevent common look-alike and sound-alike errors. Team members rarely captured specific information about why the mistakes had been made. Or the changes they had made to prevent a recurrence and to help aid future reflection and learning. The pharmacist analysed the data collected every two or three months to establish patterns of mistakes. But they did not record their analysis. So, they may miss opportunities to reflect and make improvements. The pharmacy recorded dispensing errors, which were errors identified after the person had received their medicines. But the SOP available to help team members manage errors did not include specific information about how they should record dispensing errors. Or how to retain these records for future reference. There were no dispensing error records available to see during the inspection. The pharmacy was unclear about the system in place for people to contact the pharmacy in the event of a dispensing error with the private prescribing service.

The pharmacy had a documented procedure for handling complaints and feedback from people using the NHS services. But the process was not advertised to people in the pharmacy's retail area. Team members explained people usually provided verbal feedback, or by leaving reviews online. They gave a recent example of changing their local delivery process in response to feedback, to help deliver people's medicines more quickly. There was no clearly defined process for people to contact the pharmacy directly about medicines provided against prescriptions received from the third-party prescribing service. All contact from people was made via the third-party's customer service representative. 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 the prescriber's customer services without the pharmacy's knowledge. The pharmacy had current professional indemnity insurance in place.

The pharmacy kept accurate controlled drug (CD) registers. It kept running balances for all registers. Team members audited the running balances against the physical stock quantities in CD registers each time they made an entry in the register. This meant that registers for CDs that were not used often were not frequently audited. A check of the running balances against the physical stock for three products were found to be correct. The pharmacy kept a register of CDs returned by people for destruction. It maintained an RP record. And pharmacy team members monitored and recorded fridge temperatures. The pharmacy kept private prescription and emergency supply records, which were complete and in order. This included for prescriptions received from the third-party prescribing service.

The pharmacy kept sensitive information and materials in restricted areas. It collected confidential waste in dedicated bags. The bags were sealed when full and collected for secure destruction by a waste disposal contractor. Pharmacy team members explained how important it was to protect people's privacy and how they would protect confidentiality, especially in the limited space available on the ground floor, between the pharmacy's retail area and the area where prescriptions were prepared.

Pharmacy team members gave some examples of signs that would raise their concerns about

vulnerable children and adults. And they had recently completed formal safeguarding training. They explained how they would discuss their concerns with the pharmacist owners. And they were aware of how to find information about key local safeguarding contacts by using the internet. 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-part prescribing service.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members have the right qualifications and skills for their roles and the services they provide. They complete training to help keep their knowledge and skills up to date. Pharmacy team members feel comfortable raising concerns and discussing ways to improve services.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were two pharmacists, one of whom was the SI, a pharmacy technician, one qualified dispenser and three trainee dispensers. The pharmacy appeared to be managing the workload. Team members completed training ad hoc, which included regular informal discussion with the pharmacists and other colleagues. Team members received an appraisal each year, where they discussed their successes and learning needs. One team member was currently working to improve their confidence dispensing prescriptions after spending time away from pharmacy and mostly working with over-the-counter medicines. And the pharmacists and colleagues were supporting them to achieve their goals by signposting to learning materials and providing opportunities to work with prescription medicines.

Pharmacy team members explained how they would raise professional concerns with the pharmacist owners. They felt comfortable sharing ideas to improve the pharmacy or raising a concern. And they were confident that their concerns would be considered, and changes would be made where they were needed. The pharmacy did not have a formal whistleblowing policy. But pharmacy team members were aware of how to report concerns anonymously to the GPhC and NHS if necessary.

Team members communicated with an open working dialogue during the inspection. They felt comfortable making suggestions to improve their ways of working. They explained how they had recently changed the way they managed and organised the pharmacy’s stock. And their changes had helped to ensure that the pharmacy had enough of the right medicines the following day to help prevent having to owe medicines to people. The pharmacy’s owners did not ask team members to achieve any performance-related targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It provides a suitable space for the services it provides. The pharmacy has a consultation room where people can speak to pharmacy team members privately.

Inspector's evidence

The pharmacy was clean and well maintained. And the benches where medicines were prepared were tidy and well organised. Its floors and passageways were free from clutter and obstruction. And it kept equipment and stock on shelves throughout the secure premises. The pharmacy had two consultation rooms, which pharmacy team members used to deliver some services and have private conversations with people. There was a clean, well-maintained sink in the pharmacy, which team members used for medicines preparation. There was a toilet, with a sink which provided hot and cold running water and other facilities for hand washing. The pharmacy kept heating and lighting to acceptable levels.

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 against online private prescriptions that are safe and appropriate for their needs. It does not make adequate checks to ensure the medicines it supplies for these services are safe and clinically appropriate for people. And pharmacy team members do not have access to 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 access from the street via a step. Pharmacy team members explained that people who were unable to use the step usually knocked on the door to attract attention or telephoned the pharmacy from outside to ask for help. They would then help people to use the step, or some people chose to wait in their car outside where a team member would take their prescriptions once dispensed. The pharmacy used posters and stickers on prescription bags to raise awareness of the services it could offer to people, such as the NHS Pharmacy First service. And team members also displayed various pieces of general health and wellbeing information for people to use. The pharmacy, in collaboration with the local Lions Club, provided people with the use of a container to deposit old unwanted spectacles for recycling. Pharmacy team members could provide large-print labels and instruction sheets to help people with a visual impairment access services. And they would use written communication to help people with a hearing impairment.

The pharmacy was unclear about the systems and process the third-party prescribing service employed to determine someone's identity who was accessing the service. Or the systems in place to verify the information people provided about their medical history or other diagnostic parameters, such as height and weight used to calculate BMI. And this meant there was a risk that incomplete information was used in decisions about prescribing and supplies of medicines. The pharmacy did not know if the prescribing service obtained consent from people to share their prescribing with the person's NHS prescribers, whether information was routinely shared, and what action was taken by the prescribing service if people did not consent, to help ensure joined up care. The pharmacy also did not know the contents or suitability of the prescribing service's online questionnaire it used as a basis for its prescribing decisions.

The pharmacist did not have access to the services prescribing policies and any prescriber's consultation notes to base their clinical assessment of prescriptions on. They did not access the person's completed questionnaire and they had no completed audits to understand the quantities and frequencies of different medicines being supplied. Pharmacy team members had a system where they could contact prescribers by email to discuss any interventions and anomalies in prescribing. But there was little information recorded about any subsequent conversations. And there was an occasion when the pharmacy had supplied a medicine outside of the manufacturers' product license without the prescriber's justification for the decision. The pharmacist's clinical checks of prescriptions appeared basic and made with little information, outside of what was on the prescription. The pharmacy showed it had some safeguards in place as there was evidence of supplies being refused in some instances, for example someone's request for orlistat with a BMI that was too low. But on other occasions where BMIs were below 28, supplies were still made without documented reasons as to why.

After the inspection, the pharmacy provided data of the prescriptions they had dispensed for the third-party online prescribing service between 1 March 2024 and 20 June 2024. The pharmacy regularly dispensed medicines that were liable to misuse, such as cyclizine and Nytol. And there was no evidence of any intervention to determine whether the supplies of these medicines were safe and appropriate. The pharmacy did not have access to any records of the prescribing decision being made. Or if people were given clear information about actions to take if their condition changed or if they had further concerns about their health. The SI was questioned about what safeguards were in place to prevent abuse and oversupply of cyclizine. They stated that the pharmacy regularly communicated with the prescribing service, especially when the quantities seemed excessive, and that they monitored the frequency of medicines prescribed. But they could not provide any evidence of how they monitored prescribing or what constituted an excessive quantity. They stated that the prescribing service had safeguards in place to prevent people ordering medicines too frequently. But they did not have sight of their prescribing policies and based this statement on information they had been told verbally by the service.

The pharmacy regularly dispensed medicines against private prescriptions received from the third-party prescribing service to people for chronic conditions that required ongoing monitoring. The pharmacy did not have any knowledge of how the prescribing service monitored these people to ensure that ongoing supply was safe and appropriate. For example, the pharmacy regularly dispensed salbutamol inhalers, in various brands and forms to people. It was unable to determine whether the prescribing or supplies it made were excessive because the pharmacy had no 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. In the data provided, there were rare examples of people receiving a steroid inhaler at the same time as salbutamol. The pharmacy regularly supplied levothyroxine to people. The pharmacist had no knowledge of who had made the person's diagnosis of hypothyroidism. And they had not considered that levothyroxine could be misused. The pharmacy had no access to any information about how the person's condition was being monitored. The pharmacy regularly supplied medicines to treat erectile dysfunction (ED), most commonly sildenafil, tadalafil and vardenafil in various strengths and brands. The data showed several examples of potential excessive supplies of these medicines. And in one example two different prescribers had on more than one occasion prescribed different ED medicines to the same person. This had not been queried by the pharmacy. The data provided also showed medicines being supplied to treat and manage various other long-term conditions, such as type-2 diabetes, hypertension, chronic gout, chronic migraine, and eczema without clear policies or checks on diagnosis, monitoring and contact with people's NHS GP.

The labels attached to medicines dispensed by the pharmacy displayed a telephone number for the prescribing service's customer services. The pharmacy did not provide people with information they could use to contact the pharmacy directly. The SI stated that some people had contacted the pharmacy directly by using the internet to find the pharmacy's contact details from their address provided on the label. The SI also stated that although the pharmacy had email addresses for people, there were no examples of the pharmacy using this information to contact people directly about their medicines.

Pharmacy team members made and recorded interventions they made when dispensing NHS prescriptions. They provided an example of how they had queried the dose of a medicines for a child with the prescriber. The GP had confirmed the dose had been determined by the child's hospital specialist consultant. And team members recorded their intervention on the person's electronic patient medication record (PMR).

The pharmacy provided the NHS Pharmacy First Service, and people had the option to complete a pre-

consultation questionnaire by scanning a QR code at the medicines counter. Once they had completed the online form the responsible pharmacist (RP) assessed the information and they either completed a consultation in the consultation room or, if the person was not eligible for treatment through a clinical pathway, the RP provided advice and over-the-counter (OTC) medicines if appropriate.

Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing for their NHS and private services. This maintained an audit trail of the people involved in the dispensing process. They used baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacy delivered some medicines to people locally. It recorded the deliveries it made. If the person was not at home when they attempted delivery, they reattempted delivery two further times before leaving a card through the letterbox. The card asked people to contact the pharmacy. People were asked to sign to confirm receipt of specific CDs. The pharmacy delivered medicines to people using the third-party prescribing services via a national courier service. Deliveries were tracked and people were provided with the tracking information so they could monitor their delivery. If someone was not at home when the delivery arrived, the SI explained their understanding about how the courier returned the package to the pharmacy for the team to investigate. But they were unclear about whether the courier attempted to redeliver a package, where medicines were stored while waiting to be redelivered, and how long the courier held a package before returning it to the pharmacy. The pharmacy did not supply or deliver any medicines that required cold storage.

The pharmacist counselled people receiving prescriptions for valproate when appropriate. And they checked if the person was aware of the risks if they became pregnant while taking the medicine. They also checked if the person was on a Pregnancy Prevention Programme. Team members were aware of the requirements to dispense valproate in manufacturer’s original packs. The pharmacy had completed an audit in 2024 of people who they regularly dispensed valproate to, to ensure they had received the appropriate support and information. The pharmacy supplied medicines to people in multi-compartment compliance packs when requested. It attached backing sheets to the packs, so people had written instructions of how to take their medicines. Pharmacy team members included descriptions of medicines on the backing sheets, so they could be identified in the pack. Team members documented any changes to people’s medication on the person’s PMR.

The pharmacy obtained medicines from licensed wholesalers. It had disposal facilities available for unwanted medicines, including CDs. Team members monitored the minimum and maximum temperatures in the pharmacy’s fridge each day and recorded their findings. The temperature records were within acceptable limits. Team members explained the process for checking the expiry dates of medicines. Each team member had an allocated section in the dispensary and retail area, and they completed expiry date checks approximately every two months. This activity was being completed during the inspection. When stock was received from the wholesalers and transferred from the upstairs storage area the team member checked the expiry dates and rotated the stock so medicines with the shortest expiry date were used first. All medicines checked were within their expiry date and stickers were used to highlight those with a shorter expiry date. There was no written record of the checks made, so the pharmacy did not have an audit trail to confirm all medicines had been checked. The pharmacy received notifications of medicine recalls and patient safety alerts by email and it had organised, and up-to-date printed records of the action taken, by whom and the date.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. It maintains its equipment properly, so it is safe to use. And pharmacy team members manage and use the equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. This included well-maintained technical equipment to help provide some of its services, such as ear wax removal. It had reference resources available, including the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had a set of clean, well-maintained measures available to help prepare liquid medicines. It had suitable containers available to collect and segregate its confidential waste. It kept its password-protected computer terminals and bags of medicines waiting to be collected in the secure areas of the pharmacy, away from public view and where people's private information was protected.

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.