General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Primed Pharmacy, 40/42 Main Road, Denholme, BRADFORD, West Yorkshire, BD13 4BL

Pharmacy reference: 1039469

Type of pharmacy: Community

Date of inspection: 07/03/2023

Pharmacy context

The pharmacy is in the centre of Denholme village, near Bradford. Pharmacy team members dispense NHS prescriptions and sell a range of over-the-counter medicines. They provide medicines to people in multi-compartment compliance packs, and they deliver medicines to people's homes. The pharmacy provides aesthetics products and injectable medicines for weight loss via its website, www.primedpharmacy.com. It mainly supplies these products and medicines against private prescriptions issued by UK based prescribers. The pharmacy also has a license to wholesale these products and medicines.

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 adequately identifies and manages the risks associated with its services. And it has documented procedures to help team members provide services effectively. The pharmacy completes suitable audits to help make sure it provides its services safely. Pharmacy team members understand their role in helping to protect vulnerable people. And they suitably protect people's private information. They make the records they need to by law. And they use information they record when providing services to help them make effective clinical decisions. But they don't always discuss prescriptions and treatments with prescribers to make sure they are following best practice.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) in place to help pharmacy team members manage its services. These were available to pharmacy team members electronically. Most team members had read the procedures and the electronic system captured a record of this. But there were two locum pharmacists who worked at the pharmacy occasionally who had not confirmed they had read the SOPs. The responsible pharmacist contacted both pharmacists during the inspection. And they confirmed that the pharmacists had read the procedures. The pharmacists gave their assurance that they would sign the record confirming this as soon as possible. The superintendent pharmacist (SI) reviewed the procedures every two years. The procedures had last been reviewed and updated mid-cycle when the pharmacy appointed a new SI in November 2022. Although the pharmacy provided NHS services to people from its pharmacy premises, a large proportion of its services were provided to people privately via its website, www.primedpharmacy.com. The pharmacy provided a range of non-surgical cosmetic treatments including prescription only medicines (POMs) such as botulinum toxins and other associated products. But the main proportion of its private business was supplying injectable medicines to people for weight loss against private prescriptions. To use the pharmacy's website, prescribers and aesthetics practitioners were required to register an account with the website. Pharmacy team members verified each prescriber and practitioner. The pharmacy required prescribers and practitioners to provide proof of their identity and address when they registered with the website to confirm they were based in the UK. They checked prescribers' professional registration information to confirm they had the necessary accreditation to prescribe and to confirm they were not subject to any conditions or restrictions on their prescribing practices. And they did this each time they received a prescription from a prescriber. Prescribers were required to submit proof of indemnity insurance and training records relevant to their practice on registration. And they had to complete an annual declaration of competence. Once verified, they could use the website to order products and medicines or generate electronic prescriptions if they had been verified as a prescriber. These prescriptions were then dispensed by the pharmacy. Products and their prices could only be viewed by those who had registered with the pharmacy. Non-medical aesthetic practitioners were not authorised to generate prescriptions via the pharmacy's website. These practitioners were able to place an order for any items listed on the pharmacy's website, including aesthetics products, medicines, and sundries. But to receive the items, these orders required a prescription from a prescriber that the practitioner had a pre-existing relationship with. System access was limited to each role. So, practitioners could not prescribe POMs. The pharmacy had SOPs relating specifically to its private services. These included procedures for dispensing aesthetics and weight loss medicines and dispensing unlicensed medicines. The SOPs referred to the risk assessments, which had been completed for each service. And they considered several aspects of the service to minimise risk, including how team members recorded interventions,

the implementation of maximum quantities on products to help prevent too frequent supplies and the prescription requirements for supplying unlicensed medicines to people.

The pharmacy had risk assessments (RAs) for each service it provided privately, along with separate RAs for the products it supplied on private prescription. A selection of risk assessments was seen. The service risk assessments were detailed, reflecting a treatment overview of the condition. And they included when there was the need for additional or specialist information and considerations for prescriber competency. But the documents did not show a review date. A director explained RAs were reviewed as part of an ongoing cycle of safety-related workload management. And they were reviewed when required from the result of ongoing audits. The pharmacy worked with third-party prescribing services. It asked each service for copies of their prescribing protocols when they registered with the pharmacy. This was part of the risk assessment for each service. And this meant the pharmacy could assure itself that prescribers were working in accordance with national guidance. The pharmacy had a documented RA available for its seasonal flu vaccination service. The pharmacist manager had completed the RA before the service had commenced in autumn 2022. They had considered various risks of delivering the service to people, for example making sure the correct equipment was available, that the pharmacy's consultation room was set up correctly, and that team members had been appropriately trained to deliver the service. The manager had not recorded any information about how they had mitigated the risks identified, to help aid future learning and reflection. The pharmacy had up-to-date SOPs, patient group directions (PGDs) and an NHS Service Level Agreement (SLA) available for the service. And all of these had been read and signed by the team members delivering the service to people.

The pharmacy had been approached by a private clinic providing a specialist service. The clinic was run by specialist doctors registered with the GMC and the clinic was registered by the CQC. The pharmacy was not providing this service yet. But they had prepared a risk assessment to identify the risks involved in providing the service and the safeguards needed. They had obtained prescribing protocols and clinical pathways to understand the assessment process by the prescriber, how people were monitored when taking the medicines prescribed, and how the person's GP was notified. Some of the medicines used in the clinic would be controlled drugs. The pharmacy had considered how these medicines would be managed to make sure they supplied to people safely and securely.

The pharmacy had processes in place to review the quality of the dispensing service it provided. Audits were carried out regularly. These included audit checks on the prescribing of botulinum toxins, controlled drug (CD) record keeping, products requiring refrigeration, and unlicensed medicines. The pharmacy had recently completed an audit of prescriptions they had dispensed for botulinum toxins. The audit identified a prescription where there was a large geographical distance between the prescriber and the clinic administering the medicines. And pharmacy team members had not made any intervention. Team members discussed this at a subsequent patient safety meeting. They identified an individual training need, which was addressed to prevent future occurrence. The audit methodology used a random selection of prescriptions that had been dispensed each month. On reviewing some recent prescriptions, inspectors identified one prescriber who was issuing prescriptions for botulinum toxin to clinics based all over the UK. The prescriber had declared they had completed a face-to-face consultation with each person. But the pharmacy had not checked to determine how a face-to-face consultation had been carried out. So, the pharmacy could have done more to ensure supplies were being made safely.

Pharmacy team members highlighted and recorded near miss and dispensing errors they made when dispensing for both their NHS and private services. There were documented procedures to help them do this properly. They discussed their errors and why they might have happened. And they recorded

their errors by scanning a QR code on a handheld device and recording their information on a secure portal. Team members explained that although the electronic system had helped to make it easier for them to record their near-miss errors, they did not always record their mistakes because they were too busy. This was discussed and they gave their assurances that errors were always discussed, and changes made to help prevent a recurrence. A recent example had been separating different strengths of Ozempic to help prevent team members selecting the incorrect strength. The records available showed an improvement in the details team members recorded about why mistakes had happened. But some lacked detail about causes and the actions taken to improve safety. The pharmacy recorded dispensing errors, which were errors identified after the person had received their medicines. The records available showed little detail about the causes of errors and the actions taken by team members to help prevent them happening again. Team members gave their assurances that these aspects were always discussed, and changes implemented where possible. The pharmacist manager analysed the data collected about errors each month as part of a wider patient safety review process. They discussed their findings at weekly team meetings. In response to errors, pharmacy team members had recently changed the way they dispensed prescriptions for injectable weight loss medicines. They dispensed these prescriptions in batches throughout the day. And they now organised the batches according to the strength of medicine prescribed, to help prevent them selecting the incorrect strength. The pharmacy also used a workload management tool to bring together key safety action points from across the business. This included any queries raised by pharmacy team members, review of risk assessments, audits completed, new product considerations and SOP reviews. The platform could be viewed by all team members electronically. And any changes or comments were time-stamped to give a clear audit trail of communication. Issues raised by team members using this tool were reviewed in regular management meetings, and further discussed during monthly team safety meetings involving all team members.

The pharmacy had a documented procedure to deal with complaints handling and reporting. The pharmacy also asked the prescribers it worked with for proof of their professional indemnity insurance covering their services on an annual basis. The pharmacy's system was designed to block the prescriber from generating prescriptions on the website if their indemnity insurance had expired. The pharmacy published contact information on its website. And the pharmacy's website had a contact form people could use to contact the pharmacy. The pharmacy did not have any records of any feedback received. And pharmacy team members could not give any examples of changes made in response to people's feedback.

The pharmacy had current professional indemnity insurance. It kept controlled drug (CD) registers, which it completed accurately, and kept running balances in all registers. Pharmacy team members audited these registers against the physical stock quantity at least monthly. The pharmacy kept and maintained a register of CDs returned by people for destruction. It was accurately completed. The pharmacy maintained a responsible pharmacist record. And this was also up to date and completed accurately. The pharmacist displayed their responsible pharmacist notice to people. Pharmacy team members monitored and recorded fridge temperatures daily. The pharmacy kept two different electronic records of the private prescriptions it dispensed. Private prescriptions dispensed in the NHS contract part of the business were recorded using a conventional electronic private prescription register. And the sample of these records seen were complete. The pharmacy used a different system, of their own design, for receiving, dispensing, and labelling prescriptions received in their private business. Pharmacy team members added notes to people's records at various stages of the dispensing process, and these were available to view each time they dispensed a prescription for that person. The system kept a history of all prescriptions that had been dispensed for a person. And this information, along with any notes the dispenser wanted to highlight to the pharmacist, were printed on the prescriptions. This allowed the pharmacist to clearly see the person's medication history and helped

make sure a further supply was appropriate. Team members also used the system to record and manage any interventions they made with a person's prescription.

The pharmacy kept sensitive information and materials in restricted areas of the pharmacy. It collected confidential waste in dedicated bags, which were collected periodically for secure destruction. The pharmacy had a documented procedure in place to help pharmacy team members manage sensitive information. Pharmacy team members explained how important it was to protect people's privacy and how they would protect people's confidentiality if they visited the pharmacy to access services.

The pharmacy had a documented procedure and information available to help pharmacy team members deal with a safeguarding concern. This related to its NHS services and included information about local safeguarding contacts. Pharmacy team members had completed safeguarding training in 2021 and 2022. The pharmacy supplied a high volume of weight loss medicines via its website. Risk assessments for the weight management service considered potential safeguarding risks.
Actions included an age-verification check. And requiring prescribers to submit weight measurements to ensure treatment remained appropriate. Team members had received training on new weight loss products which had given some information on the potential misuse of these medicines and how to manage these. Team members would highlight any concerns with the RP. The pharmacy’s risk assessments specified age limits for people receiving medicines for each of their services. And dispensers checked that people were an appropriate age when they processed prescriptions ready to be dispensed. The pharmacy’s system relied on the prescriber providing an accurate date of birth for people they prescribed for.

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 appropriate training to keep their knowledge up to date. And they effectively discuss and implement changes to improve their services and make the pharmacy safer. Team members feel comfortable raising concerns with the right people if necessary. And they feel well supported by their colleagues and managers.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the superintendent pharmacist (SI), a pharmacist owner, a non-pharmacist owner, seven dispensers and an administrator. Pharmacy team members had the necessary qualifications to provide dispensing services to people. They completed ongoing learning ad-hoc by reading various materials and discussing topics with the pharmacists and owners. Recently, the pharmacy had arranged clinical training to be provided to team members by a pharmaceutical company who manufactured weight loss medicines that the pharmacy provided to people. This provided team members with a better understanding of their weight loss services and enabled them to ask clinical questions on the use of the medications. The pharmacy's directors had also engaged with some of the larger clinics that used the pharmacy to provide training on a new licensed product for weight loss. Pharmacy team members were seen managing the pharmacy's workload well. Team members worked independently to record interventions about prescriptions. They had a good understanding of the pharmacy's SOPs and prescribing policies. And they could clearly explain the limits of the quantities of medicines that could be dispensed for specific conditions. And they clearly explained how their training improved understanding about which medicines required specific directions to be included on the dispensing labels.

Pharmacy team members explained they would raise professional concerns with the pharmacist manager, the SI or the pharmacy's owner, who worked at the pharmacy every day. They felt comfortable raising concerns and confident that concerns would be considered, and changes made where necessary. They explained that if they had a concern they could not raise internally, they would contact the GPhC for advice. There was no whistleblowing policy seen during the inspection. Following a discussion about ideas, team members explained how they had changed their process for dispensing different strengths of the same weight-loss medicine. Their changes involved sorting prescriptions into batches differently. And this had resulted in a reduction in the number of near-miss errors involving different strengths of medicines.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It offers a suitable space for the services provided. And it has a room where people can speak to pharmacy team members privately. Its website is professional and well maintained. And it provides people with clear information about the pharmacy and how to access to its services.

Inspector's evidence

The pharmacy's website, www.primedpharmacy.com, was used by prescribers and practitioners to order private prescriptions for medicines, injectable and oral weight loss medicines, and non-surgical cosmetic treatments, such as toxins, fillers, medicines, and ancillary items. Medicines and treatments could only be requested by professionals who were registered with the pharmacy. And this was made clear to people on the pharmacy's home page. The website included information about the pharmacy's address and contact information. It displayed the voluntary GPhC premises registration logo, which correctly linked to their registration information. The website also provided clear information about the pharmacy's superintendent pharmacist.

The pharmacy had made some interior changes to the premises since its last inspection. It had altered the area on the first floor where its private services were provided to allow for safer movement of stock and parcels from the area where prescriptions were prepared to a newly installed lift. The pharmacy was clean and well maintained. It had clearly designated areas and benches for dispensing, accuracy checking and packaging. And these areas were tidy and well organised. The pharmacy's floors and passageways were generally free from clutter and obstruction. It kept equipment and stock on shelves throughout the premises. The pharmacy had a private consultation room available, which was clearly signposted and pharmacy team members used the room to have private conversations with people. There was a clean, well-maintained sink in the dispensary 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. Overall, the pharmacy's appearance was professional and suitable for the services it provided.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has suitable safeguards to ensure it delivers its services safely. It makes adequate checks to ensure the medicines it supplies are safe and clinically appropriate for people using these services. And pharmacy team members have easy access to records to help them make effective clinical assessments. They provide most medicines with clear labelling to help make sure people can take their medicines safely. But they do not always put complete directions on the labels to help people understand the correct dose to take. The pharmacy stores and manages its medicines appropriately. And it has robust systems to manage the delivery of medicines requiring cold storage.

Inspector's evidence

The pharmacy had access to its premises from the street via steps. People knocked on the door to attract attention if they needed help. Pharmacy team members could use the electronic prescription medication records (PMR) system to produce large-print labels to help people with visual impairment. They explained how they would use written communication to help communicate with people with hearing impairment. And they would use an online translation tool to help communicate with people who did not speak English.

Most of the private prescriptions dispensed by the pharmacy were received and generated electronically using the pharmacy's website, which integrated with the pharmacy's bespoke electronic patient medication records system (PMR). Each prescription was processed by a dispenser, who checked if the prescriber was registered with their relevant UK regulator and generated a label for the products prescribed. Team members noted any extra information submitted, such as date of last face-to-face consultation, a weight measurement, and any patient-specific notes that needed to be added to someone's record. They followed the standard operating procedure (SOP) to check if the quantities prescribed were within the pharmacy's defined limits. If team members required further information to process a prescription, the prescription was moved to a "pending" queue, and they opened an intervention record. These records captured what information was required, and what action they had taken to resolve the query. Once resolved, team members recorded any information received on the intervention file and the prescription was then processed. They printed a copy of the prescription and passed to the pharmacist to complete a clinical check. The printed prescription contained the history of medicines dispensed by the pharmacy and any notes that had been added to the person's record. The pharmacist used this information to help complete their clinical check. Then they passed the prescription to other team members to dispense and complete a final accuracy check. If the pharmacist had a prescription query, they would contact the prescriber and a response was received usually by email or direct input by the prescriber onto the prescribing system. The pharmacy implemented maximum quantities for higher risk medicines such as dermal fillers, botulinum toxins and weight loss medicines. And team members were aware of these limits. If a prescription was received for a quantity higher than these limits the prescription was declined and the pharmacy contacted the prescriber. The pharmacy worked with clinicians from a variety of clinics to review the maximum quantities and frequencies for these products regularly. The pharmacy supplied people with a patient support pack when prescriptions for Saxenda, an injected medication used for weight loss, were dispensed. These packs provided people with printed supporting resources to help them manage their weight and links to online materials about how to use the medication.

The pharmacy dispensed some medicines for use outside of the manufacturer's product license. These included Ozempic and Rybelsus, medicines licensed for the treatment of diabetes, but used for weight loss. Each time they supplied these medicines, pharmacy team members provided people with an information leaflet about unlicensed medicines to help them understand the risks. The leaflet explained the implications of using a medication outside of the manufacturer's license. And it provided people with clear information about how to contact the pharmacy if people required more information. The pharmacy required the prescriber to confirm they had discussed unlicensed nature of the medicines with people before a prescription was generated. The pharmacy set up their prescribing system so that the prescriber was required to input text to provide instructions about how people should use each medicine. This was to prevent confusion when the patient information leaflets (PILs) provided by the manufacturer were not clear about the dose to use. But from a selection of records seen, several prescriptions for unlicensed medicines, such as Rybelsus and Ozempic, contained instructions like "use as directed". These medicines required instructions for increasing the dose in the first few weeks, which also differed from the licensed dose for diabetes that was shown on the manufacturers PIL. This had not been queried by the pharmacy team during dispensing, so there was a risk people may not understand the correct dose of medication to use.

Since the pharmacy's past inspection, it no longer delivered botulinum toxins to people's home address. The superintendent pharmacist (SI) explained that they required the delivery address to be the clinic registered with the pharmacy. This helped to ensure the medicine was administered by an appropriately trained practitioner, and that the cold chain could be maintained for products requiring refrigeration. But from a sample of records seen, there were a small number of botulinum toxins where the patient's address was the same as the delivery address. This was discussed, and the owner explained they were continuing to work hard to identify all these instances and intervene to make sure botulinum toxin was delivered directly to prescribers and practitioners. The pharmacy also supplied prescription-only-medicines on a wholesale basis to healthcare professionals, for which they had a license issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). In the records seen, this included botulinum toxins. And the pharmacy made regular supplies of botulinum toxin to the same prescriber. The pharmacy had not had a discussion with the prescriber about prescribing botulinum toxin to people in accordance with a prescription. And to determine the prescribers' policies to ensure that botulinum toxins were provided to people from stock in accordance with a patient specific direction (PSD), as per current best practice guidance.

Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing for both NHS and private prescriptions. This was to maintain an audit trail of the people involved in the dispensing process. The pharmacist clinically checked each prescription received in the pharmacy. And they annotated private prescriptions to confirm they had completed their checks. A dispenser was qualified to perform the final accuracy check of prescriptions. They explained they used their checking skills to perform the accuracy check of prescriptions. They explained how they would not carry out final accuracy checks unless the clinical check had been completed. They also gave clear examples of the types of prescriptions they were not permitted to check, such as prescriptions for controlled drugs and prescriptions for some higher-risk medicines, such as methotrexate. The dispenser explained that the limitations of their role had been discussed and agreed verbally with the superintendent pharmacist (SI) and the pharmacy manager. But these limitations had not been documented in an SOP to help support their role or to help define their responsibilities when working with locum pharmacist.

Pharmacy team members used dispensing baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacy supplied medicines to people in multi-compartment compliance packs when requested to help them take their medicines correctly. It attached backing

sheets to the packs, so people had written instructions of how to take their medicines, and descriptions of what the medicines looked like, so they could be identified in the pack. And they provided people with patient information leaflets about their medicines each month. Pharmacy team members documented any changes to medicines provided in packs on the person's master record sheet, which was a record of all their medicines and where they were placed in the packs.

The pharmacy stored medicines on shelves, and it kept all stock in restricted areas of the premises where necessary. It had adequate disposal facilities available for unwanted medicines, including controlled drugs (CDs). The pharmacy used electronic data logging systems to continually monitor the temperatures in several fridges. The system alerted the SI and the pharmacy owners 24 hours a day if a temperature was outside of expected ranges. The temperature records seen were within acceptable limits. Pharmacy team members checked medicine expiry dates every three months, and up-to-date records were seen. They highlighted and recorded any short-dated items up to three months before their expiry. And they removed expiring items at the beginning of the product's month of expiry.

Prescriptions dispensed through the pharmacy's website were delivered using a national courier service. 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. And they were dispatched using a tracked service. 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 transmitted temperature information in real time to the pharmacy so they could determine whether the package had been maintained at the expected temperature. The pharmacy was alerted to any dispatched deliveries that had been in transit for more than 48 hours, so they could be recalled to the pharmacy and the products disposed of. Pharmacy team members then investigated why the package had not been delivered and arranged for a new package to be redelivered if necessary. The pharmacy delivered medicines to people's homes locally using its own delivery driver. It used an electronic system to compile a list of the deliveries which was uploaded to the delivery driver's hand-held device. The system allowed pharmacy team members to track the delivery driver's progress throughout their delivery run. And this helped them to locate prescriptions and resolve queries from people who telephoned the pharmacy. The information uploaded to the driver's device included detail about each prescription, such as the presence of an item that needed to be stored in a fridge or a controlled drug. The delivery driver left a card through the letterbox if someone was not at home when they delivered, asking them to contact the pharmacy. And they returned any undelivered items to the pharmacy at the end of their delivery run.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available, which it properly maintains. And it manages and uses the equipment in ways that protect people’s confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. It used a labelling system of its own design to dispense prescriptions from its associated private prescribing services. The system captured the necessary information, and pharmacy team members were able to access the information easily at each stage of the dispensing process. The pharmacy had the resources it needed to provide the services it offered. These resources included 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 for liquid medicines preparation. It had suitable containers and a shredder available to collect, segregate and destroy 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. It had several fridges and freezers available to maintain medicines and equipment at the correct temperatures.

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.