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: 04/11/2020

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. This inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not adequately identify and manage the risks associated with its prescribing service. It does not carry out risk assessments for this service or have procedures for diagnostic pathways. It does not always identify 'red flag' symptoms or refer people to other healthcare providers when needed.
		1.2	Standard not met	The pharmacy does not audit or monitor the safety and quality of the various elements of its prescribing service.
		1.6	Standard not met	The pharmacy's private prescribing service consultation records are poor. So, this makes it more difficult to understand the reason for the prescription and the clinical evidence available to the prescriber at the time. Prescriptions written as part of this service are not always recorded correctly on the pharmacy's private prescription record.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy cannot adequately demonstrate that the pharmacist independent prescriber is prescribing medicines within his area of competence.
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 always provide its prescribing service safely. So, people using this service could be put at risk. And it does not always supply medicines prescribed as part of this service against a legally valid prescription.
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 identify or manage all the risks associated with its prescribing service. And it does not routinely monitor the safety and quality of this service. It keeps some records of consultations with people using the prescribing service, but these are generally poor. And it does not always make proper records when it dispenses medicines against private prescriptions. However, the pharmacy does adequately manage the risks associated with its other services. It records and regularly reviews any mistakes that happen during the prescription dispensing process. And it uses this information to help make its dispensing activities safer. It largely protects people's personal information and people are able to provide feedback about the pharmacy's services. And team members understand their role in protecting vulnerable people.

Inspector's evidence

The pharmacy offered a prescribing service, on a walk-in basis, which was run by the pharmacist independent prescriber (PIP), who was also the superintendent pharmacist. The pharmacy walk-in service was not commissioned by a National Health Service commissioner and it was being provided on a private healthcare basis. So, 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 safe provision of its prescribing service to the public. The pharmacy could not show that all the clinical risks associated with its prescribing services were identified. The pharmacy did not follow formal exclusion and inclusion criteria to assist the prescriber with the diagnosis of people presenting with different clinical conditions. There was no evidence that the service operated in line with clear 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 significantly missing 'red flag' indicators that could have a serious impact on the patient's health.

The pharmacy did not have robust systems in place to monitor or review its prescribing service. No evidence was available to demonstrate that the pharmacy was proactively auditing or monitoring its prescribing service to ensure that all medicines were prescribed safely.

The standard of record keeping for the prescribing service was poor. The pharmacy had developed an electronic consultation template that 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 family history, social history and previous medical history. Therefore, key information that would normally underpin good clinical prescribing was not recorded on the template and may not have been available to the prescriber to inform clinical decision making at the point of prescribing.

The consultation template was not completed for all patient consultations. This information was provided during a second visit to the pharmacy to further explore issues that had arisen during the first visit. Some patient records consisted solely of a 'dispensing token' that was then used to dispense the medicines against. Often there would be no accompanying consultation record to explain the

prescribing decision and the clinical information available to the prescriber at the time.

Where consultation notes had been made, either in written or electronic format, the quality of the record keeping was generally poor. Several consultation notes had little detail, and on occasions, notes of consultations were not recorded at all. This made it more difficult to show why a medicine was prescribed and what information was available to the prescriber to support the diagnosis. The phrase 'safety netted' had been written on several recent consultation records, but there was no explanation as to what this referred to. And there was no explanation on the record as to what advice had been given to people, or where they should go for further care if their symptoms persisted or worsened. There was reference made on some of the consultation records that the PIP had checked the person's NHS Summary Care Record. But there was no clear comprehensive record made about the person's previous medical history or medications they may have been taking.

Medicines were often dispensed on the basis of the prescriber writing the name of the medicine on the consultation template with the prescriber's signature at the foot of the template. This was then used in place of a private prescription and medicines were dispensed against the information on the computer template. The signature on the template did not meet the requirements of an advanced electronic signature.

No evidence was provided during the inspection to demonstrate good shared care with the patient's usual GP. Assurance was given that the pharmacy shared outcome of its patient care episodes with the patient's GP, but no evidence was available to confirm whether this happened. The notes on the consultation template could be altered or obliterated and there was no audit trail to show changes which were made. And there were different versions of the template itself found, with no version control. This is suboptimal record keeping and governance because other people providing care cannot be confident that the notes accurately record the information as it was presented at the time.

In relation to the pharmacy's NHS services, the pharmacy adopted adequate measures for identifying and managing risks associated with these activities. These included the use of up-to-date standard operating procedures (SOPs). It also recorded and reviewed near misses, where a dispensing mistake was identified before the medicine had reached a person. And dispensing errors, where a dispensing mistake had reached a person. Near misses were highlighted with the team member involved at the time of the incident, and they identified and rectified their own mistakes. The trainee dispenser said that there had not been any recent dispensing incidents. But ones which had been previously reported to the pharmacy had been documented. The pharmacy had carried out workplace risk assessments in relation to Covid-19.

There was limited space in the dispensary, but 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. Team members signed the dispensing label when they dispensed and checked each item to show who had completed these tasks.

On the day of the inspection there was also another pharmacist present who was acting as the responsible pharmacist (RP). The trainee dispenser said that the PIP would provide cover and act as the RP if the regular RP had not turned up in the morning. She knew that she should not sell pharmacy-only medicines or hand out dispensed items if there was no pharmacist on the premises.

The pharmacy had current professional indemnity and public liability insurance. All necessary information was recorded when a supply of an unlicensed medicine was made. And the emergency supply records were completed correctly. Controlled drug (CD) registers examined were filled in correctly. CD running balances were checked at regular intervals. The recorded quantity of one CD item

checked at random was the same as the physical amount of stock available. The RP record was largely completed correctly but there were a few occasions recently when the PIP had not completed the record when he had finished his shift and a different pharmacist was working the following day. The RP notice was not displayed at the start of the inspection. The RP printed a notice and displayed this in the shop area when prompted by the inspector. The pharmacy used the pharmacy's computer system to keep a record of private prescriptions. And the information checked matched the information on the prescriptions. But this record did not show all of the prescriptions which had been written by the PIP at the pharmacy. Not keeping accurate records of all private prescriptions could make it harder for the pharmacy to find these details if there was a future query. The RP and the dispenser gave assurances that all private prescriptions would be recorded correctly in the future.

Confidential waste was removed by a specialist waste contractor. Computers were password protected and the people using the pharmacy could not see information on the computer screens. Bagged items waiting collection could not be viewed by people in the shop area. The RP said that her smartcard was not working, and team members were using the PIP's smartcard to access the NHS electronic services during the inspection. The RP said that she was in the process of addressing the issues with her smartcard.

The pharmacy carried out patient satisfaction surveys. Results from the 2019 to 2020 survey were available on the NHS website and the people who had responded were largely satisfied with the service received overall. The pharmacy's complaints procedure was available for team members to follow if needed and details about it were displayed in the shop area. Team members were not aware of any recent complaints.

The RP had completed the Centre for Pharmacy Postgraduate Education (CPPE) training about protecting vulnerable people. The trainee dispenser said that she had undertaken some safeguarding training. She was able to describe potential signs that might indicate a safeguarding concern and would refer any concerns to the pharmacist. And she said that she was not aware of any safeguarding concerns at the pharmacy. The pharmacy had contact details available for agencies who dealt with safeguarding vulnerable people.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy cannot adequately demonstrate that the pharmacist independent prescriber always follows best practice guidelines or prescribes medicines within his scope of competence. 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. The support staff do the right training for their roles. And they are provided with some ongoing training to support their learning needs and maintain their knowledge and skills.

Inspector's evidence

There were two pharmacists present during the inspection. One was the RP and the other was the PIP who ran the pharmacy's walk-in clinic. There was one trained dispenser (NVQ level 3 student) and two trainee dispensers working during the inspection. Trainee team members were enrolled on accredited courses for their role and 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. She worked as the company's operations manager.

One of the trainee dispensers was covering the medicines counter on the day of the inspection. She appeared confident when speaking with people and 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 trainee dispenser said that team members were allowed time during the day to undertake their coursework where needed. The RP said that she passed on relevant information and updates to team members. The pharmacists were aware of the continuing professional development requirement for the professional revalidation process.

The operations manager said that she carried out regular appraisals and performance reviews for the team members. The trainee dispenser said that she felt comfortable about discussing any issues with the pharmacists or making any suggestions. She said information was usually passed on informally during the day. Targets were not set for team members.

The PIP felt able to take professional decisions and did this regularly during consultations with people when deciding the best course of treatment or referral to other healthcare professionals. The PIP had been qualified for around twelve years as a prescriber. He had gained his prescribing qualification through working in general practice where he dealt with minor ailments and acute infections. No records were available during the inspection or the second visit to verify the PIP's qualifications or to evidence completion of specialist training courses to cover the range of medicines he was prescribing, declarations of competencies or extra qualification certificates. Prior to the Covid-19 pandemic, the PIP used to meet with a local GP surgery, although it was not clear what areas or topics were covered during these meetings. The PIP explained that he had spent time with an ENT consultant over 10 years ago and a few days at the Medway hospital with a heart consultant around eight years ago. He

mentioned PCT courses and that he had done some training the previous year about urology and asthma. He confirmed that he had not undertaken any CPPE courses or written courses recently.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises 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.

Inspector's evidence

The premises were secured from unauthorised access and pharmacy-only medicines were kept behind the counter. There was a clear view of the medicines counter from the dispensary and the RP 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. This could increase the chance of conversations at the counter being heard. The trainee dispenser asked people to wait outside for their medicines, to limit the number of people in the shop area. The trainee dispenser said that she would offer the use of the consultation room if someone wanted to discuss something in private, or use the shop area if there were no other people.

Air conditioning was not available but the room temperature on the day of the inspection was suitable for storing medicines. There was a small screen at the medicines counter to help reduce the spread of infection. People usually stood at the screen when speaking with team members who were behind the counter. But there were occasions when people stood to the side of the screen while speaking with team members.

The walk-in clinic was provided from the consultation room and this was 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 which was used as a waiting area. The dispenser explained that only two people were allowed in the waiting area at a time. But, there often more than two people in the waiting area. Staff were unable to see how many people were in the waiting area from the pharmacy. The dispenser said that people were given a numbered ticket and asked to wait outside or in their cars if there was no space in the waiting area. A screen in the waiting area displayed a number which prompted people to know that it was their turn. People accessed the consultation room through the rear door of the pharmacy which led directly into the consultation room. 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.

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

Summary findings

The pharmacy does not have appropriate systems in place to ensure that its prescribing service operates safely. It does not adequately manage the risks of dealing with patients who present themselves to its prescribing service with different illnesses that have similar symptoms or ones that may need urgent or emergency treatment. And it does not monitor or review its prescribing activity, particularly with antibiotics, in order to keep good antimicrobial stewardship. Some people are not referred to other healthcare providers when needed and this may put them at risk of further complications or have health implications. However, overall, the pharmacy provides its other 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.

Inspector's evidence

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 on the basis that they were 'infective' in 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 because patients might be severely or acutely ill. People may underestimate the severity of their conditions, and present themselves to the pharmacy walk-in centre instead of an Accident and Emergency department. In the circumstances, it is essential that the walk-in centre has robust systems in place to accurately assess the nature and severity of a patient's condition.

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. There was no evidence available at the pharmacy of capacity risk assessments or contingency planning to deal with service interruption due to either staff shortages or increased demands. People did not make appointments for the prescribing service, and instead they waited in the waiting room for the PIP to see them. People waiting to see the PIP were not triaged according to the seriousness or urgency of their condition. Each person was provided with the next numbered ticket and they would have to wait in line to see the PIP.

At the second visit, the operations manager and a first-year pharmacy student produced a folder which included documents about 'red flag' symptoms, triage and an independent consultation risk assessment SOP. Team members had signed to show that they had read and understood the information. These policies and procedures were still being worked on and the pharmacy was still in the process of training the team about the triage system. Confirmation was given that these policies and procedures had been put together after the inspection.

The majority of the health conditions being treated through the pharmacy's walk-in service were

diagnosed to be 'infective' in origin, and consequently were associated with antibiotic prescribing. There was no evidence that the quality of the pharmacy's prescribing decisions had been reviewed or that the level of its antibiotic prescribing had been monitored or reviewed. There were no audits of prescribing trends or assessing compliance with good microbial stewardship. There was evidence that the prescribing service did not follow best practice guidelines as well as unjustified antimicrobial overprescribing.

A sample of consultation records was examined and many of them contained little information. However, from the information that had been recorded, there was evidence that the prescribing service did not always follow best practice guidelines. There was some evidence that antibiotics had been prescribed repeatedly to people without clear justification. There were circumstances where the PIP had prescribed in areas or specialities when guidelines recommend referral to specialist or emergency care, which significantly undermines people's safety.

Based on the information recorded on the consultation notes, on several occasions the PIP had potentially failed to identify warning signs and symptoms of severe acute illness which could consequently lead to severe harm. The consultation records did not clearly show that the PIP had carried out the necessary further investigation and history taking. Doing this would have helped to demonstrate that the PIP had made an informed diagnosis and did not miss red flags or life-threatening conditions.

Several consultation records examined appeared to show people presenting with severe respiratory and urinary conditions which as per current best practice guidelines would require Accident and Emergency referral and potential hospital admission. The PIP had prescribed antibiotics for these people. There was little evidence of any referrals and it was often not clear what advice people had been given about any action to take if the conditions did not get better.

The pharmacy provided the inspector with the last three months prescribing for the PIP, and this showed that there were some people receiving medicines for long-term conditions, or conditions which required the person to be monitored regularly by a consultant or specialist. Some of these medicines were not used to treat acute conditions, and there is a risk that these people were not monitored in line with guidelines.

There was wide step-free access at the front entrance to the pharmacy. 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. The operations manager said that she was sure that the delivery driver maintained distance while making deliveries. The driver also worked at another pharmacy within the company and the operations manager said that the delivery records were kept at the other pharmacy. 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. The PIP said that the pharmacist handed these out so that there was the opportunity to check that these people were having the relevant tests done at appropriate intervals. Prescriptions for Schedule 3 and 4 CDs were highlighted. This helped to minimise the chance of these medicines being supplied when the prescription was no longer valid. The PIP 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 had the relevant patient information leaflets or warning cards available. And, most of the boxes for these medicines had the relevant warning card attached.

Stock was stored in an organised manner in the dispensary and short-dated items were not marked. There were a few medicines in brown dispensing bottles found with dispensing stock and these did not have the information on, such as medicine name, batch number and expiry date. The dispenser said that since the last inspection, the pharmacy had made improvements to the date-checking system and he had removed all of the date-expired medicines from the dispensing stock. Several historical chemicals were found on high shelves in the dispensary. This included products which were potentially hazardous. During the last inspection, the operations manager said that she would contact the National Pharmacy Association and arrange safe destruction of the chemicals. The PIP confirmed that he was in the process of addressing how to dispose of them. CDs were kept secure and denaturing kits were available for the safe destruction of CDs. CDs that people had returned and expired CDs were clearly marked and kept separate. Returned CDs were recorded in a register and destroyed with a witness; two signatures were recorded.

The dispenser said that 'owings' notes were provided when prescriptions could not be dispensed in full and people were kept informed about supply issues. And that prescriptions for alternate medicines were requested from prescribers where needed. He explained that prescriptions were usually dispensed when the person presented to collect their medicines. This helped to reduce the amount of bagged items waiting collection.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. Drug alerts and recalls were received from the NHS, MHRA and wholesalers. 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 dispenser gave assurances that he would keep a record in the future.

The PIP 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, and 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 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. The backing sheets were not attached to the packs and this could increase the chance of them being misplaced. Medication descriptions were put on the packs to help people and their carers identify the medicines inside. And patient information leaflets were routinely supplied.

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 were 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 and the carbon monoxide testing machine was calibrated by an outside agency. The urine test strips were in date and the otoscope was cleaned before each use. The phone in the dispensary was portable so it could be taken to a more private area where needed. Team members wore masks while at work and hand sanitiser, aprons and gloves were available in the pharmacy.

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.