General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Treated Pharmacy, Unit 18, Waters Meeting Business Park, Britannia Way, Bolton, Lancashire, BL2 2HH

Pharmacy reference: 9010946

Type of pharmacy: Community

Date of inspection: 15/11/2022

Pharmacy context

This pharmacy provides its services to people through its website (www.uk.treated.com). The website allows people to access the pharmacy's online prescribing service which offers prescription medicines for a wide range of conditions. The prescribing service is regulated and inspected by the Care Quality Commission (CQC). The pharmacy mainly supplies medicines for the treatment of erectile dysfunction, contraception, menopause and weight loss. People do not visit the pharmacy in person. The pharmacy has an NHS contract, and it supplies a small number of NHS prescriptions.

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 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 not all met	4.2	Standard not met	The pharmacy does not seek assurance that the prescribing service verifies the information entered onto the online consultation before supplying medicines for weight loss and other conditions which require ongoing monitoring, such as asthma. Or that the prescribing service informs the patient's regular prescriber or GP of every supply of medicines for conditions which require ongoing monitoring.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy reviews and monitors the quality of its services and it takes some action to improve patient safety. But it could do more to effectively manage the risks associated with some of its prescribing services to make sure people receive the most appropriate treatment. Pharmacy team members work to professional standards, and they are clear about their roles and responsibilities. Team members complete the records that are needed by law and keep people's private information safe.

Inspector's evidence

The pharmacy's main business was the supply of prescription only medicines (POMs) to people living in the UK. These medicines were supplied against private prescriptions issued by two medical prescribers and two pharmacist independent prescribers (PIPs). One of the medical prescribers was the clinical director of the prescribing service. He was registered with the General Medical Council (GMC), and the prescribing service was regulated by the Care Quality Commission (CQC). People accessed the services via the pharmacy's website.

Most people using the website subscribed to receive medicines on a regular basis. People receiving their medicines by subscription were not required to complete an online consultation for every supply but were required to inform the prescriber if there were any changes. They had their treatment reviewed at a time interval specified in the clinical framework for the condition. The reviews took the form of additional consultation questions or a discussion with the prescriber by telephone. People prescribed medicines for weight loss were required to have a review every sixteen weeks. The first review for weight loss checked that the patient had lost 5% of their initial body weight to be able to continue beyond 16 weeks.

There were standard operating procedures (SOPs) for the services provided, with signatures showing that members of the pharmacy team had read and accepted them. The pharmacist superintendent (SI) had recently reviewed the SOPs. Roles and responsibilities were set out in SOPs and the pharmacy team members were performing duties which were in line with their role.

The pharmacy had clinical frameworks which had been developed by the SI, clinical director and a PIP. They referenced UK national guidance such as the National Institute for Health and Care Excellence (NICE) and were reviewed when guidance changed. The frameworks contained clinical information about the condition and details of how and when medicines should be prescribed. The frameworks identified some or the risks associated with the services, but they did not always effectively manage them. For example, the risk of supplying vulnerable people with eating disorders, body dysmorphia and mental health issues had not been sufficiently addressed. The pharmacy promoted on its website and supplied some medicines for conditions which they had not been licensed for, such as Ozempic for weight loss and Cipramil for premature ejaculation. This meant that they were promoted outside of their marketing authorisation. Patients were advised by the prescriber that the use was unlicensed, and they were prescribing the medicine 'off-label'. They were advised to read the patient information leaflet that comes with the medication, and they were sent a link to the pharmacy's off-label prescribing policy on the website. There was a record of the prescriber's justification for their prescribing decisions.

The pharmacy had carried out two recent audits, one on asthma inhalers and one on levothyroxine. The clinical director reviewed prescribing in the team and carried out prescribing audits in addition to the pharmacy's audits. For example, there was an audit of the management of patients with ED for all patients between 20/06/2022 and 19/08/2022. Several of the men, who had started a new subscription, said that they had not discussed ED with their GP. The audit showed that 84% of these men were advised by the prescriber to see their GP. This led to a change to the medical questionnaire to automate the advice given to patients who indicated that they had not discussed ED with their GP. A follow up audit was carried out between 20/08/2022 and 19/10/2022 and this time 100% of men who had not discussed ED with their GP were advised by the prescriber to see their GP. This improved adherence to national guidance. The clinical director discussed details of audits with the prescribers and the SI at clinical meetings. The pharmacy's risk register, regulatory changes, incidents, safeguarding, training, complaints and feedback were also discussed at these meetings. The SI provided copies of minutes from a meeting in August 2022.

People were required to set up an account when they started using the pharmacy's online services. Duplicate patient accounts were flagged by IP addresses, email address, billing address, payment method and shipping address. All patient' identity (ID) checks were carried out using a third-party identity checking service. This checked the patient's ID by address, first name, second name and date of birth. If these failed the pharmacy would ask for further ID proof by means of passport or driving license. If two people ordered from the same address an automated flag would notify customer care and they would need to ensure validity of the two separate customers at the same address. The patient's previous order history was checked by the prescriber, and by the pharmacist during the clinical screening to ensure any inappropriate requests were identified, as the system did not flag repeat or multiple requests automatically. Examples of a pharmacist picking up inappropriate orders were seen on messages between the pharmacist and prescriber. The SI explained that she transferred these messages onto a clinical intervention log periodically.

Dispensing incidents were recorded and discussed with the pharmacy team at monthly team meetings to ensure learning was shared. Near misses were recorded and had been reviewed quarterly, and a copy of the latest review dated May 2022 – August 2022 was provided. The IT system had an additional safety feature which identified if the wrong medicine was selected during the assembly process. Each prescription had a unique barcode that related to the medicines prescribed. Once the medicines had been picked by a dispenser, the barcode on the medicine container was scanned and if there were any discrepancies between the medicine container and the prescription barcode, the IT system flagged this as an incorrect selection. Errors identified by this system were recorded as near misses, to help with learning.

The complaints procedure was explained on the pharmacy's websites with the contact details of the pharmacy's customer care team. The pharmacy used Trust Pilot to monitor customer service, and reviews could be seen on the website. A current certificate of professional indemnity insurance and insurance policies were available in the pharmacy. The SI confirmed that there were separate insurance arrangements for the prescribing service, and the prescribers were named on the policy. The responsible pharmacist (RP) record was appropriately maintained, and the RP notice was conspicuously displayed as per the RP regulations. Private prescriptions were recorded electronically. There was a controlled drug (CD) register. No transactions had been recorded in the last four years as the pharmacy had not supplied any schedule 2 CDs during this time.

All members of the pharmacy team were required to sign a confidentiality clause. They completed training on information governance (IG) and the General Data Protection Regulation (GDPR) which was refreshed annually. Confidential waste was collected in a designated place and shredded. A member of

the team correctly described the difference between confidential and general waste. The pharmacy's privacy policy was available on the website and included a data handling and cookie policy.

Pharmacy team members completed training on safeguarding children and vulnerable adults at a level relevant to their role in the pharmacy. There was a safeguarding policy and the contact numbers of who to report concerns to in the local area were available. The SI said she would look up the details if a safeguarding concern related to a person living in a different part of the country.

Principle 2 - Staffing ✔ Standards met

Summary findings

Team members are well trained, and the pharmacy provides the team with opportunities to share ideas and learning. The pharmacy encourages its team members to keep their skills up to date and supports their development. Team members are comfortable providing feedback to their managers and they receive feedback about their own performance.

Inspector's evidence

The SI was working as the RP. There were also two dispensers (NVQ2 or equivalent), one customer service representative, the operations director, and the operations manager on duty. The staffing level was adequate for the volume of work during the inspection. Planned absences were organised to ensure staffing levels were appropriate and details were recorded on team rotas. The SI worked three days a week and was contactable by telephone on her days off. Regular locum pharmacists provided cover on the other two days. The pharmacy team members were allocated specific tasks on a daily, weekly and monthly basis.

The clinical director led the prescribing team and monitored the team's prescribing. He and the other medical prescriber had experience as GPs and had prescribed for the pharmacy for several years. One of the PIPs had worked for the pharmacy for a couple of years and he had experience of working in a GP practice. A new PIP had recently been recruited and he was currently shadowing the other prescribers. He was reviewing consultations, but he hadn't carried out much prescribing yet. There was an e-Learning platform for the prescribers' training which included safeguarding, note keeping, confidentiality, privacy and work environment. Training modules were completed for each drug and condition before the prescribers were allowed to prescribe in a specific area. Updates to national guidance such as NICE guidance and significant events were discussed at clinical meetings. The company had been part of a CQC digital health providers forum over the last few years. They shared any internal significant events at this forum.

The pharmacy had a communications board which displayed team members' tasks and competencies, pharmacy team rota's, minutes of team meetings and useful information such as whistleblowing and safeguarding policies. Notices showing GPhC standards were on display. There were detailed training records for all team members and a training matrix was displayed on the communications board. Certificates showing completed training were on display. Pharmacy team members were expected to complete a different e-Learning module each month. A pharmacy team member logged into the e-Learning platform and demonstrated that she had completed training modules on a regular basis over the last 12 months. The pharmacy allocated specific time for the team members to complete training.

The pharmacy team members were given feedback informally from the pharmacists on an ongoing basis. For example, when a near miss or dispensing error had occurred. Team members were encouraged to give suggestions. A dispenser said that the SI was very supportive and approachable, and she would be comfortable discussing issues and concerns with her. Team members received a probationary review after three months in their role and a formal appraisal on an annual basis, where performance and development were discussed. A dispenser provided a copy of her last appraisal carried out in March 2022. The RP explained that there were no formal targets or incentives for any

aspects of the pharmacy's services, so she did not feel under pressure.

Principle 3 - Premises ✔ Standards met

Summary findings

The physical premises are clean, hygienic, properly maintained and fitted to a high standard. They provide a professional environment for the services carried out. The pharmacy's website has useful information about the pharmacy and the prescribing service which enables people using the service to make an informed decision about their care.

Inspector's evidence

The pharmacy was situated in a large unit in a business park. It was closed to the public and there was no external signage highlighting the fact that it was a pharmacy. Working areas were clean, spacious, free from obstructions and professional in appearance. The pharmacy had been fitted out to a very high standard, with a bespoke design, and the fixtures and fittings were good. The pharmacy team were responsible for keeping the pharmacy clean and a cleaner was employed on a part-time basis. All areas of the premises were cleaned regularly. The temperature in the pharmacy was controlled by air conditioning units. Lighting was adequate. The pharmacy premises were well maintained and in a good state of repair. Maintenance problems were reported to the operations manager and dealt with accordingly.

The premises were extensive and covered two floors of the building. Staff facilities included offices, a board room, a prayer room, break rooms and games areas. There was a canteen with a kitchen area containing a kettle, fridge and sink. Staff toilets with wash hand basins and antibacterial hand wash were available. There was a separate dispensary sink for medicines preparation with hot and cold running water.

The pharmacy's website was rebranded in August 2022 and was in line with GPhC guidance. The pharmacy's name, address, GPhC registration number, e-mail address and phone number were displayed on the websites. There were links to the GPhC register showing the registration details of the pharmacy via the voluntary GPhC logo. The name and details of the SI, clinical director and prescribers were available on the websites and there was a link to check registration details of the prescribers.

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

Summary findings

The pharmacy doesn't always seek assurance that the prescribing service confirms a diagnosis, verifies the information provided, or informs the patient's usual doctor after every supply when prescribing medicines which require ongoing monitoring. Overall, the pharmacy dispensing operation is well managed and its services are easy for people to access. It gets its medicines from licensed suppliers and the team carries out checks to ensure medicines are in suitable condition to supply.

Inspector's evidence

People accessed the pharmacy's services via the website and could communicate with the pharmacist and team members via telephone or email. A messaging system was used to communicate messages between the pharmacy's prescribers and the person requesting the medicine, and this supported a chat facility for two-way communication. Prescriptions were generated once the consultation was approved and sent electronically to the pharmacy. The prescription also linked to the messaging system so communications with the person were visible to the pharmacy team members, and they were also able to see the consultation questionnaire.

The services were advertised on the pharmacy's website and the pharmacy team were clear about what services were provided and when to refer people elsewhere. The pharmacy took part in healthy living campaigns. For example, people requesting a smoking cessation medicine were sent leaflets to help support them.

The pharmacy had an NHS contract and had dispensed a small number of NHS prescriptions. Once registered and nominated for the electronic prescription service (EPS), people could request repeat NHS prescriptions via the customer care team at the pharmacy. The SI explained that NHS prescriptions were usually received for medicines which were in short supply at high street pharmacies, such as HRT.

The prescribers produced prescriptions based on the information people provided when completing the online consultation questionnaires. Consent to inform the patient's GP was requested in all consultations, but most people did not provide consent, so the prescriber did not notify the patient's GP. It was mandatory, however, for supplies of levothyroxine and salbutamol. The SI explained that when consent was provided the prescribers informed people's GP by post or email. Copies of the notifications could be seen on the person's records. GPs were informed in retrospect of the supply of a medicine, so this meant that a supply could be made which the patient's own GP did not agree to. The SI said that following notification, if a GP indicated that the patient was unknown to them, or believed the supply was not clinically appropriate, then a note would be added to the patient's profile, so no more prescriptions would be supplied to them.

The pharmacy could access people's Summary Care Records (SCR) and consent was requested during the asthma questionnaire, but this was not mandatory. There were questions aimed to help identify poorly controlled asthma on the consultation. But there was no system in place to verify a diagnosis of asthma or the date of the last asthma review, before supplying inhalers, if people had not consented to allow access to their SCRs. Some people had subscription plans which allowed them to request up to 12 salbutamol inhalers in a twelve-month period. This could be considered excessive and indicate their asthma was not well controlled. The GP was only informed of the first supply in the subscription period, so they would be unaware of further supplies during that period. This was not appropriate for

conditions requiring monitoring, such as asthma, when the number of inhalers being used was an important indicator of how well their asthma was controlled. A sample of PMRs for people receiving salbutamol inhalers was checked. One patient had received four inhalers within two months and another patient had received six inhalers within three months. The second patient claimed to have lost some of their inhalers when travelling. The prescriber had a telephone call with the patient and obtained verbal consent to access their SCRs before prescribing the second supply. However, the SI explained that she had not been able to check this person's SCRs, as she could not find them, yet the supply went ahead. The pharmacy had carried out an audit on the number of salbutamol inhalers each patient ordered over a 12-month period between 15 August 2021 and 15 August 2022. One patient had ordered ten inhalers and another patient seven inhalers in the 12-month period. The SI explained she had not reviewed the audit or discussed it with the prescribers yet, but the pharmacist carrying out the audit had suggested excessive ordering of asthma inhalers should be flagged up to the prescriber and a note should be added to highlight the number of inhalers the patient had ordered previously, to help inform the prescriber's decision.

People requesting levothyroxine were required to prove that they had a thyroid disorder by selecting one of three options: (a) uploading a thyroid function test result showing their name and the date of the test (b) uploading a prescription counterfoil showing their name, the date of the prescription issue and the relevant medication or (c) give consent to share information from their SCR. Medication was only provided if the uploaded evidence or SCR information indicated that supplying this medication was appropriate. The pharmacy had accessed SCR on the samples checked. The date the SCR was accessed, and the dosage of the previously prescribed levothyroxine was recorded on the patient's record. The consultation requested that an electrocardiogram (ECG) was conducted prior to starting levothyroxine, but it wasn't necessary to provide evidence of this. The pharmacy had carried out an audit of levothyroxine prescribing in the last year, and this showed which options patients had chosen to provide evidence. The audit highlighted that access to SCRs was not always recorded by the pharmacist. So, all pharmacists were reminded to report their findings from SCRs in the patients notes and add the time the SCR was accessed and their name.

Physical examination, face-to-face consultation or sharing information with the patient's usual GP was not part of the process when prescribing weight loss products. People were required to enter their weight and height as part of the weight loss consultation, but there was no verification that the information entered by the person requesting the medicine was correct, and there was a possibility people might try circumvent the system in order to obtain a supply which may not be clinically appropriate. This could mean vulnerable people may be able to obtain medicines which might not be suitable. The only safeguard in place was to ask questions around mental health in relation to weight in the online consultation. But this assumed people had understood the questions and answered them accurately. More robust controls such as a video call had been considered but not introduced. A review was required at the 16-week stage for people prescribed weight loss medication, and the patient's weight was requested as part of this, so medication such as Saxenda could be stopped if not proving effective. But this review also relied on the person receiving treatment providing accurate information as no physical examination was carried out. One of the prescribers had recently prescribed Saxenda for a patient with a body mass index (BMI) less than 30 without weight related co-morbidities, which is 'off-label'. When this was challenged by the pharmacist, the prescriber justified their decision in a message on the patient's record. The prescriber had also been prescribing Ozempic for weight loss, for around two weeks. This was not a licensed indication and the prescriber had sent communications to patients advising them that the use was not licensed.

The pharmacy supplied PrEP. Patients were asked questions about kidney function, but tests result were not required to be uploaded during the consultation. A small number of antibiotics were

prescribed for urinary tract infection (UTI); trimethoprim and Macrobid MR. There was no requirement to provide evidence of a UTI before a supply was made.

Pharmacists and prescribers communicated by telephone, messaging system and email, and the SI said the clinical director and prescribers were very accessible. The prescribers had access to a British National Formulary (BNF), and there were in-built functions in the system that prevented certain prescribing activities. For example, the prescribing of two drugs of the same class. The pharmacy kept a clinical interventions log of queries with prescribers, and any actions taken as a result. Prescribers requested the pharmacist to access SCRs when necessary and asked general questions about stock issues and medicine storage. The pharmacists queried things such as a discrepancy between the patient's address on SCR and the one on their PMR, which had to be verified, before a supply could be made. Another query a pharmacist made was when a patient was prescribed terbinafine, who hadn't provided a declaration about their liver function test (LFT). In this case the prescriber went ahead with the prescription and their justification was available in a message on the patient's records.

Both NHS and private prescriptions were mainly supplied by courier. Royal Mail was used for some areas of the UK. All deliveries could be tracked. Medicines returned by the courier due to failed delivery were not re-used. Medicines requiring refrigeration, such as Saxenda, were sent by a next day service in a special container with ice packs, to ensure they were maintained at the correct temperature during delivery.

The dispensary was spacious, and the workflow was organised into separate areas with designated areas for clinical screening, assembly, checking, packing and shipping. The dispensary shelves were well organised, neat and tidy. Medicines were stored in their original containers at an appropriate temperature. Date checking was carried out and documented. Dispensed by and checked by boxes were completed on the medication labels to provide a dispensing audit trail. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. There was a CD cabinet which was securely fixed to the wall, but the pharmacy did not currently stock any CDs requiring safe storage and it was empty. Recognised licensed wholesalers were used for the supply of medicines. No extemporaneous dispensing was carried out and no medicines were obtained from 'Specials'.

Alerts and recalls were received via email from the NHS and MHRA. The most recent one was received on 11 November 2022. These were read, acted on by a member of the pharmacy team and a detailed record was kept. This ensured that the team could easily respond to queries and provided assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have access to the equipment and facilities they need for the services they provide. They maintain the equipment so that it is safe to use.

Inspector's evidence

The pharmacy team had access to the BNF and were able to use the internet to access websites for up-to-date information. For example, Medicines Complete. Any problems with equipment were reported to the operations manager. There were two medical fridges, one for stock and the other for assembled prescriptions awaiting distribution. Both fridges were fitted with internal thermometers and the minimum and maximum temperatures were being recorded daily. All electrical equipment appeared to be in working order and had been PAT tested for safety. There was a selection of liquid measures with British Standard and crown marks. The pharmacy had equipment for counting loose tablets and capsules, including tablet triangles.

An in-house IT system was used, and IT support was available on site. Confirmation was given that IT met the latest security specification. Computers and the patient medication records (PMR) were password protected and passwords were changed frequently. Microsoft Azure was used, and the website was https secured. Cordless telephones were available in the pharmacy which were used to hold private conversations with people when needed.

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.