General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Karsons Pharma, 33 Pattens Lane, CHATHAM, Kent, ME4 6JR

Pharmacy reference: 1032675

Type of pharmacy: Community

Date of inspection: 27/01/2020

Pharmacy context

The pharmacy is located on a busy street near to a town centre in a largely residential area. The pharmacy receives around 80% of its prescriptions electronically. The pharmacy provides a range of services, including Medicines Use Reviews and the New Medicine Service. It also provides medicines as part of the Community Pharmacist Consultation Service. And it supplies medications in multi-compartment compliance packs to a small number of people who live in their own homes to help them manage their medicines. It provides substance misuse medications to a small number of people. The pharmacy provides a walk-in service for acute illness and conditions for adults and children on a private healthcare basis. The regular pharmacist is a prescriber and issues prescriptions as part of this service.

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 always identify the risks associated with its prescribing service. It does not carry out risk assessments for this or have procedures or diagnostic pathways.
		1.2	Standard not met	The pharmacy does not review the risks associated with its prescribing service.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not have systems in place to ensure the quality and appropriateness of its private prescribing service.
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 fully manage all the risks associated with all the services it provides to people. In particular, it cannot show that it routinely assesses the risks of providing its clinical prescribing service. And it does not routinely monitor the safety and quality of this prescribing service. However, it does record and regularly review any mistakes that happen during the prescription dispensing process. And it uses this information to help make its dispensing activities safer. It largely keeps the records it needs to keep by law. And team members understand their role in protecting vulnerable people. It largely protects people's personal information and people are able to provide feedback about the pharmacy's services.

Inspector's evidence

In relation to the pharmacy's NHS services, it adopted adequate measures for identifying and managing risks associated with these activities. These included the use of documented, up-to-date standard operating procedures (SOPs). It also recorded and reviewed near miss and dispensing incidents to learn and improve from these. Near misses were highlighted with the team member involved at the time of the incident; they identified and rectified their own mistakes. The trainee dispenser said that the previous near miss records had been taken by another pharmacist from within the organisation, possibly to be reviewed. These were brought to the pharmacy during the inspection by the pharmacist who managed the other pharmacy within the company. She explained that she regularly reviewed these for patterns and provided feedback to the staff as appropriate. Team members gave an example of a pattern they had seen of near misses involving candesartan, and explained that they had separated the different strengths on the shelves. The dispenser said that there had not been any recent dispensing incidents. The responsible pharmacist (RP) was not sure where these would be recorded and thought it might be using an online reporting system.

There was limited space for dispensing in the dispensary. An organised workflow helped staff to prioritise tasks and manage the workload. Baskets were used to minimise the risk of medicines being transferred to a different prescription. The team members signed the dispensing label when they dispensed and checked each item to show who had completed these tasks.

Team members' roles and responsibilities were specified in the SOPs. The medicines counter assistant (MCA) said that she would attempt to contact the pharmacist if they had not turned up in the morning. And she was clear about which tasks should not be carried out if there was no pharmacist.

The pharmacy had current professional indemnity and public liability insurance. All necessary information was recorded when a supply of an unlicensed medicine was made. There were signed in-date patient group directions available for the relevant services offered. And the emergency supply records were completed correctly. Controlled drug (CD) registers examined were largely filled in correctly. Most CD running balances were checked at regular intervals, but some liquid CDs did not receive regular checks. The dispenser said that she would include the liquids in with the regular checks of other CDs. The recorded quantity of one CD item checked at random was the same as the physical amount of stock available. The private prescription records were largely completed correctly, but the prescriber's details were not always correct. This could make it harder for the pharmacy to find these details if there was a future query. The responsible pharmacist (RP) log was completed correctly. But

there were two RP notices displayed in the shop area at the start of the inspection. The second was removed by a member of the team when prompted.

Confidential waste was removed by a specialist waste contractor. But some pieces of paper with people's personal information was found in with the general waste. One of the pieces of paper gave indication as to which type of medicine the person took. The papers were immediately removed and staff said that they would place them straight into confidential waste in the future. Computers were password protected and the people using the pharmacy could not see information on the computer screens. The RP said that her smartcard was not working and this had been reported. Team members were using the other pharmacists smartcard to access the NHS electronic services during the inspection. Bagged items waiting collection could not be viewed by people in the shop area.

The pharmacy carried out yearly patient satisfaction surveys; results from the 2018 to 2019 survey were not available on the NHS website. Team members were not aware of any recent complaints. The complaints procedure was available for team members to follow if needed and details about it were displayed in the shop area.

The RP had completed the Centre for Pharmacy Postgraduate Education training about protecting vulnerable people. The MCA could not recall having completed any safeguarding training. But she was able to describe potential signs that might indicate a safeguarding concern and would refer any concerns to the pharmacist. The RP said that there had not been any safeguarding concerns at the pharmacy. The pharmacy had contact details available for agencies who dealt with safeguarding vulnerable people.

The pharmacy also offered a prescribing service, on a walk-in basis, and run by the superintendent (SI) who was a pharmacist independent prescriber (PIP). The pharmacy walk-in service was not commissioned by a National Health Service commissioner and it was being provided on a private healthcare basis. The service performance was not bound to contractual and quality measures which necessitated the presence of a robust independent auditing and monitoring process to maintain the quality of the service provided.

The pharmacy did not have a formalised process or system in place to identify the risks associated with the provision of this prescribing service to the public. The pharmacy could not show that all the clinical risks associated with its prescribing services were identified. For example, the pharmacy did not follow formal exclusion and inclusion criteria to aid the diagnosis of people presenting with different clinical conditions. There were no diagnostic pathways specific to the condition being treated and it relied predominantly on the professional judgement of the PIP. This increased the likelihood of missing a differential diagnosis or more worrying missing a severe 'red flag'. The pharmacy did not monitor or review its prescribing service. There was no evidence that the pharmacy was auditing or monitoring the various elements of the prescribing services it provided.

The pharmacy had developed an electronic consultation template which was filled in during each consultation. The template gathered information about the person's presenting complaint, vital observations, diagnosis and treatment provided. However, the template did not capture other equally relevant information such as allergy status, drug history and previous medical history. The lack of this crucial information at the point of prescribing will increase the likelihood of inappropriate prescribing decisions being made. This will also have a negative impact on the pharmacy's ability to review prescribing near misses or errors as this information will be needed to assess the appropriateness of the prescribing activity involved. The pharmacy shared outcomes of its patient care episodes with the patient's GPs. The consultation form was stored on an encrypted tablet and emailed securely to the person's GP as a discharge summary.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to provide its services safely. The team discusses adverse incidents and uses these to learn and improve. And they can raise any concerns or make suggestions and have regular meetings. They do the right training for their roles. And they are provided with some ongoing to support their learning needs and maintain their knowledge and skills.

Inspector's evidence

There were two pharmacists present; one was the RP and the other was the SI who was also a PIP and ran the pharmacy's walk-in clinic. There was also one trained dispenser, two trainee dispensers and one trained MCA working during the inspection. Most team members had completed an accredited course for their role and the rest were undertaking training. They worked well together and communicated effectively to ensure that tasks were prioritised and the workload was well managed. A pharmacist who usually managed the other pharmacy within the company visited the pharmacy during the inspection.

The MCA appeared confident when speaking with people. She was aware of the restrictions on sales of pseudoephedrine containing products. She explained that she would refer to the pharmacist if a person regularly requested to purchase medicines which could be abused or may require additional care. Effective questioning techniques were used to establish whether the medicines were suitable for the person.

The MCA said that team members were not provided with ongoing training on a regular basis, but they did receive some. She explained that she received information about some medicines from drug representatives and had also received information about skin conditions and other products. She said that she did not usually have time to undertake any training during the working day and often completed this at home. She said that she received certificates for any training which she had completed. The pharmacists were aware of the continuing professional development requirement for the professional revalidation process. The PIP said that he was due to attend a course about clinical skills for prescribing.

The pharmacist who managed the other pharmacy within the company said that she carried out regular appraisals and performance reviews for the team members. The MCA said that she felt comfortable about discussing any issues with the pharmacists or making any suggestions. Team members said that meetings were held every couple of months, but that information was usually passed on informally during the day. Targets were not set for team members.

The PIP said that he felt able to take professional decisions and regularly did so during consultations with people when deciding the best course of treatment or referral to other healthcare professionals. The PIP had been qualified for ten years as a prescriber. He had gained his prescribing qualification through working in general practice where he dealt with minor ailments and acute infections. There were no records about declarations of competencies or extra qualification certificates available at the pharmacy to review.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises largely provide a safe, secure, and clean environment for the pharmacy's services. People can have a conversation with a team member in a private area. But the pharmacy could do more to keep some areas tidy and free from clutter.

Inspector's evidence

The premises were secured from unauthorised access. Pharmacy-only medicines were kept behind the counter. And there was a clear view of the medicines counter from the dispensary and the pharmacist could hear conversations at the counter and could intervene when needed. There was one chair in the shop area and this was positioned next to the medicines counter.

Air conditioning was not available; the room temperature on the day of the inspection was suitable for storing medicines. The trainee dispenser said that the room temperature was warm in the summer months, but this was not monitored. They said that they would monitor this to ensure that it was with the recommended temperature for storing medicines. There was a pile of dispensed medicines in bags on the floor in the corner of the dispensary; the dispenser said that this was not their usual practice, and they were waiting for people to collect them. The MCA said that she would offer the use of the consultation room if someone wanted to discuss something in private.

The walk-in clinic was provided from the consultation room. This was located to the rear of the dispensary. People wishing to use the walk-in service waited in a room between the pharmacy and the shop next door. They accessed the consultation room through the rear door of the pharmacy. There were several steps up to the door and it was not accessible to wheelchair users. The room was suitably equipped, well-screened, and kept secure when not in use. Low-level conversations in the consultation room could not be heard from the shop area. The toilet area and hand washing facilities were clean and not used for storing pharmacy items. This area was located in the consultation room.

Several people walked through the main dispensary following a consultation with the PIP, and some of these people had small children with them. On the way through the dispensary there were places where other people’s personal information was visible, for example on computer screens and prescriptions. Team members said that it could sometimes be distracting when people walked through. The SI gave assurances that people would not be allowed to go through the dispensary in the future.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not have systems in place to ensure the quality and appropriateness of its private prescribing service. It does not manage the risks of dealing with patients who present themselves to its prescribing service with undifferentiated illnesses. And it does not monitor or review its prescribing activity, particularly with antibiotics, in order to keep good antimicrobial stewardship. However, overall, the pharmacy provides its community pharmacy services safely. The pharmacy gets its medicines from reputable suppliers and generally stores them properly. It responds appropriately to drug alerts and product recalls. This helps make sure that its medicines and devices are safe for people to use. People with a range of needs can access the pharmacy's services. But the pharmacy doesn't always highlight prescriptions for higher-risk medicines. And this may mean that it misses opportunities to speak with people when they collect these medicines.

Inspector's evidence

There was step-free access to the pharmacy through a wide entrance. Team members had a clear view of the main entrance from the medicines counter and could help people into the premises where needed. Services and opening times were clearly advertised, and a variety of health information leaflets was available.

Deliveries were made by a delivery driver. There were no delivery records kept at the pharmacy as the driver also worked at another pharmacy within the company. And the records were kept at the other pharmacy. The trainee dispenser said that people's signatures were recorded for deliveries where possible. When the person was not at home, the delivery was returned to the pharmacy before the end of the working day. A card was left at the address asking the person to contact the pharmacy to rearrange delivery.

Prescriptions for higher-risk medicines such as warfarin or methotrexate were not highlighted. So, opportunities to speak with these people when they collected their medicines might be missed. And the pharmacy may also miss opportunities to check that these people were having the relevant tests done at appropriate intervals. Prescriptions for Schedule 3 and 4 CDs were not highlighted. This could increase the chance of these medicines being supplied when the prescription was no longer valid. The RP said that the pharmacy supplied valproate medicines to a few people. But there were currently no people in the at-risk group who needed to be on the Pregnancy Prevention Programme. The pharmacy did not have the relevant patient information leaflets or warning cards available. But, most of the boxes for these medicines had the relevant warning card attached. The RP said that she would order replacement leaflets and cards from the manufacturer.

Stock was stored in an organised manner in the dispensary, but short-dated items were not marked. There were several date-expired items found in with dispensing stock; one such medicine found had expired in January 2018. Date-checking records were sometimes inconsistent, and the dispenser said that some sections of the pharmacy had been checked but this had not been recorded. The most recent record for some sections went back to 2015. The pharmacist said that they would review the recording system and ensure the stock was date-checked regularly in the future. Stock approaching its use-by date was not routinely marked as such, although staff said that they had previously used stickers for this purpose. Several historical chemicals were found on high shelves in the dispensary. This included

products which were potentially hazardous. The pharmacist from the other pharmacy within the company said that she would contact the National Pharmacy Association and arrange safe destruction of the chemicals. CDs were kept secure. Denaturing kits were available for the safe destruction of CDs. CDs that people had returned and expired CDs were clearly marked and segregated. Returned CDs were recorded in a register and destroyed with a witness; two signatures were recorded.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. Drug alerts and recalls were received from the NHS and the MHRA. The dispenser explained the action the pharmacy took in response to any alerts or recalls. But no record of any action taken was kept, which could make it harder for the pharmacy to show what it had done in response. The pharmacy had the equipment to be able to comply with the EU Falsified Medicines Directive but it was not yet being fully used. The trainee dispenser said that he had undertaken some training on how the system worked. He was not sure when the pharmacy was likely to start using the equipment.

The RP said that 'owings' notes were provided when prescriptions could not be dispensed in full and people were kept informed about supply issues. Prescriptions for alternate medicines were requested from prescribers where needed. Prescriptions were not kept at the pharmacy until the remainder was dispensed. This could make it harder for team members to refer to the original prescription and could potentially increase the chance of errors. The trainee dispenser said that prescriptions were usually dispensed when the person presented to collect their medicines. The prescriptions were not always kept with the items until they were collected. This made it harder for the pharmacy to know if the prescription was in date when the items were handed out.

The RP said that assessments were carried out by people's GPs to show that they needed their medicines in multi-compartment compliance packs. The prescriptions for these packs were ordered in advance so that any issues could be addressed before people needed their medicines. Prescriptions for 'when required' medicines were not routinely requested; the dispenser said that people usually contacted the pharmacy if they needed them when their packs were due. The pharmacy kept a record for each person which included any changes to their medication and they also kept any hospital discharge letters for future reference. Packs were suitably labelled and but there was no audit trail to show who had dispensed and checked each pack. This could make it harder for the pharmacy to identify who had done these tasks and limit the opportunities to learn from any mistakes. And the backing sheets were not attached to the packs This could increase the chance of them being misplaced. Medication descriptions were not put on the packs to help people and their carers identify the medicines inside. And patient information leaflets were not routinely supplied. This could make it harder for people to have up-to-date information about how to take their medicines safely. These points were discussed with the team during the inspection.

The pharmacy provided a walk-in service for acute illness and conditions for adults and children on a private healthcare basis. Most of these illnesses and conditions were diagnosed and treated as of an infective origin such as urinary tract or upper respiratory tract infections. The service was provided by the PIP who carried out the consultation with people and if needed he generated a private prescription which was then dispensed by the pharmacy. Walk-in services have a high-risk profile as patients might be severely or acutely ill and mistakenly underestimating the severity of their conditions, and present themselves to the pharmacy instead of pharmacy instead of an Accident and Emergency department. The pharmacy did not carry out risk assessments to identify the various risks associated with the set-up of this service. Work planning might be challenging due to the walk-in nature of this service, rendering it difficult to predict the number of people presenting to the pharmacy. Therefore, people might need to be signposted or referred to other healthcare providers on the occasions when the pharmacy capacity was unable to deal with a high number of people. The pharmacy did not provide evidence of capacity risk assessments or contingency planning to deal with service interruption due to either staff

shortages or increased demands. Team members said that people did not make appointments for the prescribing service, and instead they waited in the waiting room to be seen by the PIP. Several people were asked to return later in the day or the following day as there were many people waiting to be seen by the PIP.

The majority of the health conditions being treated through their walk-in service were diagnosed to be of an infective origin, and consequently were associated with antibiotic prescribing. The pharmacy did not provide evidence that its prescribing activity and more specifically its antibiotic prescribing were monitored or reviewed. There were no audits of prescribing trends or assessing compliance with good microbial stewardship. The pharmacy used national antibiotic guidelines without considering the suitability of the nationally recommended antibiotics guidelines to the geographical guidelines.

From the sample of prescriptions seen, the pharmacy did not follow the local guidelines for the treatment of respiratory and urinary tract infections. For respiratory infections, the pharmacy did not differentiate between the site of infection (lower or upper) and did not grade the severity of the infections which are the main determents of the antibiotic choice. While for urinary tract infections, it offered antibiotics which have higher bacterial resistance rate within the pharmacy locality without any evidence of considering the resistance status.

The pharmacy did not take sufficient actions to implement service improvements or to ensure that its prescribing activity is being reviewed and monitored, as described in principle one.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. It uses its equipment to help protect people's personal information.

Inspector's evidence

Suitable equipment for measuring liquids was available. Separate liquid measures was used for methadone use only. Triangle tablet counters were available and clean; a separate counter was not marked for methotrexate use only. The trainee dispenser explained that the counter was cleaned thoroughly after use.

Up-to-date reference sources were available in the pharmacy and online. The pharmacist said that the blood pressure monitor was replaced every two years. The carbon monoxide testing machine was calibrated by an outside agency. The urine test strips were in date and otoscope was cleasned before each use. The phone in the dispensary was portable so it could be taken to a more private area where needed.

Fridge temperatures were checked daily; maximum and minimum temperatures were recorded. Records indicated that the temperatures were consistently within the recommended range. The fridges were suitable for storing medicines and were not overstocked.

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.