

Registered pharmacy inspection report

Pharmacy Name: Halliwell Midnight Pharmacy, 34 Halliwell Road,
BOLTON, Lancashire, BL1 3QS

Pharmacy reference: 1099351

Type of pharmacy: Community

Date of inspection: 20/02/2023

Pharmacy context

This is a busy pharmacy located on a main road close to the centre of town. It trades extended hours, opening early in the morning and closing late in the evening. The pharmacy dispenses NHS prescriptions, and it sells a range of over-the-counter medicines. It supplies a large number of prescription medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. The pharmacy also has a private prescribing service which people can access from its website www.prescriptiondoctor.com. It is a pharmacist led prescribing service, so it is not regulated by the Care Quality Commission (CQC).

Overall inspection outcome

✓ **Standards met**

Required Action: None

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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

Overall, the pharmacy's working practices are suitably effective. The pharmacy manages its NHS services reasonably safely and it keeps the records required by law. The pharmacy team members discuss any errors, but they do not always record or review them, so they could miss additional learning opportunities. The pharmacy has risk assessments and policies for its online prescribing services, but these sometimes lack clarity, which means team members might not always work effectively. And the pharmacy could improve the quality of its audits, so it can demonstrate and make sure its online prescribing services are safe.

Inspector's evidence

There were standard operating procedures (SOPs) for the pharmacy's services which had been updated in August 2021. Roles and responsibilities of the pharmacy team were described in individual SOPs. A number of the SOPs had not been signed by the current team members. This included the SOP relating to working in the absence of a responsible pharmacist (RP). A dispenser who had not signed the SOPs confirmed she had read them, so the training records did not accurately reflect which team members had read the SOPs. A medicine counter assistant (MCA) was able to describe her responsibilities and provided some examples of what could and could not be carried out during the absence of a pharmacist. But the lack of formal training on SOPs could mean that some members of the team may not always fully understand their roles and responsibilities. Team members did not usually wear uniforms or anything to indicate their roles, so this might not be clear to members of the public.

The pharmacist said that if he identified an error during the final accuracy check, he would ask the team member to rectify the mistake and discuss what may have caused it. The team made changes to prevent similar errors occurring. For example, omeprazole capsules and omeprazole tablets had been separated from one another on the shelves to help prevent picking errors. Near miss errors were not generally recorded. So, the pharmacy could not review these mistakes to check for trends or any underlying causes. If a dispensing error occurred, the pharmacist said he would report it to the superintendent pharmacist (SI). But he was not sure what records were made following a dispensing error.

The pharmacy supplied a large number of prescription only medicines (POMs) to people living in the UK through its website. Medicines were supplied against private prescriptions issued by a pharmacist independent prescriber (PIP) following the completion of an online questionnaire. The pharmacy separated the functions of the prescriber pharmacist from the functions of the RP. The PIP was based remotely. This ensured that the prescriber pharmacist was not the pharmacist undertaking the final clinical and accuracy checks. Prescriptions were received electronically through a specialised computer system. The prescriber had his own access to the computer system and his IP address was shown on the prescription which the team members could check to ensure the prescription was authentic. Prescriptions issued covered a wide range of medicines including antibiotics for sexually transmitted diseases (STDs), urinary tract infections (UTIs) and skin conditions, Saxenda injections for weight loss, aciclovir for herpes, hormone replacement therapy (HRT), contraceptives, treatments for erectile dysfunction (ED), pre-exposure prophylaxis for HIV (PrEP) and asthma inhalers.

The pharmacy's prescribing service currently used the same PIP to generate all of the prescriptions and the prescribing service could only be accessed via its website. All prescriptions generated by the

website were dispensed exclusively by the pharmacy. The pharmacy did not routinely supply prescriptions issued by other online prescribing services. There were separate folders of policies and SOPs for the prescribing service. The pharmacy had an identity (ID) checking policy and all people using the prescribing service had their ID checked by a third-party provider. This checked the person's ID by name, address, and date of birth. If the person failed the third-party ID check, then the pharmacy asked for further proof of ID such as a passport or driving licence. There was an order processing guide which outlined how the team processed the requests for medicines. Duplicate accounts were identified by the customer service team checking IP addresses, email address, billing address, payment method and shipping address against their registered address.

The pharmacy had risk assessments for the clinical conditions it provided prescribing services for. The prescribing policies were underpinned by National Institute for Health and Care Excellence (NICE) and or other evidence based clinical guidelines. The risk assessments combined with the pharmacy's prescribing policies reflected clinical risks for each condition. There were clinical justifications for the request of medicines for the conditions based on the history of the presentation and relevant exclusion criteria based on precaution or red flag symptoms. However, risk assessments and prescribing policies were not always clear on how the prescriber should verify important aspects of the person's medical history. For example, if accessing Summary Care Records (SCRs) and notifying a person's GP was mandatory.

The prescribing policy for asthma allowed for the issue of one inhaler every 28 days or two inhalers every 56 days. If this was followed through it could mean somebody might receive 12 inhalers in one year, which would indicate that their asthma was not well controlled. Salbutamol requests for asthma could not be processed unless a person had documentation on their SCR which demonstrated an asthma diagnosis. But it wasn't clear if the prescriber was also checking SCR to confirm the person was using a regular preventer inhaler or had a recent asthma review as would be expected for someone with asthma.

The pharmacy supplied PrEP which should not be prescribed for people with renal impairment and ongoing renal monitoring is required for anyone taking this medication. The prescribing policy did not reflect how this information was collected and verified. People requesting PrEP were required to provide evidence of a negative HIV test. This requirement was included in the risk assessment and prescribing policy for PrEP. And appropriate test kits could be obtained via the website. Examples were seen when requests were declined because there was no response to the request by the prescriber for confirmation of a HIV negative test. Prescribing policies for conditions where antimicrobials could be supplied did not document whether accessing SCR was mandatory. There was evidence that the prescriber actively requested access to SCRs where he felt it was necessary to do so. The prescriber tagged orders that required access to SCR, and the pharmacist uploaded this information to the person's account for the prescriber to view. Where people had not given consent to access their SCR, the prescriber or one of the team members would contact the person asking for consent.

Prescribing audits were carried out but the samples sizes were insufficient for the level of prescribing that the pharmacy was providing and the audits did not always provide sufficient insight. An asthma audit had been completed for one week in July 2021. It had a small sample size and only checked if the patients were ordering too early. An audit for weight loss medication was carried out in October 2022 but only used a sample of ten Saxenda, ten Mysimba and ten orlistat prescriptions which was less than one week's supplies. A UTI audit conducted in October 2022 covered the full month and was of better quality. The audit checked cross referenced prescriptions with NICE and local guidelines, checked how any red flag symptoms had been addressed and how counselling points and safety netting had been considered. An example was seen when the PIP had not followed the pharmacy's prescribing policy for HRT. A person had been prescribed oestrogen gel alone without progesterone, and they had not had a

hysterectomy. This was against the pharmacy's prescribing policy which stated that 'For patients who have not had a hysterectomy, a combination with a progesterone is given due to risk of endometrial cancer.' Evidence was seen of email communications between the PIP and other people advising them of the need to take progesterone alongside oestrogen gel, asking what progesterone they were taking and advising them to contact their GP, if they were not getting it through the online prescribing service. But this was not consistent and suggested that non-compliance with prescribing policies was not effectively audited.

The pharmacy had a complaints procedure which included recording the issue and referring it to the SI to be followed up. However, there were no details about the procedure on display in the pharmacy, so people visiting the pharmacy might not know how to raise a concern or give feedback. The Prescription doctor website gave the contact details of customer service and there was a form to report complaints on. The pharmacy used a recognised online review platform to monitor customer service. The pharmacy's certificate of professional indemnity insurance displayed in the dispensary had expired but the pharmacist printed off a current certificate during the inspection. He confirmed that this covered the pharmacy's internet business. Following the inspection, the pharmacy provided a current insurance certificate for the PIP, which covered his activity as an independent prescriber.

The RP record was available, and it was generally in order although a couple of entries were missing. Records for controlled drugs (CDs) were maintained electronically and running balances were recorded. A sample of random balances were checked and found to be correct. Records for unlicensed specials appeared to be in order. Private prescriptions were recorded electronically. The incorrect prescriber had been recorded on at least forty prescriptions from the prescribing service in the last three months. Names of previous prescribers who had stopped prescribing for the pharmacy had been entered in error, and when checked the prescriptions had been signed by the current PIP. This created an inaccurate audit trail and could lead to confusion in the event of a problem or query. The pharmacy kept a record of all patient consultations and interventions on its own internal systems. They recorded if SCRs had been accessed. It kept records for the refusal of medication requests and communication with a person's GP. The pharmacy also kept a record of all the private prescriptions they supplied. Digital copies of private prescriptions could be easily retrieved.

There was a risk assessment which included website and data security. There was an IT security policy with a statement that the user agreed to comply fully with the Company's Data Protection Policy and the General Data Protection Regulation. (GDPR). A dispenser said she had not been asked to read any information about confidentiality when she started working at the pharmacy. And policies specifically relating to confidentiality and data protection in the pharmacy were not available. But the dispenser understood the basic principle and she was able to explain how to keep people's information safe. And she correctly described what confidential information was and explained how it was segregated and removed by a waste carrier. Open waste bags of confidential waste were stored in the consultation room, which risks inadvertent data breaches. The RP explained that they had been put in the consultation room ready for collection, and the bags would normally have been sealed. He pointed this out to a member of the pharmacy team who sealed the bags ready for collection. Information about the pharmacy's privacy policy, and how people's information was handled and stored was available on the Prescription doctor website, but there was no information displayed in the pharmacy to inform people about this.

Safeguarding procedures could not be found. And some team members did not remember reading procedures about safeguarding or completing safeguarding related training. So, there may be a risk that signs of concern might go unnoticed. A dispenser said she would report any safeguarding concerns to the pharmacist on duty. And team members knew where to find the local council's safeguarding number in case of a concern. The pharmacist confirmed he had completed level two safeguarding

training. The PIP has completed level two and three training on safeguarding. The questionnaire format of the online consultation could make it more difficult to assess the mental capacity of a person using the prescribing service and to determine whether a remote consultation was appropriate for them. And there was a risk that a vulnerable person could obtain medicines using another person's ID, which was a safeguarding concern.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy team members have the appropriate qualifications for the jobs they do. They can provide feedback to their manager about the pharmacy and its services, and they feel reasonably well supported. But team members do not get regular ongoing training, so there may be gaps in their knowledge and skills. And the pharmacist prescriber has a very high workload which could compromise his ability to make appropriate prescribing decisions.

Inspector's evidence

The RP was a regular locum pharmacist. There were two trainee pharmacists, one dispenser, three trainee dispensers, two MCAs and two delivery drivers on the pharmacy team. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other. Some members of the team were part-time staff who worked flexible hours. And there was a staggered holiday system in place. This helped ensure adequate staffing levels. There was a customer service assistant working in a separate room above the pharmacy where the prescribing service operated from. The pharmacy's IT manager was present for part of the inspection.

Members of the pharmacy team carrying out the services had completed appropriate qualifications or had been enrolled onto recognised courses. On-going training and protected training time was not routinely provided. Members of the team said they had not completed any additional training during the previous year. And there was no formal appraisal programme. So, learning and development opportunities might be missed. Team member said they felt a good level of support from the pharmacists and other members of the team. And if a member of the team had a concern, they felt comfortable talking to the SI. Other issues were discussed informally within the team.

The PIP was a newly qualified prescriber pharmacist. He had undertaken extra courses for specialist weight loss training which covered injectable medication and an online course on HRT. The PIP prescribed high volumes of prescriptions for the pharmacy's prescribing service, mainly in the evenings. The IT manager acknowledged his workload was very high and explained that the pharmacy was trying to recruit additional prescribers to support him.

The pharmacists were empowered to exercise their professional judgement and could comply with their own professional and legal obligations. For example, refusing requests for medication via the online prescribing service, where the patient's request was not appropriate. The pharmacy had records of a large number of refusals for people who had ordered medicines via the website too many times, or had ordered medication too early, or had expressed symptoms that would exclude them from treatment or had a medical condition on their SCR that would contraindicate them from treatment. The PIP could change the treatment and or quantities prescribed where required. Treatment was jointly considered with the patient, but the final decision was always with the prescriber.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy generally provides a suitable environment for people to receive healthcare services. It has a private consultation room that enables it to provide members of the public with the opportunity to have confidential conversations. The pharmacy's website has useful information about its services, but it does not provide clear information about the prescriber's qualifications to enable people using the service to make an informed decision about their care.

Inspector's evidence

The pharmacy premises including the shop front and fascia were in an adequate state of repair. The retail area was free from obstructions, professional in appearance and had a waiting area with three chairs. The temperature and lighting were adequately controlled. Maintenance problems were reported to the SI who organised the required work, and the response time was appropriate to the nature of the issue. New flooring had been recently installed.

There was a separate room on the first floor where excess stock was stored, and the multi-compartment compliance packs for patients in care homes were assembled and stored. Staff facilities included a small kitchen and a WC with a wash hand basin and hand wash. There was a separate dispensary sink for medicines preparation with hot and cold running water. The consultation room was spacious, and it was seen to be used to provide some services.

The pharmacy website's layout was compliant with GPhC regulation. People were required to complete a consultation before a medication could be selected. And the consultation questionnaire did not indicate if an input would prevent a medication being issued. The name and physical address of the pharmacy was displayed on the website and the registration number of the pharmacy and SI. The website displayed the name and registration number of the PIP, but it did not make it clear that he was a non-medical independent prescriber.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy offers a wide range of healthcare services, which are generally well managed and easy for people to access. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply. The pharmacy's online prescribing service often supplies people with prescription medicines for weight loss without informing their usual doctor. This means their doctor may not have relevant and up-to-date information about the person to support ongoing safe and effective care.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. Some services were advertised in the window such as travel vaccinations, but other services were not promoted, so people might not know they were offered. And the incorrect opening times were displayed due to recent changes. There was a small range of healthcare leaflets and some information on healthy living was on display. Useful information on medical conditions and the medicines offered by the prescribing service was available on the website.

People requesting prescription medicines from the prescribing service were asked a series of questions and their responses were sent to the prescriber for approval before a supply was made. The online consultation questionnaires contained two parts. The first part was standardised for all conditions and the second part of the questionnaire was specific for individual medicines. The consultation questionnaire responses could be viewed by both the pharmacy and the prescriber and key questions were highlighted in red. Patient consent to access to SCRs was requested in most of the questionnaires, and providing consent was mandatory for asthma and weight loss. Several examples were seen when the pharmacist or prescriber had viewed a patient's SCR before prescribing or supplying a medicine and pdf copy of their SCR was available on the pharmacy's computer. Consent to share information with their GP was requested in most of the questionnaires and it was mandatory for asthma. People could enter their GP practice details using the website's database. If an email address wasn't available on the database, a letter would be printed off and posted to the GP practice to ensure the information was shared. Evidence was seen of both emails and letters to people's GPs. People using the prescribing service communicated with the prescriber, pharmacy, or customer service team via a chat messaging system and all the messages could be viewed by the prescriber, customer service team and pharmacist. 'Tags' were applied to the patient's records building up a profile of the person. Tags included:- 'ID verified', 'await results,' 'evidence uploaded' and 'review symptoms/therapy before next order.'

There were medication ordering limits for certain medicines built into the prescribing portal which were programmed to alert when orders were placed too soon. This was intended to prevent people from ordering too many medicines. Reorder time limits were set for asthma inhalers with a maximum number of two inhalers on each prescription and no more than one inhaler per month. An example was seen when a new patient requested an asthma inhaler but when their SCR was checked there was no record of an asthma diagnosis, so this was declined. Another request was declined because the SCR showed that they had not had an asthma review within the last 12 months. One example was seen when a supply was made after the SCR was checked as this indicated an asthma plan had been put in place in November 2022.

People completing the consultation questionnaire for weight loss were required to enter their height and weight, and the pharmacy took steps to verify that this information was correct. This could be done by uploading a letter from a health specialist confirming the person's weight, a video/image of the person showing their body profile or evidence from their SCRs. People were also allowed to upload a photograph showing the scales alongside their photographic ID. However, there was nothing to indicate that this photo was a recent photograph as it did not contain the date, and there was nothing so show that the person on the scales was the person requesting the medication, as only their feet could be seen. The IT manager reported that these were temporary measures until a video consultation facility could be added to the website. He confirmed that work had started on this. Examples were seen where SCRs had been used to verify people's weight as it had been recently recorded on their SCR. One example was seen when it had been noted on a person's SCR that they were morbidly obese. Two examples were seen when vulnerable people with eating disorders had been refused their request for weight loss medication and they were signposted to their GP. One person was refused the weight loss medication Mysimba because a check of the SCR indicated that they had already been prescribed a similar treatment by their GP. People's GPs were not routinely informed when weight loss medicines were supplied. This posed a risk as it may mean that GPs do not have full and accurate information about their patient's treatment. Treatment with Saxenda should be discontinued after 12 weeks if patients have not lost at least 5% of their initial body weight, as per the licensing requirement. The IT manager demonstrated a 12-week assessment tool which was being used to help monitor weight loss treatments. The person was asked to enter their waist and hip size as part of the online consultation and the waist to hip ratio was used by the prescriber as an additional assessment. The IT manager explained that technology had been introduced so that this ratio was calculated automatically and provided an additional safeguard and monitoring tool. People were sent a Saxenda booklet with their order and an email with advice and information about diet, exercise, hydration, storage and disposal. Advice was also provided on how to administer the injection with a link where they could obtain further information.

A follow up email was sent to all people receiving medicine 28 days after their supply asking if they were having any problems or side effects and to confirm the medicine was working. The option of contacting the prescriber directly was available by replying to the email. However, the word 'doctor' was used on the email, and as the current prescriber was a pharmacist, this was misleading.

The pharmacy team used printed copies of the private prescriptions when assembling medicines. This activity was carried out during the afternoon. When they had been checked by the pharmacist, they were packed up in cardboard boxes to protect the medicines. A 'signed for' Royal Mail service was used to deliver the medicines to people, and this could be tracked by the customer service team in the pharmacy. Medicines requiring cold storage, such as Saxenda, were placed in special packs with ice block to ensure their integrity during transit. Medicines returned to the pharmacy because they could not be delivered by Royal Mail were not re-used and were destroyed if the person didn't want them to be resent. There was a delivery service for NHS prescriptions. A delivery record was kept of successful deliveries. If a person was not home to accept the delivery, the medicine would be brought back to the pharmacy with a delivery note posted through the letterbox.

Space was adequate in the dispensary. Dispensed by and checked by boxes were initialled on some medication labels to provide an audit trail. Stickers were put on assembled prescription bags in the pharmacy to indicate when a fridge line or CD was prescribed. The pharmacy had a process to ensure prescriptions containing schedule 3 or 4 CDs had not expired. But the pharmacy did not have a process to highlight high-risk medicines (such as warfarin, methotrexate, and valproate) in order to remind members of the team to provide counselling. The team were aware about the risks associated with the use of valproate during pregnancy. Educational material was available to hand out when the medicines were supplied. The pharmacist said he had spoken to patients who were at risk, but there were

currently no regular patients who met the risk criteria. The MCA described how she would sell a medicine over the counter. She was clear about when to refer to the pharmacist.

A large number of multi-compartment compliance aid packs were assembled in the pharmacy. These included care homes patients as well as community patients. The pharmacist said he would speak to patients to check if the use of a compliance aid pack would be appropriate for their needs. But details about this was not recorded, so would not be available in case of a query. Records were used to ensure all of the prescriptions requested had been received by the pharmacy. Patient information leaflets (PILs) were not routinely provided. So, people may not always have all the necessary information to take their medicines safely.

There were two medical fridges. Both fridges had a built-in thermometer which was within 2-8-degrees Celsius range during the inspection. Records indicated the minimum and maximum temperatures were being monitored regularly for both fridges. Licensed wholesalers were used for the supply of medicines and appropriate records were usually maintained for medicines ordered from 'Specials.' No extemporaneous dispensing was carried out. A trainee pharmacist confirmed she had recently completed date checking within the dispensary. A record of medicines due to expire had been recorded to be removed at the start of the month of expiry. But records were not kept showing when date checking had been completed. So, some areas of the dispensary might be overlooked. Liquid medicines did not always have the date of opening written on them, including a bottle of gabapentin oral solution which expired 30 days after opening. So, team members would not be able to check whether it was fit for purpose when dispensing.

Drug recalls were received electronically. But there were no records made of the action taken, so the pharmacy may not be able to provide 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 could access the internet for the most up-to-date information. For example, the electronic British National Formulary (BNF) and medicines compendium (eMC) websites. Electrical equipment appeared to be in good working order. There was a selection of clean glass liquid measures with British standard and crown marks. Separate measures were used for methadone solution. The pharmacy had a small range of clean equipment for counting loose tablets. There was a separate marked tablet triangle for cytotoxic drugs to reduce the risk of contamination. Medicine containers were appropriately capped to prevent contamination. Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.