General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Hythe Pharmacy, 1-2 Hythe Quay, Colchester, Essex, CO2 8JB

Pharmacy reference: 9012036

Type of pharmacy: Community

Date of inspection: 20/11/2023

Pharmacy context

This community pharmacy is located in Hythe, near Colchester. It provides a variety of services including dispensing of NHS prescriptions, the New Medicine Service (NMS) and it provides medicines in multi-compartment compliance packs for people who have difficulty remembering to take their medicines. The pharmacy has a clinic next door where in recent months it has started to provide other services including travel vaccinations and prescribing services carried out by nurse and pharmacist independent prescribers. Most of the services in the clinic are carried out under patient group directions (PGDs).

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 have prescribing policies or documented risk assessments for all aspects of its prescribing service in place. And it cannot show that it routinely shares appropriate information about the medicines it supplies with other healthcare providers involved in the care of the person.
		1.2	Standard not met	The pharmacy does not undertake audits to monitor the quality of its prescribing service.
		1.6	Standard not met	The pharmacy cannot show that it keeps adequate records about all consultations with people who use the prescribing service.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	3.1	Good practice	The pharmacy premises are clean, safe and very well maintained.
		3.5	Good practice	The pharmacy provides its services in an environment that is modern, professional and safe.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot demonstrate that its prescribing service is always provided safely. It does not keep adequate records about consultations with people or the medicines it has supplied, including medicines for weight loss. And it cannot show that it always shares information with other healthcare providers where this is appropriate.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not manage all the risks associated with its services. It has not carried out formal risk assessments of all aspects of its prescribing service. The pharmacy cannot show that it routinely keeps records of all consultations its prescribers have with people. And it does not regularly monitor the quality or safety its prescribing service. However, its team members record and regularly review any dispensing mistakes to learn from these events. And the pharmacy generally keeps the records its needs to by law. People can provide feedback about its services. And its team knows how to protect vulnerable people.

Inspector's evidence

The correct responsible pharmacist (RP) notice was displayed in the pharmacy. The RP was also a pharmacist independent prescriber (PIP) and the owner.

The pharmacy provided a wide range of private services. These services were provided face-to-face at the private clinic next to the pharmacy. These were registered as one premises. Some private services were provided via patient group directions (PGDs) including weight loss, travel vaccinations and salbutamol for asthma. And there was a framework in place which included all the relevant questions to ask the person when undertaking a consultation.
The pharmacy also offered a private prescribing service where people were issued prescriptions following a consultation with either a pharmacist independent prescriber or a nurse prescriber. No formal documented risk assessments had been undertaken for the prescribing service for any condition. And the pharmacy had not completed any clinical or prescribing audits. However, the RP was able to demonstrate verbally what he would clinically assess when undertaking a consultation.

For weight loss, which was provided under a PGD there was a set of screening questions before the pharmacist would undertake a full weight check to work out the BMI. People would need to have to have a BMI of above 30 to qualify for the various weight loss treatments. The pharmacy offered the option for people to consent to share information about the medicines they had been supplied with their regular GP. And the RP explained this information would then be sent by the admin team. Evidence was provided after the inspection to show that this was routinely occurring for medicines supplied via a PGD such as travel vaccinations, however, there was no evidence of information being provided when medicines were being prescribed.

The majority of necessary records were kept for private consultations and in most records checked, a treatment plan was documented. However, for weight loss consultations provided by the nurse, no consultation notes or records of the supply of weight loss medicines could be found by the pharmacy when provided by the nurse. The lack of ready access to records could make it harder to establish what weight loss treatments people have had.

In relation to pharmacy activities other than the prescribing service, team members knew their roles and responsibilities in the pharmacy. And they were observed working in a safe and efficient manner. The pharmacy had a range of standard operating procedures (SOPs) available for these activities, and there was a record to show that team members had read the SOPs. The SOPs were due to be reviewed next year. Team members knew what activities they could and could not do in the absence of a

pharmacist. The team recorded near misses on paper. (Near misses were dispensing mistakes that are spotted and corrected before a medicine leaves the pharmacy). The pharmacy manager reviewed the near misses at the end of each month for any trends or patterns in the types of near misses occurring. Dispensing errors (mistakes that were not detected before a medicine was handed out) were recorded on paper sheets in more detail than near misses. Team members said a dispensing error had not occurred for some time but, if an error occurred, an error report would be completed, and a meeting would take place to discuss the error.

The dispensary team had recently completed several audits including a sodium valproate safety audit, an audit about medicines for urinary tract infections (UTIs) and an audit about using more carbon friendly inhalers. These audits helped team members to improve their knowledge of the medicines they were providing.

People could submit complaints or feedback about the pharmacy in several different ways, including by email, in person or by phone. The pharmacy manager said she would usually record and resolve any complaints locally but could escalate to the SI if necessary. Confidential waste was stored in designated baskets in the pharmacy and regularly shredded on site. No confidential waste was found in the general waste bins. And no person-identifiable information could be seen from outside the dispensary. The RP confirmed he had completed safeguarding level three training with the Centre for Pharmacy Postgraduate Education (CPPE) and that team members had also completed safeguarding training. There was also a folder in the dispensary with details of local safeguarding contacts.

The pharmacy had current indemnity insurance. Records in the controlled drug (CD) register were largely complete but there were some headings for medicines that had been missed. A random check of two CDs showed the quantity in stock matched the running balance in the register. Records about private prescriptions were not always complete with several entries seen missing the name and address of the prescriber. The RP said these details would be included going forward. Records about supplies made of unlicensed medicines were complete. The pharmacy did very few emergency supplies of medicines, however records for these did not always contain an appropriate reason for nature of the supply. The RP stated that in future all emergency supplies would have a suitable reason recorded for the nature of the supply. The RP record was complete with all entries having a start and finish time.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload safely. And team members do the right training for their roles. Pharmacy team members have a regular formal review of their progress. And they feel comfortable about providing feedback or raising concerns if needed.

Inspector's evidence

On the day of the inspection, the dispensary team consisted of the RP, a pharmacy manager, an accuracy checking technician (ACT), two dispensers and a counter assistant. The clinical team consisted of the RP who was an independent prescriber (PIP) and split his time between working in the pharmacy and the clinic, a nurse prescriber (NMP), and a pharmacist and nurse who were not prescribers. The clinical team members who were prescribers dealt with services through PGDs and private consultations while the non-prescribers mainly did vaccinations through the national protocol. Clinical checks of prescriptions issued by prescribers in the clinic were done by the RP working in the pharmacy. People could also take the private prescription to another pharmacy to be dispensed.

The RP confirmed the pharmacy had enough team members to manage the workload and the team was up to date with dispensing. The pharmacy manager confirmed all dispensary team members had either completed the appropriate training with an accredited training course. And there were some certificates available to show this. The pharmacy manager said the team did ongoing training in the pharmacy and shared relevant updates such as clinical guideline updates to the pharmacy team. Team members had a yearly formal appraisal to review their performance and were given objectives to work towards. Team members said they had no issues raising any concerns in the pharmacy and would usually go to the pharmacy manager or SI with any issues they had. Team members confirmed they were not set any targets relating directly to services. Prescribers were remunerated on an hourly rate and not per prescription to reduce any chance of prescribing for profit.

The RP explained that he had completed his prescriber course in hypertension. He provided further evidence after the inspection that he had completed courses for physical examination and diagnosis and consulting in minor ailments. The RP also stated that he has attended webinars for PIPs when possible. There was no ongoing training for the clinical team and no evidence seen of any formal reviews or appraisals of clinical team members taking place. However, the RP explained as the prescribing service is in its infancy there were plans to incorporate this moving forward.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is very clean and tidy and provides a safe and appropriate environment for people to access its services. People can have a conversation with a team member in a private area. And the pharmacy is kept secure from unauthorised access.

Inspector's evidence

The front facia of the pharmacy was in a good state of repair and was modern and professional looking. The pharmacy had chairs for people who wished to wait for their prescription. Pharmacy only (P) medicines were stored securely. The shop floor area of the pharmacy was clean and tidy, as was the dispensary area which had just enough space for the team to work in. There was a sink for preparing liquid medicines which was generally clean. The temperature and lighting in the pharmacy were adequate. And it had air conditioning to adjust the temperature if required. The pharmacy had a staff toilet with access to hot and cold running water and handwash. It also had a consultation room for people who wished to have a conversation in private. It was clean and tidy and allowed for a conversation at normal volume to be had without being heard from the outside. However, the door of the room contained small windows which meant privacy may not be completely maintained in the room. The pharmacy was kept secure from unauthorised access. The clinic area of the pharmacy was very clean, modern looking and professional. It had three clinic rooms, a reception desk and a waiting area with chairs for people to wait to be seen.

The pharmacy's website could be used to book appointments at the clinic, but people could not have remote consultations via the website. The website did not have details of the SI or any prescribers working in the clinic. It also did not have any registration details of the pharmacy. So, this could make it harder for people to find out more information about the pharmacy.

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

Summary findings

The pharmacy cannot demonstrate that it provides all its services safely. It cannot show that it always shares information about the medicines it supplies through its private prescribing service with people's regular prescribers, where people have given consent for this to happen. And it doesn't adequately record all its consultations. However, the pharmacy dispenses medicines safely and stores its medicines appropriately. And the team takes the right action in response to safety alerts and recalls ensuring that people get medicines that are fit for purpose. People with different needs can access the pharmacy's services.

Inspector's evidence

The pharmacy clinic mainly operated as a pre-booked service. Walk-in appointments were also offered if an appointment slot was available. Services were advertised on the pharmacy's website. Consultations took place face-to-face in dedicated consultation rooms within the clinic. Consultations were undertaken by a prescriber or non-prescriber depending on the nature of the appointment and the potential treatment required. Medicines were only supplied to people after they were assessed face-to-face.

The prescribers kept records of consultations on a separate system. This was password protected and only the prescribers and SI had access to this. The records of prescriptions issued, and medicines supplied by the pharmacy were checked on the pharmacy system where the RP could see how many medicines had been prescribed and how often. This allowed the RP to intervene if needed. Prescribers used appropriate clinical guidelines to aid clinical decision making. The clinical team members worked under PGDs to provide treatments such as travel vaccinations, weight loss and salbutamol treatment for asthma. These had comprehensive information covering the key questions to ask before supplying the medicines. These were signed by the SI to give authorisation to administer the treatment. Furthermore, the PGDs were online and there were records of the vaccinations supplied including batch numbers and expiry dates which kept in a separate folder. However, the nurse was not named on the PGD paperwork despite working under the PGD. The manager explained this was a clerical error and has since amended this.

Appropriate questions were asked during consultations and the prescribers used their own professional judgement when supplying medicines under a PGD. The RP explained that when anyone presented with an acute complaint, he would tailor the consultation depending on the individual that was being treated. The RP was aware of medicines that had a potential for misuse and stated that he checked for inappropriate and unsafe quantities and would raise this with the prescriber if necessary. There were no examples of interventions taking place; the RP explained that there had been no instances which required intervention yet, but he would intervene if needed.

The face-to-face consultation for weight loss covered all the key information and documented records of BMI. The RP explained that if the BMI was above 30 the prescriber would supply. However, when reviewing records, none were seen of the nurse-led weight loss consultations despite being told by the RP that supplies had been made. The RP could not explain why this was not recorded but said this would be documented moving forward. Medicines that were high-risk such as those liable to misuse were not issued by the clinic. The RP stated that if a person did give consent, the pharmacy would send

information to the GP about the medicines it had supplied. Evidence was provided after the inspection to show that this was routinely occurring for medicines supplied via a PGD such as travel vaccinations, however, there was no evidence of information being provided when medicines were being prescribed. This meant the pharmacy did not have assurance that the treatment was being appropriately monitored by a person's GP.

The pharmacy had step-free access via a ramp and a manual door. It was able to cater for people with different needs, for example by printing large-print labels for people with sight issues. It also had a hearing loop. There was just enough space for wheelchairs and pushchairs to access the dispensary counter. The dispensary had separate areas for dispensing and checking medicines. Baskets were used to separate prescriptions and reduce the chance of prescriptions getting mixed up. Checked medicines that were seen contained a dispensing label which had the initials of the dispenser and checker, and this provided an audit trail. The pharmacy provided a delivery service to people who had difficulty collecting their medicines. The pharmacy provided the driver with a delivery list which the driver returned to the pharmacy. This was then stored in a folder in the dispensary. If there was a failed delivery, a note was put through the door to arrange redelivery and the medicines returned to the pharmacy.

The pharmacy used stickers to highlight prescriptions that contained a high-risk medicine, a CD or an item requiring refrigeration. The SI confirmed that he always handed out high-risk medicines and that people received the appropriate counselling for their medicines. Team members were aware of the risks of sodium valproate, and the RP knew what to do if a person in the at-risk category presented at the pharmacy. Team members were shown where to apply a dispensing label to a box of sodium valproate so as not to cover any important safety information.

Multi-compartment compliance packs seen contained the required dosage information but did not contain the necessary warning information for medicines. The team confirmed that warning notices would be added to the packs going forward. The packs did contain a description of the contents, which included the colour, shape, and any markings on the medicines to help people identify their medicines. Team members confirmed that patient information leaflets (PILs) were included with the first compliance packs that people received but not always included in subsequent packs. The team were reminded that it is a legal requirement to supply PILs with all packs. The team said in future all packs would be supplied with PILs. They also stated that they would contact the surgery regarding any queries they had with prescriptions such as unexpected changes to people's treatment.

The pharmacy obtained medicines from licensed wholesalers and invoices were seen confirming this. CDs requiring safe custody were stored securely. The pharmacy had some expired CDs which needed destroying, but these took up little space in the cabinet. Medicines requiring refrigeration were stored appropriately. The pharmacy had two fridges, one for storing stock in the dispensary and one for storing stock in the clinic. Fridge temperatures for both fridges were checked and recorded daily, and records seen were all in the required range. The current temperatures were within the required appropriate range during the inspection.

Expiry date checks of medicines were carried out monthly on a rota basis with a different section of the pharmacy being checked each time. The pharmacy used stickers to highlight stock soon to expire. A random check of medicines on the shelves found no out-of-date medicines. Safety alerts of medicines and medical devices were received by email. These were actioned as appropriate and archived in a folder kept in the dispensary.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide a safe and effective service. And it uses this equipment to protect people's privacy.

Inspector's evidence

The pharmacy had computers with access to the internet, allowing the team to access any online resources it needed. Computers were password protected and faced away from public view to protect people's privacy. Team members were observed using their own NHS smartcards, and the pharmacy had cordless phones to allow conversations to be had in private. The pharmacy had appropriate glass measures for measuring liquids. And it had triangles for counting tablets and a separate one for cytotoxic medicines such as methotrexate to prevent cross-contamination; these were clean. There was a blood pressure machine in the consultation room. The RP was unsure how old it was and if it needed replacement or recalibration. She said she would confirm this with the SI, and it would be replaced or recalibrated if necessary.

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.