General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Saltley Pharmacy, 118 Washwood Heath Road, Saltley, BIRMINGHAM, West Midlands, B8 1RE

Pharmacy reference: 1038185

Type of pharmacy: Community

Date of inspection: 14/11/2024

Pharmacy context

This community pharmacy is located next to a GP practice in the Saltley area of Birmingham. People who use the pharmacy are from the local community and a home delivery service is available. The pharmacy dispenses NHS prescriptions, and it provides some other NHS funded services. The pharmacy team dispenses medicines into multi-compartment compliance packs for people to help make sure they remember to take them.

The pharmacy dispenses private prescriptions for a third-party online prescribing service which provides weight loss treatments. The prescribing service is registered with the Care Quality Commission (CQC). This inspection focused on this aspect of the pharmacy's services. Not all standards were inspected on this occasion.

Enforcement action has been taken against this pharmacy, which remains in force at the time of this inspection, and there are restrictions on the provision of some services. The enforcement action taken allows the pharmacy to continue providing other services, which are not affected by the restrictions imposed.

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 has not assessed and managed the risks associated with working with the third-party prescribing service and providing services at a distance. The standard operating procedures associated with weight loss service lack sufficient detail.
		1.2	Standard not met	The pharmacy does not have an effective system for carrying out ongoing audits for the weight loss services, so it can promptly identify and address issues.
		1.6	Standard not met	The pharmacy does not keep appropriate private prescription records for the weight loss medicines it supplies on behalf the third-party prescribing service. The records that it can access are held by a third-party so they could be changed or deleted without the pharmacy's knowledge.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy cannot demonstrate that the team members involved with the supply of medicines for the third-party prescribing service are suitably trained and competent to carry out the tasks that they are undertaking.
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 supply weight loss medicines on behalf of the third-party private online prescribing service in a safe an effective manner. Standard operating procedures are not being followed and the pharmacy does not have enough information about the person receiving the treatment to carry out an effective clinical check before it supplies them with medication.
		4.3	Standard not met	Weight loss medicines that require cold-chain storage are not always stored in accordance with the manufacturer's instructions, and the pharmacy cannot demonstrate that the medicines are kept at an appropriate temperature during

Principle	Principle finding	Exception standard reference	Notable practice	Why
				transit to the recipient.
5. Equipment and facilities	Not assessed	N/A	N/A	N/A

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

Summary findings

The pharmacy does not manage and identify the risks associated with the third-party online prescribing service that it works in partnership with. It cannot demonstrate it has adequate safeguards and the pharmacy has not completed adequate risk assessments before working with the prescribing service to ensure that its working practices are safe and legal. This means that people may be able to access medicines which may not be suitable and could cause them harm. The pharmacy relies on the prescribing service to undertake parts of the service, including record keeping. This means there was a risk that private prescription information could be changed, deleted or the pharmacy's access to records be removed or restricted.

Inspector's evidence

The pharmacy had started working with the third-party CQC registered prescribing service in September 2024 when a representative from the pharmacy had signed a service level agreement (SLA) with the prescribing service. The SLA covered the responsibilities and expectations of both the pharmacy and the prescribing service. It specified the two injectable weight loss medicines that the pharmacy was responsible for supplying against prescriptions issued by prescribers working for the prescribing service. Members of the public accessed the weight loss service through a website that was owned and managed by the prescribing service. The pharmacy dispensed the medications which were then delivered directly to people using Royal Mail. The pharmacy team did not have any direct contact with the person receiving the medication.

The pharmacy had checked whether the prescribing service was registered with CQC, and the prescribers were registered in the UK before entering the business arrangement. This had assured them that the prescribing service was registered and regulated with a UK healthcare regulator, and they trusted the prescribing service to undertake certain checks before prescribing. For example, identification checks, informing the persons usual prescriber, injection technique training, ongoing monitoring, and verifying the persons BMI. The pharmacy did not carry out any ongoing monitoring of the service to assure themselves that the prescribing service was undertaking these checks in practice. The superintendent pharmacist (SI) explained that he had taken advice from his membership body before entering into the agreement with the prescribing service and he explained the due diligence checks that he had completed. For example, he had checked that the prescribing service was registered with CQC, that the prescribing service's prescribers were registered with the Nursing and Midwifery Council (NMC) using the NMC website, and whether he required additional indemnity insurance for the pharmacy. He said that he had carried out a risk assessment and written a standard operating procedure for the service. The SI provided a copy of the SLA and a risk assessment for the service after the inspection.

There was a folder containing a range of standard operating procedures (SOPs) which covered most of the activities of the pharmacy and the services provided. Except for the weight loss service SOP, the SOPs had been prepared using commercially available SOP templates. The SOPs had been reviewed and updated at regular intervals. The templates contained audit information such as the name of the pharmacist that had approved the SOP for use, the date that it had been reviewed and signature sheets were used to record staff training. The SOP for the weight loss service was a simple document and the team had some difficulty in locating it amongst other paperwork. The document lacked any detail to support the process. It was not accompanied by a training record, and it was unclear which pharmacist had written the SOP and when.

The SOP stated, 'Pharmacist will check via SCR the patient records and review appropriateness of the drug'. The 'SCR' is the person's NHS health record or National Care Record (NCR). The SLA stated that the pharmacy should 'Review the patient's SCR as part of the dispensing process to ensure the patient meets the inclusion criteria for treatment'. The pharmacy only had limited information available to them on the prescribing service's system. Whilst the SI said that he was carrying out this NCR check and gave some examples of the medical conditions that would exclude people from being suitable for these medicines, its effectiveness in ensuring people met the inclusion criteria was unclear.

The SOPs also stated 'Pharmacist to carry out audit for 1 in 20 customers. This had not been done and there were no additional details to suggest what that audit should consist of. The pharmacy had not undertaken any audits of the service since it had started.

The risk assessment for the service was basic. It outlined how the service operated but it did not identify the risks associated with it, explain how risks were mitigated, or indicate how and when the risk assessment would be reviewed. The pharmacy team members were unaware of the risk assessment, and they had not contributed to its development. There were some key risks that were not mentioned in the risk assessment. For example, the risks associated with delivering cold chain medicines, the risks associated with the pharmacy checking the person's NHS NCR due to the limitations of the information available, and the risks associated with the additional workload on the pharmacy team.

The prescribing service handled any customer service issues or complaints. The SI explained that in the time that they had been working with the clinic he was unaware of any allegations of dispensing errors, faulty devices, failed deliveries, or customer complaints. The website contained a 'contact us' section and an email address which were both monitored by the prescribing service. The pharmacy address and GPhC registration number was on the website, but not the telephone number. The SI said that he thought that people would use an internet search engine to find the pharmacy's telephone number if they wanted to query something directly with the pharmacy, but he felt that they would contact the prescribing service in the first instance.

There was no responsible pharmacist (RP) notice displayed at the start of the inspection. This was rectified when the RP was made aware. The RP record was not up to date and had not been completed for the past week. Again, this was rectified by the RP. The pharmacy dispensed private prescriptions issued by the prescribing service's nurse prescribers. The last prescription that had been printed by the pharmacy was dated 17 October 2024. The RP explained that he had been checking them against an electronic copy held on a laptop since then, rather than printing them out. The pharmacy did not maintain private prescription records for the service. The SI explained that the service used a standalone system provided by the prescribing service for producing dispensing labels and that he had instructed the team to print the prescriptions and to use the pharmacy's usual computer system to make a second record so that a private prescription register entry was made. However, this was not being done so the pharmacy did not have an independent record of the supplies it made, only those held on the prescribing service's software. The delivery records were also held on the prescribing service's software. There was a risk that private prescription information could be changed, deleted or the pharmacy's access to records be removed or restricted.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy cannot demonstrate that team members involved with the supply of medicines for the third-party prescribing service are suitably trained and competent to carry out the tasks that they are undertaking.

Inspector's evidence

The pharmacy team present at the time of inspection comprised of the responsible pharmacist, a medicines counter assistant and an assistant not yet enrolled on a course as he was working his induction period. The team were joined by the superintendent pharmacist (SI) who usually worked at another pharmacy nearby.

The SI explained that the pharmacy worked with two ‘business managers’ who visited the pharmacy every lunchtime to dispense the weight loss prescriptions. They carried out dispensing duties such as labelling weight loss medicines and checking fridge temperatures. One of the business managers arrived at the pharmacy during the inspection. They had not completed any pharmacy accredited training for their role. The SI was unsure whether the other business manager had already completed a course.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is generally clean and tidy and provides a suitable environment for the delivery of healthcare services. The website for the online prescribing service that the pharmacy is partnered with does not contain sufficient information about the prescribers so people can make an informed decision when accessing the service.

Inspector's evidence

The prescribing service offered a weight loss service to members of the public through its website. The SI confirmed that the website was not owned or managed by the pharmacy. The website listed the name and address of the dispensing pharmacy, and the name and GPhC registration number of the superintendent. It was not clear from the website which company offered the prescribing service and there were no details of the prescribers or the prescribing service address. People could select one of the prescription only weight loss injections, the quantity and strength and add to their based before they had completed a consultation. The CQC logo was not displayed and there was no reference to CQC registration on the website. The website states that the services were provided in partnership with independent prescribers registered with GMC or GPhC which was not the case. There was a graphic on the website which showed people how many ‘clicks’ of their injection they could administer to give themselves a part dose. This information was outside of the medicines produce licence and could be seen to be encouraging people to administer medication against the prescriber’s instructions.

The premises were smart in appearance and appeared to be well maintained. Any maintenance issues were reported to the superintendent. Two new consultation rooms had been recently installed. One was used as a consultation room and the other was used as an office where weight loss prescriptions were dispensed. The RP said that the room was usually kept locked until the business manager arrived, and he did not know the password to the computer that was in there. There was a large pile of cardboard boxes and black bin bags outside the back door of the pharmacy. These were unsightly and a fire hazard due to their proximity to the main road and a car park. They SI was made aware and agreed to review the process for refuse and recycling collections.

The signage above the pharmacy had recently been changed and the pharmacy had been unofficially renamed. This had led to some confusion with local surgeries, and the SI said that he had received several telephone calls asking whether the pharmacy had been sold.

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

Summary findings

The pharmacy does not always carry out enough checks to make sure that weight loss medicines are safe and appropriate for the people it supplies. Whilst it depends on the online prescribing service to carryout various checks as part of the consultation process, it cannot demonstrate that these are being carried out to make sure the health and wellbeing of people using the service is protected. Weight loss medicines are not always supplied with the appropriate warning and guidance labels attached so people may not have all of the information they need to use and their medicines safely. Fridge temperature records are not maintained so there is a lack of assurance that cold-chain medicines have been stored within the required temperature range. And the pharmacy does not independently verify that the delivery packaging kept medicines at the correct temperature during transit to people.

Inspector's evidence

The RP explained the process that was followed on a day-to-day basis for the weight loss service. He said that a business manager arrived with a laptop at lunchtime and the prescriptions were dispensed using the equipment in the office. The postage label was also printed. The RP then accuracy checked the dispensed prescriptions against the information on the laptop screen. The medicines were then packaged and put into a post bag and taken away by the business manager. The SI added that he had access to the prescribing service's prescription system, and he carried out a check on the person's NHS NCR prior to releasing the prescription for dispensing. The NHS NCR check was done remotely by the SI as he had decided not to burden the RP with the additional workload that it created.

The SI demonstrated what information the pharmacy had access to. He could see the patient's name and address, their BMI, and their electronic prescription. The pharmacy did not have access to the responses to the online questionnaire, any counselling or consultation notes. The pharmacy did not have access to the person's previous ordering history so they could not verify whether people met the BMI related inclusion criteria for ongoing treatment or check whether their dose had been increased through the medication strengths appropriately. The SI checked the NHS NCR for any medical conditions or prescribed medication that he thought contra-indicated the prescribed weight loss medication and may not have been disclosed to the prescriber. This check was recorded on the prescribing service's system by clicking a box, but no specific notes were made. The SLA referred to prescribing guidelines and the prescribing service providing the pharmacy with clear inclusion and exclusion criteria. This information was not available at the pharmacy and was supplied to the inspector after the inspection. Patient's provided consent for the prescribers and pharmacy to access their NHS NCR as part of the prescribing service's terms and conditions and they could not proceed with the consultation if they did not agree.

The dispensing labels were produced manually, rather than being produced by the pharmacy's usual patient medication record system. An example of a dispensing label for a weight loss medicine was seen. It did not contain the cautionary and advisory warning of 'store in a refrigerator, do not freeze'. This could increase the risk of people not storing their medicines properly.

Two large fridges were used to store the stock for the weight loss service. Each fridge was used to store a different brand of the injectable weight loss medicine. Each shelf contained a different strength which helped the business managers to control the stock levels. There was a freezer for storing ice packs used to keep the medication cool during transportation. The pharmacy had not carried out a verification audit to check whether the ice packs and packaging used for deliveries of cold chain medicines kept the medicines within the required temperature range during transit. The in-built fridge thermometers were showing that the current fridge temperatures were outside of the required temperature range of 2°C and 8°Celsius. The pharmacy team members were not confident in demonstrating how they checked the temperature of the fridges used to store weight loss medicines despite them saying they checked the temperatures daily. And the weight loss stock fridge temperatures were not recorded on the log as stated in the SOP, so the pharmacy could not demonstrate that these checks were completed. The normal dispensing fridge was checked daily, within the required range and the temperature recorded.

There was a full box containing weight loss injections on the worktop in the office that had not been put into the fridge on receipt. The individual boxes did not feel cold to the touch and the RP was unsure when they had been delivered to the pharmacy. The business manager said they had arrived earlier that day, however, the box was in the office before he'd arrived at the pharmacy. The SI agreed to investigate when the medicines had been delivered and only use the stock if he was certain that the stock had been stored at the required temperature.

The pharmacy had a delivery driver for local NHS prescription deliveries. Prescriptions for the weight loss service were delivered using Royal Mail. The pharmacy had not incorporated deliveries into the risk assessment, nor had the SOP for deliveries been updated. The postage label contained the prescribing service's address as the return address rather than the pharmacy. The SI was unaware of this, and it was unclear what the prescribing service did with medication that was returned. This was not covered in the SLA.

Principle 5 - Equipment and facilities ✔ Not assessed

Summary findings

Principle 5 was not assessed on this occasion.

Inspector's evidence

Principle 5 was not inspected on this occasion.

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.