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: 21/07/2022

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 be able to wholesale these products and medicines.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 does not properly assess the risks of its private services, including the medicines it provides to people. It does not have adequate documented procedures for its private services. And it doesn't have suitable risk assessments for the medicines it supplies. This includes for weight loss medicines, aesthetics products, including botulinum toxins, and medicines being used outside of the manufacturer's product license.
		1.2	Standard not met	The pharmacy does not proactively audit or review the quality and safety of its private services. It does not have adequate systems in place to identify trends to prompt effective interventions. There are no systems to audit the higher risk and higher volume medicines it supplies. And no systems to effectively identify and challenge overprescribing and oversupply.
		1.6	Standard not met	The pharmacy does not keep complete and accurate records for its private services, to help pharmacy team members make effective clinical assessments of these prescriptions.
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 to ensure the safe and effective delivery of its private services. The pharmacy does not request information from their prescribers to make adequate clinical checks and to make sure the medicines they supply are safe and appropriate for people. They do not always make appropriate clinical interventions. And they do not record or have easy access to information to be able to make effective clinical assessments.
5. Equipment	Standards	N/A	N/A	N/A

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	met			

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy identifies and manages the risks with providing its NHS services. And the team follows suitable written procedures. But the pharmacy does not meaningfully assess the risks of providing its private services to people. And it does not have adequate written procedures for these services. The pharmacy does not actively review or monitor its private services to ensure it provides them safely. The pharmacy keeps the records it should for its NHS services. But it keeps incomplete records for its private services. This means team members may not have all the information they need to ensure they supply medicines safely. 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 standard operating procedures (SOPs) in place to help pharmacy team members manage its NHS services. Pharmacy team members had read the procedures and had signed to confirm their understanding. And the superintendent pharmacist (SI) reviewed the procedures every two years. 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. 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 supplied by the pharmacy. There were some SOPs relating to its private services. But there were several areas of the business that did not have a documented SOP. These included written procedures for supplying unlicensed medicines to people, for managing and recording clinical interventions and for managing ongoing monitoring of people's treatment to establish the safety of repeat supplies. This also included identifying and managing overprescribing and supply of products, especially those liable to misuse. There was no guidance to support pharmacy team members to make decisions about whether quantities or frequencies of supplies were acceptable.

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. Pharmacy team members 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. The pharmacy did not ask prescribers to provide evidence of their training or competence to prescribe. This included for aesthetics and weight management. The pharmacy owner explained they had asked for this information previously. But as the pharmacy had become busier, this became too difficult to administrate, so they had stopped. 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 in order to receive the items, these orders required a prescription from a prescriber that the practitioner had a pre-existing relationship with. The pharmacy asked practitioners to state which areas

they were competent to practice in. But they did not ask practitioners to provide proof of their competence or training. The pharmacy did not routinely check these areas of competence against the products being requested by practitioners. And it did not periodically check whether practitioners continued to remain competent in their stated areas of practice. The pharmacy did not request information from prescribers or practitioners about their professional indemnity insurance arrangements. And this did not form part of the website's terms and conditions.

The pharmacy did not have any risk assessments for the private services they provided. And they did not assess the risks of supplying specific medicines and products to people privately. The pharmacy regularly supplied Saxenda to people. It 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 prescribers that used its website. The pharmacy therefore did not have all the information from the prescriber to help complete a full risk assessment of the pharmacy's private services and the medicines it supplied. The pharmacy frequently supplied Ozempic, and less commonly Rybelsus to people for weight loss, which was outside of the manufacturer's product license. It had not assessed the risks of supplying unlicensed medicines to people and the steps they should take to make sure these medicines were used safely. The pharmacy had not checked the prescribers' prescribing policies for unlicensed medicines. And it had not checked that prescribers informed people of the unlicensed use. The pharmacy did not communicate the unlicensed indication to either the prescribers or the people receiving the medicine.

The pharmacy regularly supplied botulinum toxins to people on prescription. The pharmacy had not completed any assessments or checks to make sure that people had received a physical face-to-face consultation with a prescriber before prescribing the medicine, in accordance with GPhC guidance and guidance published by the Joint Council for Cosmetic Practitioners (JCCP).

The pharmacy owner confirmed that the pharmacy had not completed any risk assessments. He showed a brief risk register of risks team members had identified since January 2022. The register considered some risks, such as the risks of a prescriber prescribing for themselves. But they confirmed that nothing had been done to address the risks identified.

The pharmacy did not carry out any audits of the private services it provided, or on the supplies of medicines it made to people using these services. After the inspection, the inspector checked some recent private prescription data, about supplies made by the pharmacy. The data provided several examples of trends 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.

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. But team members could not give any examples of changes they had made to prevent errors happening again. The records available contained little or no information about why mistakes had been made. Or any changes team members had made to prevent them happening again. The pharmacy did not analyse the data collected for patterns. This meant team members might miss out on opportunities to learn and make improvements to the pharmacy's services.

The pharmacy had a documented procedure to deal with complaints handling and reporting. It 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 up-to-date professional indemnity insurance in place. It maintained a responsible pharmacist record electronically, which was mostly complete. The pharmacy kept electronic controlled drug (CD) registers complete and in order. It kept running balances in all registers. These were audited against the physical stock quantity monthly. The inspector checked the running balances against the physical stock for three products. And these were correct. 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 recorded private prescriptions dispensed in its private business using a labelling system that had been designed by the pharmacy's owners. The system did not record clinical interventions made by pharmacy team members, it did not provide information about interactions or contraindications, and it did not allow team members to see someone's full medication history when labelling and clinically checking their prescription. In some records seen, the system also did not record the full details of the directions prescribed. The pharmacy did not record clinically significant information to establish whether supplies were appropriate for people, for example asking for and recording people's BMI to establish if a supply of a weight loss medicines was appropriate. This meant that the pharmacist did not have access to information to help make a proper and accurate clinical assessment of a prescription. The superintendent pharmacist (SI) gave an example of an intervention he had made with a prescription for a female patient calling for diazepam tablets. A dispenser identified that the person had received a month's supply approximately 10 days earlier. The dispenser had identified this by remembering the name of the person being prescribed for, rather than using the pharmacy's systems to highlight overprescribing. The SI explained he had not supplied the second prescription on account of the medicine being supplied to the person 10 days earlier. He showed the inspector copies of the prescriptions. The second prescription, that had not been supplied, also had sildenafil tablets on the same prescription. The SI admitted he had not considered querying that sildenafil had been prescribed for a female patient.

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 did not have 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. The pharmacy supplied a high volume of weight loss medicines via its website. These medicines have a high risk of being misused by people. The pharmacy did not have any dedicated procedures or training in place to help pharmacy team members identify and manage potential misuse of these medicines.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members have the right qualifications for their roles and the services they provide. They complete some training ad-hoc to keep their knowledge up to date. But their training often does not reflect the specialist private services they provide for people. Pharmacy team members feel comfortable discussing ideas and concerns.

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 pharmacist. The superintendent pharmacist (SI) provided an example of using manufacturer's product information to provide training to team members about a weight loss medicine commonly supplied to people via the private services. But there were no other examples of team members completing training specific to the specialist private services the pharmacy was providing.

Pharmacy team members explained they would raise professional concerns with the SI or the pharmacy's owners. They felt comfortable raising concerns and confident that concerns would be considered. They were less confident that changes would always be made where they were needed in a timely way. 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 available during the inspection.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. And it provides a suitable space for its services. The pharmacy has a suitable room where people can speak with pharmacy team members privately. Its website is generally acceptable. But it is not clear that the website is for use only by professionals, and some information on it is incorrect. So, this may be confusing or misleading to people using the website.

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 people who were registered with the pharmacy. But this was not made clear to people accessing the website and may cause confusion.

The website included information about the pharmacy's address and contact information. It displayed the voluntary GPhC premises registration logo, but this was incorrectly linked to another pharmacy's registration information. The website also provided incorrect information about the pharmacy's superintendent pharmacist. And this could be misleading to people using the website.

The pharmacy's premises were clean and well maintained, and they were tidy and well organised. The floors and passageways were free from clutter and obstruction. Pharmacy team members kept equipment and stock on shelves throughout the premises. The pharmacy had a private consultation room available. 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 and another sink for cleaning and hand hygiene. There was a toilet, with a sink which provided cold running water and other facilities for hand washing. The pharmacy maintained heat and light to acceptable levels. Its overall appearance was professional, including the pharmacy's exterior which portrayed a professional healthcare setting. The pharmacy's professional areas were well defined by the layout and were well signposted from the retail area. Pharmacy team members prevented access to the restricted areas of the pharmacy.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy does not have adequate safeguards in place to ensure it delivers its private services safely. It does not make adequate checks to ensure the medicines it supplies are safe and clinically appropriate for people using these services. And pharmacy team members do not keep or have easy access to records to make effective clinical assessments. The pharmacy suitably manages its NHS services. And it stores and manages its medicines appropriately, including managing 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 generated electronically using the pharmacy's website. 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 requested. A copy of the prescription was printed and passed to other team members to dispense. The website required prescribers to be verified as prescribers when they registered with the website. They then used a simple login to access the website when they wanted to select and prescribe products and medicines. The pharmacy was unable to provide assurances that the electronic prescriptions its website generated met the requirements for the inclusion of an advanced electronic signature.

The pharmacy used a labelling system of its own design to dispense and record private prescriptions, which was linked to its website. A pharmacy owner described the process whereby pharmacy team members would alert the pharmacist when labelling prescriptions to any frequent or regular items being issued for the same person. But this process was not demonstrated when watching team members carrying out the process in practice and relied on team members memory, rather than the information held in the labelling system. The pharmacy's labelling system did not allow easy access to people's previous dispensing information. So, pharmacy team members, including the pharmacist carrying out clinical assessments, did not routinely check to see when the patient last received a prescription. And what the prescription was for. The labelling system did not alert team members to any interactions or contraindications when medicines were dispensed. The superintendent pharmacist explained they did not record any interventions they made when dispensing these prescriptions. They gave an example of intervening to stop an inappropriate request for diazepam tablets. But they did not record their intervention and decision making. This meant that the pharmacist did not have access to all the necessary information to make effective and accurate clinical assessment of the prescriptions being dispensed. Or reflect on their practice and monitor inappropriate prescribing.

The pharmacy frequently dispensed medicines through its private services to people for weight loss. It did not request or record any clinical or monitoring information from prescribers to determine whether the medicines were appropriate for people. Or whether people had achieved the necessary weight loss

required to justify ongoing prescribing and supply of the treatment. The pharmacy did not request to see any prescribing policies from the prescribers it worked with to help the pharmacy team determine the parameters prescribers applied to ensure safe prescribing and ongoing monitoring. The pharmacy did not ask for any information as to whether prescribers informed people's NHS prescribers of any treatment to ensure joined up care. The pharmacy did not have any documented procedures or criteria to help team members determine the appropriate maximum or minimum quantities that should be safely supplied to people, or how often these should be supplied, especially for higher-risk medicines that could potentially be misused. From the data provided by the pharmacy of the supplies it had made, there was evidence of potential oversupplies of higher-risk medicines to people, such as Saxenda. And there were supplies of Ozempic and botulinum toxin which could not be determined as appropriate without intervention or knowledge of prescribers' policies or contacting the prescriber. Pharmacy team members did not have the systems in place to ensure they contacted the prescriber to discuss any anomalies in prescribing and make records of interventions.

From the records available, most prescriptions contained the directions "Use as directed". This included medicines that were being supplied outside of the manufacturer's product license, such as Ozempic and Rybelsus, and for injectable botulinum toxins for cosmetic purposes. This lack of directions made it difficult for pharmacists to determine if the supply was appropriate. And the lack of clear instructions increased the risks of inappropriate use by people. The pharmacy did not make any checks to ensure that people had received a physical face-to-face consultation with their prescriber when receiving prescriptions for botulinum toxins, in accordance with current guidance published by the Joint Council for Cosmetic Practitioners (JCCP) and the GPhC. There was also evidence of prescribers prescribing botulinum toxin for people and practitioners in various locations across the UK. This had not been queried by the pharmacy to ensure that physical face-to-face consultations were taking place.

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. They 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. Pharmacy team members included 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 private services and it was difficult for pharmacy team members to easily access the information they needed. The resources the pharmacy had available 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 medicines preparation. It had a suitable shredder available to destroy its confidential waste. It kept its computer terminals in the secure areas of the pharmacy, away from public view. And these were password protected. The pharmacy restricted access to all equipment. 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.